

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

CHARITY BLOCK, Individually and,
as Parent and Legal Guardian of K.K. a
Minor,

Plaintiffs,

v.

WYETH PHARMACEUTICALS, INC.,
and PFIZER, INC.,

Defendants.

Case No. _____

**COMPLAINT AND
DEMAND FOR JURY TRIAL**

COMPLAINT

1. Charity Block, (hereinafter referred to as “Ms. Block” or “Mother Plaintiff”), individually and as Guardian and Natural Parent of K.K., a Minor, (hereinafter “K.K.” or “Infant Plaintiff”), and collectively “Plaintiffs”, by and through their undersigned counsel, hereby submit this Complaint against Defendants WYETH PHARMACEUTICALS, INC. and PFIZER, INC.

2. As more specifically pleaded below, each Plaintiff maintains that the pharmaceutical drug EFFEXOR®, EFFEXOR XR® and/or venlafaxine HCl (hereinafter collectively “Effexor”) is defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce and lacked proper warnings as to the dangers associated with its use.

PLAINTIFFS

3. Plaintiffs are individuals, or the duly authorized representatives of an individual, who, at all times relevant to the allegations in the Complaint, were residents of the State of Utah, and currently reside in Salt Lake County, Utah.

4. The Infant Plaintiff, K.K., is a minor child who was born November 30, 2009, with significant congenital anomalies, including cardiac anomalies, a ventricular septal defect

(“VSD”), patent foramen ovale (“PFO”), central diaphragmatic hernia, hypoplastic lungs, and omphalocele, as well as other conditions, as a result of Ms. Block’s ingestion of Effexor. The Infant Plaintiff is represented in this action by Mother Plaintiff who is his natural guardian and next of kin.

5. The Mother Plaintiff, Charity Block, is a competent adult and the biological mother of the Infant Plaintiff, K.K. She brings this action on behalf of K.K. and individually to recover medical and other expenses related to treatment resulting from K.K.’s birth defect(s), disorder(s) and/or related illnesses and for general and special damages, including punitive damages, and such other relief as requested herein for injuries suffered as a direct result of Ms. Block’s ingestion of Effexor.

6. At all times relevant to the allegations in the Complaint, Plaintiffs resided in the United States of America or its territories.

7. “Plaintiffs” as used herein refers to the Infant Plaintiff and Mother Plaintiff, collectively.

DEFENDANTS

8. Defendant, WYETH PHARMACEUTICALS, INC. was a corporation organized under the laws of the State of Delaware with its principal place of business in Philadelphia, Pennsylvania. Upon information and belief, Wyeth Pharmaceuticals, Inc. was purchased by Pfizer, Inc. in October of 2009. Wyeth Pharmaceuticals, Inc. is now a subsidiary of Pfizer, Inc., and is located in Madison, New Jersey. Wyeth Pharmaceuticals, Inc. may be served with process by serving its parent company, Pfizer, Inc., at 401 North Middletown Road, Pearl River, NY 10965-1298.

9. Defendant, PFIZER, INC. was, and still is, a corporation duly existing under and by virtue of the laws of the State of Delaware with its principal place of business in the

New York City, New York. Pfizer may be served with process by serving its registered agent CT Corporation at 1108 E South Union Ave, Midvale, UT 84047.

10. For purposes of this Complaint, Plaintiffs will reference the various Defendants by name or by the role they played in the events and occurrences giving rise to this litigation. Therefore, Plaintiffs refer to PFIZER, INC. as “Pfizer” and Wyeth Pharmaceuticals as “Wyeth” and collectively as “Manufacturing Defendants,” or “Defendants.”

JURISDICTION AND VENUE

11. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

12. This Court has diversity jurisdiction over the parties in this action pursuant to 28 U.S.C. § 1332 insofar as the Plaintiffs are citizens of different states than the Defendants, and the amount in controversy exceeds \$75,000.00, exclusive of interest and costs.

13. Venue is proper in this District because at all times material to this action, Defendant Pfizer and/or its predecessors in interest and/or its subsidiaries, including Wyeth, regularly engaged in business in the State of Utah and this District, including advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling, and/or testing of the pharmaceutical drug Effexor. Defendant Pfizer carried on a continuous and systematic part of its business in Utah. Defendant Pfizer's subsidiary, Wyeth Pharmaceuticals, Inc., distributes Effexor throughout the United States, including the State of Utah. Furthermore, as Defendant Pfizer regularly solicited and transacted business in the State of Utah and this District, received substantial revenues from the State of Utah and this District, and/or distributed products in the State of Utah and this District, Defendant Pfizer is subject to suit in the State of Utah and this District. In addition, Defendant Pfizer reasonably

expected that Effexor would be used or consumed in Utah and this District. Furthermore, a substantial part of the events and omissions giving rise to Plaintiffs' injuries occurred in this District, as Mother Plaintiff Charity Block has at all relevant times resided in this judicial district, was prescribed Effexor in this district, and ingested Effexor in this district, and the Infant Plaintiff was born in this district and suffered injuries in this district.

GENERAL ALLEGATIONS

14. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

Plaintiffs

15. The Mother Plaintiff, Charity Block, took Effexor as prescribed by her treating physician(s) while pregnant with the Infant Plaintiff, K.K. Ms. Block continued to use Effexor on the schedule and for the period of time prescribed by her physician(s).

16. The Mother Plaintiff and/or the Mother Plaintiff's physician(s) relied upon the fact that any birth defects and other serious pregnancy issues associated with the use of Effexor would have been listed or emphasized within the Effexor prescribing information and/or drug label as a basis to believe that Effexor was safe for use during her pregnancy and would not cause birth defects.

17. Despite the exercise of reasonable diligence in investigating the cause of the injuries, including consultations with her medical care providers, Ms. Block was not told that Effexor could have caused the Infant Plaintiff's injuries. Nor did Ms. Block see or read any information suggesting Effexor caused the Infant Plaintiff's injuries until a date within the applicable statute of limitations for filing Plaintiffs' claims.

18. Had Ms. Block been adequately warned that Effexor could cause birth defects if ingested during pregnancy, she would not have taken the drug.

19. When K.K. was born, he suffered from significant birth defects as described, *supra*, at ¶ 4, resulting in surgical intervention and treatment.

20. The defects suffered by the Infant Plaintiff were a direct result of his mother's ingestion of Effexor during her pregnancy in a manner and dosage recommended and prescribed by her doctor(s).

Defendants

21. The drug "venlafaxine hydrochloride" was advertised, analyzed, assembled, compounded, designed, developed, distributed, formulated, inspected, labeled, manufactured, marketed, packed, produced, promoted, processed, researched, sold, and tested by the Manufacturing Defendants, their predecessors in interest and their subsidiaries, under the trade names Effexor® and Effexor XR® and is a member of a class of drugs known as "serotonin and norepinephrine reuptake inhibitors" or "SNRIs." Effexor was first approved for use in the United States by the FDA in 1993 for the treatment of major depression in adults.

22. Under the FDA scheme, Pfizer and Wyeth and their predecessors knew, as a New Drug Application applicant, that they 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, physicians, Mother Plaintiff's physicians, Mother Plaintiff and other foreseeable prescribers and users of Effexor once the NDA was approved.

23. Under the FDA scheme, Pfizer and Wyeth and their predecessors have a duty to ensure their 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 is obtained.

24. Prior to Ms. Block becoming pregnant, Pfizer and Wyeth knew or should have known that taking Effexor during pregnancy poses risks to the developing fetus. Pfizer and Wyeth knew or should have known that Effexor crosses the placenta, which could have important implications for the developing fetus.

25. Prior to Ms. Block becoming pregnant, Pfizer and Wyeth knew or should have known that children were being born with birth defects, including heart defects and other similar conditions, to women who took Effexor during pregnancy.

26. Prior to the time that Ms. Block ingested Effexor during her pregnancy, Pfizer and Wyeth knew of the dangerous birth defects associated with Effexor's use during pregnancy from the preclinical studies and the subsequent published studies confirming these risks. Pfizer and Wyeth took no action to adequately warn or remedy the risks, but instead, concealed, suppressed, and failed to disclose the dangers.

27. Pfizer and Wyeth had access to this information and knew that birth defects would result from the use of Effexor by women who became pregnant and the fact that physicians and consumers, such as the Mother Plaintiff herein, did not fully understand the risks associated with Effexor.

28. Pfizer and Wyeth failed to fully, truthfully and accurately disclose Effexor data to the FDA, the Mother Plaintiff and the Mother Plaintiff's physicians, and as a result negligently, intentionally and fraudulently misled the medical community, physicians, the Mother Plaintiff's physicians, and Mother Plaintiff about the risks to a fetus associated with the use of Effexor during pregnancy.

29. Through the *Physicians' Desk Reference*, drug package inserts, patient information forms, counseling warnings, literature, marketing materials and other labeling information for Effexor, Pfizer and Wyeth knowingly, intentionally and negligently disseminated incomplete, inaccurate, and/or misleading warnings and information about the true risks to a fetus when Effexor is ingested during pregnancy, which misled the medical community, physicians and Mother Plaintiff's physicians.

30. At all times material hereto, Pfizer and Wyeth 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 use of Effexor and that, consequently, there was a widespread tendency for physicians to prescribe Effexor for use to women of childbearing potential. Consequently, Pfizer and Wyeth knew or should have known that the warnings and labels, including but not limited to, package inserts and the *Physicians' Desk Reference* prescribing information for Effexor, did not adequately inform physicians about the birth defect risks associated with Effexor.

31. Pfizer and Wyeth failed to adequately warn physicians and Mother Plaintiff about the birth defect risks associated with Effexor, despite the fact that the Manufacturing Defendants knew that physicians, the medical community, Mother Plaintiff, and others similarly situated relied on Pfizer and Wyeth to disclose what they knew or should have known from a prudent review of the information that it possessed or to which they had access.

32. Because of the misleading information that Pfizer and Wyeth provided to physicians, Mother Plaintiff and the FDA about the true birth defect risks associated with the use of Effexor and because of the failure of Pfizer and Wyeth to adequately inform physicians generally, including Mother Plaintiff's physicians, about the true birth defect risks associated with the use of Effexor, Mother Plaintiff's physicians never informed her of any birth defect risks associated with Effexor. Indeed, it is believed that Pfizer and Wyeth represented to

physicians that Effexor was safe for use by women of childbearing years and their unborn children.

33. Pfizer and Wyeth knew, or should have known, that the warnings, including but not limited to the label and package insert for Effexor, did not disclose the true risks of birth defects from the use of Effexor. Pfizer and Wyeth failed to use reasonable care to modify the warnings, including but not limited to the label and package insert for Effexor, in order to warn physicians adequately about the true birth defect risks from the use of Effexor by women who became pregnant.

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

35. Thus, prior to Ms. Block's pregnancy, Pfizer and Wyeth 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 Effexor and birth defects, including heart defects 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, etc. Pfizer and Wyeth breached this duty.

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

37. Pfizer and Wyeth failed to disclose adequately the increased risk of birth defects associated with Effexor to the medical community, including Ms. Block's physicians, and the Plaintiff. The Manufacturing Defendants were aware that their 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 Effexor by physicians who were not aware of this information. By failing to disclose this information to the medical community and the Plaintiffs, Pfizer and Wyeth manifested a flagrant disregard of the safety of persons who might be harmed by Effexor, and this conduct caused serious and permanent injuries to the Plaintiffs.

38. Pfizer and Wyeth, and their agents, servants and employees acting in the course and scope of their employment, negligently and carelessly breached their duties to the medical community, Ms. Block's physicians, Plaintiffs and other foreseeable users similarly situated, which breaches of duty include, but are not limited to:

- a) failing to ensure that Effexor warnings to the medical community, physicians, Mother Plaintiff's physicians and Mother Plaintiff 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, Mother Plaintiff's physicians, and Mother Plaintiff with adequate and clinically relevant information, data and warnings regarding the adverse health risks associated with exposure to Effexor, and/or that there existed safer and more or equally effective alternative drug products;

- c) failing to conduct post market safety surveillance and report that information to the medical community, physicians, Mother Plaintiff's physicians and Mother Plaintiff;

- d) failing to include adequate warnings and/or provide adequate and clinically relevant information and data that would alert the medical community, physicians, Mother Plaintiff's physicians, and Mother Plaintiff to the dangerous risks of Effexor;

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

f) failing to review all adverse drug event information 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 Effexor to the medical community, physicians, Mother Plaintiff's physicians, and Mother Plaintiff;

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

h) failing to periodically review all medical literature regarding Effexor and other serotonin drugs and failing to report data, regardless of the degree of significance, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety resulting from the use of Effexor;

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

j) failing to warn adequately the medical community, physicians, Mother Plaintiff's physicians, and Mother Plaintiff of the dangers of using Effexor during pregnancy, including the risk of birth defects;

k) representing that Effexor was safe for use during pregnancy when, in fact, Pfizer and Wyeth knew or should have known that it was unsafe for this use and that Effexor was associated with birth defects;

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

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

n) failing to act as a reasonably prudent drug manufacturer in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling and testing of Effexor; and/or

o) failing to perform adequate and necessary studies to determine and analyze the safety and risks associated with Effexor use during pregnancy.

39. As a direct and proximate result of Pfizer's and Wyeth's actions, Mother Plaintiff, and upon information and belief, Mother Plaintiff's prescribing physicians, were unaware, and could not reasonably know, or through reasonable diligence could not have reasonably known, that Effexor exposed Mother Plaintiff to the risks and injuries alleged herein, and that those risks were the direct and proximate result of Defendants' acts and omissions.

Injuries

40. As a direct and proximate result of the conduct of Defendants as described herein and as a result of Ms. Block's ingestion of Effexor, the Infant Plaintiff suffered from physical injuries.

41. Infant Plaintiff's serious injuries were the foreseeable and proximate result of Defendants' acts and/or omissions, including, but not limited to, dissemination of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information to the medical community, physicians, Mother Plaintiff's physicians, pharmacists and Mother Plaintiff.

42. As a direct and proximate result of the conduct of Defendants as described herein, Mother Plaintiff suffered costs and expenses for the Infant Plaintiff's injuries and care. These injuries and damages were the foreseeable and proximate result of Defendants' acts and/or omissions, including, but not limited to, dissemination of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information to the medical community, Mother Plaintiff's physicians, pharmacists and Mother Plaintiff.

43. Mother Plaintiff, as result of her ingestion of Effexor and as a direct and proximate result of the conduct of Defendants described herein, have suffered, and will suffer in the future, great emotional pain, mental anguish and other serious injury and loss, including loss of consortium, services, support, companionship, society, love and affection. These injuries and damages were the foreseeable and proximate result of Defendants' acts and/or omissions, including, but not limited to, dissemination of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information to the medical community, Mother Plaintiff's physicians, pharmacists and Mother Plaintiff.

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

COUNT ONE – STRICT PRODUCT LIABILITY – FAILURE TO WARN

45. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

46. Manufacturing 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 appropriate use of Effexor to Mother Plaintiff and Mother Plaintiff's prescribing physicians.

47. Pfizer and Wyeth, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Manufacturing 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 Effexor were inadequate.

48. Mother Plaintiff and Mother Plaintiff's prescribing physicians did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to her or to her physicians.

49. Manufacturing Defendants had a continuing duty to provide consumers, including Mother Plaintiff and her physicians, with warnings and other clinically relevant information and data regarding the risks and dangers associated with Effexor as it became or could have become available to Manufacturing Defendants.

50. Manufacturing Defendants manufactured, marketed, promoted, distributed, and sold an unreasonably dangerous and defective prescription drug, Effexor, in the stream of commerce, to health care providers empowered to prescribe and dispense Effexor to consumers, including Mother Plaintiff, without adequate warnings and other clinically relevant information and data. Through both omissions and affirmative misstatements, Manufacturing Defendants misled the medical community, including Mother Plaintiff's physicians, about the risks and benefits of Effexor, which resulted in injury to Plaintiffs.

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

52. Manufacturing Defendants knew or should have known that consumers, and Mother Plaintiff specifically, would foreseeably and needlessly suffer injury as a result of the Manufacturing Defendants' failures.

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

- a) failing to ensure that Effexor warnings to the medical community, physicians, Mother Plaintiff's physicians, and Mother Plaintiff were accurate and adequate despite having extensive knowledge of the risks associated with Effexor;
- b) failing in their obligation to provide the medical community, physicians, Mother Plaintiff's physicians, and Mother Plaintiff with adequate clinically relevant information, and data and warnings regarding the adverse health risks associated with exposure to Effexor, and/or that there existed safer and more or equally effective alternative drug products;
- c) failing to conduct post market safety surveillance and report that information to the medical community, Mother Plaintiff's physicians, and Mother Plaintiff;
- d) failing to include adequate warnings and/or providing adequate and clinically relevant information and data that would alert the medical community, Mother Plaintiff's physicians, and Mother Plaintiff to the dangerous risks of Effexor, including, among other things, the association with birth defects;
- e) failing to continually monitor, test, and analyze data regarding safety, efficacy, and prescribing practices of their marketed drug Effexor;
- f) failing to review all adverse drug event information and to report any information bearing upon the adequacy and/or accuracy of their warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Effexor to the medical community, Mother Plaintiff's physicians, and Mother Plaintiff;
- g) failing to provide adequate post-marketing warnings and instructions after Manufacturing Defendants knew or should have known of the significant risks of, among other things, birth defects associated with the use of Effexor;
- h) failing to periodically review all medical literature regarding Effexor and the other serotonin drugs and failing to report data, regardless of the degree of significance, regarding the adequacy and/or accuracy of their warnings, efficacy, or safety of Effexor;
- i) failing to disclose the results of the testing and other information in their possession regarding the possibility that Effexor can interfere with the proper development of an unborn fetus;

j) failing to warn adequately the medical community, the general public, and Mother Plaintiff of the dangers of using Effexor during pregnancy, including the risk of birth defects; and/or

k) representing that Effexor was safe for use during pregnancy, when in fact, Manufacturing Defendants knew or should have known that Effexor was unsafe for this use and that Effexor use is associated with birth defects.

54. Manufacturing Defendants continued to aggressively manufacture, market, promote, distribute, and sell Effexor, even after they knew or should have known of the unreasonable risks of birth defects associated with the use of Effexor.

55. Manufacturing Defendants had an obligation to provide Mother Plaintiff and Mother Plaintiff's physicians with adequate and clinically relevant information, and data and warnings regarding the adverse health risks associated with exposure to Effexor, and/or that there existed safer and more or equally effective alternative drug products.

56. By failing to provide Mother Plaintiff and Mother Plaintiff's physicians with adequate, clinically relevant information, and data and warnings regarding the adverse health risks associated with exposure to Effexor, and/or to inform them that there existed safer and more or equally effective alternative drug products, Manufacturing Defendants breached their duty of reasonable care and safety.

57. As a direct and proximate result of the actions and inactions of Manufacturing Defendants as set forth above, Charity Block and K.K. were exposed to Effexor, and as a result suffered, and continue to suffer, the injuries and damages, as set forth herein.

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

COUNT TWO – STRICT PRODUCT LIABILITY – DESIGN DEFECT

58. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

59. Manufacturing Defendants manufactured, marketed, promoted, distributed, and sold Effexor in the stream of commerce which was:

- a) unreasonably defective in design because it is a teratogenic compound that unreasonably increased the risks of birth defects;
- b) defective in design and was not reasonably safe as intended to be used, subjecting Mother Plaintiff to risks which exceeded the benefits of Effexor;
- c) defective in design, making use of Effexor more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with Mother Plaintiff's and Infant Plaintiff's underlying condition;
- d) defective in design in that Effexor contained insufficient, incorrect, and defective warnings in that they failed to alert physicians, including Mother Plaintiff's physicians, and users, including Mother Plaintiff, of the risks of adverse effects; and/or
- e) defective in design in that Effexor was not safe for its intended use and was inadequately tested.

60. Manufacturing Defendants knew and intended that Effexor would be used by consumers, including Mother Plaintiff, without any inspection for defects, and that Mother Plaintiff and her physicians would rely upon the representations made by Manufacturing Defendants on Effexor's product labels and otherwise.

61. Prior to the manufacturing, sale, and distribution of Effexor, Manufacturing Defendants knew, or were reckless in not knowing, that Effexor was in a defective condition.

62. Mother Plaintiff used Effexor for its intended purpose and could not have discovered any defect therein through the exercise of due care.

63. At the time that Manufacturing Defendants manufactured, marketed, promoted, distributed, and sold Effexor there existed safer and more or equally effective alternative drug products.

64. As a direct and proximate result of the actions and inactions of Manufacturing Defendants as set forth above, Plaintiffs were exposed to Effexor, and as a result, suffered, and continue to suffer, injuries and damages, as set forth herein.

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

COUNT THREE – NEGLIGENCE

65. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

66. Manufacturing Defendants are liable to Plaintiffs pursuant to 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, packing, producing, promoting, processing, researching, selling and testing Effexor.

67. At all times mentioned herein, Manufacturing Defendants were under a duty to exercise reasonable care in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling, and testing Effexor to ensure that use of Effexor did not result in avoidable injuries.

68. At all times relevant to this lawsuit, Manufacturing Defendants owed a duty to consumers, including Mother Plaintiff and her health care providers, to assess, manage, and communicate the risks, dangers, and adverse effects of Effexor, and to warn the medical community, consumers, Mother Plaintiff, and the Mother Plaintiff's physicians of those risks, dangers, and adverse effects.

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

70. Manufacturing Defendants negligently and carelessly breached the above-described duties to Plaintiffs by committing negligent acts and/or omissions, including, but not limited to, the following:

- a) failing to ensure Effexor's warnings to the medical community, physicians, Mother Plaintiff's physicians, and Mother Plaintiff were accurate and adequate, despite having extensive knowledge of the risks associated with Effexor;
- b) failing in their obligation to provide the medical community, physicians, Mother Plaintiff's physicians, and Mother Plaintiff with adequate and clinically relevant information, and data and warnings regarding the adverse health risks associated with exposure to Effexor, and/or that there existed safer and more or equally effective alternative drug products;
- c) failing to conduct post market safety surveillance and report that information to the medical community, physicians, Mother Plaintiff's physicians, and Mother Plaintiff;
- d) failing to include adequate warnings and/or provide adequate and clinically relevant information and data that would alert the medical community, physicians, Mother Plaintiff's physicians, and Mother Plaintiff to the dangerous risks of Effexor;

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

f) failing to review all adverse drug event information and to report any information bearing upon the adequacy and/or accuracy of their warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Effexor to the medical community, physicians, Mother Plaintiff's physicians, and Mother Plaintiff;

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

h) failing to periodically review all medical literature regarding Effexor and other serotonin drugs and failing to report data, regardless of the degree of significance, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Effexor;

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

j) failing to warn adequately the medical community, physicians, Mother Plaintiff's physicians, and Mother Plaintiff of the dangers of using Effexor during pregnancy, including the risk of birth defects;

k) representing that Effexor was safe for use during pregnancy when, in fact, Manufacturing Defendants knew or should have known that Effexor was unsafe for this use and that Effexor was associated with birth defects;

l) promoting and marketing Effexor for use with pregnant women, despite the fact that the Manufacturing Defendants knew or should have known that Effexor was associated with an increased risk of abnormalities;

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

n) failing to independently monitor their sales of Effexor and the medical literature, which would have alerted them to

the fact that Effexor was widely over-prescribed to women of childbearing potential as a result of inadequate warnings in the package inserts and PDR prescribing information for Effexor, and as a result of the over-promotion of Effexor;

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

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

q) failing to use ordinary care in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling, and testing Effexor so as to reveal and communicate the risk of birth defects to the medical community, Mother Plaintiff's physicians, and Mother Plaintiff;

r) failing to accompany Effexor with adequate information that would alert the medical community, Mother Plaintiff's physicians, and Mother Plaintiff to the potential adverse side effects associated with the use of Effexor 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 Effexor;

t) continuing to promote the safety and effectiveness of Effexor, while downplaying their risks, even after Manufacturing Defendants knew or should have known of the risks of Effexor;

u) failing to provide consumers, such as Mother Plaintiff and Plaintiffs' physicians, with scientific data which indicated that Effexor was unreasonably dangerous, and that there were no women of childbearing potential and/or pregnant women in whom the benefits of Effexor outweighed the risks;

v) being careless and negligent in that Manufacturing Defendants knew or should have known that Effexor 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 Effexor 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 Effexor in a zealous and unreasonable way, 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 same or similar circumstances.

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

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

73. The conduct of Manufacturing Defendants was a direct and proximate cause of Plaintiffs' injuries. Manufacturing Defendants knew or should have known that Effexor could be dangerous and unsafe for pregnant women and the developing fetus.

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

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

COUNT FOUR – NEGLIGENT DESIGN

75. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

76. Manufacturing Defendants are liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts for the negligent design of Effexor.

77. At all times relevant to this lawsuit, Manufacturing Defendants owed a duty to consumers, including Plaintiffs and their health care providers, to exercise reasonable care in the design of Effexor.

78. Manufacturing Defendants negligently and carelessly breached this duty of care to Plaintiffs because they designed Effexor which:

- a) was and is unreasonably defective in design because it is a teratogenic compound that unreasonably increased the risk of birth defects;
- b) was and is defective in design and was not reasonably safe as intended to be used, subjecting Plaintiffs to risks which exceeded the benefits of Effexor;
- c) was and is defective in design, making use of Effexor more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with Mother Plaintiff's underlying condition;
- d) was and is defective in design, making use of Effexor 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, including Mother Plaintiff's physicians, and users, including Mother Plaintiff 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; and/or
- g) was and is defective in design because its risks exceeded

any benefit of Effexor.

79. Manufacturing Defendants failed to act as a reasonably prudent drug manufacturer, seller, promoter, distributor, or marketer would have acted with respect to the design of Effexor.

80. As a direct and proximate result of the negligent acts and/or omissions of the Manufacturing Defendants, Plaintiffs suffered injuries and damages, as set forth herein.

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

COUNT FIVE – FRAUD, MISREPRESENTATION AND SUPPRESSION

81. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

82. Manufacturing Defendants are liable to Plaintiffs under the state common law and/or state Product Liability Acts for fraudulently, intentionally, and/or negligently misrepresenting to the public, and to Mother Plaintiff, both directly and by and through Mother Plaintiff's prescribing physicians, the safety and effectiveness of Effexor when used by women of childbearing potential, and/or fraudulently, intentionally, and/or negligently concealing, suppressing or omitting material, adverse information regarding the safety and effectiveness of Effexor when used by women of childbearing potential.

83. Manufacturing Defendants' fraudulent, intentional, and/or negligent material misrepresentations and omissions regarding the safety and efficacy of Effexor and of Effexor's side effects, including the risk of birth defects, were communicated to Mother Plaintiff directly through promotional materials, advertising, product inserts, and the monograph provided with

Mother Plaintiff's prescription with the intent that the Mother Plaintiff use Effexor. The safety and efficacy of Effexor was also fraudulently, intentionally, and/or negligently misrepresented to Mother Plaintiff's prescribing physician(s) with the intent that such misrepresentations would cause Effexor to be prescribed to Mother Plaintiff.

84. Manufacturing Defendants either knew or should have known that the material representations they were making regarding Effexor's safety, efficacy, and side effects were false.

85. Manufacturing 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 Mother Plaintiff, Mother Plaintiff's physician(s), and the consuming public to use and prescribe Effexor. Manufacturing Defendants fraudulently, intentionally, and/or negligently knew or should have known that Mother Plaintiff, Mother Plaintiff's physician(s), and the consuming public would rely on such material misrepresentations and/or omissions in selecting Effexor for the treatment of Mother Plaintiff. Manufacturing Defendants knew or should have known that Mother Plaintiff and Mother Plaintiff's physician(s) would rely upon their false representations and/or omissions.

86. Manufacturing 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 Effexor had defects, dangers, and characteristics that were other than what had been represented to the medical community and the consuming public, including the Plaintiffs herein. Those misrepresentations and omissions further include, but are not limited to, the following particulars:

- a) Manufacturing 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 Effexor;

b) Manufacturing Defendants failed to disclose or concealed data showing that Effexor increased the risk of birth defects;

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

d) Manufacturing Defendants concealed and continue to conceal past and present facts, evidencing an association between the use of Effexor and dangerous side effects, including the increased risk of birth defects, from the consuming public, including Plaintiffs and Mother Plaintiff's physicians.

87. Manufacturing Defendants' material misrepresentations and/or active concealment, suppression, and omissions were perpetuated directly and/or indirectly by Manufacturing 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 Manufacturing Defendants, their sales representatives, employees, distributors, agents, and/or detail persons.

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

89. Through its product inserts, Manufacturing Defendants continued to misrepresent the potential risks and complications associated with Effexor.

90. Manufacturing Defendants had a post-sale duty to warn physicians and Plaintiffs about the potential risks and complications associated with Effexor they manufactured and sold in a timely manner.

91. Manufacturing Defendants fraudulently, intentionally, and/or negligently misrepresented the safety and efficacy of Effexor in their labeling, advertising, product

inserts, promotional materials, or other marketing.

92. If Mother Plaintiff and Mother Plaintiff's physicians had known the true facts concerning the risks of Effexor, in particular, the risk of birth defects, they would not have prescribed and used Effexor, and would have instead prescribed and used one of the safer alternatives, or no drug.

93. Charity Block and her physicians' reliance upon the Defendant Manufacturers' material misrepresentations were justified, among other reasons, because said misrepresentations and omissions were made by individuals and entities who were in a position to know the true facts concerning Effexor, while Mother Plaintiff and Mother Plaintiff's physicians were not in a position to know the true facts, and because Manufacturing Defendants overstated the benefits and safety of Effexor, and concomitantly downplayed the risks of its use, including birth defects, thereby inducing Mother Plaintiff and Mother Plaintiff's physician(s) to use Effexor, in lieu of other, safer alternatives, or no drug at all.

94. As a direct and proximate result of Mother Plaintiff and Mother Plaintiff's physicians' reliance on Manufacturing Defendants' misrepresentations and concealment concerning the risks and benefits of Effexor, Plaintiffs suffered injuries and damages, as set forth herein.

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

COUNT SIX – CONSTRUCTIVE FRAUD

95. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

96. Manufacturing Defendants are liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts for constructive fraud in the manufacturing, distribution, and sale of Effexor.

97. At the time Effexor was manufactured, distributed, and sold by Manufacturing Defendants to Plaintiffs, Pfizer and Wyeth were in a unique position of knowledge concerning the safety and effectiveness of Effexor, which knowledge was not possessed by Mother Plaintiff or Mother Plaintiff's physicians, and Manufacturing Defendants thereby held a position of superiority over Plaintiffs.

98. Through their unique knowledge and expertise regarding the defective nature of Effexor, and through their marketing statements to physicians and patients in advertisements, promotional materials, and other communications, Manufacturing Defendants professed that they were in possession of facts demonstrating that Effexor was safe and effective for its intended use and was not defective.

99. Manufacturing Defendants' representations to Mother Plaintiff's physicians were made to induce the purchase of Effexor, and Mother Plaintiff and her physicians relied upon those statements when purchasing and using Effexor.

100. Pfizer and Wyeth took unconscionable advantage of their dominant position of knowledge with regard to Mother Plaintiff and her physicians and engaged in constructive fraud in their relationship.

101. Mother Plaintiff and her physicians reasonably relied on Manufacturing Defendants' representations.

102. As a direct and proximate result of Manufacturing Defendants' constructive fraud, Plaintiffs have suffered injuries and damages, as set forth herein.

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

COUNT SEVEN – BREACH OF EXPRESS AND IMPLIED WARRANTIES

103. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

104. Pfizer and Wyeth are liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts for the breach of express and implied warranties of Effexor.

105. At all times hereinafter mentioned, upon information and belief, Manufacturing Defendants, by directly and indirectly advertising, marketing, and promoting Effexor for the treatment of women, including women of childbearing potential and pregnant women, and by placing Effexor in the stream of commerce knowing that Effexor would be prescribed to pregnant women in reliance upon the representations or omissions of Manufacturing Defendants, expressly warranted to all foreseeable users of Effexor, including Mother Plaintiff and the Mother Plaintiff's physicians, that Effexor was safe and effective for the treatment of women during pregnancy and without significant risk to the fetus.

106. Pfizer and Wyeth impliedly warranted in manufacturing, distributing, selling, advertising, marketing, and promoting Effexor to all foreseeable users, including Mother Plaintiff and Mother Plaintiff's physicians, that Effexor was safe and effective for the purposes for which it had been placed in the stream of commerce by Manufacturing Defendants, including for the treatment of pregnant women, and that Effexor 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.

107. At all times relevant hereto, Mother Plaintiff and Mother Plaintiff's physicians relied upon the aforesaid express and implied warranties by Manufacturing Defendants.

108. Mother Plaintiff's use of Effexor, and Mother Plaintiff's physicians' prescribing of Effexor was consistent with the purposes for which Manufacturing Defendants directly and indirectly advertised, marketed, and promoted Effexor, and Mother Plaintiff's use of Effexor, and Mother Plaintiff's physicians' prescribing of Effexor was reasonably contemplated, intended, and foreseen by Manufacturing Defendants at the time of the distribution and sale of Effexor by Manufacturing Defendants, and, therefore, Mother Plaintiff's use of Effexor was within the scope of the above-described express and implied warranties.

109. Manufacturing Defendants breached the aforesaid express and implied warranties because Effexor 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 Mother Plaintiff's use of Effexor for treatment during her pregnancy caused the Infant Plaintiff's injuries.

110. As a direct and proximate result of Manufacturing Defendants' breach of express and implied warranties, Plaintiffs suffered injuries and damages, as set forth herein.

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

COUNT EIGHT - GROSS NEGLIGENCE/MALICE

111. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

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

113. 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 Mother Plaintiff's and Infant Plaintiff's health and the health of the consuming public.

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

115. Defendants had actual, subjective awareness of the risk of injury posed by Effexor and the Effexor 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 Effexor and the Effexor information and warnings. Yet, Defendants proceeded in flagrant disregard of the safety and in conscious disregard of the rights, safety, and welfare of Plaintiffs.

116. The acts and omissions of Defendants demonstrate that they did not care about the peril they subjected upon Plaintiffs such that their conduct was grossly negligent.

117. Further, the wrongs done by the Defendants were aggravated by the kind of malice, fraud, and flagrant disregard for the rights of others, the public, and Plaintiffs for which the law allows the imposition of exemplary damages in that the 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 representation 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 Mother Plaintiff. Mother Plaintiff relied on the representation and suffered injury as a proximate result of this reliance.

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

119. 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.

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

COUNT NINE - LOSS OF CONSORTIUM AND PECUNIARY LOSS

120. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

121. The Defendants are liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts.

122. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Charity Block and K.K. were exposed to Effexor and Plaintiffs have suffered, and will continue to suffer, the past and future injuries, damages, and losses as a result of the Infant Plaintiff's injuries, as set forth herein.

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

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

COUNT TEN – VIOLATION OF UTAH CONSUMER SALES PRACTICES ACT

124. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

125. Defendants are liable to Plaintiffs under the Utah Consumer Sales Practices Act, Utah Code Ann. § 13-11, et seq.

126. At the time of Mother Plaintiff's purchase of Effexor as prescribed by her physicians, and/or the original purchase of Effexor by Mother Plaintiff's healthcare providers, 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 Mother Plaintiff's and Infant Plaintiff's health and the health of the consuming public.

127. The Utah Consumer Sales Practices Act provides that “No supplier shall commit an unconscionable act or practice in connection with a consumer transaction.” Further, “An unconscionable act or practice by a supplier violates this section whether it occurs before, during, or after the transaction.”

128. The acts and omissions of Defendants violated the Utah Consumer Sales Practices Act, in that their actions constitute unconscionable actions or representations in violation of the law. Defendants specific actions or representations which violated the Act may include but are not limited to:

- a) That Effexor possesses sponsorship, approval, performance characteristics, accessories, uses, or benefits that it did not have;
- b) That Effexor is of a particular standard, quality, grade, style, prescription, or model, standards which it did not meet; and/or,
- c) Plaintiff relied on Defendants’ misleading statements about the safety and efficacy of Effexor, which Mother Plaintiff relied on to the detriment of herself and K.K.

129. Defendants had actual, subjective awareness of the risk of injury posed by Effexor and the Effexor 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 Effexor and the Effexor information and warnings. Yet, Defendants proceeded in flagrant disregard of the safety and in conscious disregard to the rights, safety, and welfare of Plaintiffs.

130. Defendants’ unconscionable acts, as described above and throughout this complaint, which Mother Plaintiff relied upon to her own detriment, entitle Plaintiffs to treble damages for violations of the Utah Consumer Sales Practices Act.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Manufacturing Defendants for an amount in excess of \$75,000.00, exclusive of interest

and costs, for compensatory and punitive damages, treble damages, delay damages, costs of suit in an amount to be determined upon the trial of this matter.

COUNT ELEVEN – PUNITIVE DAMAGES

131. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

132. Plaintiffs are entitled to punitive damages, pursuant to state common law or the applicable statutory provision, because the Defendants' actions were reckless and with flagrant disregard for the public's safety and welfare. The Defendants knowingly withheld, concealed or misrepresented the risks and dangers of Effexor and the Effexor information and warnings, including the risk of 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 Effexor, including birth defects, despite information demonstrating Effexor was unreasonably dangerous and did so in conscious, flagrant disregard of the risk of serious injury posed to Mother Plaintiff and Infant Plaintiff by these known misrepresentations and/or omissions.

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

134. The conduct of Manufacturing Defendants in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling, and/or testing Effexor, and in failing to warn Mother Plaintiff, Mother Plaintiff's physicians,

pharmacists and other members of the public of the dangers inherent in the use of Effexor, which were known to the Defendants, was attended by circumstances of fraud, malice, or willful and wanton conduct, done flagrantly, heedlessly and recklessly, without regard to consequences, or of the rights and safety of others, including Plaintiffs.

135. The Manufacturing Defendants knew that Effexor had unreasonably dangerous risks and caused serious side effects of which Mother Plaintiff and her physicians and pharmacists would not be aware. The Defendants nevertheless advertised, analyzed, assembled, compounded, designed, developed, distributed, formulated, inspected, labeled, manufactured, marketed, packaged, produced, promoted, processed, researched, sold, and tested Effexor knowing that there were safer methods and products available.

136. The Defendants' actions were performed flagrantly, willfully, deliberately, intentionally, and with reckless disregard for the rights and safety of Mother Plaintiff and Infant Plaintiff and the public and caused substantial physical and financial injury.

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

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

JURY DEMAND

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

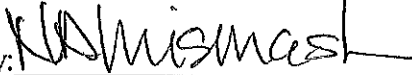
CONCLUSION AND PRAYER

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

- (A) Money Damages representing fair, just, and reasonable compensation for their respective common law and statutory claims in excess of \$75,000.00, exclusive of interest and costs;
- (B) Punitive and/or Treble Damages pursuant to state law;
- (C) Attorneys' fees pursuant to state law;
- (D) Pre-judgment and post-judgment interests as authorized by law on the judgments which enter on Plaintiffs' behalf;
- (E) Costs of suit and expenses; and
- (F) Such other relief as is deemed just and appropriate.

Respectfully Submitted,

ROBERT J. DeBRY & ASSOCIATES

By: 

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Dated: 7/1/2013

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Attorneys for Plaintiffs

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

CHARITY BLOCK, Individually and as Parent and Legal Guardian of K.K., a Minor,

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

(c) Attorneys (Firm Name, Address, and Telephone Number)

Nancy A. Mismash, Robert J. DeBry & Associates, 4252 South 700 East, Salt Lake City, UT 84107 (801) 262-8915.

DEFENDANTS

WYETH PHARMACEUTICALS, INC., and PFIZER, INC.,

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

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

Attorneys (If Known)

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

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

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

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

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

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	PERSONAL INJURY <input checked="" type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement	<input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act	<input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g))
			IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609
				<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District (specify)
- ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

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

Brief description of cause:

Birth defects of minor child resulting in Mother's use of Effexor

VII. REQUESTED IN COMPLAINT:

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

DEMAND \$

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

VIII. RELATED CASE(S)

IF ANY

(See instructions):

JUDGE

DOCKET NUMBER

DATE 7/1/2013

SIGNATURE OF ATTORNEY OF RECORD

Nancy A. Mismash

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG. JUDGE