COMPLAINT AND DEMAND FOR JURY TRIAL

Defendant.

Plaintiffs, JADE BYINGTON and JASON BYINGTON, on behalf of themselves individually, and on behalf of their minor child, SADIE BYINGTON, bring this action against Defendant, Pfizer, Inc., by and through their undersigned attorneys. For their complaint, Plaintiffs allege and state as follows:

STATEMENT OF THE CASE

- 1. Pfizer designs, manufactures, markets and sells the drug Zoloft. Pfizer markets Zoloft as a drug to treat, among other things, depression. Pfizer does not know how Zoloft allegedly helps those suffering from depression.
- 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, 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 variety of methods, Pfizer actually encouraged doctors to prescribe Zoloft to women of

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child bearing 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. JADE BYINGTON was prescribed and took Zoloft. Because she and her doctor did not know Zoloft could cause birth defects, she was told to continue taking the drug after she discovered she was pregnant.
- 6. On October 14, 2003, JADE BYINGTON gave birth to SADIE BYINGTON.
- 7. Just after giving birth, doctors told JADE BYINGTON that her baby's heart had not formed correctly.
- 8. SADIE BYINGTON was diagnosed with injuries including, but not limited to, an atrial septal defect, a ventricular spetal defect and coarctation of the aora.
- 9. As a baby and throughout childhood, SADIE BYINGTON's heart health has been closely monitored by doctors.
- 10. 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

11. Pfizer, Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 235 East 42nd Street, New York, New York. 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).

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- 12. Plaintiff is a citizen of the State of Idaho and was so at the time of the injuries complained of herein.
- 13. Jurisdiction is based on diversity of citizenship. This Court has jurisdiction pursuant to 28 U.S.C. §1332. The amount in controversy is substantially in excess of seventy-five thousand dollars (\$75,000) exclusive of interest and costs. Pfizer is a resident of this district. Accordingly, venue is proper in this district.

FACTUAL ALLEGATIONS

- 14. Pfizer designed, developed, manufactured, marketed and sold Zoloft.
- 15. Zoloft is a selective serotonin reuptake inhibitor (SSRI) marketed, primarily, as an antidepressant medication.
- 16. Pfizer does not know the mechanism of action by which Zoloft would treat depression. Pfizer, in its marketing, claims that Zoloft's effect on serotonin in the brain is a potential mechanism through which Zoloft treats depression.
- 17. Pfizer also promotes Zoloft as a treatment for obsessive-compulsive disorder, panic attacks, posttraumatic stress disorder, and social anxiety disorder.
- 18. 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.
- 19. Plaintiff JADE BYINGTON's physician prescribed Zoloft and Plaintiff purchased and took Zoloft. While taking Zoloft, Plaintiff discovered she was pregnant. Plaintiff continued to take Zoloft during her first trimester of pregnancy.
 - 20. Plaintiff SADIE BYINGTON was born on OCTOBER 14, 2003.
- 21. After the birth, doctors informed JADE BYINGTON that her baby had serious heart defects.

22. Throughout childhood, SADIE BYINGTON and SADIE BYINGTON's parents have suffered physically and emotionally from the birth defect caused by Zoloft. SADIE BYINGTON continues to have regular doctor 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

- 23. 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 cardiac defects.
- 24. Pfizer knew about these adverse side effects, yet, without further testing, Pfizer began marketing and selling Zoloft to physicians and the public.
- 25. 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 to prescribe Zoloft to women of childbearing age, women who were trying to conceive and even to pregnant women.
- 26. 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, craniosynostosis, omphalocele, gastroschisis, persistent pulmonary hypertension of the newborn (PPHN), Tetralogy of Fallot, pulmonary atresia, limb deformations, spina bifida, cleft palate, and patent ductus arteriosus.

- 27. In September 2005, the manufacturers of the SSRI drug Paxil, a drug very similar to Zoloft, added language to the drug's label warning doctors and patients of cardiac malformations and other structural birth defects when Paxil was ingested during pregnancy.
- 28. Pfizer had no justifiable reason to believe that Zoloft was materially less likely to cause birth defects than Paxil.
- 29. 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.
- 30. Many observational studies show a statistically significant increase in birth defects associated with the use of Zoloft.
- 31. 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 Persistent Pulmonary Hypertension of the Newborn ("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 pregnancy.
- 32. 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)].
- 33. 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.

- 34. 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 sertraline during pregnancy [OR 1.51 (95% CI: 0.84-2.69)].
- 35. 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.
- 36. 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 80 percent increase in 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.

37. The current Zoloft label <u>still</u> does not warn doctors or patients about the increased risk of cardiac malformations and other birth defects seen in babies whose MOTHERs took Zoloft.

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

- 38. To date, Pfizer has failed to adequately warn or inform consumers and doctors, such as JADE BYINGTON's prescribing physician, of the known effects in Zoloft that can lead to heart malformations and other birth defects. Pfizer fraudulently concealed these effects and made misrepresentations to the damage and detriment of Plaintiffs.
- 39. 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 health care providers' access to this negative data and promote only the most favorable aspects of the data from these studies. 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 health care providers to prescribe Zoloft, particularly to women of childbearing years.

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- 40. 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.
- 41. 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).
 - 1) A drug is misbranded if any one of several circumstances exists, such as:
 - a. False or Misleading. A drug is misbranded if its labeling is "false or misleading in any particular." 21 U.S.C. § 352(a).
 - b. 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).
 - c. 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).
 - 2) It will be so deemed if, for example, it:

a. 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);

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- b. Contains an unsupported comparative claim or superiority claim. 21
 C.F.R. § 202.1(e)(6)(i) and (ii);
- c. Contains unsupported favorable information or opinions. 21 C.F.R. §
 202.1(e)(6)(iii);
- d. Selectively presents favorable information on safety or side effects.
 4521 C.F.R. § 202.1(e)(6)(iv);
- e. Suggests that study information has more general application. 4621 C.F.R. § 202.1(e)(6)(v);
- f. Uses literature references that do not support the claim in question.

 4721 C.F.R. § 202.1(e)(6)(vi);
- g. Uses data that have no clinical significance. 4821 C.F.R. § 202.1(e)(6)(vii);
- h. Uses statements from authorities out of context, or ignoring negative or inconsistent views. 4921 C.F.R. § 202.1(e)(6)(viii)-(ix);
- 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
- j. 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).

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42. As alleged herein, as a direct and proximate result of the Defendant's 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

- 43. 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. Furthermore, the proper and effective use of Zoloft by JADE BYINGTON 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.
- 44. Pfizer knew of the dangerous birth defects associated with Zoloft use during pregnancy from the preclinical studies and the subsequent published studies confirming these risks. Pfizer took no action to properly study Zoloft or 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 STATUTES OF LIMITATIONS

45. In Idaho, the statute of limitations for claims brought by minors does not run until six years after reaching the age of majority, which is 18. See I.C. 5-230.

Therefore, until six years after SADIE BYINGTON turns 18, the statute of limitations for her claims in this action are tolled.

- 46. Further, the running of any statute of limitations has been tolled by reason of Defendant's fraudulent concealment. Through its affirmative misrepresentations and omissions, Defendant actively concealed from Plaintiffs, and their prescribing physician, the true risks associated with taking Zoloft.
- 47. As a result of Defendant's actions, Plaintiffs and their prescribing physician were unaware, and could not reasonably know or have learned through reasonable diligence, that JADE BYINGTON had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendant's acts and omissions.
- 48. Plaintiffs had no knowledge that the Defendant was engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by the Defendant, Plaintiffs could not have reasonably discovered the wrongdoing at any time prior. Additionally, the economics of this fraud should be considered. The Defendant had the ability to and did spend enormous amounts of money in furtherance of its purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiffs and their medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on only the Defendant's representations.

CAUSES OF ACTION

COUNT I BREACH OF WARRANTY

- 49. Plaintiffs repeat and reiterate all foregoing paragraphs of this Complaint as if fully set forth herein.
- 50. At all times herein, Pfizer, by direct and indirect advertising, marketing and promoting Zoloft for the treatment of depression and other conditions during pregnancy, placed this drug in the stream of commerce. Knowing that Zoloft would be prescribed for the treatment of depression and other conditions during pregnancy, Pfizer expressly warranted to all foreseeable users of this drug, including JADE BYINGTON, that Zoloft was safe and effective for the treatment of depression and other conditions during pregnancy.
- 51. Pfizer impliedly warranted in manufacturing, distributing, selling, advertising, marketing and promoting Zoloft to all foreseeable users, including JADE BYINGTON, 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 the intended purposes.
- 52. JADE BYINGTON relied upon the aforesaid express and implied warranties by Pfizer.
- 53. JADE BYINGTON's use of Zoloft prior to conception and through the first trimester of pregnancy was consistent with the purposes for which Pfizer directly and indirectly advertised, marketed and promoted Zoloft. JADE BYINGTON's use of Zoloft was reasonably contemplated, intended and foreseen by Pfizer at the time of the

distribution and sale of Zoloft by Pfizer. Therefore, JADE BYINGTON's use of Zoloft was within the scope of the above-described express and implied warranties.

- 54. Pfizer breached the express and implied warranties because Zoloft was not safe and effective for the treatment of depression and other conditions during pregnancy.
- 55. As a direct and proximate result of Pfizer's breach of express and implied warranty, Plaintiffs suffered severe and permanent physical injuries which are continuing in nature.

WHEREFORE, Plaintiffs demand judgment against Pfizer for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT II NEGLIGENCE

- 56. Plaintiffs repeat and reiterate the foregoing paragraphs in this Complaint as if fully set forth herein.
- 57. At all times herein, Pfizer was under a duty to exercise reasonable care in the design manufacture, testing, processing, marketing, advertising, labeling, packaging distribution, and sale of Zoloft. 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.
- 58. 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.

- 59. 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 of the safety of the public, including the 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 JADE BYINGTON and her prescribing physician, to believe that Zoloft was effective for the treatment of depression and other conditions during pregnancy.
- 60. Pfizer failed to exercise reasonable care in the design, manufacture, testing, processing, marketing, advertising, labeling, packaging, rebranding, distribution and/or sale of Zoloft in one or more of the following respects:
 - a) Designing, marketing, processing, advertising, packaging, distributing and/or selling a product that Defendant knew, or should have known, carried the risk of serious; lifethreatening side effects;
 - b) Failure to adequately test the product prior to placing the drug Zoloft on the market;
 - c) Failure to use care in designing, developing and manufacturing its product so as to avoid posing unnecessary health risks to users of such product;
 - failure to conduct adequate pre-clinical testing and postmarketing surveillance to determine the safety of Zoloft use during pregnancy;
 - e) Failure to advise consumers, such as JADE BYINGTON, that ingestion of Zoloft during pregnancy could result in severe and disabling side effects and birth defects;

- f) Failure to advise the medical and scientific communities of the potential for severe and disabling side effects and birth defects;
- g) Failure to provide timely and/or adequate warnings about the potential health risks associated with the use of Zoloft during pregnancy; and
- h) Any and all other acts of negligence with respect to Zoloft which may be shown at trial.
- 61. Pfizer's conduct is unreasonable and negligent and was a proximate cause of SADIE BYINGTON's injures and of SADIE BYINGTON'S parents' mental anguish and financial damages.
- 62. At all times hereinafter mentioned, Plaintiffs did not contribute to their injuries by reason of any negligence or culpable conduct on their part.
- 63. As a result of the aforesaid occurrences, Plaintiffs suffered extensive monetary and pecuniary losses and other compensatory damages were also incurred and paid out including necessary medical, hospital, and concomitant expenses.
- 64. As a direct and proximate result of Pfizer's carelessness and negligence, SADIE BYINGTON suffered severe and permanent physical and emotional injuries which are continuing in nature.

WHEREFORE, Plaintiffs demand judgment against Pfizer for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT III PUNITIVE DAMAGES

65. Plaintiff repeats and reiterates the foregoing paragraphs in this Complaint as if fully set forth herein.

- 66. At all times material hereto, Pfizer knew or should have known that Zoloft was inherently dangerous when used during pregnancy and that it caused serious birth defects in the unborn child.
- 67. At all times material hereto, Pfizer attempted to misrepresent and did misrepresent facts concerning the safety of Zoloft.
- 68. Pfizer's misrepresentations include knowingly withholding material information from the medical community, the public, including JADE BYINGTON, and the FDA concerning the safety of the subject product.
- 69. 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 the Plaintiffs herein, in conscious and/or negligent disregard of the foreseeable harm caused by Zoloft.
- 70. Pfizer intentionally concealed and/or recklessly failed to disclose to the medical community, the public, including the Plaintiff herein, and the FDA the potentially life threatening side effects and birth defects associated with the use of Zoloft in order to ensure continued and increased sales.
- 71. Pfizer's intentional and/or reckless failure to disclose information deprived JADE BYINGTON of necessary information to enable her to weigh the true risks of using Zoloft during pregnancy against its benefits.
- 72. As a direct and proximate result of Pfizer's conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiffs, SADIE BYINGTON suffered severe and permanent physical injuries, including but not limited to, cardiac defects, numerous invasive procedures and open heart surgery. Plaintiffs

endured substantial conscious pain and suffering, both physical and emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment of their child, suffered lost income, and was otherwise emotionally and economically injured. Plaintiffs have suffered severe pecuniary loss and seek actual and punitive damages from Pfizer as alleged herein.

73. The aforesaid conduct of Pfizer was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including the Plaintiffs, thereby entitling the Plaintiffs to punitive damages in an amount appropriate to punish Pfizer and deter them from similar conduct in the future.

WHEREFORE, Plaintiffs demand judgment against Pfizer for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IV FRAUD

- 74. Plaintiffs repeat and reiterate the foregoing paragraphs in this Complaint as if fully set forth herein.
- 75. Pfizer widely advertised and promoted Zoloft as a safe and effective medication for use during pregnancy.
- 76. Pfizer had a duty to disclose material information about serious side effects to consumers, such as JADE BYINGTON. Additionally, by virtue of Pfizer's partial disclosures about the medication, in which Pfizer touted Zoloft as safe and effective treatment, Pfizer had a duty to disclose all facts about the risks of use associated with the medication, including the potential for the medication to cause severe birth defects when used during pregnancy. Pfizer intentionally failed to disclose this

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information for the purpose of inducing consumers, such as JADE BYINGTON, to purchase and ingest Pfizer's dangerous product.

- 77. Had JADE BYINGTON been aware of the hazards associated with the use of Zoloft during pregnancy, she would not have purchased and/or ingested the product that lead proximately to the injuries as alleged herein.
- 78. Pfizer's advertisements regarding Zoloft made material misrepresentations to the effect that Zoloft was a safe and effective treatment, misrepresentations Pfizer knew to be false, for the purpose of fraudulently inducing consumers, such as JADE BYINGTON, to purchase such product. JADE BYINGTON also relied on these material misrepresentations in deciding to purchase and consume Zoloft to her own detriment and to her child's detriment.
- 79. The damages sustained by Plaintiffs were a direct and foreseeable result of, and were proximately caused by Pfizer's misrepresentations, concealment and omissions.
- 80. Pfizer's conduct was willful, wanton, and reckless. Based on the intentionally dishonest nature of Pfizer's conduct, which was directed at JADE BYINGTON and the public generally, Pfizer should also be held liable for punitive damages.
- 81. By reason of the foregoing, the Plaintiffs sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiffs seek punitive and exemplary damages against Pfizer in an amount to be determined upon the trial of this matter.

WHEREFORE, Plaintiffs demand judgment against Pfizer for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT V NEGLIGENT MISREPRESENTATION

- 82. Plaintiffs repeat and reiterate the foregoing paragraphs in this Complaint as if fully set forth herein.
- 83. After Pfizer became aware of the risks of ingesting Zoloft during pregnancy, Pfizer failed to communicate to JADE BYINGTON and other members of the general public that the ingestion of this drug while pregnant could have the increased risk of serious birth defects.
- 84. Pfizer failed to warn the Plaintiff, and other consumers, of the defective condition of Zoloft, as manufactured and/or supplied by Pfizer.
- 85. 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.
- 86. The above misrepresentations were made to JADE BYINGTON, as well as the general public. JADE BYINGTON and her healthcare providers justifiably relied on Pfizer's misrepresentations.
- 87. JADE BYINGTON 's ingestion of Zoloft was to her detriment and the detriment of her child, SADIE BYINGTON. Pfizer's negligent misrepresentations proximately caused the Plaintiffs' injuries and monetary losses.

WHEREFORE, Plaintiffs demand judgment against Pfizer for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VI NEGLIGENCE PER SE

- 88. Plaintiffs repeat and reiterate the foregoing paragraphs in this Complaint as if set forth herein.
 - 89. Pfizer has an obligation to not violate the law.

- 90. 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.
- 91. JADE BYINGTON, as a purchaser and consumer of Zoloft, is within the class of persons that statues described above are designed to protect.
- 92. Injury due to false, misleading and/or reckless advertising and promotion, and misbranding, and as otherwise set forth in this Complaint, is the specific type of harm these statutes are designed to prevent.
- 93. Pfizer is responsible to Plaintiffs for injuries incurred for its violations of the statutes described above under the doctrine of negligence *per se*.
- 94. As a direct and proximate result of the negligence and negligence per se of Pfizer and as a result of the 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.

95. WHEREFORE, Plaintiffs demand judgment against Pfizer for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VII UNJUST ENRICHMENT

- 96. Plaintiffs repeat and reiterate the foregoing paragraphs in this Complaint as if fully set forth herein.
- 97. As an intended and expected result of its conscious wrongdoing, Defendant has profited and benefited from the purchases of Zoloft by JADE BYINGTON.
- 98. Defendant has voluntarily accepted and retained these profits and benefits, derived from the JADE BYINGTON and others, with full knowledge and awareness that, as a result of Defendant's fraud and other conscious and intentional wrongdoing, JADE BYINGTON did not receive a product of the quality, nature or fitness that had been represented by Defendant or that she, as a reasonable consumer, expected.
- 99. By virtue of the conscious wrongdoing alleged herein, Defendant has been unjustly enriched at the expense of JADE BYINGTON, who is entitled to in equity, and hereby seeks the disgorgement and restitution of Defendant's 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 Defendant's unjust enrichment.
- 100. WHEREFORE, Plaintiffs demand judgment against Pfizer for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

NO ELECTION OR WAIVER

The facts, circumstances and claims set forth above are pled cumulatively and alternatively, with no election or waiver of remedies until such time as the trier of fact has decided disputed issues of fact.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury on all Counts and as to all issues.

Date: July 13, 2012

Respectfully submitted,

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