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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

In re: Forest Research Institute Cases	)	MASTER DOCKET NO. 13-cv-1832 (RBK/AMD)
CHANDRA SHUCK, individually and as the personal representative of the estate of M.M.S., Deceased	)	CIVIL ACTION NO._____ (RBK/AMD)
Plaintiff,	)	
vs	)	**COMPLAINT**
FOREST LABORATORIES, INC.; FOREST PHARMACEUTICALS, INC.; FOREST RESEARCH INSTITUTE, INC.; AND H. LUNDBECK A/S D/B/A KEFALAS A/S,	)	
Defendants.	)	

TO THE HONORABLE JUDGE OF SAID COURT:

CHANDRA SHUCK, individually and as the personal representative for the estate of M.M.S., by and through the undersigned counsel, hereby sues the defendants Forest Laboratories, Inc.; Forest Pharmaceuticals, Inc.; Forest Research Institute, Inc.; and H. Lundbeck A/S d/b/a Kefalas A/S (hereinafter referred to as "Defendants"), and allege as follows:

NATURE OF THE ACTION

1. This is a products liability case arising out of personal injuries and death of M.M.S., who was born on April 7, 2005, in Grand Rapids, Michigan. M.M.S. resided with her parents, Joel and Chandra Shuck in Lowell, Michigan until her death on April 21, 2005. M.M.S. sustained injuries that caused her death and damages as a result of serious birth defects caused by Chandra Shuck's ingestion of Lexapro, a prescription drug distributed, manufactured and marketed by Defendants, during her pregnancy with M.M.S.

2. At all times material hereto, Lexapro was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold by Defendants.

3. This is an action for damages that exceed the jurisdictional minimum of this Court. Jurisdiction is proper as Forest Research Institute, Inc. was, and still is, a New Jersey corporation who regularly conducts business, receives substantial revenues, and sells and performs services in Atlantic County and in the state of New Jersey. Furthermore, a substantial part of the events and omissions giving rise to Plaintiff's injuries occurred in this District.

4. This suit is brought under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1, *et seq.* ("Products Liability Act"), The New Jersey Wrongful Death Act, N.J.S.A. 2A:31-1, and the New Jersey Survivors Act, N.J.S.A. 2A:15-3 to recover damages and other relief, including the costs of suit and reasonable attorneys' and expert fees, for the injuries Plaintiff has sustained as a result of Defendants' acts and omissions in violation of the New Jersey Products Liability Act, New Jersey Wrongful Death Act, and New Jersey Survivors Act.

PARTIES

5. Chandra Shuck is a competent adult and the mother of M.M.S. She is a resident of the State of Michigan, Kent County. She brings this action individually and as the personal representative for the estate of M.M.S.

6. At all relevant times alleged herein, one or more of the corporate Defendants was, and now is, a corporation with its principal place of business in the State of New Jersey.

7. At all relevant times alleged herein, one or more of the individual Defendants was, and now is, a resident of the State of New Jersey.

8. At all relevant times alleged herein, the Defendants were in the business of researching, designing, developing, licensing, compounding, testing, producing, manufacturing, assembling, processing, packaging, inspecting, labeling, warranting, marketing, promoting, advertising, distributing, selling, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, the pharmaceutical product known as Lexapro. M.M.S. suffered damages and any resulting injuries and death as a result of her mother, Chandra Shuck's, use of Lexapro.

9. At all times relevant hereto, Defendants designed, developed, manufactured, promoted, marketed, distributed, tested, warranted and sold Lexapro in interstate commerce throughout the United States including, inter alia, New Jersey. Furthermore, Defendants conducted substantial business, advertised Lexapro, received substantial compensation and profits from sales of the Lexapro, made material omissions and misrepresentations, and committed breaches of warranties throughout the United States including, inter alia, New Jersey.

10. At all times relevant hereto, Defendants, and each of them, were engaged in the business of researching, designing, developing, licensing, compounding, testing, producing, manufacturing, assembling, processing, packaging, inspecting, labeling, warranting, marketing, promoting, advertising, distributing, selling, and introducing Lexapro into interstate commerce, either directly or indirectly through third parties or related entities.

11. On information and belief, Defendant Forest Laboratories, Inc., a New York Corporation, was and still is, a corporation duly existing under and virtue of the laws of the State of New York with its principal place of business in New York, New York. At all times hereinafter mentioned, defendant Forest Laboratories, Inc. was, and still is, a pharmaceutical company involved in research, development, testing, manufacture, production, promotion, distribution and marketing of pharmaceuticals for distribution, sale and use by the general public of the drug Lexapro (known generically as escitalopram), an antidepressant, throughout the United States and the State of New Jersey.

12. On information and belief, Forest Pharmaceuticals, Inc., a wholly-owned subsidiary of Forest Laboratories, Inc., is a Missouri Corporation with its principal place of

business located in St. Louis, Missouri. At all times hereinafter mentioned, defendant Forest Pharmaceuticals, Inc. was, and still is, a pharmaceutical company involved in research, development, testing, manufacture, production, promotion, distribution and marketing of pharmaceuticals for distribution, sale and use by the general public of the drug Lexapro (known generically as escitalopram), an antidepressant, throughout the United States and the State of New Jersey.

13. On information and belief, Forest Research Institute, Inc., a wholly-owned subsidiary of Forest Laboratories, Inc., was and still is, a corporation duly existing under and virtue of the laws of the State of New Jersey with its principal place of business at Harborside Financial Center, Plaza V, Suite 1900, Jersey City, New Jersey. At all times hereinafter mentioned, defendant Forest Research Institute, Inc. was, and still is, a pharmaceutical company involved in research, development, testing, manufacture, production, promotion, distribution and marketing of pharmaceuticals for distribution, sale and use by the general public of the drug Lexapro (known generically as escitalopram), an antidepressant, throughout the United States and the State of New Jersey, including in Atlantic County.

14. On information and belief, decisions and conduct concerning drug safety, regulatory affairs, advertisement and promotion of Lexapro were centralized in defendant Forest Research Institute, Inc.'s New Jersey offices. Accordingly, the acts and omissions complained of herein emanated from New Jersey.

15. Forest Laboratories, Inc., Forest Pharmaceuticals, Inc. and Forest Research Institute, Inc. hereinafter collectively shall be referred to as the "Forest Defendants."

16. On information and belief, Defendant H. Lundbeck A/S d/b/a Kefalas A/S, a Danish company ("Lundbeck"), was, and still is, a company duly existing under virtue of the laws of Denmark. At all times hereinafter mentioned, defendant H. Lundbeck A/S d/b/a Kefalas A/S was, and still is, a pharmaceutical company involved in research, development, testing, manufacture, production, promotion, distribution and marketing of pharmaceuticals for distribution, sale and use by the general public of the drug Lexapro (known generically as escitalopram), an antidepressant, throughout Europe, the United States and the State of New

Jersey.

17. Forest Defendants and Defendant Lundbeck entered into a License and Supply Agreement regarding the research and development of Lundbeck's original compound known as Citalopram on October 3, 1995.

18. Forest Defendants and Defendant Lundbeck entered into a License Agreement regarding the marketing, selling, and distributing of Lundbeck's original compound known as Escitalopram on March 27, 1998.

19. Forest Defendants and Defendant Lundbeck entered into an Amended and Restated License Agreement regarding the marketing, selling, and distributing of Lundbeck's original compound known as Escitalopram on May 29, 2002.

20. Forest Defendants and Defendant Lundbeck entered into a Pharmacovigilance Exchange Agreement.

21. According to the Forest – Lundbeck Pharmacovigilance Exchange Agreement, Lundbeck is responsible for reviewing the worldwide scientific literature in order to identify adverse events for Lexapro and Celexa.

22. Each party under the Forest – Lundbeck Pharmacovigilance Exchange Agreement had the right to monitor each other's facilities and review data relating to drug safety.

23. According to the Forest – Lundbeck Pharmacovigilance Exchange Agreement, the Global database employed to assess all safety signals, including pregnancy reports, relied upon by Forest Defendants and Defendant Lundbeck, resided with Defendant Lundbeck.

24. Forest Defendants and Defendant Lundbeck held Joint Publication Planning Meetings to discuss regulatory and marketing issues in Europe and the United States regarding Celexa and Lexapro.

25. Forest Defendants and Defendant Lundbeck held Joint Advisory Board Meetings to discuss scientific and safety issues regarding Celexa and Lexapro.

26. Forest Defendants and Defendant Lundbeck conducted regular Joint Safety

Committee Meetings where they discussed safety data to determine possible impact on labeling regarding Celexa and Lexapro.

27. On information and belief, Forest Defendants and Defendant Lundbeck regularly met to discuss safety data and possible labeling changes regarding Celexa and Lexapro.

28. On information and belief, Defendant Lundbeck has licensed to Forest Defendants the rights to market and sell Celexa (known generically as citalopram) and Lexapro (known generically as escitalopram) in the United States.

29. On information and belief, at all times relevant hereto, the Defendants were each engaged in the business of researching, designing, developing, licensing, compounding, testing, producing, manufacturing, assembling, processing, packaging, inspecting, labeling, warranting, marketing, promoting, advertising, distributing, selling, and/or introducing into interstate commerce Lexapro, either directly or indirectly through third parties or related entities and/or the Defendants are otherwise responsible as corporate successors for the liabilities of the entities that designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold Lexapro. Plaintiff is informed and believes Defendants manufactured the Lexapro that was dispensed to Chandra Shuck.

30. On information and belief, at all relevant times, the Defendants were present and doing business in the State of New Jersey.

31. On information and belief, at all relevant times, the Defendants transacted, solicited, and conducted business in the State of New Jersey and derived substantial revenue from such business, specifically relating to the sale of Lexapro and otherwise.

32. On information and belief, at all relevant times, the Defendants expected or should have expected that their acts would have consequences within the United States of America, including the State of New Jersey.

33. At all times herein alleged, each of the Defendants was an agent, servant, partner, aider and abettor, co-conspirator and joint-venturer of each of the remaining Defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture and rendered substantial assistance and

encouragement to the other Defendants, knowing their conduct constituted a breach of duty owed to Plaintiff.

34. There exists, and at all times herein alleged, there existed, a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter-ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as an entity distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction fraud and would promote injustice.

35. At all times herein alleged, the officers and directors of the Defendants named herein participated in, authorized and directed the production and promotion of Lexapro when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of Lexapro and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff.

36. Defendants, and each of them, acted independently of, or jointly with, other Defendants, and are all in some manner legally responsible for the events and happenings herein referred to, and caused damages proximately and foreseeably to Plaintiff as alleged herein.

GENERAL ALLEGATIONS

37. The drug "escitalopram" is manufactured, promoted, distributed, labeled and marketed by Defendants under the trade name Lexapro. The drug "citalopram" is also manufactured, promoted, distributed, labeled and marketed by Defendants and its trade name is Celexa. Both drugs are members of the class of drugs known as "selective serotonin reuptake inhibitors" or "SSRIs."

38. Defendant Lundbeck manufactures the active pharmaceutical ingredient in Celexa and Lexapro, which is then supplied to the Forest Defendants to complete the manufacture of the Celexa and Lexapro pills that are packaged and distributed throughout the United States. On information and belief, the Forest Defendants and Lundbeck also collaborate on the marketing of

both products in the United States. Defendant Lundbeck conducted Global pharmacovigilance, including monitoring the worldwide literature.

39. Celexa is Forest's first approved antidepressant in the SSRI class and was launched in the commercial market in August 1998. Celexa, a patented drug, had a five-year exclusive marketing period, originally set to expire in 2003. At this time, Celexa would become "generic" and other manufacturers could market citalopram.

40. In order to protect its market share and the higher pricing that comes with on-patent drugs (by 2000-2001, Celexa accounted for 70-80% of the Forest Defendant's profits), the Forest Defendants worked with licensor Lundbeck to develop Lexapro. Lexapro has the same active ingredient as Celexa, making it essentially the same drug, but Lexapro has sufficiently claimed differences to obtain patent protection. This allowed Forest Defendants to gain market-exclusivity far beyond that of Celexa. Despite the similarity between the two drugs, Forest Defendants, in an effort to maximize profits, put all of their attention and marketing resources into Lexapro.

41. Lexapro was first approved for use in the United States by the FDA in 2002 for the treatment of depression in adults. Lexapro has never been approved by the FDA for use in pregnant women.

42. Chandra Shuck, M.M.S.'s mother, took Lexapro as prescribed by her treating physician during her pregnancy with M.M.S.

43. At the time Lexapro was prescribed to Ms. Shuck, Defendants knew through pre-market studies and post-marketing studies and reports of SSRI antidepressants, including but not limited to both Celexa and Lexapro, that Lexapro was associated with a significantly increased risk of cardiac and other birth defects in babies whose mothers ingested Lexapro during pregnancy. Other studies showed that increased levels of serotonin, the primary human substance affected by Lexapro, had profound effects on the pre-natal development of study animals.

44. Notwithstanding this knowledge, Defendants aggressively and actively promoted Lexapro for use with women of child-bearing years, including pregnant women. The Defendants

encouraged their sales force to promote Lexapro to women of child-bearing years and touted Lexapro as being a safe alternative for pregnant women. In fact, none of this was true.

45. The Defendants have never informed doctors of these serious risks, even though third-party research shows the association between Lexapro and cardiac and other types of birth defects. Defendants continue to represent that Lexapro is safe for use for women of child-bearing years, including during pregnancy, and continue to mislead both consumers and physicians by failing to include a proper warning on the Lexapro label about the increased risk of birth defects.

46. When M.M.S. was born, she was diagnosed with life-threatening congenital heart defects, including an atrial septal defect, a ventricular septal defect, a patent ductus arteriosus, a patent foramen ovale, a coarctation of aorta, a right ventricular outflow tract obstruction defects, a left ventricular outflow tract obstruction defects and pulmonary hypertension. In order to treat these conditions, M.M.S. underwent four open-heart surgeries, in her short life, and was never even released from the hospital.

47. M.M.S.'s birth defects and death were a direct result of her mother's ingestion of Lexapro during her pregnancy. Prior to the time Ms. Shuck ingested Lexapro during her pregnancy with M.M.S., the Defendants knew or should have known that Lexapro was associated with an increased risk of congenital defects in babies of mothers who ingest Lexapro during pregnancy. Further, given that Celexa is essentially the same drug as Lexapro, Defendants knew or should have known based on any and all information available to Defendants regarding the side effects of Lexapro, that both Celexa and Lexapro were associated with an increased risk of congenital defects in babies of mothers who ingest either drug during pregnancy.

48. During the entire time Celexa and Lexapro have been on the market in the United States, FDA regulations required the Defendants to issue stronger warnings whenever there existed reasonable evidence of an association between a serious hazard and Celexa and/or Lexapro. The regulations specifically state that a causal link need not have been proven to issue

the new warnings. Further, the regulations explicitly allowed the Defendants to issue such a warning without prior FDA approval.

49. Thus, prior to Ms. Shuck's pregnancy with M.M.S., the 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 Lexapro (and Celexa) and birth defects through all means necessary, including but not limited to labeling, continuing education, symposiums, posters, sales calls to doctors, advertisements and promotional materials, etc. The Defendants breached this duty.

50. Plaintiff filed this lawsuit within the applicable limitations period of first suspecting that Lexapro was the cause of M.M.S.'s injuries and death.

51. Plaintiff was prevented from discovering this information sooner because the Defendants herein misrepresented and continue to misrepresent to the public and to the medical profession that the drug is safe to take during pregnancy. The Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

52. Plaintiff's injuries were caused by Lexapro's defects and the wrongful conduct, acts, omissions, and fraudulent misrepresentations of Defendants. As a result of Defendants' claims and representations regarding the effectiveness and safety of Lexapro, Ms. Shuck was prescribed Lexapro and used and consumed Lexapro in accordance with their directions. Had the Defendants properly disclosed risks associated with the Lexapro, Ms. Shuck would not have used it during her pregnancy with M.M.S., and M.M.S. would not have suffered the serious and permanent injuries as described herein.

53. Prior to Ms. Shuck's use of Lexapro, the Defendants knew or should have known that the use of Lexapro created a significantly increased risk of birth defects occurring when taken during pregnancy, and that during pregnancy, even when used as directed, Lexapro was unreasonably dangerous to consumers.

54. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Lexapro during pregnancy, Defendants failed to warn Ms. Shuck, her health care providers, or the public and the medical community of said serious risks before Ms. Shuck used Lexapro.

55. Had Ms. Shuck's prescribing physicians and health care providers known the risks and dangers associated with Lexapro, they would not have prescribed it or would have advised her to discontinue using Lexapro during her pregnancy, and M.M.S. would not have suffered serious injuries, consequent damages and death.

56. Had Ms. Shuck known the risks and dangers associated with Lexapro, she would not have used it during her pregnancy, and M.M.S. would not have suffered serious injuries, consequent damages and death.

57. As a direct and proximate result of Lexapro's defects and the wrongful conduct, acts, omissions, and fraudulent misrepresentations of Defendants, Plaintiff has suffered significant harm, conscious pain and suffering, physical injury and bodily impairment resulting in permanent physical deficits, permanent impairment, loss of companionship and society and other sequelae likely to continue into the future.

58. As a further direct and proximate result of Lexapro's defects and the wrongful conduct, acts, omissions, and fraudulent misrepresentations of Defendants, Plaintiff has also incurred medical expenses and other economic harm including loss of earnings and services, and will continue to incur expenses, loss of earnings and future earning capacity.

59. As a further direct and proximate result of Lexapro's defects and the wrongful conduct, acts, omissions, and fraudulent misrepresentations of Defendants, M.M.S. has required medical treatment, and has incurred, medical, incidental, and service expenses pertaining to her injuries.

60. Defendants falsely and fraudulently represented to Ms. Shuck, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, the FDA, and the public in general, that Lexapro was safe and effective for its indicated use during pregnancy.

61. These false representations were made by Defendants with the intent of defrauding and deceiving Ms. Shuck, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, the FDA, and the public in general, and were made with the intent of inducing them to recommend, dispense and purchase Lexapro, all of which evinced a callous, reckless and willful indifference to safety.

62. Defendants knew and were aware or should have been aware that Lexapro had not been sufficiently tested for use during pregnancy, was defective in its design and testing, and lacked adequate and sufficient warnings.

63. Defendants knew or should have known that Lexapro increased the risk of birth defects when used during pregnancy, was inherently dangerous in a manner that exceeded any purported benefit of the medication, and that the labeling was inaccurate and downplayed warnings.

64. Defendants were under a duty to disclose to Ms. Shuck and her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, the FDA, and the public in general, the defective nature of Lexapro.

65. Defendants had sole access to material facts concerning the defective nature of Lexapro and its propensity to increase the risks of birth defects, and hence, cause damage to consumers, including Plaintiff.

66. Defendants made the misrepresentations and actively concealed information concerning the safety and efficacy of Lexapro with the intention and specific desire that the medical, pharmaceutical and scientific communities, and consumers, including Ms. Shuck, her prescribing physicians and healthcare providers, would rely on such in selecting Lexapro to treat her depression.

67. Defendants made these misrepresentations and actively concealed information concerning the safety and efficacy of Lexapro in their labeling, advertising, product inserts, promotional material or other marketing efforts.

68. The misrepresentations and active concealments by Defendants were perpetuated directly and indirectly by Defendants, their sales representative, employees, distributors, agents

and detail persons.

69. Defendants knew that Ms. Shuck, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, the FDA, and the public in general, had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Lexapro, as set forth herein.

70. The misrepresentations and active concealment by Defendants constitute a continuing tort. Indeed, through Defendants' product inserts, Defendants continue to misrepresent the potential risks and serious side effects associated with the use of Lexapro when used during pregnancy.

71. Moreover, Defendants had a post-sale duty to warn the medical, pharmaceutical and scientific communities, and users and consumers of the drug, including Ms. Shuck, about the potential risks and serious side effects associated with the use of Lexapro in a timely manner, yet they failed to provide such warnings.

72. As a result of the Defendants' advertising and marketing efforts, concealment and misrepresentations, Lexapro is and continues to be pervasively prescribed and used throughout the United States and in New Jersey.

73. During the time that Lexapro has been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Lexapro.

74. At all times material hereto, the Defendants knew or should have known that most physicians were not aware of, or did not fully appreciate the seriousness of the risks associated with use of Lexapro during pregnancy, either as Lexapro, or in the generic form of escitalopram, and Defendants knew or should have known that package inserts for Lexapro and generic versions of the drug were deficient, inaccurate, false and misleading in communicating to the medical community in general, to physicians, or to the public, information about the risks associated with the drug when used during pregnancy.

75. The Defendants failed to adequately inform physicians and misled physicians about the risks associated with Lexapro, despite the fact that they knew that the medical

community in general, physicians, pharmacists, Ms. Shuck, and others similarly situated relied on them to disclose and communicate to doctors what they knew and what experts in the use and effects of the drug would know from a prudent review of the information that they possessed or were reasonably able to obtain.

76. Because of the misleading and inaccurate information that Defendants disseminated to physicians, and because of the failure of the Defendants generally to adequately and effectively inform physicians, the medical community or the FDA about the true risks associated with the use of Lexapro and generic escitalopram, Ms. Shuck's physicians did not know or appreciate fully the risks associated with using Lexapro during pregnancy.

77. Defendants knew, and through the exercise of reasonable care should have known, that the labeling for Lexapro and generic escitalopram substantially understated the risks and overstated the efficacy of the drug. They failed to use reasonable care to ascertain or communicate to physicians or to the public information that would constitute adequate and effective warnings to physicians or to the public about the true risks of using the drug during pregnancy.

78. Defendants were aware that their individual and collective failure to communicate to the medical community and to physicians, information known to them about the risks of use during pregnancy and that using Lexapro would be likely to result in serious injury to patients who received the drug in accordance with prescriptions issued by physicians who were unaware of this information. By failing to communicate this information to the medical community or the FDA, the Defendants acted in willful and wanton disregard of the rights of Plaintiff, and this conduct caused serious injury to M.M.S. and Plaintiff's resulting damages.

79. As manufacturers and distributors of prescription drug products, specifically Lexapro and/or generic escitalopram, each of the Defendants has a duty to adequately communicate warnings to physicians and the medical community (or to patients who could be expected to take the drug) and to exercise due care to conduct safety surveillance for the drug and otherwise ensure that the warnings they are required to disseminate about the drug are

accurate and adequate, and that these warnings are effectively communicated to physicians, pharmacists, and patients using the drug.

80. Each of the Defendants breached its duty to ensure that adequate warnings were provided to the medical community, Ms. Shuck's physicians, Ms. Shuck, and/or other foreseeable Lexapro and/or escitalopram users similarly situated, in that they failed to:

a. ensure Lexapro and/or escitalopram warnings to the medical community, physicians, and Ms. Shuck's physician were accurate and adequate, despite having extensive knowledge of the risks associated with using the drug during pregnancy;

b. ensure that Lexapro and/or escitalopram warnings were effectively communicated to the medical community, physicians and Ms. Shuck, despite having extensive knowledge of the inappropriate use of the drug during pregnancy;

c. conduct post market safety surveillance and report that information to the FDA, the medical community, Ms. Shuck's physicians, Ms. Shuck and other foreseeable users;

d. review all adverse drug event (ADE) information for Lexapro and/or escitalopram, and to report information bearing significantly upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Lexapro and/or escitalopram products to the FDA, medical community, Ms. Shuck's physicians, Ms. Shuck and other like foreseeable users;

e. periodically review all medical literature regarding Lexapro and/or escitalopram products and report to the FDA, the medical community, or other interested individuals significant data concerning the efficacy or safety of Lexapro and/or escitalopram

products;

f. independently monitor sales of Lexapro and/or escitalopram products, and the medical literature, which would have alerted them to the fact that Lexapro was widely over prescribed, and was being prescribed to pregnancy women and women in their child-bearing years owing to the inadequate warnings provided to doctors;

g. engage in responsible testing, research, and pharmacovigilance practices regarding their Lexapro and/or escitalopram products, including a failure to perform studies and/or monitor, which would accurately determine the risks attendant to using Lexapro during pregnancy, and failed to engage in marketing practices designed to minimize the risks associated with Lexapro and/or escitalopram.

81. The acts, conduct, and omissions of Defendants, and each of them, as alleged throughout this Complaint were fraudulent, willful and malicious and were done with a conscious disregard for the rights of Plaintiff and other users of Lexapro and/or escitalopram products, and for the primary purpose of increasing Defendants' profits from the sale and distribution of the drug. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against each Defendant in an amount appropriate to punish and make an example of each Defendant.

82. Prior to the manufacturing, sale and distribution of Lexapro and/or escitalopram products, Defendants, and each of them, knew that the drugs were in a defective condition as previously described herein and knew that those who were prescribed the drugs would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants and each of them through their officers, directors, managers, and agents, had knowledge that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff, and as such, consumers of the drug were unreasonably subjected to risk of injury or death.

83. Despite such knowledge, Defendants, and each of them, acting through their officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in the drugs and failed to warn the public, including to the Plaintiff, Ms. Shuck's prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, the FDA, and the public in general, of the extreme risk of injury occasioned by said defects inherent in the drugs. Defendants and their individual agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution and marketing of the drugs knowing that the public, including Plaintiff, would be exposed to serious danger in order to advance Defendants' own pecuniary interest and monetary profits.

84. Defendants' conduct was despicable, and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with reckless, willful and conscious disregard for safety, entitling Plaintiff to exemplary damages under the New Jersey Products Liability Act.

85. All of the actions alleged in this Complaint are and were under the ultimate control and supervision of Defendants.

86. Plaintiff maintains and reserves her rights to plead additional facts, theories of liability, causes of action in her complaint, and/or to present evidence pertaining to the acts and omissions of Defendants as may be subsequently identified through discovery and investigation in this matter. Plaintiff reserves the right to present such evidence at the time of trial based upon such subsequently discovered acts, omissions or damages that are heretofore unknown or unidentified prior to the date of the service of this complaint and maintains and reserves her rights to thereafter move the court to conform pleadings to proof in this matter.

COUNT I

PRODUCTS LIABILITY ACT – FAILURE TO WARN

87. Plaintiff re-alleges and incorporates herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

88. Defendants designed, tested, manufactured, marketed, sold and/or distributed

Lexapro. As such, Defendants had a duty to warn the using public, including Plaintiff, of the health risks associated with using Lexapro during pregnancy.

89. Lexapro was under the exclusive control of Defendants and was unaccompanied by appropriate warnings regarding the health risks associated with its use during pregnancy. The warnings did not accurately reflect the risk, incidence, symptoms, scope or severity of such injury to the consumer. The advertising and promotional activities of Defendants further diluted or minimized the warnings given with Lexapro.

90. Lexapro was defective and unreasonably dangerous at the time of its manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution in that, and not by way of limitation, the Lexapro warnings, instructions and directions failed to warn of the dangerous risks posed by Lexapro when taken during pregnancy, including increased dangerous propensities as compared to other similar and comparable alternatives, which risks were known or reasonably scientifically knowable to Defendants.

91. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field. Defendants, and each of them, knew or should have known of the defective condition, characteristics and risks associated with Lexapro, as previously set forth herein.

92. At all times herein alleged, Lexapro was defective and Defendants, and each of them, knew that the Lexapro was to be used by consumers without inspection for defects therein. Moreover, Ms. Shuck, her prescribing physicians and health care providers, neither knew, nor had reason to know at the time of her use of Lexapro of the existence of the aforementioned defects. Ordinary consumers, including Plaintiff, could not have recognized the potential risks or side effects of Lexapro through the exercise of reasonable care because Defendants failed to include appropriate warnings.

93. At all times herein mentioned, Lexapro was prescribed and used by Plaintiff as intended by Defendants and in a manner reasonably foreseeable to Defendants.

94. Defendants had a continuing duty to warn consumers, including Plaintiff and her healthcare providers, of the dangers associated with Lexapro. By negligently and/or wantonly

failing to adequately warn of the dangers of use of Lexapro, Defendants breached their duty.

95. Although Defendants knew of the defective nature of Lexapro, they continued to design, manufacture, market and sell it without providing accurate, adequate and complete warnings concerning its use during pregnancy, so as to maximize sales and profits at the expense of public health and safety, in knowing, conscious and deliberate disregard for the foreseeable harm caused by Lexapro.

96. As a direct and proximate result of Defendants' failure to adequately warn and other actions of Defendants described herein, Plaintiff has sustained serious and permanent injuries, and will continue to suffer injury, harm and damages as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II

PRODUCTS LIABILITY ACT – DEFECTIVE DESIGN

97. Plaintiff re-alleges and incorporates herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

98. At all times relevant hereto, Defendants, and each of them, engaged in the business of selling, distributing, supplying, manufacturing, marketing and promoting Lexapro, which is defective and unreasonably dangerous to consumers, including Plaintiff.

99. At all times relevant hereto, Lexapro was sold, distributed, supplied, manufactured, marketed and/or promoted by Defendants, and was expected to reach and did reach consumers in New Jersey and throughout the United States, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendants.

100. At all times relevant hereto, Lexapro was sold, marketed, distributed, supplied, manufactured and/or promoted by the Defendants, in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include the following:

a. When placed in the stream of commerce, Lexapro contained unreasonably dangerous design defects and was not reasonably fit, suitable and/or safe as intended to be used, in that its foreseeable risks exceeded its benefits;

b. When placed in the stream of commerce, Lexapro was defective in design and formulation, making use of the drug during pregnancy more dangerous than an ordinary consumer would expect;

c. Lexapro was insufficiently tested;

d. Lexapro caused harmful effects that outweighed any potential utility;

e. Lexapro was not accompanied by adequate instructions and/or warnings to fully apprise the consumers, including Plaintiff, of the full nature and extent of the risks and side effects associated with its use, thereby rendering the Defendants liable to Plaintiff, individually and collectively.

101. Although Defendants actually knew or should have known of the defective nature of Lexapro, it continued to design, manufacture, market and sell Lexapro so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious and deliberate disregard of the foreseeable harm caused by Lexapro.

102. As a direct and proximate result of the design defects of Lexapro, Plaintiff has sustained serious and permanent injuries, and will continue to suffer injury, harm and damages as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III

BREACH OF EXPRESS WARRANTY

103. Plaintiff re-alleges and incorporates herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

104. At all times herein alleged, Defendants, and each of them, expressly represented and warranted to Ms. Shuck and her prescribing physicians and healthcare providers, the

medical, scientific, pharmaceutical and healthcare communities, the FDA, and the public in general, by and through statements made by Defendants, their authorized agents, and sales representatives, orally and in publications, package inserts, and other written materials intended for physicians, patients, and the general public, that Lexapro was safe, effective, fit, and proper for it intended use, that Lexapro was of merchantable quality, that Lexapro did not cause a significant risk of harm to the fetus when used during pregnancy and that Lexapro was adequately tested. Lexapro was purchased in reliance upon said express warranties.

105. In using Lexapro, Ms. Shuck and her prescribing physicians and healthcare providers, relied on the skill, judgment, representations, and express warranties of Defendants. Said warranties and representations were false, in that Lexapro did not conform to Defendants' express representations because it was not safe or merchantable and was unfit for the use for which it was intended or in a reasonably foreseeable manner, in violation of N.J.S.A. 12A:2-313 *et seq*.

106. As a direct and proximate result of Defendants' express warranties of Lexapro, Plaintiff has sustained serious and permanent injuries, and will continue to suffer injury, harm and damages as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV

FRAUD and FRAUDULENT CONCEALMENT

107. Plaintiff re-alleges and incorporates herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

108. Plaintiff is informed and believes and based thereon alleges that Defendants, while knowing that Lexapro poses a significant risk of harm to the fetus when used during pregnancy, orchestrated a sophisticated, comprehensive, multi-pronged marketing scheme to convince Ms. Shuck and the general consuming public, the healthcare community and others that Lexapro was safe and effective for use during pregnancy.

109. Plaintiff is informed and believes and based thereon alleges that, while knowing that Lexapro is not effective, and that it poses a significant risk of injury to a fetus when used during pregnancy, Defendants implemented a false, fraudulent and misleading nationwide marketing campaign concerning Lexapro.

110. Plaintiff is informed and believes and based thereon alleges that, while knowing that Lexapro poses a significant increase in risk to the fetus when used during pregnancy of adverse events including, but not limited to, birth defects, heart defects, serious injuries and death, Defendants implemented a false, fraudulent and misleading nationwide "Direct to Consumer" (DTC) advertising campaign via television commercials on major television networks, internet advertisements on major internet sites and search engines, and print advertisements in major newspapers and magazines with national circulation.

111. Plaintiff is informed and believes and based thereon alleges that Defendants' false, fraudulent and misleading DTC advertising and marketing of Lexapro specifically state that Lexapro is safe and effective for use during pregnancy.

112. Plaintiff is informed and believes and based thereon alleges that said false, fraudulent and misleading advertising, marketing messages, publications and all other such public statements were issued by Defendants in order to conceal (and did so conceal) the true risks of Lexapro use during pregnancy, to conceal the causal relationship between use of Lexapro and the injuries and damages suffered by Plaintiff, to conceal the grounds and/or basis for a legal cause of action by Plaintiff against Defendants herein. Said fraud, fraudulent concealment and fraudulent means to achieve said concealment caused Plaintiff to reasonably and detrimentally rely on such fraudulent statements and conduct. When Plaintiff discovered the Defendants' fraud, fraudulent concealment and other acts and omissions that resulted in successful suppression and denial of the increased risk of birth defects and other injuries caused by the use of Lexapro during pregnancy, Plaintiff pursues this action.

113. Plaintiff is informed and believes and based thereon alleges that Defendants, and each of them, further falsely and fraudulently represented to Ms. Shuck and her physicians, and members of the general public, that Lexapro was safe for use during pregnancy in treatment of

depression and anxiety. The representations by Defendants, and each of them, were in fact, false. The true facts were that Lexapro was not safe for use by and members of the general public during pregnancy and was, in fact, extremely dangerous to consumers.

114. Plaintiff is informed and believes and based thereon alleges that Defendants, and each of them, further misrepresented the safety of Lexapro, represented that Lexapro was safe and effective and safe for use during pregnancy, and concealed warnings of the known or knowable risks of taking Lexapro during pregnancy.

115. Plaintiff is informed and believes and based thereon alleges that when the Defendants, and each of them, made the representations as alleged herein, they knew that such representations were false. Defendants, and each of them, made the representations with the intent to defraud and deceive Ms. Shuck and her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, the FDA, and the public in general, and with the intent to induce them to use the products and act in the manner alleged in this complaint.

116. Ms. Shuck and her prescribing physicians and healthcare providers took the actions alleged in this complaint, while ignorant of the falsity of the representations and reasonably believed them to be true. In reliance upon such representations, she was induced to, and did, use Lexapro as described in this complaint. If she had known the actual facts, she would not have taken such actions nor would she have used Lexapro during her pregnancy with M.M.S. Her reliance upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts. As a direct and proximate result of Defendants' fraud and deceit, Plaintiff sustained the injuries and damages described in this complaint.

117. By and through the Defendants' false statements, fraudulent conduct and fraudulent concealment of facts as alleged herein, Plaintiff was prevented from discovering the wrongful conduct of Defendants with regard to Lexapro and was thereby prevented from discovering her causes of action against Defendants herein. Therefore, Defendants are estopped from asserting any statute of limitations defenses in this matter as such statutes of limitation have

been delayed in accrual and/or have been tolled due to Defendants' conduct. So long as Defendants continue to deny the increased risk of birth defects, the adverse events and the causal relationship between Lexapro and Plaintiff's injuries, all such statutes of limitation applicable to the causes of action asserted herein are, and will continue to be, tolled.

118. As a direct and proximate result of Defendants' fraud and deceit, Plaintiff has sustained serious and permanent injuries, and will continue to suffer injury, harm and damages as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V

PUNITIVE DAMAGES UNDER COMMON LAW AND PRODUCTS LIABIITY ACT

119. Plaintiff re-alleges and incorporates herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

120. Although Defendants knew, should have known and/or recklessly disregarded the fact that Lexapro causes significant risk of harm to the fetus when used during pregnancy, Defendants continued to market Lexapro to consumers, including Plaintiff and Ms. Shuck's healthcare providers, without disclosing this risk.

121. Defendants knew of Lexapro's defective nature, as set forth herein, but continued to design, manufacture, market and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by Lexapro.

122. Defendants intentionally concealed or recklessly failed to disclose to the public, including Plaintiff, the potentially life-threatening side effects of Lexapro to ensure their continued and increased sales. Defendants failed to provide warnings that would have dissuaded physicians and healthcare providers from prescribing Lexapro during pregnancy and consumers from purchasing and consuming Lexapro during pregnancy, thus depriving healthcare providers and consumers from weighing the true risks against the benefits of prescribing and/or purchasing

and consuming.

123. Defendants' aforementioned conduct was committed with knowing, conscious and deliberate disregard for the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VI

LOSS OF CONSORTIUM/PER QUOD CLAIM

124. Plaintiff re-alleges and incorporates herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

125. By reason of the foregoing, M.M.S.'s parents have necessarily paid and have become liable to pay for medical aid, treatment, attendance and medications, and funeral expenses.

126. By reason of the foregoing, M.M.S.'s parents further have been caused presently and in the future the loss of their child's companionship, services and society.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VII

WRONGFUL DEATH

127. Plaintiff re-alleges and incorporates herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

128. As a result of the wrongful acts and/or omissions of the Defendants as set forth herein, M.M.S. died on April 21, 2005 at the age of fifteen days. As a result thereof, M.M.S.

suffered injuries to the fullest extent allowable under N.J.S.A. 2A:15-3.

129. Had M.M.S. survived, she could have maintained a cause of action at the moment of her death pursuant to N.J.S.A. 2A:15-3.

130. Plaintiff has been duly appointed as Personal Representative of M.M.S.'s estate by a court of competent jurisdiction.

131. By reason of the foregoing wrongful acts and/or omissions on the part of Defendants, Plaintiff was further obliged to expend diverse sums of money for funeral expenses occasioned by M.M.S.'s death.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VIII

SURVIVAL ACTION

132. Plaintiff re-alleges and incorporates herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

133. As a result of the wrongful acts and/or omissions of the Defendants as set forth herein, M.M.S. suffered substantial conscious pain and suffering prior to her death.

134. Plaintiff, on behalf of M.M.S.'s estate, seeks damages compensable under the Survival Act, N.J.S.A. 2A:14-5 (or any successor statute) against Defendants. Plaintiff, in her own right, seeks damages compensable under the Survival Act, N.J.S.A. 2A:15-3 (or any successor statute) against Defendants.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

PRAYER

WHEREFORE, Plaintiff prays for judgment against Defendants Forest Laboratories, Inc.; Forest Pharmaceuticals, Inc.; Forest Research Institute, Inc.; and H. Lundbeck A/S d/b/a Kefalas A/S, inclusive, jointly and severally, and as appropriate to each cause of action alleged and as

appropriate to the particular standing of Plaintiff as follows:

1. Past and future general damages, the exact amount of which has yet to be ascertained, in an amount which will conform to proof at time of trial;

2. Past and future economic and special damages according to proof at the time of trial;

3. Loss of earnings and impaired earning capacity according to proof at the time of trial;

4. Medical expenses, past and future, according to proof at the time of trial;

5. For past and future mental and emotional distress, according to proof;

6. Punitive or exemplary damages according to proof at the time of trial;

7. Attorney's fees;

8. For costs of suit incurred herein;

9. For pre-judgment interest as provided by law; and

10. For such other and further relief as the Court may deem just and proper.

Dated: January 8, 2014

SEEGER WEISS LLP

By: /s Christopher A. Seeger

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DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial on all claims so triable.

Dated: January 8, 2014 SEEGER WEISS LLP

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