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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MELISSA J. HAGAN AND MICHAEL A. HAGAN, INDIVIDUALLY AND AS PARENTS AND NATURAL GUARDIANS OF DECEDENT A.H., A MINOR CHILD,

Plaintiffs,

v.

PFIZER INC., a Delaware Corporation,

Defendant.

Civil Action No.:

COMPLAINT

JURY TRIAL DEMANDED

Plaintiffs Melissa J. Hagan and Michael A. Hagan bring this action for damages against Defendant Pfizer Inc., and for their causes of action allege:

PARTIES

1. Melissa J. Hagan and Michael A. Hagan ("Plaintiffs") are the parents of A.H., Deceased ("Decedent A.H.").

2. Plaintiff Melissa J. Hagan ("Mrs. Hagan") took the drug ZOLOFT® during her pregnancy.

3. Decedent A.H. was born in November 2009 at Henrico Doctors' Hospital in Richmond, Henrico County, Virginia and died seventeen days later on December 12, 2009 at the University of Virginia Medical Center in Charlottesville, VA.

4. Pfizer Inc. ("Pfizer") is a Delaware corporation with its principal place of business in New York City, 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 Virginia, New York, and throughout the United States. Pfizer may be served with process by registered mail, return receipt requested, upon CT Corporation System, 111 Eighth Avenue, New York, NY 10011.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction of this matter pursuant to 28 U.S.C. §1332 because complete diversity exists as between the parties. Defendant Pfizer is a Delaware corporation with a principal place of business of New York, New York. Plaintiffs are citizens of a state other than New York or Delaware and Plaintiffs seek damages in excess of $75,000.

6. Venue is proper in this Court because at all times relevant to this Complaint, Pfizer has and continues to engage in continual business in this District and maintains its principal place of business in New York, New York. Additionally, a significant amount of the wrongful death acts and omissions alleged by Plaintiffs took place in this District.

GENERAL ALLEGATIONS

7. Plaintiffs are the natural parents of the deceased, a minor child, who was born with, and died as a result of, multiple congenital cardiac birth defects, including, but not limited to, transposition of the great arteries, ventricular septal defect, patent foramen ovale, double outlet right ventricle, secundum atrial septal defect, and respiratory distress, and other

cardiopulmonary defects, as a result of Mrs. Hagan's ingestion of ZOLOFT® as prescribed by her treating physicians during her pregnancy.

8. Plaintiffs bring this action to recover wrongful death damages, medical and other expenses related to the treatment resulting from Decedent A.H.'s birth defects, disorders, related illnesses and his death, and for general and special damages, including punitive damages, and such other relief as requested herein for injuries and death suffered as a direct result of Mrs. Hagan's ingestion of ZOLOFT®.

9. Plaintiffs are the parents of Decedent A.H. and this action is brought on their behalf pursuant to Va. Code § 8.01-50 (2011), Virginia's Wrongful Death Statute.

10. Plaintiffs have standing to prosecute this wrongful death action pursuant to the provisions of Va. Code § 8.01-50 in that Decedent A. H. was unmarried and had no children, therefore, Plaintiffs are the sole persons entitled to recover under Va. Code § 8.01-50 (2011).

11. 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®.

12. The drug "Sertraline" is manufactured, promoted, distributed, labeled and marketed by Pfizer under the trade name ZOLOFT®, ZOLOFT® Oral Suspension, and ZOLOFT® CR (hereinafter "ZOLOFT"), 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, 2001; 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 mg.

13. Decedent A.H.'s injuries and death were a direct result of Mrs. Hagan's ingestion of ZOLOFT® during her pregnancy in a manner and dosage recommended by Pfizer and prescribed by Mrs. Hagan's doctors.

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

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

15. Prior to Mrs. Hagan 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.

16. Prior to the time that Mrs. Hagan ingested ZOLOFT® during pregnancy, Pfizer knew or should have known that ZOLOFT® posed an increased risk of congenital birth defects, heart defects, PPHN and other related conditions.

17. Prior to Mrs. Hagan'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 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.

18. Prior to the time that Mrs. Hagan 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.

19. Prior to the time that Mrs. Hagan 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, and other cardiopulmonary defects.

20. 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).

21. Prior to the time that Mrs. Hagan 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); Buproprion (Wellbutrin); Citalopram (Celexa); Escitalopram (Lexapro); Fluvoxamine (Luvox); Fluoxentine (Prozac); Paroxetine (Paxil); and, Venlafaxine (Effexor).

22. Before Mrs. Hagan ingested ZOLOFT®, Pfizer knew of studies within the same class of drug demonstrating that mothers exposed to SSRI's late in their pregnancy 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 Fluoxentine, 335 New Eng J. Med. 1010-15 (1996).

23. 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).

24. Pfizer knew or should have known, at the latest, on or around 2005, SSRI use including ZOLOFT®, after the 20th 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).

25. 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).

26. Importantly, Pfizer knew or should have known by 2007, that SSRI's, 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).

27. 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).

28. Further studies confirmed these earlier findings. The Kornum Study looked at 216,042 women, 2062 of whom had taken an SSRI during pregnancy. The conclusions were that all SSRI's (except Paroxetine) were associated with increased risk of cardiac malformation. Notably, ZOLOFT® was associated with a threefold increased risk of cardiac malformation. ZOLOFT® was also 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).

29. 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.

30. Prior to Mrs. Hagan'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 about 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.

31. Pfizer had actual knowledge that doctors frequently prescribed ZOLOFT® to women of childbearing potential for approved uses of the drug and that doctors frequently prescribed ZOLOFT® to women of childbearing potential for un-approved, or off-label, uses of the drug.

32. Pfizer failed to disclose adequately the increased 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.

33. 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. Hagan's physicians and other foreseeable users similarly situated.

34. Despite having extensive knowledge of the extreme risks associated with the 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.

35. The current Zoloft® label *still* 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 CONTINUES TO MISREPRESENT THE SAFETY AND EFFICACY OF ZOLOFT®

36. 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 Mrs. Hagan 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.

37. 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.

COUNT I

Strict Products Liability/Defective Design

Come now Plaintiffs and for Count I of their Complaint against Pfizer allege:

38. Plaintiffs incorporate all allegations in the preceding paragraphs as if fully set forth in this Count.

39. 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. Hagan and others.

40. At the time the ZOLOFT® was manufactured and sold to Mrs. Hagan by Pfizer, it was defective in design and unreasonably dangerous, subjecting users to risks of heart attacks, strokes, and other illnesses which exceeded the benefits of the products, and for which other safer products were available.

41. Alternatively, when the ZOLOFT® products were manufactured and sold to Mrs. Hagan by Defendant, the products were defective in design and formulation, making use of the products more dangerous than other drugs for pain relief.

42. The ZOLOFT® sold to Mrs. Hagan reached her without substantial change. Mrs. Hagan was unaware of the dangerousness of the products until after his use and the development of heart attack and stroke. Mrs. Hagan ingested the ZOLOFT® without making any changes or alterations.

43. As a direct and proximate result of the defective and dangerous design of the ZOLOFT®, Decedent A.H. suffered serious cardiac defects and died. Pfizer's conduct was done

with conscious disregard for the safety of users of ZOLOFT®, including Plaintiffs and Decedent A.H., 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 Pfizer and others from engaging in the wrongful conduct; and

E. Such other and further relief as the Court deems just and proper under the circumstances.

COUNT II

Strict Products Liability/Failure to Warn

Come now Plaintiffs and for Count II of their Complaint against Defendant Pfizer allege:

44. Plaintiffs incorporate all allegations in the preceding paragraphs as if fully set forth in this Count.

45. The ZOLOFT® manufactured and supplied by Pfizer was unaccompanied by proper and adequate warnings regarding all adverse side effects associated with the use of ZOLOFT®, and the comparative severity and duration of the adverse effects. The warnings given by Pfizer did not accurately reflect the symptoms, type, scope or severity of the side effects, and in particular the risks of injuring unborn children for women who take ZOLOFT® during their pregnancy.

46. Pfizer failed to perform adequate testing and study ZOLOFT® prior to marketing it or properly analyze and warn based on results of various studies linking SSRIs including ZOLOFT® with congenital birth defects. Such adequate testing, study or analysis of the studies would have shown that ZOLOFT® possessed serious life threatening side effects to unborn children whose mothers took ZOLOFT® during pregnancy, with respect to which full and proper warnings accurately and fully reflecting symptoms, type of illness, scope and severity should have been given with respect to the use of ZOLOFT®.

47. Pfizer also failed to act properly on adverse reports it received about ZOLOFT®, and failed to properly study ZOLOFT® pre-market as well as post market and analyze and follow up on studies regarding the effects of SSRIs on unborn children whose mothers took SSRIs.

48. Pfizer failed to give adequate post-marketing warnings or instructions for the use of ZOLOFT® because after Pfizer knew or should have known of the risk of injury from ZOLOFT® use, Pfizer failed to provide adequate warnings to users or consumers and continued to aggressively promote the product to doctors, hospitals, and directly to consumers.

49. As a direct and proximate result of Pfizer's failure to warn of the potentially severe side effects of the ZOLOFT® products, as well as the other conduct mentioned in this Count, Plaintiffs' son Decedent A.H., suffered cardiac birth defects and died.

50. Pfizer's conduct was done with conscious disregard for safety, 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 Pfizer and others from engaging in the wrongful conduct; and

E. Such other and further relief as the Court deems just and proper under the circumstances.

COUNT III

Negligence/ Design Defect

Come now Plaintiffs and for Count III of their Complaint against Defendant Pfizer allege:

51. Plaintiffs incorporate all allegations in the preceding paragraphs as if fully set forth in this Count.

52. 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. Hagan and others.

53. At the time the ZOLOFT® was manufactured and sold to Mrs. Hagan by Pfizer, it was defective in design and unreasonably dangerous, subjecting users to risks of heart attacks, strokes, blood clots, and other illnesses which exceeded the benefits of the products, and for which other safer products were available.

54. Alternatively, when the ZOLOFT® products were manufactured and sold to Mrs. Hagan by Pfizer, the product was defective in design and formulation, making use of the product more dangerous than other drugs for pain relief.

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

56. 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.

57. As a direct and proximate result of the negligent design of the ZOLOFT®, Plaintiffs' son, Decedent A.H., suffered serious cardiac defects and died.

58. Pfizer's conduct was done with conscious disregard for the safety of users of ZOLOFT®, including Plaintiffs and Decedent A.H., 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. An award of punitive damages; and

E. Such other and further relief as the Court deems just and proper under the circumstances.

COUNT IV

Negligence/ Failure to Warn

Come now Plaintiffs and for Count IV of their Complaint against Defendant Pfizer, allege:

59. Plaintiffs incorporate all allegations in the preceding paragraphs as is fully set forth in this Count.

60. Pfizer owed a duty to warn of any dangerous defects or side effects; a duty to assure its product 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 their pregnancy.

61. 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, including heart attacks, strokes, hypertension, atherosclerosis, blood clots, and other serious side effects, and warn users of those risks; 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. Warn Plaintiffs that use of ZOLOFT® carried a risk of death or permanent disability from heart attack, strokes, blood clots, other cardiovascular disorders and other serious side effects; and/or

d. Advise the FDA, the health care industry, and the public about the adverse reports it had received regarding ZOLOFT®; and/or

e. Other appropriate warnings.

62. Pfizer 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 products for pain control.

63. As a direct and proximate result of Pfizer's negligence and breaches of its duty of reasonable care, Decedent A.H. was born with serious cardiac birth defects, and died from these defects, and 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 $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 Pfizer and others from engaging in the wrongful conduct; and

E. Such other and further relief as the Court deems just and proper under the circumstances.

COUNT V

Negligence

64. Plaintiffs restate and incorporate by reference all prior allegations set forth herein.

65. 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® to ensure that the use of ZOLOFT® did not result in avoidable injuries.

66. The injuries and death of Decedent A.H. as described herein were caused by the negligence of Pfizer, through its agents, servants and/or employees, acting within the course and scope of their employment including among other things:

a. failing to ensure ZOLOFT® warnings to the medical community, physicians, Mrs. Hagan, and her health care providers were accurate and adequate, despite having extensive knowledge of the risks associated with the drug;

b. failing in its obligation to provide the medical community, physicians, Mrs. Hagan, and her health care providers 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;

c. failing to conduct post-marketing safety surveillance and report that information to the medical community, physicians, Mrs. Hagan, and her health care providers;

d. failing to include adequate warnings and/or provide adequate and clinically relevant information and data that would alert the medical community, physicians, Mrs. Hagan, and her health care providers to the dangerous risks of ZOLOFT®;

e. failing continually to monitor, test, and analyze data regarding safety, efficacy and the prescribing practices for ZOLOFT®;

f. 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. Hagan, and her health care providers;

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;

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 its warnings, efficacy, or safety of ZOLOFT®;

i. 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. failing to warn adequately the medical community, physicians, Mrs. Hagan, and her health care providers;

k. 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. 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 abnormalities;

m. promoting and marketing ZOLOFT® as safe and effective for use with pregnant women when, in fact, it was unsafe;

n. 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. 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 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 the drug;

p. 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. failing to perform adequate and necessary studies to determine and analyze the safety and risks associated with ZOLOFT® use; and

r. failing to act as a reasonably prudent drug manufacturer.

67. The above-described culpable conduct by Pfizer was a proximate cause of Plaintiffs' and Decedent's injuries.

68. Pfizer knew or should have known that ZOLOFT® could be dangerous and unsafe for pregnant women and the developing fetus.

69. Decedent A.H. suffered from physical injuries and died as a direct and proximate result of the above conduct of Pfizer. Decedent A.H. sustained pain and suffering, the loss of

enjoyment of the pleasures of life without the presence of the congenital birth defect of which she suffered, and ultimately died as a result of his mother taking ZOLOFT® during pregnancy.

70. 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 $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 Pfizer and others from engaging in the wrongful conduct; and

E. Such other and further relief as the Court deems just and proper under the circumstances.

COUNT VI

Fraud, Misrepresentation and Suppression

71. Plaintiffs restate and incorporate by reference all prior allegations as if set forth herein.

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

73. 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.

74. On information and belief, 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®.

75. 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 of ZOLOFT®; and

b. The severity and frequency of adverse congenital birth defects, heart defects, PPHN and/or other related conditions caused by a mother taking ZOLOFT® during pregnancy.

76. The aforementioned misrepresentations by Pfizer were reasonably relied upon by Mrs. Hagan and/or her prescribing physicians to their detriment.

77. Decedent A.H. suffered from physical injuries as a direct and proximate result of the aforesaid conduct of Pfizer, Decedent A.H. 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 without the presence of congenital birth defects and/or other related conditions, and ultimately died, causing Plaintiffs to sustain damages in a sum in excess of the jurisdictional minimum of this Court.

78. The forgoing actions of the 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 $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 Pfizer and others from engaging in the wrongful conduct; and

E. Such other and further relief as the Court deems just and proper under the circumstances.

Dated: October 26, 2011

Respectfully submitted,

By 

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