

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

<b>IN RE: ZOLOFT (SERTRALINE HYDROCHLORIDE) PRODUCTS LIABILITY LITIGATION</b>	<b>CIVIL ACTION NO.:</b>  <b>MDL No. 2342 12-MD-2342</b>
<b>RYAN EATON and JUSTYNE EATON,</b>	
<b>Plaintiffs,</b>	
<b>vs.</b>	<b>COMPLAINT FOR DAMAGES</b>
<b>PFIZER, INC., PFIZER INTERNATIONAL, LLC, and GREENSTONE, LLC,</b>	<b>JURY TRIAL DEMANDED</b>
<b>Defendants.</b>	

**COMPLAINT**

1. Plaintiffs, Ryan Eaton and Justyne Eaton, by and through undersigned counsel, files this Complaint against Defendants Pfizer, Inc., Pfizer International, LLC, and Greenstone, LLC, (hereinafter “Defendants”) to recover for the wrongful death of their child, Aubry Eaton, and for the injuries they personally suffered as a result of Aubry’s death.

2. Justyne Eaton was prescribed and did ingest sertraline hydrochloride (“Sertraline”), marketed and sold under the brand name Zoloft® during her pregnancy with Aubry Eaton.

3. Zoloft, a prescription drug manufactured and marketed by Defendants, is defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce and lacks proper warnings as to the dangers associated with its use. Sertraline, the generic form of Zoloft®, manufactured by Greenstone, LLC, is also defective dangerous to human health,

unfit and unsuitable to be marketed and sold in commerce and lacks proper warnings as to the dangers associated with its use.

4. This wrongful death products liability action arises out of the death of Aubry Eaton, who was born with severe birth defects as a result of exposure to Zoloft and/or Sertraline in utero.

5. On January 6, 2010, Justyne Eaton gave birth to Aubry Eaton. Aubry Eaton was born with severe birth defects, including significant malformations of the brain, severe hydrocephalus, and pulmonary hypoplasia.

6. On January 6, 2010, Aubry Eaton died as a result of her birth defects.

**PARTIES**

7. Ryan Eaton and Justyne Eaton are competent adults and residents of Winnebago County, Wisconsin. Ryan Eaton and Justyne Eaton are the biological parents of Decedent Aubry Eaton. Ryan Eaton and Justyne Eaton bring this action individually to recover damages for the wrongful death of their daughter and to recover damages for their individual economic and noneconomic damages resulting from their daughter's death.

8. As the biological parents of Decedent Aubry Eaton, Ryan Eaton and Justyne are proper plaintiffs to bring this wrongful death products liability action pursuant to W.S.A. § 895.04.

9. Upon information and belief, Defendant Pfizer, Inc. ("Pfizer") is a Delaware corporation with its principal place of business located at 235 East 42<sup>nd</sup> Street, New York, New York. Pfizer may be served with process by serving its registered agent: CT Corporation, 116 Pine Nut Street, Suite 320, Harrisburg, Pennsylvania 17101.

10. Upon information and belief, Defendant Pfizer International, LLC, (“Pfizer International”) a New York limited liability company, was and still is a business entity organized under and by virtue of the laws of the State of New York with its principal place in New York, New York. Pfizer International may be served with process by serving its registered agent: CT Corporation, 111 Eighth Avenue, New York, New York 10011. At all times hereinafter mentioned, defendant Pfizer International was, and still is, a pharmaceutical company involved in the research, development, testing, manufacture, production, promotion, distribution, and marketing of pharmaceuticals for distribution, sale and use by the general public, which includes the distribution, sale, and usage of the drug Zoloft® (known generically as Sertraline), an antidepressant, throughout the United States.

11. Upon information and belief, Defendant Greensone, LLC (“Greenstone”) is a Delaware corporation with its principal place of business located at 100 Route 206 North, Peapack, New Jersey. Upon information and belief, Greenstone is a wholly owned subsidiary of Defendant Pfizer. Greenstone may be served with process by serving its registered agent: The Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware 19801.

12. Defendant Greenstone began marketing, manufacturing, selling, and distributing a generic form of Zoloft in or about June 2006; making Greenstone the manufacturer and labeler of Sertraline at all relevant times.

13. Defendants Pfizer, Pfizer International, and Greenstone are hereinafter collectively referred to as Defendants.

**JURISDICTION AND VENUE**

14. This Court has diversity subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 (a) “The district courts shall have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of \$75,000.00, exclusive of interest and costs, and is between: (1) citizens of different states.” Plaintiffs are residents of Wisconsin, Defendants Pfizer and Pfizer International are residents of New York, and Defendant Greenstone is a resident of New Jersey.

15. Damages to plaintiff are estimated in good faith to exceed the sum or value of \$75,000.00, exclusive of interests or costs. The court also has personal jurisdiction over the parties because Plaintiff submits to the jurisdiction of the Court and defendant systematically and continually conducts business here and throughout the U.S., including marketing, advertising, and sales directed to residents of the jurisdiction where plaintiff resides.

15. Venue is proper in this Court pursuant to 28 U.S.C. §1391(a)-(c) by virtue of the fact that defendants’ products were sold to and consumed by individuals in the State of Pennsylvania and thereby subjects defendants to personal jurisdiction in this action and makes them a “resident” of this judicial district.

**FACTS**

16. Defendants advertise, assemble, compound, design, develop, distribute, formulate, inspect, label, manufacture, market, package, produce, promote, process, research, test, and sell Zolof® and/or Sertraline.

17. The prescription drug Sertraline is advertised, analyzed, assembled, compounded, designed, developed, formulated, packaged, produced, processed, researched, sold, tested, manufactured, promoted, marketed, distributed, and labeled by Defendants, their predecessors in

interest and subsidiaries, under the trade name Zoloft®, Zoloft® Oral Suspension, and Zoloft® CR (collectively, Zoloft®) and is a member of a class of drugs known as “selective serotonin reuptake inhibitors” or “SSRIs.” Zoloft® was first approved for use in the United States by the Food and Drug Administration (“FDA”) for the treatment of Major Depressive Disorder (“MDD”) on December 30, 1991; Obsessive-Compulsive Disorder (“OCD”) on October 25, 1996; for children with OCD on October 10, 1997; Panic Disorder on July 8, 1997; Acute Post-Traumatic Stress Disorder (“PTSD”) on December 7, 1999, and for chronic, long-term PTSD on August 6, 2001; Premenstrual Dysphoric Disorder on May 16, 2002; and Social Anxiety Disorder on February 7, 2003. Zoloft® is supplied for oral administration as scored tablets in doses of 25, 50, and 100mg.

18. Under the FDA scheme, Defendants knew, as a New Drug Application (“NDA”) applicant, that it must fully, truthfully and accurately disclose to the FDA data and information regarding a new drug’s chemistry, proposed manufacturing process, proposed model labeling which includes warnings about risks and side effects, test results for the drug, results of animal studies, results of clinical studies, and the drug’s bioavailability, because the data and information would be relied upon by the medical community, including Justyne Eaton’s physicians, and foreseeable prescribers and users of Zoloft and/or Sertraline, including Justyne Eaton, once the NDA was approved.

19. Pfizer advertises that, through its wholly owned subsidiary Greenstone, it continues to offer generic equivalents to branded pharmaceuticals that are distributed under the manufacturer’s NDA.

20. Defendant Greenstone adopted, in substance, the test of the “package insert” for Zoloft, as revised from time to time by Pfizer, as the package insert for Sertraline, modified only

to reflect therapeutically irrelevant differences among products, such as color, shape, inactive ingredients, and source of manufacturer, as required by federal law.

21. Defendant Greenstone relied upon Pfizer to communicate to physicians adequate information concerning the appropriate length of use and risks entailed in the use of Sertraline products, including both Zoloft and the bioequivalent and therapeutically equivalent generic Sertraline, and Defendant Greenstone adopted, as applicable to its own Sertraline product, such information as was disseminated about Zoloft and/or Sertraline by Pfizer.

22. Under the FDA scheme, Defendants have a duty to ensure its warnings to the medical community are and remain accurate and adequate, to conduct safety surveillance of adverse events for the drug, to report any data related to the safety and/or accuracy of the warnings and information disseminated regarding the drug, and to update the label when new safety information was obtained.

23. The package inserts for Sertraline, and the PDR monograph for Zoloft, contained false and/or misleading statements and omitted information material to the foreseeable and ordinary contemplated uses of Sertraline and Zoloft. False and/or misleading information was also provided by Pfizer, and adopted by Greenstone, by way of Pfizer's advertising, marketing materials, detail persons, seminars, presentations, publications, notice letters, and regulatory submissions.

24. Prior to Justyne Eaton becoming pregnant, Defendants knew or should have known that taking Zoloft and/or Sertraline during pregnancy posed risks to the developing fetus. Defendants knew or should have known that Zoloft and/or Sertraline crosses the placenta, which has important implications and poses significant risks for a developing fetus.

25. Prior to Justyne Eaton becoming pregnant, Defendants knew or should have known from available information that SSRI drugs, as a class, including Zoloft and/or Sertraline posed an increased risk of multiple congenital birth defects and that children were, in fact, being born with congenital birth defects, heart defects, PPHN, and other similar conditions to women who took Zoloft and/or Sertraline during pregnancy. This class of drugs includes Citalopram (Celexa®), Escitalopram (Lexapro®), Fluvoxamine (Luvox®), Fluoxetine (Prozac®), and Paroxetine (Paxil®).

26. Prior to the time that Justyne Eaton ingested Zoloft and/or Sertraline during her pregnancy, Defendants knew of the dangerous birth defects associated with the use of Zoloft and/or Sertraline during pregnancy from the non-human mammalian, preclinical studies and the subsequent published studies confirming these risks. Defendants took no action to adequately warn or remedy the risks, but instead concealed, suppressed, and failed to disclose the dangers. Defendants had access to this information and knew that Zoloft and/or Sertraline caused congenital birth defects and knew that prescribing physicians and the consumers, such as Justyne Eaton, did not fully understand the risks associated with Zoloft and/or Sertraline exposure.

27. Defendants failed to fully, truthfully, and accurately disclose Zoloft and/or Sertraline data to the FDA, the public, including Justyne Eaton, and the medical community, including Justyne Eaton's physicians, and as result negligently, intentionally, and fraudulently misled the medical community, physicians, including Justyne Eaton's physicians, and the public, including Justyne Eaton, about the risks to a fetus caused by Zoloft and/or Sertraline exposure during pregnancy.

28. Through the *Physicians' Desk Reference*, drug package inserts, patient information forms, counseling warnings, literature, marketing materials and other labeling

information for Zoloft and/or Sertraline, Defendants knowingly, intentionally, and negligently disseminated incomplete, inaccurate, and/or misleading warnings and information about the true risks to a fetus caused by Zoloft and/or Sertraline exposure during pregnancy, which misled the community and physicians, including Justyne Eaton's physicians to believe that Zoloft and/or Sertraline exposure during pregnancy was safe.

29. At all relevant times, Defendants knew or should have known that most physicians were not aware of or did not fully appreciate the seriousness of the birth defect risks associated with the use of Zoloft and/or Sertraline and that, consequently, there was a widespread tendency for physicians to prescribe Zoloft and/or Sertraline to women for use during pregnancy and of childbearing potential. Consequently, Defendants knew or should have known that the warnings and labels, including, but not limited to, package inserts and the *Physicians' Desk Reference* monograph for Zoloft and/or Sertraline, did not adequately inform physicians about the birth defect risks associated with Zoloft and/or Sertraline exposure during pregnancy.

30. Defendants failed to adequately warn the medical community, including Justyne Eaton's physicians, and the public, including Justyne Eaton, about the risks of birth defects associated with exposure to Zoloft and/or Sertraline during pregnancy, despite the fact that Defendants knew that the medical community, including Justyne Eaton's physicians, and the public, including Justyne Eaton, relied on Defendants to disclose what they knew or should have known from a prudent review of the information that they possessed or to which they had access.

31. Defendants provided misleading information to the FDA and medical community, including Justyne Eaton's physicians, about the true birth defect risks associated with exposure to Zoloft and/or Sertraline, by representing to physicians that Zoloft and/or Sertraline was safe for use by women of childbearing years and their unborn child.



32. Defendants knew or should have known that the warnings, including, but not limited to, the label and package insert for Zoloft and/or Sertraline, did not disclose the true risks of birth defects from Zoloft and/or Sertraline exposure during pregnancy. Defendants failed to use reasonable care to modify the warnings, including but not limited to, the label and package insert for Zoloft and/or Sertraline, in order to adequately warn the medical community about the true birth defect risks from the use of Zoloft and/or Sertraline by women who became pregnant.

33. Because of the misleading information that Defendants provided to physicians, the Plaintiffs, and the FDA about the true congenital birth defect risks associated with the use of Zoloft and/or Sertraline and because of the failure of Defendants to adequately inform physicians generally, including Justyne Eaton's physicians, about the true birth defect risks associated with the use of Zoloft and/or Sertraline, Justyne Eaton's physicians never informed her of any congenital birth defects risk associated with Zoloft and/or Sertraline. Indeed, it is believed that Defendants represented to physicians that Zoloft and/or Sertraline was safe for use by women of childbearing years and their unborn children.

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

35. Thus, prior to Justyne Eaton's pregnancy, Defendants had the knowledge, the means, and the duty to provide the medical community, including Justyne Eaton's physician, and the consuming public, including Justyne Eaton, with a stronger warning regarding the association

between Zoloft and/or Sertraline and congenital birth defects, heart defects, neural tube 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. Defendants breached this duty.

36. Despite having extensive knowledge of the extreme risks associated with Zoloft and/or Sertraline usage, as well as the duty to properly and adequately warn foreseeable users, Defendants have never approached the FDA to alter the label for Zoloft and/or Sertraline and, thus, have taken no action to properly and adequately warn of the risks of birth defects associated with Zoloft and/or Sertraline usage during pregnancy.

37. Defendants failed to disclose adequately the increased risk of congenital birth defects with regard to Zoloft and/or Sertraline usage during pregnancy to the medical community, including Justyne Eaton's physicians, and the consuming public, including Justyne Eaton. Defendants were aware that their failure to disclose this information would result in serious injury and/or death to the children and/or unborn fetuses of women who were prescribed Zoloft and/or Sertraline during pregnancy by physicians who were not aware of the risks. By failing to disclose this information to the medical community, including Justyne Eaton's physicians, and the consuming public, including Justyne Eaton, Defendants acted in a willful, wanton, and outrageous manner and with disregard of the rights of Justyne Eaton, Ryan Eaton, and Aubry Eaton and this conduct caused severe injuries to and ultimately resulted in the death of Aubry Eaton.

38. Defendants, their agents, servants and employees, acting in the course and scope of their employment, negligently and carelessly breached their duties to the medical community, including Justyne Eaton's physicians, and the consuming public, including Justyne Eaton, by:

- (a) failing to ensure Zoloft and/or Sertraline warnings to the medical community, including Justyne Eaton's physicians, and the public, including Justyne Eaton, were accurate and adequate, despite having extensive knowledge of the risks associated with Zoloft and/or Sertraline usage during pregnancy;
- (b) failing in their obligation to provide the medical community, including Justyne Eaton's physicians, and the public, including Justyne Eaton, with adequately and clinically relevant information, data, and warnings regarding the adverse health risks associated with exposure to Zoloft and/or Sertraline, and/or that there existed safer \ and more or equally effective alternative drug products;
- (c) failing to conduct post market safety surveillance and to report that information to the medical community, including Justyne Eaton's physicians, and the consuming public, including Justyne Eaton;
- (d) failing to include adequate warnings and/or provide adequate and clinically relevant information and data that would alert the medical community, including Justyne Eaton's physicians, and the consuming public, including Justyne Eaton, to the dangerous risks of Zoloft and/or Sertraline usage during pregnancy;
- (e) failing continually monitor, test, and analyze data regarding safety, efficacy, and the prescribing practices for Zoloft and/or Sertraline;
- (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 and/or Sertraline to the medical community, including Justyne Eaton's physicians, and the consuming public, including Justyne Eaton;
- (g) failing to provide adequate post-marketing warnings and instructions after Defendants knew or should have known of the significant risks of, among other things, congenital birth defects risks with Zoloft and/or Sertraline usage during pregnancy;
- (h) failing to periodically review all medical literature regarding Zoloft and/or Sertraline 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 and/or Sertraline;
- (i) failing to disclose the results of the testing and othe information in its possession regarding the possibility that Zoloft and/or Sertraline can interfere with the proper development of an unborn fetus;
- (j) failing to adequately warn the medical community, including Justyne Eaton's physicians, and the consuming public, including Justyne Eaton, of the dangers of using Zoloft and/or Sertraline during pregnancy, including the risk of birth defects;

- (k) representing that Zoloft and/or Sertraline was safe for use during pregnancy when, in fact, Defendants knew or should have known that it was unsafe for this use and that Zoloft and/or Sertraline usage during pregnancy was associated with congenital birth defects;
- (l) promoting and marketing Zoloft and/or Sertraline for use with pregnant women, despite the fact that Defendants knew or should have known that Zoloft and/or Sertraline was associated with an increased risk of birth defects;
- (m) failing to independently monitor their sales of Zoloft and/or Sertraline and the medical literature, which would have alerted them to the fact that Zoloft and/or Sertraline was widely over-prescribed to women of childbearing potential as a result of inadequate warnings, including those in the package inserts and PDR monographs for Zoloft and/or Sertraline, and as a result of the over-promotion of the drug;
- (n) failing to act as reasonably prudent drug manufacturers in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packaging, producing, promoting, processing, researching, selling, and testing of Zoloft and/or Sertraline; and/or
- (o) failing to perform adequate and necessary studies to determine and analyze the safety and risks associated with Zoloft and/or Sertraline usage during pregnancy.

39. Had the Zoloft and/or Sertraline product information warned of the significant risks of birth defects in a developing fetus if used while pregnant, Justyne Eaton would not have ingested Zoloft and/or Sertraline during her pregnancy and her prescribing physicians would not have prescribed Zoloft and/or Sertraline for her to use during pregnancy.

40. As a direct and proximate result of the actions of Defendants, Justyne Eaton and her physicians were unaware and could not reasonably know, or through reasonable diligence could not have reasonably known, that Zoloft and/or Sertraline exposed Aubry Eaton to the risks and injuries alleged herein, including death, and that those risks were the direct and proximate result of Defendants' acts and omissions.

**PFIZER AND GREENSTONE**

41. Greenstone became a wholly-owned subsidiary of Pfizer, Inc. in April, 2003. IN 2006, when the patent for Zoloft was expiring, Pfizer announced that Greenstone would release an authorized generic version of Zoloft. In this way, Pfizer sought to establish a strong presence in the generic marketplace even before other manufacturers could gain approval for their generic versions.

42. Prescription drugs may be approved for sale in the United States in one of three ways. For a new drug, the proponent of the drug files a NDA with FDA and must obtain approval to sell the drug pursuant to that NDA. Ordinary generic drugs, biologically equivalent to a drug that has already been approved, must obtain separate approval through an abbreviated approval process for generic equivalents. The applicant for a generic drug submits an Abbreviated New Drug Application (“ANDA”), which usually does not need to include the kind of preclinical and clinical data used to establish safety and efficacy in a NDA. Instead, the ANDA must demonstrate that the generic version is bioequivalent to an already-approved drug. Authorized generics, by contrast, are manufactured and sold under the original NDA in an enterprise between the branded drug maker and the manufacturer of the generic version.

43. Thus, while the inventor or manufacturer of the branded version may play no role in the sale and marketing of an ordinary generic, authorized generics, by definition, involve the participation and approval of the original applicant of the NDA. In effect, the original sponsor of the NDA licenses the generic manufacturer to manufacture and sell the sponsor’s product under a generic label.

44. The original NDA for Zoloft was submitted to the FDA by Pfizer and Zoloft has been sold at all times by Pfizer pursuant to that original NDA.

45. The Sertraline sold by Greenstone is and was at all relevant times an authorized generic drug, manufactured and sold by Greenstone in cooperation with Defendant Pfizer under Pfizer's NDA.

46. Greenstone manufactured and sold Sertraline pursuant to a contractual agreement with Pfizer pursuant to which Pfizer supplied the NDA license to Greenstone to manufacture and sell Sertraline. Pursuant to the parties' contractual agreement, Greenstone effectively acted as Pfizer's agent in selling Sertraline.

47. At all times relevant to this litigation, Defendants Pfizer and Greenstone engaged in joint efforts to manufacture, market, promote, distribute, and sell Sertraline.

48. Defendants each have an independent duty to continue to monitor the safety of Sertraline by performing adequate and sufficient pharmacovigilance.

49. Defendant each have an independent duty to add or strengthen a warning about a significant hazard as soon as there is reasonable evidence of a causal association with the drug.

50. In marketing, distributing, and selling Sertraline, Greenstone relied upon and continues to rely upon all tests and clinical studies performed by Pfizer on Zoloft.

51. In marketing, distributing, and selling Sertraline, Greenstone relied upon and continues to rely upon Pfizer's manufacturing, design, and labeling of Zoloft, including the warnings and product information associated with Zoloft.

52. In marketing, distributing, and selling Sertraline, Greenstone relied and continues to rely upon Pfizer's marketing and promotion of Zoloft.

53. Pfizer knew or should have known that generic drug manufacturers, specifically Greenstone, would rely upon the design, manufacture, testing, processing, marketing, advertising, labeling, packaging, and product information associated with Zoloft.

54. Pfizer knew, or should have known that, when labeling Sertraline, other generic drug manufacturers, specifically ANDA holders, would be required by FDA regulations to use warnings and labels identical to the warnings and labels associated with Zoloft and those manufacturers do not have the ability to unilaterally add a stronger warning label.

55. Pfizer knew, or should have known, when it filed its NDA in 1992, that in partial exchange for a multi-year monopoly selling Zoloft, it assumed the duty of putting an accurate label on Zoloft for the benefit of all end users of Sertraline, including Plaintiffs, no matter the manufacturer.

56. In addition to the monopoly Pfizer enjoyed for years pursuant to its NDA license, it also acquired the ability to be the first to market the generic form of Sertraline and did take advantage of this strategy by allowing Greenstone to manufacture Sertraline under its NDA license, thereby providing Greenstone with the ability to unilaterally strengthen a warning label.

57. Pfizer knew, or should have known, that Greenstone and Pfizer, as NDA license manufacturers, had the authority to implement label strengthening changes pursuant to 21 CFR 314.70(c)(6)(iii).

58. Greenstone knew, or should have known, that Greenstone and Pfizer, as NDA license manufacturers, had the authority to implement label strengthening changes pursuant to 21 CFR 314.70(c)(6)(iii).

59. Pfizer and Greenstone knew, or should have known, that a significant number of physicians rely upon the marketing, advertising, labeling, and product information associated with Zoloft, when they prescribed Zoloft and permit generic substitution.

60. Pfizer and Greenstone knew, or should have known, that a significant number of consumers rely upon the marketing, advertising, labeling, and product information associated with Zoloft, when they ingested Sertraline.

61. Pfizer and Greenstone knew, or should have known, that Zoloft prescriptions often are filled with generic Sertraline because generic Sertraline is less expensive than Zoloft and because it is not illegal or improper for a pharmacist to fill a brand-name drug prescription with an equivalent generic drug and, in fact, pharmacists are encouraged to fill a brand-name prescription with an equivalent generic drug.

62. At all times relevant to this litigation, Pfizer and Greenstone operated in concert with one another. Defendants' joint endeavors are evident in the following ways:

- (a) At all times relevant, Pfizer and Greenstone made joint tactical and strategic decisions for the marketing and selling of the brand and generic form of Sertraline;
- (b) At all times relevant, Pfizer and Greenstone manufactured the identical drug: Sertraline;
- (c) Pfizer responds to consumer calls regarding Greenstone's drug, Sertraline. Greenstone's customer service line (800-447-3360) is a self-proclaimed "Pfizer/Greenstone" phone line;
- (d) Pfizer advertises that through Greenstone it continues to offer generic equivalents to branded pharmaceuticals, including Sertraline, that are distributed under Zoloft's NDA;
- (e) Pfizer had led or, at a minimum, joined in Greenstone's product recalls;
- (f) On March 26, 2011, Greenstone announced that it would voluntarily recall certain of its products, specifically citalopram and finasteride; Pfizer led and/or joined that particular recall effort;
- (g) During the 2011 recall of citalopram and finasteride, Pfizer continuously offered official statements about the nature of the recall, the impact of the recall, the labeling process which was the alleged basis for the recall, and various other critical facts which were indicative of Pfizer's complete control and domination over Greenstone and its business operations; and



63. Pfizer and Greenstone are jointly and severably liable for the acts complained of herein.

**CAUSES OF ACTION**

**COUNT I:**  
**STRICT PRODUCT LIABILITY – FAILURE TO WARN**

64. Plaintiffs Ryan Eaton and Justyne Eaton incorporate by reference all of the above paragraphs as if fully set forth herein.

65. Defendants are liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts for the negligent and/or willful failure to provide adequate warnings and other clinically relevant information and data regarding the use of Zoloft and/or Sertraline to the Plaintiffs and Justyne Eaton's prescribing physicians.

66. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known that the warnings and other clinically relevant information and data which they distributed regarding the risks of birth defects associated with the use of Zoloft and/or Sertraline were inadequate.

67. Justyne Eaton and her prescribing physicians did not have the same knowledge as Defendants, and no adequate warning or other clinically relevant information and data was communicated to Justyne Eaton or her physicians.

68. Defendants had a continuing duty to provide consumers, including Justyne Eaton, and her physicians with warnings and other clinically relevant information and data regarding the risks and dangers associated with Zoloft and/or Sertraline as it became or could have become available.

69. Defendants manufacture, market, promote, distribute, and place in the stream of commerce an unreasonably dangerous and defective prescription drug, Zoloft and/or Sertraline

which is prescribed by health care providers to consumers, including Justyne Eaton, without adequate warnings and other clinically relevant information and data. Through both omissions and affirmative misstatements, Defendants misled the medical community about the risks and benefits of Zoloft and/or Sertraline, which resulted in Aubry Eaton's birth defects and, ultimately, her death.

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

71. Defendants knew or should have known that consumers, including Justyne Eaton, would foreseeably and needlessly suffer injury as a result of Defendant's failures.

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

- (a) failing to ensure Zoloft and/or Sertraline warnings to the medical community, including Justyne Eaton's physicians, and the public, including Justyne Eaton, were accurate and adequate, despite having extensive knowledge of the risks associated with Zoloft and/or Sertraline usage during pregnancy;
- (b) failing in their obligations to provide the medical community, including Justyne Eaton's physicians, and the public, including Justyne Eaton, with adequate, clinically relevant information, and data and warnings regarding the adverse health risks associated with exposure to Zoloft and/or Sertraline, and/or that there existed safer and more or equally effective alternative drug products;
- (c) failing to conduct post-market safety surveillance and failing to report that information to the medical community, including Justyne Eaton's physicians, and consumers, including Justyne Eaton;
- (d) failing to include adequate warnings and/or providing adequate and clinically relevant information and data that would alert the medical community, including Justyne Eaton's physicians, and consumers, including Justyne Eaton, to the dangerous risks of Zoloft and/or Sertraline usage during pregnancy, including, among other things, the

association with birth defects;

- (e) failing to continually monitor, test, and analyze data regarding safety, efficacy, and prescribing practices;
- (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 and/or Sertraline to the medical community, including Justyne Eaton's physicians, and the consuming public, including Justyne Eaton;
- (g) failing to provide adequate post-marketing warnings and instructions after Defendants knew or should have known of the significant risks of, among other things, congenital birth defects risks with Zoloft and/or Sertraline usage during pregnancy;
- (h) failing to periodically review all medical literature regarding Zoloft and/or Sertraline 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 and/or Sertraline;
- (i) failing to disclose the results of the testing and other information in its possession regarding the possibility that Zoloft and/or Sertraline can interfere with the proper development of an unborn fetus;
- (j) failing to adequately warn the medical community, including Justyne Eaton's physicians, and the consuming public, including Justyne Eaton, of the dangers of using Zoloft and/or Sertraline during pregnancy, including the risk of birth defects; and/or
- (k) representing that Zoloft and/or Sertraline was safe for use during pregnancy when, in fact, Defendants knew or should have known that it was unsafe for this use and that Zoloft and/or Sertraline usage during pregnancy was associated with congenital birth defects;

73. Defendants continued to aggressively manufacture, market, promote, distribute, and sell Zoloft and/or Sertraline even after they knew or should have known of the unreasonable risk of congenital birth defects from Zoloft and/or Sertraline usage during pregnancy.

74. Defendants had an obligation to provide Justyne Eaton and her physicians with adequate and clinically relevant information, data and warnings regarding the adverse health

risks to unborn fetus associated with exposure to Zoloft and/or Sertraline, and/or there existed safer and more or equally effective alternative drug products.

75. Decedent Aubry Eaton was, and is, a person that Defendants should reasonably have foreseen as being subject to the harm caused by the device's defective condition.

76. Defendants' Zoloft and/or Sertraline was expected to, and did, reach Plaintiff Justyne Eaton, without substantial change in its condition as manufactured, distributed, and sold.

77. As a result of Zoloft and/or Sertraline's defective condition, namely the lack of sufficient warnings, Plaintiffs suffered the injuries and damages as alleged herein.

78. As a direct and proximate result of the aforesaid conduct, Plaintiffs Ryan Eaton and Justyne Eaton sustained pecuniary loss resulting from the loss of their daughter's society, companionship, comfort, attention, protection, care, love, affection, services, moral support, and general damages, including significant mental anguish and pain and suffering.

79. As a direct and proximate result of the actions and inactions of Defendants as set forth herein, and the death of Aubry Eaton, Ryan Eaton and Justyne Eaton have suffered the injuries and damages as alleged herein.

**COUNT II**  
**STRICT PRODUCT LIABILITY – DESIGN DEFECT**

80. Plaintiffs Ryan Eaton and Justyne Eaton incorporate by reference all of the above paragraphs as if fully set forth herein.

81. Defendants are liable to Plaintiffs under state common law and/or the applicable state Products Liability Acts for the defective design of Zoloft and/or Sertraline.

82. Defendants manufacture, market, promote, distribute, and place in the stream of commerce Zoloft and/or Sertraline which is:

(a) unreasonably defective in design because it is a teratogenic compound that

unreasonably increases the risk of birth defects;

- (b) defective in design and is not reasonably safe as intended to be used, subjecting consumers, including Justyne Eaton, to risks which exceeded the benefits of Zoloft and/or Sertraline;
- (c) defective in design, making use of Zoloft and/or Sertraline more dangerous than the ordinary consumer would expect and more dangerous than other risks associated with Justyne Eaton's underlying condition;
- (d) defective in design, making use of Zoloft and/or Sertraline more dangerous than the ordinary consumer would expect and more dangerous than other risks associated with like products;
- (e) defective in design in that Zoloft and/or Sertraline contains insufficient, incorrect, and defective warnings in that they fail to alert physicians, including Justyne Eaton's physicians, and users, including Justyne Eaton, of the risks of adverse effects; and/or
- (f) defective in design in that Zoloft and/or Sertraline is not safe for its intended purpose and is inadequately tested.

83. Defendants knew and intended that Zoloft and/or Sertraline would be used by consumers, including Justyne Eaton, without any inspection for defects, and that Justyne Eaton and her physicians would rely upon the representations made by Defendants on Zoloft's and/or Sertraline's product labels and otherwise.

84. Prior to the manufacturing, sale, and distribution of Zoloft and/or Sertraline, Defendants knew, or were reckless in not knowing, that Zoloft and/or Sertraline was in a defective condition.

85. Justyne Eaton used Zoloft and/or Sertraline for its intended purpose and could not have discovered any defect therein through the exercise of due care.

86. Decedent Aubry Eaton was, and is, a person that Defendants should reasonably have foreseen as being subject to the harm caused by the device's defective condition.

87. Defendants' Zoloft and/or Sertraline was expected to, and did, reach Plaintiff Justyne Eaton, without substantial change in its condition as manufactured, distributed, and sold.

88. At the time Defendants manufactured, marketed, promoted, distributed, and sold Zoloft and/or Sertraline, there existed safer and more or equally effective alternative drug products.

89. As a direct and proximate result of the aforesaid conduct, Plaintiffs Ryan Eaton and Justyne Eaton sustained pecuniary loss resulting from the loss of their daughter's society, companionship, comfort, attention, protection, care, love, affection, services, moral support, and general damages, including significant mental anguish and pain and suffering.

90. As a direct and proximate result of the actions and inactions of Defendants as set forth herein, and the death of Aubry Eaton, Ryan Eaton and Justyne Eaton have suffered the injuries and damages as alleged herein.

**COUNT III**  
**NEGLIGENCE**

91. Plaintiffs Ryan Eaton and Justyne Eaton incorporate by reference all of the above paragraphs as if fully set forth herein.

92. Defendants are liable to Plaintiffs under the state common law and/or state Product Liability Acts due to their negligent advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packaging, producing, promoting, processing, researching, selling, and testing of Zoloft and/or Sertraline.

93. At all times relevant, Defendants were under a duty to exercise reasonable care in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packaging, producing, promoting, processing, researching, selling, and testing of Zoloft and/or Sertraline to ensure the use of Zoloft and/or Sertraline did not result in avoidable injuries.

94. At all times relevant, Defendants owed a duty to consumers to assess, manage, and communicate the risk, dangers, and adverse effects of Zoloft and/or Sertraline, and to warn the medical community, including Justyne Eaton's physicians, and consumers, including Justyne Eaton, of those risks, dangers, and adverse effects.

95. Defendants' duties include, but are not limited to, carefully and properly advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packaging, producing, promoting, processing, researching, selling, and testing the Zoloft and/or Sertraline, which was placed into the stream of commerce, and providing adequate information regarding the appropriate use of Zoloft and/or Sertraline.

96. Defendants negligently and carelessly breached the above-described duties to Ryan Eaton, Justyne Eaton, and decedent Aubry Eaton by committing negligent acts and/or omissions, including, but not limited to, the following:

- (a) failing to ensure Zoloft and/or Sertraline warnings to the medical community, including Justyne Eaton's physicians, and the public, including Justyne Eaton, were accurate and adequate, despite having extensive knowledge of the risks associated with Zoloft and/or Sertraline usage during pregnancy;
- (b) failing in their obligations to provide the medical community, including Justyne Eaton's physicians, and the public, including Justyne Eaton, with adequate, clinically relevant information, and data and warnings regarding the adverse health risks associated with exposure to Zoloft and/or Sertraline, and/or that there existed safer and more or equally effective alternative drug products;
- (c) failing to conduct post-market safety surveillance and failing to report that information to the medical community, including Justyne Eaton's physicians, and consumers, including Justyne Eaton;
- (d) failing to include adequate warnings and/or providing adequate and clinically relevant information and data that would alert the medical community, including Justyne Eaton's physicians, and consumers, including Justyne Eaton, to the dangerous risks of Zoloft and/or Sertraline usage during pregnancy, including, among other things, the association with birth defects;

- (e) failing to continually monitor, test, and analyze data regarding safety, efficacy, and prescribing practices for Zoloft and/or Sertraline;
- (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 and/or Sertraline to the medical community, including Justyne Eaton's physicians, and the consuming public, including Justyne Eaton;
- (g) failing to provide adequate post-marketing warnings and instructions after Defendants knew or should have known of the significant risks of, among other things, congenital birth defects risks with Zoloft and/or Sertraline usage during pregnancy;
- (h) failing to periodically review all medical literature regarding Zoloft and/or Sertraline 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 and/or Sertraline;
- (i) failing to disclose the results of the testing and other information in its possession regarding the possibility that Zoloft and/or Sertraline can interfere with the proper development of an unborn fetus;
- (j) failing to adequately warn the medical community, including Justyne Eaton's physicians, and the consuming public, including Justyne Eaton, of the dangers of using Zoloft and/or Sertraline during pregnancy, including the risk of birth defects; and/or
- (k) representing that Zoloft and/or Sertraline was safe for use during pregnancy when, in fact, Defendants knew or should have known that it was unsafe for this use and that Zoloft and/or Sertraline usage during pregnancy was associated with congenital birth defects;
- (l) promoting and marketing Zoloft and/or Sertraline for use with pregnant women, despite the fact that Defendants knew or should have known that Zoloft and/or Sertraline was associated with an increased risk of birth defects;
- (m) promoting and marketing Zoloft and/or Sertraline as safe and effective for use with pregnant women when, in fact, it was unsafe;
- (n) failing to independently monitor their sales of Zoloft and/or Sertraline and the medical literature, which would have alerted them to the fact that Zoloft and/or Sertraline was widely over-prescribed to women of childbearing potential as a result of inadequate warnings, including those in the package inserts and PDR monographs for Zoloft and/or Sertraline, and as a result of the over-promotion of the drug;
- (o) failing to act as reasonably prudent drug manufacturers in advertising, analyzing,



assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packaging, producing, promoting, processing, researching, selling, and testing of Zoloft and/or Sertaline;

- (p) failing to perform adequate and necessary studies to determine and analyze the safety and risks associated with Zoloft and/or Sertraline usage during pregnancy;
- (q) failing to use ordinary care in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packaging, producing, promoting, processing, researching, selling, and testing of Zoloft and/or Sertaline so as to reveal and communicate the risk of congenital birth defects to the medical community, including Justyne Eaton's physicians, and consumers, such as Justyne Eaton;
- (r) failing to accompany Zoloft and/or Sertraline with adequate information that would alert the medical community, including Justyne Eaton's physicians, and consumers, including Justyne Eaton, to the potential adverse side effects associated with the use of Zoloft and/or Sertraline during pregnancy and the nature, severity, and duration of such adverse effects;
- (s) failing to conduct adequate post-marketing studies, non-clinical and clinical testing, and post-marketing surveillance and analyses to determine and communicate the safety profile and side effects of Zoloft and/or Sertraline;
- (t) continuing to promote the safety and effectiveness of Zoloft and/or Sertraline while downplaying the risks even after Defendants knew or should have known of the risks of Zoloft and/or Sertraline usage during pregnancy;
- (u) failing to provide consumers, such as Justyne Eaton, and her physician with scientific data which indicated that Zoloft and/or Sertraline was unreasonably dangerous during pregnancy, and there were no women of childbearing potential and/or pregnant women in whom the benefits of Zoloft outweighed the risks;
- (v) being careless and negligent in that Defendants knew or should have known that Zoloft and/or Sertraline was a substance that would be actively transported through the placenta during pregnancy and could inhibit the health and development of the fetus;
- (w) negligently and carelessly promoting Zoloft and/or Sertraline as safe and effective for use with women of childbearing potential and/or pregnant women when, in fact, it was unsafe;
- (x) negligently and carelessly over-promoting Zoloft and/or Sertraline in a zealous and unreasonable fashion, without regard to the potential danger that it posed to an unborn fetus; and/or

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

97. Although Defendants knew or should have known that Zoloft and/or Sertraline causes unreasonably dangerous side effects, including birth defects, they continue to market Zoloft and/or Sertraline, despite the fact there are safer and more or equally effective alternative drug products.

98. Defendants knew or should have known that consumers, such as Justyne Eaton, would suffer injury as a result of their failure to exercise ordinary care, as described herein.

99. The conduct of Defendants was a direct and proximate cause of Aubry Eaton's injuries and death. Defendants knew or should have known that Zoloft and/or Sertraline can be dangerous and unsafe for pregnant women and the developing fetus.

100. As a direct and proximate result of the aforesaid conduct, Plaintiffs Ryan Eaton and Justyne Eaton sustained pecuniary loss resulting from the loss of their daughter's society, companionship, comfort, attention, protection, care, love, affection, services, moral support, and general damages, including significant mental anguish and pain and suffering.

101. As a direct and proximate result of the actions and inactions of Defendants as set forth herein, and the death of Aubry Eaton, Ryan Eaton and Justyne Eaton have suffered the injuries and damages as alleged herein.

**COUNT IV:**  
**NEGLIGENT DESIGN**

102. Plaintiffs Ryan Eaton and Justyne Eaton incorporate by reference all of the above paragraphs as if fully set forth herein.

103. Defendants are liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts for the negligent design of Zoloft and/or Sertaline.

104. At all times relevant, Defendant owed a duty to consumers, including Plaintiff Justyne Eaton, and her health care providers, to exercise reasonable care in the design of Zoloft and/or Sertraline.

105. Defendants negligently and carelessly breached this duty of care to Plaintiffs because they designed Zoloft and/or Sertraline which:

- (a) was and is unreasonably defective in design because it is a teratogenic compound that unreasonably increased the risks of congenital birth defects;
- (b) was and is defective in design and was not reasonably safe as intended to be used, subjecting Justyne Eaton and Decedent Aubry Eaton to risks which exceeded the benefits of Zoloft and/or Sertraline;
- (c) was and is defective in design, making use of Zoloft and/or Sertraline more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with Justyne Eaton's underlying condition;
- (d) was and is defective in design, making use of Zoloft and/or Sertraline more dangerous than the ordinary consumer would expect and more dangerous than other risks associated with like products;
- (e) was and is defective in design in that it contained insufficient, incorrect and defective warnings in that they failed to alert physicians and users, including Justyne Eaton, of the risks of adverse effects;
- (f) was and is defective in design in that it was not safe for its intended use and was inadequately tested;
- (g) was and is defective in design because its risks exceeded any benefit of Zoloft and/or Sertraline;
- (h) failed to act as a reasonably prudent drug manufacturer, seller, promoter, distributor, marketer, or seller would have acted with respect to the design of Zoloft and/or Sertraline.

**COUNT V:**  
**FRAUD, MISREPRESENTATION, AND SUPPRESSION**

106. Plaintiffs Ryan Eaton and Justyne Eaton incorporate by reference all of the above paragraphs as if fully set forth herein.

107. Defendants are liable to Plaintiffs under the state common law and/or state Products Liability Acts for fraudulently, intentionally, and/or negligently misrepresenting to the public, and to Justyne Eaton, both directly and by and through her prescribing physicians, the safety and efficacy of Zoloft and/or Sertraline when used by women of childbearing potential, and/or fraudulently, intentionally, and negligently concealing, suppressing or omitting material, adverse information regarding the safety and effectiveness of Zoloft and/or Sertraline when used by women of childbearing potential.

108. Defendants' fraudulent, intentional, and/or negligent material misrepresentations and omissions regarding the safety and efficacy of Zoloft and/or Sertraline and of Zoloft's and/or Sertraline's side effects, including the risk of birth defects, were communicated to Justyne Eaton directly through promotional materials, advertising, product inserts, and the monograph provided with Justyne Eaton's prescription with the intent that Justyne Eaton use Zoloft and/or Sertraline. The safety and efficacy of Zoloft and/or Sertraline was also fraudulently, intentionally, and/or negligently misrepresented to Justyne Eaton's prescribing physicians with the intent that such misrepresentations would cause Zoloft and/or Sertraline to be prescribed to Justyne Eaton.

109. Defendants either knew or should have known that the material misrepresentations they were making regarding Zoloft's and/or Sertraline's safety, efficacy, and side-effects were false.

110. Defendants fraudulently, intentionally, and/or negligently made the misrepresentations and/or actively concealed, suppressed, or omitted this material information with the intention and specific desire to induce Justyne Eaton, her physicians, the medical community, and the consuming public to use and prescribe Zoloft and/or Sertraline.

111. Plaintiff Justyne Eaton, and/or her prescribing physicians, justifiably relied on the material misrepresentations and/or omissions as alleged herein when selecting Zoloft and/or Sertraline for the treatment of her condition.

112. Defendants knew, or should have known that Justyne Eaton, and/or her physicians, would rely on such material misrepresentations and/or omissions in selecting Zoloft and/or Sertraline for the treatment of Justyne Eaton.

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

- (a) Defendants failed to disclose, or concealed, that their pre-clinical and clinical testing, and post-marketing surveillance was inadequate to determine the safety and side effects of Zoloft and/or Sertraline;
- (b) Defendants failed to disclose, or concealed, data showing that Zoloft and/or Sertraline increased the risk of congenital birth defects;
- (c) Defendants failed to include adequate warnings with Zoloft and/or Sertraline about the potential and actual risks, and nature, scope, severity, and duration of any serious side effects of this drug, including, without limitation, the increased risk of congenital birth defects, other injuries and death, either compared to use of alternate drug products in its class or compared to use of no drug products; and/or
- (d) Defendants concealed and continue to conceal past and present facts, including that as early as the 1990's, Defendants were aware of and concealed their knowledge of an association between the use of Zoloft and/or Sertraline and dangerous side effects, including the increased risk of congenital birth defects, from the consuming public, including Justyne Eaton and her physicians.

112. Defendants' material misrepresentations and/or active concealment, suppression, and omissions were perpetuated directly and/or indirectly by Defendants, their sales

representatives, employees, distributors, agents, and/or detail persons, through the databases, printouts, monographs, and other information drafted, prepared, marketed, sold, and supplied by Defendants, their sales representatives, employees, distributors, agents, and/or detail persons.

113. Defendants' material misrepresentations and/or active concealment, suppression, and omissions constitute a continuing tort.

114. Through its product inserts, Defendants continue to misrepresent the potential risks and complications associated with Zoloft and/or Sertraline.

115. Defendants had a post-sale duty to timely warn physicians, including Justyne Eaton's physicians, and consumers, such as Justyne Eaton, about the potential risks and complications associated with Zoloft and/or Sertraline.

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

117. If Justyne Eaton and her physicians had known the true facts concerning the risks of Zoloft and/or Sertraline, in particular, the risk of congenital birth defects, they would not have prescribed and used Zoloft and/or Sertraline and would have instead prescribed and used one of the safer alternatives, or no drug.

118. Plaintiffs' and Justyne Eaton's physicians' reliance upon Defendants material misrepresentations and/or omissions was justified, among other reasons, because said misrepresentations and/or omissions were made by individuals and entities who were in a position to know the true facts concerning Zoloft and/or Sertraline, while Justyne Eaton and her physicians were not in a position to know the true facts, and because Defendants overstated the benefits and safety of Zoloft and/or Sertraline, and concomitantly downplayed the risks of its

use, including birth defects, thereby inducing Justyne Eaton and her physicians to use Zoloft and/or Sertraline, in lieu of, safer alternatives, or no drug at all.

119. As a direct and proximate result of the aforesaid conduct, Plaintiffs Ryan Eaton and Justyne Eaton sustained pecuniary loss resulting from the loss of their daughter's society, companionship, comfort, attention, protection, care, love, affection, services, moral support, and general damages, including significant mental anguish and pain and suffering.

120. As a direct and proximate result of the actions and inactions of Defendants as set forth herein, and the death of Aubry Eaton, Ryan Eaton and Justyne Eaton have suffered the injuries and damages as alleged herein.

**COUNT VI:**  
**CONSTRUCTIVE FRAUD**

121. Plaintiffs Ryan Eaton and Justyne Eaton incorporate by reference all of the above paragraphs as if fully set forth herein.

122. Defendants are liable to Plaintiffs under the state common law and/or state Product Liability Acts for constructive fraud.

123. At the time Zoloft and/or Sertraline was manufactured, distributed, and sold by Defendants to Justyne Eaton, Defendants were in a unique position of knowledge concerning the safety and effectiveness of Zoloft and/or Sertraline, which knowledge was not possessed by Justyne Eaton or her physicians, and Defendants thereby held a position of superiority over Justyne Eaton.

124. Through their unique knowledge and expertise regarding the defective nature of Zoloft and/or Sertraline, and through their marketing statements to physicians and patients in advertisements, promotional materials, and other communications, Defendants professed that

they were in possession of facts demonstrating that Zoloft and/or Sertraline was safe and effective for its intended use and was not defective.

125. Defendants' representations to Justyne Eaton and her physicians were made to induce Justyne Eaton's physicians to prescribe and Justyne Eaton to purchase Zoloft and/or Sertraline.

126. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Justyne Eaton and her physicians and engaged in constructive fraud in their relationship.

127. Justyne Eaton and her physicians reasonably relied on Defendants' representations regarding Zoloft and/or Sertraline.

128. As a direct and proximate result of the aforesaid conduct, Plaintiffs Ryan Eaton and Justyne Eaton sustained pecuniary loss resulting from the loss of their daughter's society, companionship, comfort, attention, protection, care, love, affection, services, moral support, and general damages, including significant mental anguish and pain and suffering.

129. As a direct and proximate result of the actions and inactions of Defendants as set forth herein, and the death of Aubry Eaton, Ryan Eaton and Justyne Eaton have suffered the injuries and damages as alleged herein.

**COUNT VII:**  
**BREACH OF EXPRESS AND IMPLIED WARRANTIES**

130. Plaintiffs Ryan Eaton and Justyne Eaton incorporate by reference all of the above paragraphs as if fully set forth herein.

131. Defendants are liable to Plaintiffs under the state common law and/or state Product Liability Acts for breach of express and implied warranties.



132. At all times relevant, and upon information and belief, by directly and indirectly advertising, marketing, and promoting Zoloft and/or Sertraline for the treatment of women, including women of childbearing potential and pregnant women, and by placing Zoloft and/or Sertraline in the stream of commerce knowing that Zoloft and/or Sertraline would be prescribed to pregnant women in reliance upon the representations or omissions of Defendants, expressly warranted to all foreseeable users of Zoloft and/or Sertraline, including Justyne Eaton and her physicians, that Zoloft and/or Sertraline was safe and effective for the treatment of women during pregnancy and without significant risk to the fetus.

133. Defendants impliedly warranted in manufacturing, distributing, selling, advertising, marketing, and promoting Zoloft and/or Sertraline to all foreseeable users, including Justyne Eaton and her physicians, that Zoloft and/or Sertraline was safe and effective for the purposes for which it had been placed in the stream of commerce by Defendants, including for the treatment of pregnant women, and that Zoloft and/or Sertraline was reasonably safe, proper, merchantable, and fit for its intended purpose, including for the treatment of pregnant women and without significant risk to the fetus.

134. At all times relevant, Justyne Eaton and her physicians relied upon the aforesaid express and implied warranties.

135. Justyne Eaton's ingestion of Zoloft and/or Sertraline during pregnancy, and her physicians' prescribing of Zoloft and/or Sertraline, were consistent with the purposes for which Defendants directly and indirectly advertised, marketed, and promoted Zoloft and/or Sertraline, and Justyne Eaton's use of Zoloft and/or Sertraline, and her physicians' prescribing of Zoloft and/or Sertraline, was reasonably contemplated, intended, and foreseen by Defendants at the time of the distribution and sale of Zoloft and/or Sertraline by Defendants, and, therefore,

Justyne Eaton's use of Zoloft and/or Sertraline was within the scope of the above-described express and implied warranties.

136. Defendants breached the aforesaid express and implied warranties because Zoloft and/or Sertraline was not safe and effective for the treatment of women during pregnancy because it exposed the developing fetus to a significant risk of serious injury, and because Justyne Eaton's use of Zoloft and/or Sertraline during her pregnancy caused Aubry Eaton's birth defects and death.

137. As a direct and proximate result of the aforesaid conduct, Plaintiffs Ryan Eaton and Justyne Eaton sustained pecuniary loss resulting from the loss of their daughter's society, companionship, comfort, attention, protection, care, love, affection, services, moral support, and general damages, including significant mental anguish and pain and suffering.

138. As a direct and proximate result of the actions and inactions of Defendants as set forth herein, and the death of Aubry Eaton, Ryan Eaton and Justyne Eaton have suffered the injuries and damages as alleged herein.

**COUNT VIII:**  
**GROSS NEGLIGENCE/MALICE**

139. Plaintiffs Ryan Eaton and Justyne Eaton incorporate by reference all of the above paragraphs as if fully set forth herein.

140. Defendants are liable to Plaintiffs under the state common law and/or state Product Liability Acts for gross negligence and/or malice.

141. While performing each of the acts and omissions previously set forth in this Complaint, Defendants actually knew of the defective nature of their products and the inadequacy of their warnings as set forth herein, yet Defendants continued to author, create, design, distribute, edit, manufacture, market, sell, and provide their products in their defective

condition so as to maximize sales and profits at the expense of Plaintiffs' health and the health of the consuming public.

142. The acts and omissions of Defendants involved an extreme degree of risk, given the probability and magnitude of causing harm to Plaintiffs and others.

143. Defendants had actual, subjective awareness of the risk of injury posed by Zoloft and/or Sertraline and the Zoloft and/or Sertraline information and warnings, to consumers such as Plaintiffs. Moreover, a reasonable company in the position of the Defendants would have been aware of the risk of injury posed to consumers by the use of Zoloft and/or Sertraline and the Zoloft and/or Sertraline information and warnings. Yet, Defendants proceeded in conscious disregard to the rights, safety, and welfare of Plaintiffs.

144. The acts and omissions of Defendants demonstrate that they did not care about the peril they subjected upon Plaintiffs, or their deceased daughter Aubry Eaton, such that their conduct was grossly negligent.

145. Further, the wrongs done by the Defendants were aggravated by the kind of malice, fraud, and reckless disregard of the rights of others, the public, and Plaintiffs for which the law allows the imposition of exemplary damages in that Defendants' conduct:

- (a) when viewed objectively from the Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and the Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; and/or
- (b) included a material misrepresentation that was false, with the Defendants knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiffs. Plaintiffs relied on the representation and suffered injury as a proximate result of this reliance.

146. Plaintiffs therefore seek to assert claims for exemplary damages at the appropriate time under governing law in an amount with the jurisdictional limits of the Court.

147. Plaintiffs also allege that the acts and omissions of the Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiffs. In that regard, Plaintiffs will seek exemplary damages in an amount that would punish the Defendants for their conduct and which would deter other similar defendants from engaging in such misconduct in the future.

148. As a direct and proximate result of the aforesaid conduct, Plaintiffs Ryan Eaton and Justyne Eaton sustained pecuniary loss resulting from the loss of their daughter's society, companionship, comfort, attention, protection, care, love, affection, services, moral support, and general damages, including significant mental anguish and pain and suffering.

149. As a direct and proximate result of the actions and inactions of Defendants as set forth herein, and the death of Aubry Eaton, Ryan Eaton and Justyne Eaton have suffered the injuries and damages as alleged herein.

**COUNT IX:**  
**LOSS OF CONSORTIUM AND PECUNIARY LOSS**

150. Plaintiffs Ryan Eaton and Justyne Eaton incorporate by reference all of the above paragraphs as if fully set forth herein.

151. Defendants are liable to Plaintiffs under the state common law and/or state Product Liability Acts for loss of consortium and pecuniary loss.

152. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Justyne Eaton and Aubry Eaton were exposed to Zoloft and/or Sertraline and all Plaintiffs have suffered, and will continue to suffer, the past and future injuries, damages, and losses as a result of Aubry Eaton's birth defects and death, as set forth herein.

153. The Defendants are liable to Plaintiffs for all general, special, and punitive damages, delay damages, and other relief to which they are entitled by law.

154. As a direct and proximate result of the aforesaid conduct, Plaintiffs Ryan Eaton and Justyne Eaton sustained pecuniary loss resulting from the loss of their daughter's society, companionship, comfort, attention, protection, care, love, affection, services, moral support, and general damages, including significant mental anguish and pain and suffering.

155. As a direct and proximate result of the actions and inactions of Defendants as set forth herein, and the death of Aubry Eaton, Ryan Eaton and Justyne Eaton have suffered the injuries and damages as alleged herein.

**COUNT X:**  
**PUNITIVE DAMAGES**

156. Plaintiffs Ryan Eaton and Justyne Eaton incorporate by reference all of the above paragraphs as if fully set forth herein.

157. Plaintiffs are entitled to punitive damages, pursuant to state common law or the applicable statutory provisions, because the Defendants' actions were reckless and without regard for the public's safety and welfare. The Defendants knowingly withheld, concealed, or misrepresented the risks and dangers of Zoloft and/or Sertraline and the Zoloft and/or Sertraline information and warnings, including the risk of congenital birth defects, from both the medical community and the public at large, including Plaintiffs, their physicians and pharmacists. The Defendants downplayed, understated, and disregarded their knowledge of the serious and permanent side effects associated with the use of Zoloft and/or Sertraline, including congenital birth defects, despite information demonstrating Zoloft and/or Sertraline was unreasonably dangerous and in conscious disregard of the risks of serious injury posed to Plaintiffs by these known misrepresentations and/or omissions.

158. At all times relevant, the Defendants had a duty to exercise reasonable care in the advertising, analyzing, assembling, compounding, designing, developing, distributing,

formulating, inspecting, labeling, manufacturing, packaging, producing, promoting, processing, researching, selling, and/or testing of Zoloft and/or Sertraline.

159. The conduct of the Defendants in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, packaging, producing, promoting, processing, researching, selling, and/or testing of Zoloft and/or Sertraline, and in failing to warn Plaintiff Justyne Eaton, and Justyne Eaton's prescribing physicians and pharmacists, and other members of the public of the dangers inherent in the use of Zoloft and/or Sertraline, which were known to Defendants, was attended by circumstances of fraud, malice, or willful and wanton conduct, done heedlessly and recklessly, without regard to consequences, or of the rights and safety of others, including Plaintiffs.

160. The Defendants knew that Zoloft and/or Sertraline and unreasonably dangerous risks and caused serious side effects of which Plaintiff Justyne Eaton, and her physicians and pharmacists, would not be aware. The Defendants nevertheless engaged in the advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, packaging, producing, promoting, processing, researching, selling, and/or testing of Zoloft and/or Sertraline while knowing that there were safer methods and products available.

161. The Defendants actions were performed willfully, deliberately, intentionally, and with reckless disregard for the rights and safety of Plaintiffs and the public and caused substantial injuries and damages.

162. The conduct of Defendants, undertaken with knowledge, for these purposes, evinces gross negligence and a willful, wanton, and conscious disregard for the rights and safety of consumers, including the Plaintiffs, and as a direct and proximate result of the Defendants'

actions and inactions, Plaintiffs suffered injuries due to Defendants' disregard for Plaintiffs' rights and safety, and therefore, Plaintiffs are entitled to an award of punitive damages from Defendants.

163. As a direct and proximate result of the aforesaid conduct, Plaintiffs Ryan Eaton and Justyne Eaton sustained pecuniary loss resulting from the loss of their daughter's society, companionship, comfort, attention, protection, care, love, affection, services, moral support, and general damages, including significant mental anguish and pain and suffering.

164. As a direct and proximate result of the actions and inactions of Defendants as set forth herein, and the death of Aubry Eaton, Ryan Eaton and Justyne Eaton have suffered the injuries and damages as alleged herein.

**COUNT XI:**  
**CONSUMER FRAUD ACT**

165. Plaintiffs Ryan Eaton and Justyne Eaton incorporate by reference all of the above paragraphs as if fully set forth herein.

166. Defendants engaged in commercial conduct by selling Zoloft and/or Sertraline.

167. Defendants misrepresented and omitted material information regarding Zoloft and/or Sertraline by failing to disclose known risks.

168. Defendants misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of material facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of Zoloft and/or Sertraline, in violation of the Uniform Consumer Fraud and Deceptive Business Practices Act and the Wisconsin Consumer Act, Wis. Stat. Ann. § 421-427, and similar statutes.

169. Wisconsin has enacted statutory provisions to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. Defendants violated these statutes by knowingly and falsely representing that Zoloft and/or Sertraline was fit to be used for the purpose for which it was intended, when Defendants knew that Zoloft and/or Sertraline was defective and dangerous, and by other acts and omissions alleged herein.

170. Defendants engaged in the deceptive acts and practices alleged herein in order to sell Zoloft and/or Sertraline to the public, including Plaintiff Justyne Eaton.

171. As a direct and proximate result of Defendants' violations of Wis. Stat. Ann. § 421-427, Plaintiffs have suffered damages, for which Plaintiffs are entitled compensatory damages, equitable and declaratory relief, punitive damages, costs, and reasonable attorneys' fees.

172. As a direct and proximate result of the actions and inactions of Defendants as set forth herein, and the death of Aubry Eaton, Ryan Eaton and Justyne Eaton have suffered the injuries and damages as alleged herein.

**COUNT XII:**  
**WRONGFUL DEATH**

173. Plaintiffs Ryan Eaton and Justyne Eaton incorporate by reference all of the above paragraphs as if fully set forth herein.

174. As a direct and proximate result of the aforesaid conduct of Defendants, because of her mother's ingestion of Zoloft and/or Sertraline during pregnancy, Decedent Aubry Eaton developed congenital birth defects which caused extreme pain, suffering, mental anguish, and ultimately caused her death.



176. As a direct and proximate result of the aforesaid conduct of Defendants, Mr. and Mrs. Eaton have sustained injuries and damages, including but not limited to severe mental anguish and pain and suffering as a result of their infant daughter's death.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs Ryan Eaton and Justyne Eaton demand judgment against Defendants, jointly and severally, as follows:

- (a) Actual damages in an amount to be determined at trial;
- (b) General, economic, and special damages in an amount to be determined at trial;
- (c) Loss of earnings and impaired earning capacity according to proof at the time of trial;
- (d) Medical expenses according to proof at the time of trial;
- (e) For mental and emotional distress, according to proof;
- (f) Cost and expenses of this litigation;
- (g) Reasonable attorneys' fees and costs as provided by law;
- (h) For pre-judgment and post-judgment interest as provided by law; and
- (i) Punitive or exemplary damages according to proof at the time of trial;
- (j) Grant all such other relief this Court may deem necessary, just, and proper

**DEMAND FOR JURY TRIAL**

Plaintiffs Ryan Eaton and Justyne Eaton hereby demand a trial by jury in this case as to such issues so triable.

Respectfully submitted,

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