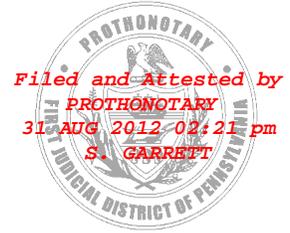


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Attorney for Plaintiffs

LILYPEARL VICTORY DEMASTUS, a
minor, by SANDRA DEMASTUS and
PATRICK DEMASTUS, Guardians, and
SANDRA DEMASTUS and PATRICK
DEMASTUS, individually,
1775 Pickens Rd.
Lynn, TN 38472

Plaintiffs,

vs.

WYETH PHARMACEUTICALS, INC.
50 Arcola Road
Collegeville, PA 19426

WYETH, LLC
50 Arcola Road
Collegeville, PA 19426

WYETH
50 Arcola Road
Collegeville, PA 19426

COURT OF COMMON PLEAS
TRIAL DIVISION
PHILADELPHIA COUNTY

AUGUST TERM

NO.

JURY TRIAL DEMANDED

COMPLAINT

COMPLAINT

1. Plaintiffs, SANDRA DEMASTUS (“Mother Plaintiff”) and PATRICK DEMASTUS (“Father Plaintiff”), individually and as Guardian for LILYPEARL VICTORY DEMASTUS, (“Minor Plaintiff”) a minor, (collectively “Plaintiffs”) by and through their undersigned counsel, hereby submit this Complaint against Defendants WYETH PHARMACEUTICALS, INC., WYETH, LLC and WYETH (“collectively “Defendants”).

2. As more specifically pleaded below, Plaintiffs allege that the pharmaceutical drug EFFEXOR, EFFEXOR XR® and/or venlafaxine (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.

I. PLAINTIFFS

3. Plaintiffs are individuals, who at all times relevant to the allegations in the Complaint, are residents of the State of Tennessee.

4. The Minor Plaintiff, LilyPearl, is a minor child who was born January 25, 2005, with congenital defects, including craniosynostosis, and other related conditions as a result of her mother’s ingestion of Effexor. The Minor Plaintiff is represented in this action by Mother Plaintiff and Father Plaintiff who are her natural guardians and next friends.

5. The Mother Plaintiff Sandra Demastus and the Father Plaintiff Patrick Demastus referred to herein are competent adults and the biological parents of the Minor Plaintiff. They bring this action on behalf of the Minor Plaintiff and individually to recover medical and other expenses related to treatment resulting from the Minor Plaintiff’s birth defect(s), disorder(s) and/or related illnesses and for general and special damages, including punitive damages, and

such other relief as requested herein for injuries suffered as a direct result of the Mother Plaintiff'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.

II. DEFENDANTS

7. Defendant, WYETH PHARMACEUTICALS, INC., has a principal place of business at 500 Arcola Road, Collegeville, Pennsylvania 19426. Upon information and belief, Pennsylvania is the nerve center of Wyeth Pharmaceuticals, Inc.'s business as it was the site of the corporation's headquarters and the place where the corporation's officers would direct, control and coordinate the corporation's activities.

8. Defendant, WYETH, LLC, has a principal place of business at 500 Arcola Road, Collegeville, Pennsylvania 19426. Upon information and belief, Pennsylvania is the nerve center of Wyeth, LLC's business as it was the site of the corporation's headquarters and the place where the corporation's officers would direct, control and coordinate the corporation's activities.

9. Defendant, WYETH, has a principal place of business at 500 Arcola Road, Collegeville, Pennsylvania 19426. Upon information and belief, Pennsylvania is the nerve center of Wyeth's business as it was the site of the corporation's headquarters and the place where the corporation's officers would direct, control and coordinate the corporation's activities.

III. JURISDICTION AND VENUE

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

11. Jurisdiction and venue are proper as Defendants, and each of them, are subject to suit in the Commonwealth of Pennsylvania because presently, and at all times material to this action, Defendants maintained their principle place of business in Pennsylvania as determined under the “nerve center” test set forth in *Hertz Corp. v. Friend*, 130 S.Ct. 1181 (2010). Additionally, Defendants regularly solicited and transacted business in the Commonwealth of Pennsylvania, received substantial revenues from the Commonwealth of Pennsylvania, and sold products and performed services in the Commonwealth of Pennsylvania. Defendants carried on a continuous and systematic part of their business in Pennsylvania and in Philadelphia County. Furthermore, as Defendants regularly solicited and transacted business, received substantial revenues from the Commonwealth of Pennsylvania, and/or distributed products in the Commonwealth of Pennsylvania and the City of Philadelphia, Defendants are subject to suit in the Commonwealth of Pennsylvania and Philadelphia County. In addition, Defendants reasonably expected that their products, including Effexor would be used in Pennsylvania and Philadelphia County. Furthermore, a part of the events and omissions giving rise to Plaintiffs’ injuries occurred in this District.

12. At all times material to this action, Defendants Wyeth Pharmaceuticals, Inc., Wyeth LLC and Wyeth regularly engaged in business in the Commonwealth of Pennsylvania and the County of Philadelphia, including advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling, and testing of the pharmaceutical drug Effexor. Defendants carried on a continuous and systematic part of their business in Pennsylvania and in Philadelphia County. Defendants are located in Philadelphia, and distribute Effexor throughout the United States. Furthermore, as Defendants regularly

solicited and transacted business, received substantial revenues from the Commonwealth of Pennsylvania, and/or distributed products in the Commonwealth of Pennsylvania and the City of Philadelphia, Defendants is subject to suit in the Commonwealth of Pennsylvania. In addition, Defendants reasonably expected that Effexor would be used or consumed in Pennsylvania and Philadelphia County. Furthermore, a part of the events and omissions giving rise to Plaintiffs' injuries occurred in this District.

IV. GENERAL ALLEGATIONS

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

Plaintiffs

14. The Mother Plaintiff took Effexor as prescribed by her treating physician(s) while pregnant with the Minor Plaintiff. The Mother Plaintiff continued to use Effexor on the schedule and for the period of time prescribed by the Mother Plaintiff's physician(s).

15. The Mother Plaintiff and/or the Mother Plaintiff's physician 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 in the Effexor label or drug information as a basis to believe that Effexor was safe for use during pregnancy and would not cause birth defects.

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

17. Had the Mother Plaintiff been adequately warned that Effexor could cause congenital birth defects if ingested during pregnancy, she would not have taken the drug.

18. When the Minor Plaintiff was born, she was suffering from life-threatening congenital defects, including craniosynostosis.

19. The defects suffered by the Minor Plaintiff were a direct result of her mother's ingestion of Effexor during her pregnancy in a manner and dosage recommended and prescribed by her doctor.

Defendants

20. The drug "venlafaxine hydrochloride" was and is advertised, analyzed, assembled, compounded, designed, developed, distributed, formulated, inspected, labeled, manufactured, marketed, packed, produced, promoted, processed, researched, sold, and tested by Defendants, their predecessors in interest and its subsidiaries, under the trade name Effexor[®] 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.

21. Under the FDA scheme, Defendants, knew, as a New Drug Application 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, physicians, Plaintiffs' physicians, Mother Plaintiff and other foreseeable prescribers and users of Effexor once the NDA was approved.

22. Under the FDA scheme, Defendants had 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. Prior to Mother Plaintiff becoming pregnant, Defendants knew or should have known that taking Effexor during pregnancy posed risks to the developing fetus. Defendants knew or should have known that Effexor crosses the placenta, which could have important implications for the developing fetus.

24. Prior to Mother Plaintiff becoming pregnant, Defendants knew or should have known that children were being born with congenital birth defects, heart defects, PPHN, and other similar conditions to women who took Effexor during pregnancy.

25. Prior to the time that Mother Plaintiff ingested Effexor during her pregnancy, Defendants 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. Defendants took no action to adequately warn or remedy the risks, but instead, concealed, suppressed, and failed to disclose the dangers. Even in the face of the numerous published studies, Defendants continue to fail to warn of these dangers through revised drug labeling.

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

27. Defendants failed to fully, truthfully and accurately disclose Effexor data to the FDA, the Plaintiffs 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 Plaintiffs about the risks to a fetus associated with the use of Effexor during pregnancy.

28. Through the *Physicians' Desk Reference*, drug package inserts, patient information forms, counseling warnings, literature, marketing materials and other labeling information for Effexor, Defendants 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 the Mother Plaintiff's physicians.

29. At all times material hereto, Defendants knew or should have known that most physicians were not aware of or did not fully appreciate the seriousness of the congenital 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, Defendants knew or should have known that the warnings and labels, including but not limited to, package inserts and the *Physician's Desk Reference* monograph for Effexor, did not adequately Defendants physicians about the birth defects risks associated with Effexor.

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

31. 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 Defendants and because of the failure of Defendants to adequately inform physicians generally, including the Mother Plaintiff's physicians, about the true birth defect risks associated with the use of Effexor the Mother Plaintiff's physicians never informed her of any congenital birth defects risks associated with Effexor. Indeed, it is believed that Defendants represented to physicians that Effexor was safe for use by women of childbearing years and their unborn children.

32. Defendants 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. Defendants 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 congenital birth defect risks from the use of Effexor by women who became pregnant.

33. During the entire time Effexor 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 Effexor. 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.

34. Thus, prior to the Mother Plaintiff's pregnancy, Defendants 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 congenital birth defects, heart

defects, PPHN, and other related conditions, through all means necessary, including, but not limited to, labeling, continuing education, symposiums, posters, sales calls to doctors, advertisements, and promotional materials, etc. Defendants breached this duty.

35. Despite having extensive knowledge of the extreme risks associated with the Effexor, as well as the absolute duty to properly and adequately warn foreseeable users, 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.

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

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

- a) failing to ensure Effexor warnings to the medical community, physicians, the Mother Plaintiff's physicians and Plaintiffs 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, the Mother Plaintiff's physicians, and Plaintiffs 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, the Mother Plaintiff's physicians and Plaintiffs;
- 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 Plaintiffs 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 (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 Effexor to the medical community, physicians, the Mother Plaintiff's physicians, and Plaintiffs;
- 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 of Effexor;
- h) failing to periodically review all medical literature regarding Effexor 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 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, the Mother Plaintiff's physicians, and Plaintiffs of the dangers of using Effexor during pregnancy, including the risk of congenital birth defects;

- k) representing that Effexor was safe for use during pregnancy when, in fact, Defendants knew or should have known that it was unsafe for this use and that Effexor was associated with congenital birth defects;
- l) promoting and marketing Effexor for use with pregnant women, despite the fact that WYETH knew or should have known that Effexor was associated with an increased risk of congenital abnormalities;
- m) promoting and marketing Effexor as safe and effective for use with pregnant women when, in fact, it was unsafe;
- n) promoting and marketing Effexor for non-approved (off-label) uses and/or illegally over-promoting, marketing, advertising and selling Effexor in a zealous and unreasonable way, without regard to the potential danger that it poses for an unborn fetus;
- o) failing to independently monitor their sales of 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 monographs for Effexor, and as a result of the over-promotion of the drug;
- p) 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
- q) failing to perform adequate and necessary studies to determine and analyze the safety and risks associated with Effexor use.

38. As a direct and proximate result of Defendants' actions, Plaintiffs, 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 the Plaintiffs to the risks and injuries alleged herein, and that those risks were the direct and proximate result of Defendants' acts or omissions.

Injuries

39. As a direct and proximate result of the conduct of Defendants as described herein and as a result of the Mother Plaintiff's ingestion of Effexor, the Minor Plaintiff suffers from physical injuries, some or all of which are permanent, and the Minor Plaintiff may suffer in the future from other diseases or conditions which have not yet been diagnosed. Further, the Minor Plaintiff has sustained in the past, and will sustain in the future, pain and suffering, mental anguish, embarrassment and humiliation, psychological injury, disability, disfigurement caused by the surgeries and procedures the Minor Plaintiff has already undergone, and the surgeries and procedures that Minor Plaintiff will need to undergo in the future, and the loss of enjoyment of the pleasures of life without the presence of congenital birth defects, and/or other related conditions, as well as past and future general and special damages, including past and future medical care and treatment, lost wages and lost earning capacity.

40. Minor Plaintiff's serious and permanent 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 Plaintiffs.

41. As a direct and proximate result of the conduct of Defendants as described herein, Mother Plaintiff has suffered and will in the future continue to suffer medical, nursing, hospital, pharmacy, rehabilitative and related costs and expenses for the Minor Plaintiff's injuries and care, along with lost wages, lost earning capacity, economic losses, and other damages for which

they are entitled to compensation. 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 Plaintiffs.

42. As result of the Mother Plaintiff's ingestion of Effexor and as a direct and proximate result of the conduct of Defendants described herein, Plaintiffs 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 Plaintiffs.

43. 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.

V. DISCOVERY RULE, TOLLING AND FRAUDULENT CONCEALMENT

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

45. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, fraudulent concealment, and/or minority tolling.

46. Plaintiffs plead that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and

diligence should have known, of facts indicating that Plaintiffs had been injured, the cause of the injury, and the tortuous nature of the wrongdoing that caused the injury.

47. Despite diligent investigation by Plaintiffs into the cause of their injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages, and their relationship to Effexor was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

48. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiffs and Plaintiff's physicians and pharmacists of the true risks associated with taking Effexor. As a result of Defendants' fraudulent concealment, Plaintiffs and Plaintiff's prescribing physicians and pharmacists were unaware, and could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

49. The running of the statute of limitations in this cause may be tolled due to the pendency of a class action proceeding against one or more of the Defendants herein. Class Action tolling is proper where Plaintiffs are members of an asserted class and the claims asserted in the class action proceeding are the same as the claims asserted in this action.

50. The statute of limitations is tolled due to the minority of the Plaintiff.

51. The statute of limitations is tolled due to the disability of Plaintiffs. Plaintiffs were under one or more of the following recognized disabilities: mental illness, infancy,

insanity, inability to comprehend the nature of legal proceedings, imprisonment, absence from the state due to government service, or other legal disability recognized by the applicable state law.

52. Defendants are estopped from asserting a statute of limitations defense because all Defendants fraudulently concealed from Plaintiffs the nature of Plaintiffs' injury and the connection between the injury and Defendants' tortious conduct.

VI. CLAIMS FOR RELIEF

53. The Plaintiffs set forth the following statements and claims in the alternative such that the sufficiency of this Complaint shall not be defeated by an inconsistency or insufficiency (if any) among any one or more of the alternative statements or claims.

COUNT ONE – STRICT PRODUCT LIABILITY – FAILURE TO WARN

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

55. 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 the Plaintiffs and the Mother Plaintiff's prescribing physicians.

56. 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 congenital birth defects associated with the use of Effexor were inadequate.

57. Plaintiffs, and the 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 them or to their physicians.

58. Defendants had a continuing duty to provide consumers, including Plaintiffs and their 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 Defendants.

59. 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, Defendants misled the medical community about the risks and benefits of Effexor, which resulted in injury to Plaintiffs.

60. Despite the fact that Defendants knew or should have known that Effexor caused unreasonable and dangerous side effects, including congenital 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.

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

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

- a) failing to ensure Effexor warnings to the medical community, physicians, the Mother Plaintiff's physicians, and Plaintiffs 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, the Mother Plaintiff's physicians, and Plaintiffs 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, the Mother Plaintiff's physicians, and Plaintiffs;
- d) failing to include adequate warnings and/or providing adequate and clinically relevant information and data that would alert the medical community, the Mother Plaintiff's physicians, and Plaintiffs to the dangerous risks of Effexor, including, among other things, the association with congenital birth defects;
- e) failing to continually monitor, test, and analyze data regarding safety, efficacy, and prescribing practices of their marketed drugs, including Effexor;
- f) failing to review all adverse drug event information (AER) 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, the Mother Plaintiff's physicians, and Plaintiffs;
- 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 of Effexor;
- h) failing to periodically review all medical literature regarding Effexor 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 Plaintiffs of the dangers of using Effexor during pregnancy, including the risk of congenital birth defects; and/or
- k) representing that Effexor was safe for use during pregnancy, when in fact, Defendants knew or should have known that Effexor was unsafe for this use and that Effexor was associated with congenital birth defects.

63. Defendants continued to aggressively manufacture, market, promote, distribute, and sell Effexor, even after they knew or should have known of the unreasonable risks of congenital birth defects from Effexor.

64. Defendants had an obligation to provide Plaintiffs and the 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.

65. By failing to provide Plaintiffs and the 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, Defendants breached their duty of reasonable care and safety.

66. As a direct and proximate result of the actions and inactions of Defendants as set forth above, Plaintiffs were exposed to Effexor, 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 Defendants for an amount in excess of \$50,000.00, compensatory and punitive 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

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

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

69. 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 congenital birth defects;
- b) defective in design and was not reasonably safe as intended to be used, subjecting Plaintiffs 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 Plaintiff's underlying condition;
- d) 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) defective in design in that Effexor contained insufficient, incorrect, and defective warnings in that they failed to alert physicians and users, including Plaintiffs, of the risks of adverse effects; and/or
- f) defective in design in that Effexor was not safe for its intended use and was inadequately tested.

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

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

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

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

74. As a direct and proximate result of the actions and inactions of 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 Defendants for an amount in excess of \$50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

COUNT THREE – NEGLIGENCE

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

76. Defendants are liable to Plaintiffs pursuant to state common law and/or state Product Liability Acts due to their negligent advertizing, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling and testing Effexor.

77. At all times mentioned herein, 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.

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

79. 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.

80. 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, the Mother Plaintiff's physicians, and Plaintiffs 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, the Mother Plaintiff's physicians, and Plaintiffs 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, the Mother Plaintiff's physicians, and Plaintiffs;
- d) failing to include adequate warnings and/or provide adequate and clinically relevant information and data that would alert the medical community, physicians, the Mother Plaintiff's physicians, and Plaintiffs 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 (AER) 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, the Mother Plaintiff's physicians, and Plaintiffs;
- 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 of Effexor;
- h) failing to periodically review all medical literature regarding Effexor 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, the Mother Plaintiff's physicians, and Plaintiffs of the dangers of using Effexor during pregnancy, including the risk of congenital birth defects;
- k) representing that Effexor was safe for use during pregnancy when, in fact, Defendants knew or should have known that Effexor was unsafe for this use and that Effexor was associated with congenital birth defects;

- l) promoting and marketing Effexor for use with pregnant women, despite the fact that the Defendants knew or should have known that Effexor was associated with an increased risk of congenital abnormalities;
- m) promoting and marketing Effexor as safe and effective for use with pregnant women when, in fact, it was unsafe;
- n) promoting and marketing Effexor for non-approved (off-label) uses and/or illegally over-promoting, marketing, advertising, and selling Effexor in a zealous and unreasonable way, without regard to the potential danger that it posed for an unborn fetus;
- o) 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 monographs for Effexor, and as a result of the over-promotion of Effexor;
- p) 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;
- q) failing to perform adequate and necessary studies to determine and analyze the safety and risks associated with Effexor's use;
- r) 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 congenital birth defects to the medical community, the Mother Plaintiff's physicians, and Plaintiffs;
- s) failing to accompany Effexor with adequate information that would alert the medical community, the Mother Plaintiff's physicians, and Plaintiffs to the potential adverse

side effects associated with the use of Effexor and the nature, severity, and duration of such adverse effects;

- t) 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;
- u) continuing to promote the safety and effectiveness of Effexor, while downplaying their risks, even after Defendants knew or should have known of the risks of Effexor;
- v) failing to provide consumers, such as Plaintiffs 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;
- w) being careless and negligent in that 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;
- x) 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;
- y) 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
- z) negligently and carelessly failing to act as a reasonably prudent drug manufacturer, distributor, marketer, promoter, or seller would under same or similar circumstances.

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

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

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

84. As a direct and proximate result of the negligent acts and/or omissions of 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 Defendant for an amount in excess of \$50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

COUNT FOUR – NEGLIGENT DESIGN

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

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

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

88. 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 risks of congenital 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 the 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 and users, including the 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;
- g) was and is defective in design because its risks exceeded any benefit of Effexor; and/or
- h) failed to act as a reasonably prudent drug manufacturer, seller, promoter, distributor, or marketer would have acted with respect to the design of Effexor.

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

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Defendants for an amount in excess of \$50,000.00, compensatory and punitive damages, delay damages, costs of suit in an amount to be determined upon the trial of this matter.

COUNT FIVE – FRAUD, MISREPRESENTATION AND SUPPRESSION

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

91. 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 Plaintiffs, both directly and by and through the 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.

92. 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 congenital birth defects, were communicated to Plaintiffs directly through promotional materials, advertising, product inserts, and the monograph provided with 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 the Mother Plaintiff's prescribing physician with the intent that such misrepresentations would cause Effexor to be prescribed to the Mother Plaintiff.

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

94. 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 the Mother Plaintiff, the Mother Plaintiff's physician, and the consuming public to use and prescribe Effexor. Defendants fraudulently, intentionally, and/or negligently knew or should have known that the Mother Plaintiff, the Mother Plaintiff's physician, and the consuming public would rely on such material

misrepresentations and/or omissions in selecting Effexor for the treatment of the Mother Plaintiff. Defendants knew or should have known that the Mother Plaintiff and the Mother Plaintiff's physician would rely upon their false representations and/or omissions.

95. 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) 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) Defendants failed to disclose or concealed data showing that Effexor increased the risk of congenital birth defects;
- c) 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) Defendants concealed and continues to conceal past and present facts, including that as early as the 1990's, Defendants was aware of and concealed their knowledge of an association between the use of Effexor and dangerous side effects, including the increased risk of congenital birth defects, from the consuming public, including Plaintiffs and the Mother Plaintiff's physicians.

96. 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.

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

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

99. 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.

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

101. If Plaintiffs and the Mother Plaintiff's physicians had known the true facts concerning the risks of Effexor, in particular, the risk of congenital 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.

102. Plaintiffs' and Plaintiff's physicians' reliance upon the Defendants' material misrepresentations was 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 Plaintiffs and Plaintiff's physicians were not in a position to know the true facts, and because Defendants overstated the benefits and safety of Effexor, and concomitantly downplayed the risks of its use, including congenital birth defects, thereby

inducing the Mother Plaintiff and the Mother Plaintiff's physician to use Effexor, in lieu of other, safer alternatives, or no drug at all.

103. As a direct and proximate result of the Plaintiffs' and the Mother Plaintiff's physicians' reliance on 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 Defendants for an amount in excess of \$50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

COUNT SIX – CONSTRUCTIVE FRAUD

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

105. 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.

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

107. 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, Defendants professed that they were in possession of facts demonstrating that Effexor was safe and effective for its intended use and was not defective.

108. Defendants' representations to the Mother Plaintiff's physicians were made to induce the purchase of Effexor, and Plaintiffs and their physicians relied upon those statements when purchasing and administering Effexor.

109. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and their physicians and engaged in constructive fraud in their relationship.

110. Plaintiffs and the Mother Plaintiff's physicians reasonably relied on Defendants' representations.

111. As a direct and proximate result of 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 Defendants for an amount in excess of \$50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

COUNT SEVEN – BREACH OF EXPRESS AND IMPLIED WARRANTIES

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

113. Defendants 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.

114. At all times hereinafter mentioned, upon information and belief, 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 Defendants, expressly warranted to all

foreseeable users of Effexor, including the 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.

115. Defendants impliedly warranted in manufacturing, distributing, selling, advertising, marketing, and promoting Effexor to all foreseeable users, including the Mother Plaintiff and the 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 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.

116. At all time relevant hereto, Plaintiffs and the Mother Plaintiff's physicians relied upon the aforesaid express and implied warranties by Defendants.

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

118. 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 the Mother

Plaintiff's use of Effexor for treatment during her pregnancy caused the Minor Plaintiff's injuries.

119. As a direct and proximate result of 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 Defendants for an amount in excess of \$50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

COUNT EIGHT – NEGLIGENCE

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

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

122. 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.

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

124. 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 conscious disregard to the rights, safety, and welfare of Plaintiffs.

125. 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.

126. Further, the wrongs done by the Defendants were aggravated by the kind of malice, fraud, and reckless 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 Plaintiffs. Plaintiffs relied on the representation and suffered injury as a proximate result of this reliance.

127. 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.

128. 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 the Defendants for an amount in excess of \$50,000.00, compensatory and punitive

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

COUNT NINE - LOSS OF CONSORTIUM AND PECUNIARY LOSS

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

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

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

132. 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.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against the Defendants for an amount in excess of \$50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

COUNT TEN – PUNITIVE DAMAGES

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

134. Plaintiffs are entitled to punitive damages, pursuant to state common law or the applicable statutory provision, 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 Effexor and the Effexor 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 Effexor, including congenital birth defects, despite information demonstrating Effexor was unreasonably dangerous and in conscious disregard of the risk of serious injury posed to Plaintiffs by these known misrepresentations and/or omissions.

135. Plaintiffs are entitled to punitive damages, pursuant to state common law or the applicable statutory provision, because Defendants' actions were reckless and without regard for the public's safety and welfare. Defendants misled both the medical community and the public at large, including Plaintiffs, their physicians and pharmacists, by making false representations about and concealing pertinent information regarding Effexor and its information and warnings. Defendants downplayed, understated and disregarded its knowledge of the serious and permanent side effects associated with the use of Effexor, including congenital birth defects, despite information demonstrating the product was unreasonably dangerous.

136. At all times material hereto, the 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.

137. The conduct of the 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 Plaintiffs, the Mother's Plaintiff 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 heedlessly and recklessly, without regard to consequences, or of the rights and safety of others, including Plaintiffs.

138. The Manufacturing Defendants knew that Effexor had unreasonably dangerous risks and caused serious side effects of which Plaintiffs, their 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.

139. 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 financial injury.

140. The conduct of the 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.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against the Defendants for an amount in excess of \$50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

VII. JURY DEMAND

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

VIII. 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 \$50,000.00;
- (B) Lost Wages;
- (C) Punitive and/or Treble Damages pursuant to state law;
- (D) Attorneys' fees pursuant to state law;
- (E) Pre-judgment and post-judgment interests as authorized by law on the judgments which enter on Plaintiffs' behalf;
- (F) Costs of suit and expenses;
- (G) Delay Damages; and
- (H) Such other relief as is deemed just and appropriate.

Respectfully Submitted,

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VERIFICATION

I, Rosemary Pinto, hereby state:

1. I am the Attorney in this action;
2. I verify that the statements made in the foregoing COMPLAINT are true and correct to the best of my knowledge, information and belief, and;
3. I understand that the statements in the foregoing COMPLAINT are made subject to the penalties of 18 PA. C.S.A. § 4904 relating to the unsworn falsification to authorities.

/s/ Rosemary Pinto
ROSEMARY PINTO

August 31, 2012
(Date)