

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

NOELLE M. CICCONE, a minor by
DENISE M. CICCONE and NICHOLAS L.
CICCONE, Guardians and Individually,

Plaintiffs,

vs.

Civil Action No.:

PFIZER, INC.,

Defendant.

COMPLAINT

Plaintiffs Denise M. Ciccone, Nicholas L. Ciccone and Noelle M. Ciccone, a Minor, bring this action for damages against Defendant Pfizer, Inc., and for their causes of action allege:

PARTIES

1. Denise M. Ciccone and Nicholas L. Ciccone (hereinafter “Parent Plaintiffs”) are the parents and natural guardians of Minor Plaintiff, Noelle M. Ciccone. (hereinafter “Minor Plaintiff”). Together they comprise the Plaintiffs in this litigation.

2. Plaintiff Denise M. Ciccone (hereinafter “Mrs. Ciccone”) took the drug ZOLOFT® during her pregnancy with Minor Plaintiff, Noelle M. Ciccone.

3. Minor Plaintiff Noelle M. Ciccone was born on February 21, 2002 at West Penn Hospital in Pittsburgh, Pennsylvania.

4. Minor Plaintiff was born with congenital birth defects, clubbed foot (right foot), truncus arteriosus, and other related conditions as a result of her Mother’s ingestion of ZOLOFT®. Minor Plaintiff is represented in this action by Parent Plaintiffs, who are her parents and natural guardians.

5. Parent Plaintiffs bring this action on behalf of Minor Plaintiff and Individually, on their own behalf, to recover medical and other expenses related to treatment resulting from Minor Plaintiff's birth defect(s), disorder(s) and/or related illnesses, and for general and special damages, including punitive damages, and such other relief as requested herein for injuries suffered as a direct result of Mrs. Ciccone's ingestion of ZOLOFT®.

6. Pfizer Inc. ("Pfizer") is a Delaware corporation with its principal place of business in New York, with an address of 235 East 42nd Street, New York, NY 10017-5755. At all relevant times, Pfizer and/or its predecessors in interest were engaged in the business of research, designing, testing, formulating, inspecting, labeling, manufacturing, packaging, marketing, distributing, producing, processing, promoting, and selling the drug Sertraline under the trade name ZOLOFT® in Pennsylvania, New York, and throughout the United States. Pfizer may be served with process by serving its registered agent CT Corporation, 116 Pine Street, Suite 320, Harrisburg, PA 17101.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction of this matter pursuant to 28 U.S.C. § 1332 because complete diversity exists between the parties. Defendant Pfizer is a Delaware corporation with a principal place of business in New York, New York. Plaintiffs are citizens of a state other than New York or Delaware, specifically the Commonwealth of Pennsylvania, and Plaintiffs seek damages in excess of \$75,000.00.

8. Venue is proper in this Court because at all times relevant to this Complaint, Pfizer has and continues to engage in continual business in the Commonwealth of Pennsylvania,

and maintains its principal place of business in New York, New York. Additionally, a significant amount of the acts and omissions alleged by Plaintiffs took place in this jurisdiction.

GENERAL ALLEGATIONS

9. Plaintiffs incorporate all preceding paragraphs of this Complaint as if set forth herein more fully at length.

10. Parent Plaintiffs are the natural parents of Minor Plaintiff, Noelle M. Ciccone, who was born with congenital birth defects, truncus arteriosus and club foot (right foot), as a result of Mrs. Ciccone's ingestion of ZOLOFT® as prescribed by her treating physicians during her pregnancy.

11. Plaintiffs bring this action to recover damages, and medical and other expenses related to the treatment of Minor Plaintiff Noelle M. Ciccone's birth defects, disorders, related illnesses, and for general and special damages, including punitive damages, and such other relief as requested herein for the injuries suffered as a direct result of Mrs. Ciccone's ingestion of ZOLOFT®.

12. Pfizer, its predecessors in interest and its subsidiaries, advertised, analyzed, assembled, compounded, designed, developed, distributed, formulated, inspected, labeled, manufactured, marketed, packed, produced, promoted, processed, researched, sold and tested ZOLOFT®.

13. The drug "Sertraline" is manufactured, promoted, distributed, labeled and marketed by Pfizer under the trade name ZOLOFT®, ZOLOFT® Oral Suspension, and ZOLOFT® CR, and is a member of a class of drugs known as "selective serotonin reuptake

inhibitors” or “SSRIs.” ZOLOFT® was approved for use in the United States by the FDA for the treatment of Major Depressive Disorder (MDD), December 30, 1991; Obsessive-Compulsive Disorder (OCD), October 28, 1996; for children with OCD, October 1997; Panic Disorder, July 1997; Acute Post Traumatic Stress Disorder (PTSD), December 7, 1999, and for chronic, long term PTSD, August 16, 2011; Premenstrual Dysphoric Disorder, May 20, 2002; and Social Anxiety Disorder, February 10, 2003. ZOLOFT® is supplied for oral administration as scored tablets in doses of 25, 50 and 100 mgs.

14. Minor Plaintiff Noelle M. Ciccone’s injuries are the direct result of Mrs. Ciccone’s ingestion of ZOLOFT® during her pregnancy in a manner and dosage recommended by Pfizer and prescribed by Mrs. Ciccone’s doctors.

**PFIZER KNEW OR SHOULD HAVE KNOWN THAT ZOLOFT®
CAUSES BIRTH DEFECTS**

15. Prior to Mrs. Ciccone becoming pregnant, Pfizer knew or should have known that children were being born with congenital birth defects, including heart defects, club foot and other cardiopulmonary conditions to women who took ZOLOFT® during pregnancy.

16. Prior to Mrs. Ciccone becoming pregnant, Pfizer knew or should have known that taking ZOLOFT® during pregnancy poses risks to the developing fetus. Pfizer knew or should have known that ZOLOFT® crosses the placenta, which could have important implications for the developing fetus.

17. Prior to the time that Mrs. Ciccone ingested ZOLOFT® during her pregnancy, Pfizer knew or should have known that ZOLOFT® posed an increased risk of congenital birth defects, heart defects, PPHN, truncus arteriosus, club foot and other related conditions.

18. Prior to Mrs. Ciccone's pregnancy, Pfizer had the knowledge, the means and the duty to provide the medical community and the consuming public with a stronger warning regarding the association between ZOLOFT® and congenital birth defects, heart defects, PPHN, truncus arteriosus, club foot and other related conditions, through all means necessary including, but not limited to, labeling, continuing education, symposiums, posters, sales calls to doctors, advertisements and promotional materials. Pfizer, its agents, employees and servants breached this duty.

19. Prior to the time that Mrs. Ciccone ingested ZOLOFT® during her pregnancy, Pfizer knew or should have known from available information that ZOLOFT® posed an increased risk of congenital birth defects and other adverse malformations.

20. Prior to the time that Mrs. Ciccone ingested ZOLOFT® during her pregnancy, Pfizer knew or should have known from available information that ZOLOFT® posed an increased risk of congenital birth defects, including multiple congenital cardiac birth defects, including, but not limited to, Tetralogy of Fallot, truncus arteriosus, ventricular septal defect, atrial septal defect, confluent branch pulmonary arteries, pulmonary valve atresia, other cardiopulmonary defects, and club foot.

21. At or before FDA approval of ZOLOFT®, Pfizer knew that ZOLOFT® caused birth defects when administered to non-human mammalian species, including, but not limited to, malformations previously associated with other SSRI drugs (*e.g.*, low birth-weight, craniofacial defects such as cleft lip, and limb defects such as club foot).

22. Prior to the time that Mrs. Ciccone ingested ZOLOFT® during her pregnancy, Pfizer knew or should have known that SSRI pharmaceuticals, as a class, increase the risk of

congenital birth defects. This class includes drugs such as Amitriptyline (Elavil); Bupropion (Wellbutrin); Citalopram (Celexa); Escitalopram (Lexapro); Fluvoxamine (Luvox); Fluoxetine (Prozac); Paroxetine (Paxil); and, Venlafaxine (Effexor).

23. Before Mrs. Ciccone ingested ZOLOFT®, Pfizer knew of studies within the same class of drugs demonstrating that mothers exposed to SSRIs late in their pregnancies showed significantly higher rates of prematurity, poor neonatal adaptation, significantly lower mean birth weight and length, and Persistent Pulmonary Hypertension of the Newborn (“PPHN”). Chambers, Christina, Birth Outcomes in Pregnant Women Taking Fluoxetine, 335 New Eng J. Med. 1010-15 (1996).

24. Pfizer knew, or should have known, between 2002 and 2006 that SSRI use, including ZOLOFT®, during pregnancy caused lower gestational age and birth weight, longer hospital stays and APGAR scores being significantly lower than in non-exposed infants in control groups. Simon, Gregory, Outcome of Prenatal Antidepressant Exposure, 159 American Journal of Psychiatry 2055-2061 (2002); Oberlander, Tim, Neonatal Outcomes After Prenatal Exposure to Selective Serotonin Reuptake Inhibitor Antidepressants and Maternal Depression using Population – Based Linked Health Data, 63 Archives of General Psychiatry 898-906 (2006).

25. Pfizer knew, or should have known, at the latest in or around 2005, SSRI use including ZOLOFT®, after the twentieth week of pregnancy was significantly associated with PPHN. Chambers, Christina, Selective Serotonin Re-uptake Inhibitors and Risk of Persistent Pulmonary Hypertension of the Newborn, 354(6) New Eng. J. Med. 579-587 (2006).

26. Pfizer knew, or should have known, by 2007 that early exposure to SSRIs, including ZOLOFT®, showed significant association with anencephaly (an absence of a large part of the brain or skull), craniosynostosis (closed or fused bones on infant's skull), and omphalocele (an abdominal wall defect in which the intestines and liver remain outside the abdomen in a sac because of a defect in the development of the muscles in the abdominal wall). Alwan, Sara, Use of Selective Serotonin – Reuptake Inhibitors in Pregnancy and the Risk of Birth Defects, 356 (26) New Eng. J. Med. 2684-2692 (2007).

27. Importantly, Pfizer knew, or should have known by 2007 that SSRIs, including ZOLOFT®, doubled the risk of septal heart defects in babies born to mothers taking ZOLOFT®. Luick, Carol, First-Trimester Use of Selective Serotonin Re-uptake Inhibitors and the Risk of Birth Defects, 356 (26) New Eng. J. Med. 2675-2683 (2007).

28. These same heart defect results were further confirmed in 2009 with the publishing of the Pederson Study. This study was designed to evaluate the association between SSRI use during the first trimester of pregnancy and major malformation. The study looked at 496,881 births reported in the Danish nationwide birth registry. The study found that the use of ZOLOFT® and Celexa® were associated with an increased prevalence of septal heart defects, and the use of more than one type of SSRI during the first trimester was associated with a fourfold increase in the prevalence of septal heart defects. Pederson, Lars, Selective Serotonin Re-uptake Inhibitors in Pregnancy and Congenital Malformation: Population Based Cohort Study, 339 British Medical Journal b3569 (2009).

29. Further studies confirmed these earlier findings. The Kornum Study looked at 216,042 women, 2,062 of whom had taken an SSRI during pregnancy. The conclusions were that

all SSRIs (except Paroxetine) were associated with increased risk of cardiac malformation. Notably, ZOLOFT® was associated with a threefold increase risk of cardiac malformation. ZOLOFT® also was associated with a higher incidence of septal defects. Kornum, Jete, Use of Selective Serotonin Re-uptake Inhibitors during Early Pregnancy and Risk of Congenital Malformation; Updated Analysis, 2 Clinical Epidemiology 29-36 (2010).

30. During the entire time ZOLOFT® has been on the market in the United States, FDA regulations have required Pfizer to issue stronger warnings whenever reasonable evidence of an association between a serious risk and ZOLOFT® existed. The regulations specifically state that a causal link need not have been proven to issue the new warnings. Further, the regulations explicitly allowed Pfizer to issue such a warning without prior FDA approval.

31. Prior to Mrs. Ciccone's pregnancy, Pfizer had the knowledge, the means and the duty to provide the medical community and the consuming public with a stronger warning regarding the association between ZOLOFT® and congenital birth defects and other related conditions, through all means necessary, including, but not limited to, labeling, continuing education symposiums, posters, sales calls to doctors, and advertisements and promotional materials. Further, based upon the alarming evidence and "signals" that had been accumulating since the 1990s evidencing and demonstrating a relationship between ZOLOFT® and birth defects and/or fetal demise, including, but not limited to, the information known, or that should have been known, from all animal and human studies, case reports, adverse event reports, registries and other available sources, Pfizer had a duty to conduct post-marketing studies to evaluate fully the significance of these studies. Pfizer breached this duty.

32. Pfizer had actual knowledge that doctors frequently prescribed ZOLOFT® to women of child-bearing potential for approved uses of the drug, and that doctors frequently prescribed ZOLOFT® to women of child-bearing potential for unapproved or off-label uses of the drug.

33. Pfizer failed to disclose adequately the increase risk of congenital birth defects of ZOLOFT® to the medical community and Plaintiffs. Pfizer was aware that its failure to disclose this information to the medical community and Plaintiffs would result in serious injury and/or death to the children or unborn fetus of women who were prescribed ZOLOFT® by a physician who was not aware of this information. By failing to disclose this information to the medical community and Plaintiffs, Pfizer acted in willful, wanton and outrageous manner and with evil disregard of the rights of Plaintiffs and this conduct caused serious and permanent injuries to Plaintiffs.

34. Pfizer, its agents, servants, and employees acting in the course and scope of their employment, negligently and carelessly breached their duties to the medical community, Mrs. Ciccone's physicians and other foreseeable users similarly situated.

35. Despite having extensive knowledge of the extreme risks associated with the use of ZOLOFT®, as well as the absolute duty to properly and adequately warn foreseeable users, Pfizer never approached the FDA to alter the label for ZOLOFT® so that it properly and adequately warned of the risks of birth defects associated with the drug.

36. The current ZOLOFT® label still does not warn doctors of patients about the increased risk of cardiac malformations and other birth defects seen in babies whose mothers took ZOLOFT®.

**PFIZER CONTINUES TO MISREPRESENT
THE SAFETY AND EFFICACY OF ZOLOFT®**

37. Despite Pfizer's long-standing 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 Mrs. Ciccone 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.

38. 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.

39. Had Mrs. Ciccone been adequately warned that ZOLOFT® could cause congenital birth defects if ingested during pregnancy; congenital birth defects which Minor Plaintiff was born with and will endure for the rest of her life; Mrs. Ciccone would not have taken the drug.

COUNT I

Minor Plaintiff v. Defendant Pfizer, Inc.

Negligence - Design Defect

40. Plaintiffs incorporate all allegations in the preceding paragraphs of this Complaint as if set forth more fully herein.

41. Pfizer designed, produced, manufactured and injected into the stream of commerce, in the regular course of its business, the pharmaceutical drug ZOLOFT® which it knew would be used by Mrs. Ciccone and others.

42. At the time the ZOLOFT® was manufactured and sold to Mrs. Ciccone by Pfizer, it was defective in design and unreasonably dangerous, subjecting its users to risks of birth defects, which exceeded the benefits of the product, and for which other safer products were available.

43. Alternatively, when ZOLOFT® was manufactured and sold to Mrs. Ciccone by Pfizer, the product was defective in design and formulation, making use of the product more dangerous than other similar drugs.

44. The ZOLOFT® sold to Mrs. Ciccone reached her without substantial change. Mrs. Ciccone was unaware of the dangerousness of the product until after her use of ZOLOFT®. Mrs. Ciccone ingested the ZOLOFT® without making any changes or alterations to the drug.

45. In designing and testing ZOLOFT®, Pfizer failed to exercise the ordinary care that a careful and prudent drug manufacturer would exercise in the same or similar circumstances.

46. As a direct and proximate result of the negligent design of the ZOLOFT®, Parent Plaintiffs' daughter, Minor Plaintiff Noelle M. Ciccone, suffered and continues to suffer from birth defects, including but not limited to, truncus arteriosus and club foot (right foot).

47. Pfizer's conduct was done with conscious disregard for the safety of users of ZOLOFT®, including Plaintiffs, justifying an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment in their favor and against Pfizer for:

- a. A fair and just amount of actual damages in an amount to be proved at trial in excess of \$75,000;
- b. Costs of suit;
- c. Pre-judgment and post-judgment interest;
- d. Punitive damages in a fair and reasonable amount to punish and deter Defendant Pfizer and others from engaging in such wrongful conduct; and,
- e. Such other and further relief as this Honorable Court deems just and proper to recover for which this suit was brought.

COUNT II

Minor Plaintiff v. Defendant Pfizer, Inc.

Negligence - Failure to Warn

48. Plaintiffs incorporate all allegations in the preceding paragraphs of this Complaint as if set forth more fully herein.

49. Pfizer owed a duty to warn of any dangerous defects or side effects, a duty to assure its products did not cause users unreasonable and dangerous risks, reactions, and side effects, and a duty to provide adequate post-market surveillance and warnings as it learned of ZOLOFT's® substantial dangers, and in particular, the risks of injuring unborn children for women who take ZOLOFT® during the first trimester of their pregnancy.

50. Pfizer breached its duty of reasonable care to Plaintiffs in that Pfizer failed to:

- a. Conduct sufficient testing which, if properly performed, would have shown that ZOLOFT® had serious side effects, for women and the unborn fetus when taking during pregnancy; and/or,
- b. Include adequate warnings with the ZOLOFT® products that would alert users to the potential risks and serious side effects of the drugs; and/or,
- c. Advise the FDA, the health care industry, and the public about the adverse reports it had received regarding ZOLOFT®; and/or,
- d. Other appropriate warnings.

51. Pfizer knew or should have known that ZOLOFT® caused unreasonably dangerous risks and serious side effects of which the general public would not be aware. Pfizer nevertheless advertised, marketed and promoted its product knowing there were safer methods and similar products available.

52. As a direct and proximate result of Pfizer's negligence and breaches of its duty of reasonable care, Minor Plaintiff Noelle M. Ciccone was born with congenital birth defects, including, but not limited to, truncus arteriosus and club foot (right foot), defects which she continues to suffer from to this day and will continue to suffer from for the rest of her life.

53. As a result of Minor Plaintiff Noelle M. Ciccone's congenital birth defects, Plaintiffs have been damaged.

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendant Pfizer for:

- a. A fair and just amount of actual damages in an amount to be proved at trial in excess of \$75,000.00;
- b. Costs of suit;

- c. Pre-judgment and post-judgment interest;
- d. Punitive damages in a fair and reasonable amount to punish and deter Defendant Pfizer and others from engaging in such wrongful conduct; and,
- e. Such other and further relief as this Honorable Court deems just and proper to recover for which this suit was brought.

COUNT III

Minor Plaintiff v. Defendant Pfizer, Inc.

Negligence

54. Plaintiffs incorporate all allegations in the preceding paragraphs of this Complaint by reference as if set forth more fully herein.

55. At all times mentioned herein, Pfizer was under a duty to exercise reasonable care in researching, manufacturing, selling, merchandising, advertising, marketing, promoting, labeling, testing, distributing, and analyzing of ZOLOFT® did not result in avoidable injuries.

56. The injuries of Minor Plaintiff Noelle M. Ciccone, as described herein, were caused by the negligence of Defendant Pfizer, acting independently and by and through its duly authorized agents, servants and/or employees, who were then and there acting within the course and scope of their employment. Defendant Pfizer was negligent by, among other things:

- a. By failing to ensure ZOLOFT® warnings to the medical community, physicians, Mrs. Ciccone, and her health care providers were accurate and adequate, despite having extensive knowledge of the risks associated with the drug;
- b. By failing in its obligation to provide the medical community, physicians, Mrs. Ciccone, and her health care 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;

- c. By failing to conduct post-marketing safety surveillance and report that information to the medical community, physicians, Mrs. Ciccone, and her health care providers;
- d. By failing to include adequate warnings and/or provide adequate and clinically-relevant information and data that would alert the medical community, physicians, Mrs. Ciccone, and her health care providers to the dangerous risks of ZOLOFT®;
- e. By failing to continually monitor, test, and analyze data regarding safety, efficacy and the prescribing practices for ZOLOFT®;
- f. By failing to review all adverse drug event information (AER) and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by ZOLOFT® to the medical community, physicians, Mrs. Ciccone, and her health care providers;
- g. By 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 associated with women who are pregnant ingesting ZOLOFT® during their pregnancy;
- h. By 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®;
- i. By failing to disclose the results of the testing and other information in its possession regarding the possibility that ZOLOFT® can interfere with the proper development of an unborn fetus;
- j. By failing to adequately warn the medical community, physicians, Mrs. Ciccone, and her health care providers of

the risks associated with taking ZOLOFT® during pregnancy;

- k. By representing that ZOLOFT® was safe for use during pregnancy when, in fact, Pfizer knew, or should have known, that it was unsafe for this use and that ZOLOFT® was associated with congenital birth defects;
- l. By promoting and marketing ZOLOFT® for use with pregnant women, despite the fact that Pfizer knew, or should have known, that ZOLOFT® was associated with an increased risk of congenital birth defects and abnormalities;
- m. By promoting and marketing ZOLOFT® as safe and effective for use with pregnant women when, in fact, it was unsafe;
- n. By 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 poses for an unborn fetus;
- o. By failing to independently monitor their sales of ZOLOFT® and the medical literature, which would have alerted it to the fact that ZOLOFT® was widely over-prescribed to woman of child-bearing 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 the drug;
- p. By advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching and the sale and testing of ZOLOFT®;
- q. By failing to perform adequate and necessary studies to determine and analyze the safety and risks associated with ZOLOFT® use; and,
- r. By failing to act as a reasonably prudent drug manufacturer.

57. The aforementioned negligent conduct of Defendant Pfizer, as detailed above, was a direct and proximate cause of Minor Plaintiff Noelle M. Ciccone's injuries.

58. Pfizer knew, or should have known, that ZOLOFT® could be dangerous and unsafe for pregnant women and their developing fetuses.

59. Minor Plaintiff Noelle M. Ciccone suffered from and continues to suffer from physical injuries in the form of birth defects, including, but not limited to, truncus arteriosus and club foot (right foot), as a direct and proximate result of the negligent conduct of Defendant Pfizer, as described above.

60. Minor Plaintiff Noelle M. Ciccone endured and continues to endure pain and suffering, the loss of enjoyment of the pleasures of life and the presence of the congenital birth defects of which she suffered and will continue to suffer as a result of her mother, Mrs. Ciccone, ingesting ZOLOFT® during pregnancy.

61. The actions of Pfizer, as described herein, were intentional, malicious, wanton, willful or oppressive or were done with gross negligence and reckless indifference to Plaintiffs' and the public's safety and welfare.

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendant Pfizer for:

- a. A fair and just amount of actual damages in an amount to be proved at trial in excess of \$75,000.00;
- b. Costs of suit;
- c. Pre-judgment and post-judgment interest;

- d. Punitive damages in a fair and reasonable amount to punish and deter Defendant Pfizer and others from engaging in such wrongful conduct; and,
- e. Such other and further relief as this Honorable Court deems just and proper to recover for which this suit was brought.

COUNT IV

Minor Plaintiff v. Defendant Pfizer, Inc.

Fraud, Misrepresentation and Suppression

62. Plaintiffs incorporate all allegations in the preceding paragraphs of this Complaint as if set forth more fully herein.

63. Pfizer, having undertaken the manufacturing, marketing, dispensing, distribution and promotion of ZOLOFT® described herein, owed a duty to provide accurate and complete information regarding this product.

64. Pfizer's advertising program, by affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of ZOLOFT® was safe for human use, had no unacceptable side effects, had fewer side effects than other antidepressants, and would not interfere with daily life.

65. Pfizer purposefully concealed, failed to disclose, misstated, downplayed, and understated the health hazards and risks associated with the use of ZOLOFT®. Pfizer, through promotional literature, deceived potential users and prescribers of said drug by relying on only allegedly positive information, including testimonials from allegedly satisfied users, and manipulating statistics to suggest widespread acceptability, while concealing, misstating, and downplaying the known adverse and serious health effects. Pfizer falsely and deceptively kept

relevant information from potential ZOLOFT® users and minimized prescriber concerns regarding the safety and efficacy of ZOLOFT®.

66. In particular, in the materials disseminated by Pfizer, Pfizer falsely and deceptively misrepresented or omitted a number of material facts regarding the previously stated allegations including, but not limited to, the following:

- a. The presence and adequacy of testing ZOLOFT®; and,
- b. The severity and frequency of adverse congenital birth defects, heart defects, PPHN and/or other related conditions, including, but not limited to, truncus arteriosus and club foot, caused by a mother taking ZOLOFT® during pregnancy.

67. The aforementioned misrepresentations by Defendant Pfizer were reasonably relied upon by Mrs. Ciccone and/or her prescribing physicians to her detriment.

68. Minor Plaintiff Noelle M. Ciccone suffered from and continues to suffer from physical injuries as a direct and proximate result of the aforesaid negligent conduct of Defendant Pfizer.

69. Minor Plaintiff Noelle M. Ciccone sustained general and special damages in the past, including pain and suffering, mental anguish, embarrassment and humiliation, disfigurement and the loss of enjoyment of the pleasures of life as a result of the presence of congenital birth defects and/or other related conditions, and continues and will continue to suffer these same injuries and damages in the future, causing Plaintiffs to sustain damages in a sum in excess of the jurisdictional minimum of this Court.

70. The foregoing actions of Defendant Pfizer, as described herein, were intentional, malicious, wanton, willful or oppressive or were done with gross negligence and reckless indifference to Plaintiffs' and the public's safety and welfare.

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendant Pfizer for:

- a. A fair and just amount of actual damages in an amount to be proved at trial in excess of \$75,000.00;
- b. Costs of suit;
- c. Pre-judgment and post-judgment interest;
- d. Punitive damages in a fair and reasonable amount to punish and deter Defendant Pfizer and others from engaging in such wrongful conduct; and,
- e. Such other and further relief as this Honorable Court deems just and proper to recover for which this suit was brought.

COUNT IV

Parent Plaintiffs v. Defendant Pfizer, Inc.

Negligence – Failure to Warn

71. Plaintiffs incorporate all allegations contained in the preceding paragraphs of this Complaint as if stated more fully at length herein.

72. As a result of Defendant Pfizer's negligent conduct, as detailed in Count I of the within Complaint, Parent Plaintiffs were damaged.

WHEREFORE, Parent Plaintiffs demand judgment in their favor and against Defendant Pfizer for:

- a. All medical, hospital, surgical, nursing and other damages related to the treatment and care of the injuries suffered by Minor Plaintiff Noelle M. Ciccone for the congenital birth defects she suffered and will continue to suffer from related to Mrs. Ciccone's ingestion of ZOLOFT® during pregnancy.

COUNT V

Parent Plaintiffs v. Defendant Pfizer, Inc.

Negligence – Failure to Warn

73. Plaintiffs incorporate all allegations contained in the preceding paragraphs of this Complaint as if stated more fully at length herein.

74. As a result of Defendant Pfizer's negligent conduct, as detailed in Count II of the within Complaint, Parent Plaintiffs were damaged.

WHEREFORE, Parent Plaintiffs demand judgment in their favor and against Defendant Pfizer for:

- a. All medical, hospital, surgical, nursing and other damages related to the treatment and care of the injuries suffered by Minor Plaintiff Noelle M. Ciccone for the congenital birth defects she suffered and will continue to suffer from related to Mrs. Ciccone's ingestion of ZOLOFT® during pregnancy.

COUNT VI

Parent Plaintiffs v. Defendant Pfizer, Inc.

Negligence

75. Plaintiffs incorporate all allegations contained in the preceding paragraphs of this Complaint as if stated more fully at length herein.

76. As a result of Defendant Pfizer's negligent conduct, as detailed in Count III of the within Complaint, Parent Plaintiffs were damaged.

WHEREFORE, Parent Plaintiffs demand judgment in their favor and against Defendant Pfizer for:

- a. All medical, hospital, surgical, nursing and other damages related to the treatment and care of the injuries suffered by Minor Plaintiff Noelle M. Ciccone for the congenital birth defects she suffered and will continue to suffer from related to Mrs. Ciccone's ingestion of ZOLOFT® during pregnancy.

COUNT VII

Parent Plaintiffs v. Defendant Pfizer, Inc.

Fraud, Misrepresentation and Suppression

77. Plaintiffs incorporate all allegations contained in the preceding paragraphs of this Complaint as if stated more fully at length herein.

78. As a result of Defendant Pfizer's negligent conduct, as detailed in Count IV of the within Complaint, Parent Plaintiffs were damaged.

WHEREFORE, Parent Plaintiffs demand judgment in their favor and against Defendant Pfizer for:

- a. All medical, hospital, surgical, nursing and other damages related to the treatment and care of the injuries suffered by Minor Plaintiff Noelle M. Ciccone for the congenital birth defects she suffered and will continue to suffer from related to Mrs. Ciccone's ingestion of ZOLOFT® during pregnancy.

Respectfully submitted,

ROBERT PEIRCE & ASSOCIATES, P.C.

By: /s/ D. Aaron Rihn, Esquire

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CIVIL COVER SHEET

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 THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

Noelle M. Ciccone, a minor by Denise M. Ciccone and
Nicholas L. Ciccone, Guardians and Individually,

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

(c) Attorney's (Firm Name, Address, and Telephone Number)

D. Aaron Rihn, Esquire - Robert Peirce & Associates
2500 Gulf Tower, 707 Grant Street, Pittsburgh, PA 15219
412-281-7229

DEFENDANTS

Pfizer, Inc.

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

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

Attorneys (If Known)

II. BASIS OF JURISDICTION

(Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
☐ 2 U.S. Government Defendant
☐ 3 Federal Question (U.S. Government Not a Party)
☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES

(For Diversity Cases Only)

- | | PTF | DEF | | PTF | DEF |
|---|---------------------------------------|----------------------------|--|----------------------------|---------------------------------------|
| Citizen of This State | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated <i>or</i> Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated <i>and</i> Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT

(Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury PERSONAL INJURY <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input checked="" type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 463 Habeas Corpus - Alien Detainee <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights PRISONER PETITIONS <input type="checkbox"/> 510 Motions to Vacate Sentence Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition			

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
☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

28 USC 1332

Brief description of cause:

Diversity Products Liability Action - Pharmaceutical

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23
DEMAND \$ in excess of \$75,000.00

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

DOCKET NUMBER

DATE

SIGNATURE OF ATTORNEY OF RECORD

08/23/2012

/s/ D. Aaron Rihn

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

JS 44AREVISED June, 2009
IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA
THIS CASE DESIGNATION SHEET MUST BE COMPLETED

PART A

This case belongs on the (☐ Erie ☐ Johnstown ☒ Pittsburgh) calendar.

1. **ERIE CALENDAR** - If cause of action arose in the counties of Crawford, Elk, Erie, Forest, McKean, Venang or Warren, OR plaintiff or defendant resides in one of said counties.
2. **JOHNSTOWN CALENDAR** - If cause of action arose in the counties of Bedford, Blair, Cambria, Clearfield or Somerset OR any plaintiff or defendant resides in one of said counties.
3. Complete if on **ERIE CALENDAR**: I certify that the cause of action arose in _____ County and that the _____ resides in _____ County.
4. Complete if on **JOHNSTOWN CALENDAR**: I certify that the cause of action arose in _____ County and that the _____ resides in _____ County.

PART B (You are to check ONE of the following)

1. ☐ This case is related to Number _____. Short Caption_____.
2. ☒ This case is not related to a pending or terminated case.

DEFINITIONS OF RELATED CASES:

CIVIL: Civil cases are deemed related when a case filed relates to property included in another suit or involves the same issues of fact or it grows out of the same transactions as another suit or involves the validity or infringement of a patent involved in another suit
EMINENT DOMAIN: Cases in contiguous closely located groups and in common ownership groups which will lend themselves to consolidation for trial shall be deemed related.

HABEAS CORPUS & CIVIL RIGHTS: All habeas corpus petitions filed by the same individual shall be deemed related. All pro se Civil Rights actions by the same individual shall be deemed related.

PART C

I. CIVIL CATEGORY (Place **x** in only applicable category).

1. ☐ Antitrust and Securities Act Cases
2. ☐ Labor-Management Relations
3. ☐ Habeas corpus
4. ☐ Civil Rights
5. ☐ Patent, Copyright, and Trademark
6. ☐ Eminent Domain
7. ☐ All other federal question cases
8. ☒ All personal and property damage tort cases, including maritime, FELA, Jones Act, Motor vehicle, products liability, assault, defamation, malicious prosecution, and false arrest
9. ☐ Insurance indemnity, contract and other diversity cases.
10. ☐ Government Collection Cases (shall include HEW Student Loans (Education), V A Overpayment, Overpayment of Social Security, Enlistment Overpayment (Army, Navy, etc.), HUD Loans, GAO Loans (Misc. Types), Mortgage Foreclosures, S.BA. Loans, Civil Penalties and Coal Mine Penalty and Reclamation Fees.)

I certify that to the best of my knowledge the entries on this Case Designation Sheet are true and correct

/s/ D. Aaron Rihn

Date: 08/23/2012

ATTORNEY AT LAW

NOTE: ALL SECTIONS OF BOTH SIDES MUST BE COMPLETED BEFORE CASE CAN BE PROCESSED.

JS 44 Reverse (Rev. 12/07)

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44**Authority For Civil Cover Sheet**

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553
Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.