UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO

Z.H., by and through KEVIN HUTCHENS and CHRISTIN HUTCHENS, individually, and as parents and next friends of Z.H. Plaintiffs, v. ABBOTT LABORATORIES, INC. and ABBVIE INC. Defendants.	)	Case No. 1:14-CV-00176-CAB JURY TRIAL DEMANDED

PLAINTIFFS' FIRST AMENDED COMPLAINT

Come now Plaintiffs Z.H., a minor, by and through Kevin Hutchens and Christin Hutchens, individually, and as parents and next friends of Z.H., by and through their undersigned attorneys, for their First Amended Complaint against Defendants Abbott Laboratories, Inc. and AbbVie Inc. ("Defendants") relative to their sale and distribution and manufacturing of Depakote and Depakote ER products ("Depakote") in the United States, and in support thereof would show the following:

PARTIES AND JURISDICTION

Plaintiffs

1. Plaintiffs Z.H., a minor, by Kevin Hutchens and Christin Hutchens, individually as parents and next friends of Z.H., are citizens and residents of Ashtabula, Ohio. Plaintiff Z.H. was born in 2003. His injuries were caused by his mother's ingestion of Depakote during pregnancy, and specifically, during her first trimester of pregnancy. Plaintiffs aver that Defendant's Depakote was defectively designed, inadequately tested, dangerous to human health

and unborn, and lacked proper warnings as to the true danger associated with its use, and Plaintiff suffered injury as a result of the mother's ingestion of Depakote.

2. The foregoing Plaintiffs allege an amount in controversy in excess of $75,000.00, exclusive of interest and costs.

Defendant

3. Defendant Abbott Laboratories, Inc. now is, and at all times relevant to this action was, a corporation organized and existing under the laws of the State of Illinois, with its principal place of business and its headquarters in the State of Illinois. Defendant Abbott Laboratories Inc. will be served through its counsel who have appeared in this case.

4. Defendant AbbVie Inc. is a Delaware corporation with its principal place of business in Illinois. AbbVie Inc. was incorporated on April 10, 2012 and began operations as owner of Abbott's research-based pharmaceutical business in January of 2013. Defendant AbbVie Inc. will be served according to Rule 4 of the Federal Rules of Civil Procedure.

5. Defendants engaged in the business of designing, licensing, manufacturing, testing, advertising, warranting, distributing, supplying, selling, and introducing into the stream of commerce certain products known as Depakote. Defendants sold and marketed their Depakote and Depakote ER products in this District and throughout the United States.

JURISDICTION AND VENUE

6. This Court has subject matter over this matter pursuant to 28 U.S.C. § 1332. Plaintiffs are residents of Ohio and Defendants are residents of the state of Illinois, and therefore there is complete diversity of citizenship between Plaintiffs and the Defendants, and the amount in controversy exceeds $75,000.00.

7. Venue is proper in this district under 28 U.S.C. §§ 1391(b)(1), 1391(b)(2) and 1391(d) because a substantial part of the events giving rise to this action occurred in this district and because of Defendants' substantial contacts to this district, including direct to consumer marketing, communication with and marketing to physicians, and the sale of Depakote and other pharmaceutical products in this district.

8. This lawsuit seeks compensation, damages and other relief for injuries Plaintiffs have suffered as a result of Defendants' anti-convulsant drug commonly known as "Depakote."

UNDERLYING COMMON FACTS

9. Defendants are and at all relevant times were engaged in the business of formulating, designing, manufacturing, licensing, testing, advertising, marketing, warranting, selling, distributing, and introducing into the stream of commerce a drug compound known as "divalproex sodium," "valproic acid," or "valproate," which Defendants have sometimes marketed under brand names such as "Depakote," "Depakote ER," "Depakene," and "Depacon." Regardless of the name under which Defendants marketed, sold, and distributed the drug, all of its forms were and are, for all purposes relevant to Plaintiff's claims, chemically and pharmacologically identical. For purposes of this Complaint, these various forms and names of the drug compound will all be referred to by the common brand name, "Depakote."

10. In approximately 1978, after Defendants received approval to market Depakote in the United States for treatment of certain forms of epilepsy, Defendants began marketing and placing Depakote into the stream of commerce throughout the United States. Depakote was promoted as an effective anti-epileptic drug ("AED").

11. Depakote as formulated, designed, manufactured, licensed, tested, advertised, marketed, warranted, sold, distributed, and introduced into the stream of commerce by Defendants was and is defective and unreasonably dangerous for its intended use. In particular,

the primary compound in Depakote—valproic acid—has been established to cause severe birth defects if taken during the first trimester of pregnancy.

12. Among the "major congenital anomalies" (*i.e.*, birth defects) known to result directly from first-trimester exposure to Depakote are, either singly or in some combination with each other, spina bifida, cleft palate, cleft lip, limb and digital deformities, facial dysmorphism, mental developmental delays, genitourinary malformations, and heart defects.

13. Medical researchers have confirmed that while Depakote may be effective at controlling some forms of seizures, it is also riskier than other AEDs for women who are pregnant or who may become pregnant.

14. Defendants have been aware of the birth defects associated with Depakote on early-term pregnancies on or before the date it began marketing and distributing Depakote in the United States.

15. Scientific articles single out Depakote as among the most—if not the most—teratogenic of all AEDs. One study in 1995 reported an incidence rate of neural tube defects (such as spina bifida) *ten times greater* than with other AEDs. Another study found major congenital abnormalities in eleven percent of all infants exposed to Depakote during the earliest weeks of pregnancy.

16. As pharmaceutical research and development progressed through the 1980's and 1990's, new and better AEDs were developed and approved, which proved as effective as Depakote at controlling most seizures in most epileptic patients, but which bore far less risk of causing birth defects.

17. Despite this emerging scientific consensus, Defendants refused to communicate the true nature and extent of the risk in their product labeling and warnings to physicians and consumers.

18. Instead of working to warn doctors and women of childbearing age about the sharply heightened risks of ingesting Depakote during the early weeks of pregnancy, Defendants have sought to minimize the risk and downplay the dangers in their product labeling of Depakote.

19. Despite the risks of major congenital malformations, Defendants have aggressively pursued expansion of the uses for which Depakote is approved and marketed to doctors and patients. As early as the mid-1990's, Defendants implicitly and explicitly promoted Depakote to doctors, consumers and the general public for unapproved or "off-label" uses, such as for treatment of mild depression, the depressive state of bi-polar disorder, and chronic pain conditions such as migraine headaches.

20. Defendants have promoted these off-label uses even though there are other common drugs which are as effective or more effective for treatment of those conditions, and which do not involve the severe risk of congenital malformations associated with Depakote. In further pursuit of market share in the pharmaceutical industry, Defendants have worked aggressively to manipulate the regulatory system and gain approval for certain of these off-label uses, in hopes of concealing within government approval the dangers of using Depakote for conditions in which its use is unnecessary.

21. Defendants have concealed risks from and otherwise misled doctors who prescribe Depakote and monitor patients' drug regimen during pregnancy. Despite knowing the extremely high incidence rate of major congenital malformations in babies born to women who

take Depakote while pregnant (one study suggested a risk of up to *one in every five pregnancies*, while others have found the risk is at least one in ten), Defendants continue to downplay the risks and refuse to provide adequate information in the Depakote label and package inserts regarding the true scope and severity of the dangers. Instead, Defendants insist on using muted and understated language to suggest that women of childbearing age weigh the "potential risks," when in fact the risks are severe, well-known to Defendants, and in scientific reality in excess of the injuries and incident rates reported in the label.

22. The most tragic aspect of the inadequate label is that Depakote causes irreversible and devastating injuries to the developing child *before the mother or the physician even have a chance to discover the pregnancy*. Defendants knew or should have known they had a duty to warn doctors and patients that women who were taking Depakote should not get pregnant, and that women who might become pregnant should not take Depakote. This simple warning, commonplace with countless pharmaceuticals, would have spared each Plaintiff a lifetime of pain and suffering, inordinate healthcare costs, severe emotional and physical distress, and loss of earning potential.

23. Depakote was and is a defective product, unreasonably dangerous in light of its nature and intended use. That defect existed when the product left Defendants' control and has been the proximate cause of injuries to Plaintiffs, whose injuries were caused by the use of Depakote in its intended or foreseeable manner or in the manner recommended by Defendants.

24. Defendants knew or should have known of the dangerous condition of their product, Depakote, but failed to adequately warn or instruct physicians and consumers of the risks, dangers, and proper uses of the drug.

25. Defendants have breached their duty of reasonable care and their express and implied warranties, and have made affirmative misrepresentations as well as misrepresentations by omission, all in connection with the design, testing, manufacture, marketing, and/or labeling of Depakote.

26. As a direct and proximate result of the acts and omissions of Defendants, the Plaintiff was born with heart defects, hypospadias, limb defects and developmental delay, among other congenital malformations and birth defects. The Plaintiff continues to suffer permanent injury, pain, loss of normal life, and other non-economic damages and will continue to suffer those injuries and losses in the future.

27. As a direct and proximate result of the aforesaid acts of and/or omissions by the Defendants, the Plaintiff has:

(a) suffered severe and permanent injuries, which he will be forced to endure for the remainder of his life;

(b) suffered physical impairment and disfigurement, which he will be forced to endure for the remainder of his life;

(c) suffered physical pain and suffering which he will continue to suffer into the future;

(d) suffered mental pain and suffering which he will continue to suffer into the future;

(e) suffered loss of enjoyment of life which he will continue to suffer into the future;

(f) incurred substantial costs for medical care in the past, and will in reasonable medical probability incur substantial costs for medical care in the future;

(g) suffered a loss of earnings and of future earning capacity; and,

(h) incurred attorney's fees and expenses of litigation related to this action.

28. In addition, as a direct and proximate result of the aforesaid acts of and/or omissions by the Defendants, Plaintiffs Kevin Hutchens and Christin Hutchens have suffered individual damages, including but not limited to economic harm and loss of consortium due to the injuries caused to their son Z.H., and will continue to suffer said damages, harm and loss of consortium in the future

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

29. Defendants failed to disclose a known defect and affirmatively misrepresented that Depakote was safe for its intended use. Further, Defendants actively concealed the true risks associated with the use of Depakote. Plaintiff, the parents of the Plaintiff, and/or the prescribing physicians had no knowledge that Defendant was engaged in the wrongdoing alleged herein. Because of Defendants' concealment of and misrepresentations regarding the true risks associated with Depakote, Plaintiff, the parents of the Plaintiff, and/or the prescribing physicians could not have reasonably discovered Defendants' wrongdoing at any time prior to the commencement of this action.

30. Thus, because Defendants fraudulently concealed the defective nature of Depakote and the risks associated with its use, the running of any statute of limitations has been tolled. Likewise, Defendants are estopped from relying on any statute of limitations.

COUNT I

Strict Products Liability
Design Defect
O.R.C. § 2307.75

31. Plaintiffs incorporate the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

32. Defendants are the manufacturers, designers, marketers, distributors and sellers of Depakote.

33. The Depakote manufactured, designed, marketed, distributed and sold by Defendants was expected to and did reach the consumer, Christin Hutchens, without any alterations or changes.

34. The Depakote manufactured, designed, marketed, distributed and sold by Defendants was defective in design or formulation, because when it left the hands of Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation.

35. The Depakote manufactured, designed, marketed, distributed and sold by Defendants was defective in design or formulation, because when it left the hands of the Defendants, it was more dangerous than an ordinary consumer would expect.

36. The foreseeable risks of Depakote include an increase in the occurrence of major congenital malformations from fetal exposure to Depakote, the magnitude of which is dramatic in terms of the number of women exposed, the incidence rate, and the devastating harm to the fetus.

37. The fact that harm such as that suffered by Z.H. will occur from use of Depakote is completely foreseeable because Depakote is a teratogen; Defendants have not prohibited Depakote's use in women of childbearing years; half of all pregnancies in the United States are unplanned, and few contraception measures are 100% effective.

38. The likelihood that fetal death and injury would result from maternal use of Depakote is very high, based upon relative risk estimates of 6 or more, and studies confirming

an incidence rate for major malformations of greater than 30% for infants born of women ingesting higher dosages of valproate.

39. Depakote as manufactured, designed, marketed, distributed and sold by Defendants is much more dangerous than an ordinary consumer would expect, as maternal use of Depakote during fetal development creates a very high risk of fetal death or major congenital malformations, as well as cognitive, developmental, neurological and behavioral dysfunction.

40. At the time Defendants manufactured, designed, marketed, distributed and sold Depakote to Christin Hutchens, safer, more practical, alternative designs were available to treat seizure disorder, including but not limited to prescription drug alternatives such as carbamazepine (Tegretol), phenytoin (Dilantin) and lamotrigine (Lamictal), which pose much less risk of teratogenicity with comparable or adequate efficacy.

41. The Depakote manufactured, designed, marketed, distributed and sold by Defendants was not unavoidably unsafe, as alternative formulations for anti-seizure medications were available with comparable or adequate efficacy that did not pose the same teratogenic risk.

42. Based upon the foregoing, the Depakote manufactured, designed, marketed, distributed and sold by Defendants was defective in design pursuant to O.R.C. § 2307.75 at the time it left Defendants' control.

43. As a direct and proximate result of the defective design of Depakote consumed by Plaintiff Christin Hutchens, Plaintiff suffered damages, including but not limited to personal injury, bodily harm, emotional distress, pain and suffering, permanent physical, mental, neurologic, cognitive and behavioral injuries, loss of enjoyment of life, economic and non-

economic damages, and will continue to suffer such injuries, distress, pain and suffering, harm, damages, and economic loss in the future.

44. In addition, as a direct and proximate result of the defective design of Depakote consumed by Plaintiff Christin Hutchens, Plaintiffs Kevin Hutchens and Christin Hutchens have suffered individual damages, including but not limited to economic harm and loss of consortium due to the injuries caused to their son Z.H., and will continue to suffer said damages, harm and loss of consortium in the future.

45. Defendants' conduct as alleged in this Complaint shows that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiffs' rights, so as to warrant the imposition of punitive damages.

46. As a direct and proximate result of the defective condition of Depakote as manufactured by Defendants, Plaintiffs suffered injuries and damages as described, in excess of $75,000.00.

COUNT II

Strict Products Liability
Due To Inadequate Warning
O.R.C. § 2307.76

47. Plaintiffs incorporate the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

48. Defendants are the manufacturers, designers, marketers, distributors, and sellers of Depakote.

49. It was reasonably foreseeable that women of childbearing years, such as Christin Hutchens, would become pregnant while on Depakote, and that a very high percentage of children exposed to Depakote in utero would suffer devastating teratogenic effects as a result

50. The Depakote manufactured, designed, marketed, distributed and sold by

Defendants was defective due to inadequate warning or instruction pursuant to O.R.C. § 2307.76, because at the time it left the control of Defendants and was supplied to Plaintiff Christin Hutchens, Defendants knew or should have known that their product was unreasonably dangerous as confirmed by the extensive body of published literature and its own internal data, because Depakote substantially and significantly increases the risk of teratogenic effects compared to other treatment options for seizure control.

51. Despite the fact that Defendants knew or should have known about the increased risk of teratogenicity with Depakote as compared to other treatment options for seizure control, Defendants failed to exercise reasonable care to adequately warn of the increased teratogenicity risk. In fact, Defendants denied in the Depakote product label at the time of Plaintiff Christin Hutchens' product use that the association between Depakote and birth defects was causal.

52. The Depakote manufactured and supplied by Defendants was defective due to inadequate warning or instruction pursuant to O.R.C. § 2307.76, because at the time it left the control of Defendants and was supplied to Christin Hutchens, Defendants knew or should have known that their product was unreasonably dangerous, as confirmed by the extensive body of published literature and its own internal data, because higher doses of Depakote substantially and significantly increases the risk of teratogenic effects compared to lower doses.

53. Despite the fact that Defendants knew or should have known about the increased risk of teratogenicity with higher doses of Depakote as compared to lower doses, Defendants failed to exercise reasonable care to adequately warn of the increased teratogenicity risk with higher doses of Depakote. In fact, Defendants made no reference in the Depakote product label to the dose response relationship between Depakote and severe congenital anomalies.

54. The Depakote manufactured and supplied by Defendants was defective due to

inadequate warning or instruction pursuant to O.R.C. § 2307.76, because at the time it left the control of Defendants and was supplied to Christin Hutchens, Defendants knew or should have known that their product was unreasonably dangerous, as confirmed by the extensive body of published literature and its own internal data, because ingestion of Depakote in combination with other antiepileptic drugs substantially and significantly increases the risk of teratogenic effects compared to monotherapy use.

55. Despite the fact that Defendants knew or should have known about the increased risk of teratogenicity with use of Depakote in polytherapy as compared to monotherapy, Defendants failed to exercise reasonable care to adequately warn of the increased teratogenicity risk with polytherapy use. In fact, Defendants made no reference in the Depakote product label to increased risk of congenital malformations when Depakote was prescribed as part of a polytherapy.

56. The Depakote manufactured and supplied by Defendants was defective due to inadequate warning or instruction pursuant to O.R.C. § 2307.76, because at the time it left the control of Defendants and was supplied to Plaintiff Christin Hutchens, Defendants knew or should have known that their product was unreasonably dangerous, as confirmed by the extensive body of medical literature and Defendants' internal data, because ingestion of Depakote substantially and significantly increases the risk of impaired cognitive function, neurodevelopmental delay, autism and autistic spectrum disorders.

57. Despite the fact that Defendants knew or should have known about the increased risk of impaired cognitive function, neurodevelopmental delay, autism and autistic spectrum disorders caused by in utero exposure to Depakote, Defendants failed to exercise reasonable care to adequately warn of this increased risk. In fact, Defendants made no reference to any such

increased risk in the Depakote product label at the time of Plaintiff Christin Hutchens' product use.

58. The Depakote manufactured and supplied by Defendants was defective due to inadequate warning or instruction pursuant to O.R.C. § 2307.76, because at the time it left the control of Defendants and was supplied to Plaintiff Christin Hutchens, Defendants knew or should have known that their product was unreasonably dangerous for any use by women of childbearing years, as confirmed by the extensive body of medical literature and Defendants' internal data, because ingestion of Depakote substantially and significantly increases the risk of severe teratogenic effects to the developing fetus, the harm occurs in the very earliest weeks of pregnancy, more than half of all pregnancies in the United States are unplanned, and Depakote cannot be readily discontinued without causing adverse withdrawal effects.

59. Despite the fact that Defendants knew or should have known that Depakote should be completely contraindicated for women of childbearing years, Defendants failed to exercise reasonable care to adequately warn of the necessity of prohibiting women of childbearing years from ingesting this drug. Instead, Defendants denied that a cause and effect relationship had been proven between Depakote and birth defects, described the potential for teratogenicity as a class wide effect, and advised that the benefits and the risks of Depakote should be weighed (based upon the inaccurate and incomplete information contained in the product label), without revealing that other drugs in the class offered safer alternatives for seizure control in women of childbearing years.

60. The Depakote manufactured and supplied by Defendants was also defective due to inadequate warning or instruction pursuant to O.R.C. § 2307.76, because at the time it left the control of Defendants and was supplied to Plaintiff Christin Hutchens, Defendants knew or

should have known that their product was unreasonably dangerous for any use by women of childbearing years, as confirmed by the extensive body of medical literature and Defendants' internal data. Yet Defendants specifically claimed in the product label that no cause and effect relationship had been established between the use of Depakote and birth defects, and further claimed: "the epileptic condition itself may be more important than drug [i.e. Depakote] therapy in contributing to congenital abnormalities."

61. Despite the fact that Defendants knew or should have known that using Depakote during pregnancy created a substantially greater risk to the fetus, Defendants failed to exercise reasonable care to adequately warn women and their doctors of the unreasonable risk posed by use of Depakote during pregnancy.

62. The Depakote manufactured and supplied by Defendants was also defective pursuant to O.R.C. § 2307.76 due to inadequate post-marketing warning or instruction, because after Defendants knew or should have known of the substantially increased risks as described above, Defendants failed to provide adequate post-market or post-approval warnings to consumers and/or their health care providers, which they have authority to do as the holder of the NDAs, and failed to revise the Depakote label to warn of the serious and substantially increased risk of fetal death and major congenital malformations caused by Depakote as compared to other anti-seizure medications when taken as prescribed, when taken in higher dosages, or when combined in polytherapy; nor did Defendants warn Plaintiff Christin Hutchens or her physician that alternative safer options were available and that Depakote should not be ingested by women of childbearing years.

63. The significantly increased risk of harm from the teratogenic properties of Depakote is not an open and obvious danger or a matter of common knowledge.

64. As a direct and proximate result of Christin Hutchens' use of Depakote as manufactured, designed, marketed, distributed and sold by Defendants, Plaintiff suffered damages, including but not limited to personal injury, bodily harm, emotional distress, pain and suffering, permanent physical, mental, neurologic, cognitive and behavioral injuries, loss of enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries, distress, pain and suffering, harm, damages, and economic loss in the future.

65. In addition, as a direct and proximate result of Plaintiff Christin Hutchens' use of defective Depakote, Plaintiffs Kevin Hutchens and Christin Hutchens have suffered damages, including but not limited to economic harm and loss of consortium due to the injuries caused to their son Z.H., and will continue to suffer said damages, harm and loss of consortium in the future.

66. Defendants' conduct as alleged in this Complaint shows that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiffs' rights, so as to warrant the imposition of punitive damages.

67. 46. As a direct and proximate result of the defective condition of Depakote as manufactured by Defendants, Plaintiffs suffered injuries and damages as described, in excess of $75,000.00.

COUNT III

Strict Products Liability
Nonconformance with Representations
O.R.C. § 2307.77

68. Plaintiffs incorporate the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

69. Defendants are the manufacturers, designers, marketer, distributors and sellers of

Depakote.

70. At the time Defendants manufactured, designed, marketed, distributed and sold Depakote to Christin Hutchens, Defendants represented to consumers and the medical community through the product label that the benefits of Depakote in treating seizure disorder could outweigh the risk even for women of childbearing years.

71. However, as described herein, Defendants' Depakote failed to conform to these representations and instead is completely unacceptable for use among women of childbearing years, because the risk of fetal malformation with Depakote is so high, the risk of unplanned pregnancy is so great, and so many safer options are available to treat seizure disorder.

72. Defendants further represented in the Depakote product label that the relationship between Depakote and birth defects could not be considered causal, and rather was due to poor methodology, and Defendants claimed that genetic issues and the underlying condition of epilepsy itself could be more important in contributing to congenital anomalies than the use of Depakote.

73. However, as described herein, Defendants' Depakote failed to conform to these representations because it in fact does causally increase the risk of birth defects, and the increase cannot be attributed to poor methodology, genetics or the risks created by epilepsy itself.

74. The failure of Depakote to conform to the representations made by Defendants in the product label, as described above, render the product defective pursuant to O.R.C. § 2307.77.

75. As a direct and proximate result of Christin Hutchens' use of defective Depakote, which failed to conform to manufacturer representations as described above, Plaintiff suffered damages, including but not limited to personal injury, bodily harm, emotional distress, pain and suffering, permanent physical, mental, neurologic, cognitive and behavioral injuries, loss of

enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries, distress, pain and suffering, harm, damages, and economic loss in the future.

76. In addition, as a direct and proximate result of Plaintiff Christin Hutchens' use of defective Depakote, Plaintiffs Kevin Hutchens and Christin Hutchens have suffered individual damages, including but not limited to economic harm and loss of consortium due to the injuries caused to their son Z.H., and will continue to suffer said damages, harm and loss of consortium in the future.

77. Defendants' conduct as alleged in this Complaint shows that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiffs' rights, so as to warrant the imposition of punitive damages.

78. As a direct and proximate result of the defective condition of Depakote as manufactured by Defendants, Plaintiffs suffered injuries and damages as described, in excess of $75,000.00.

COUNT IV

Negligence

79. Plaintiffs incorporate the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

80. Defendants had a duty to exercise reasonable care in the design, manufacture, testing, sale, labeling and/or distribution of Depakote it placed into the stream of commerce, including a duty to assure that the product did not cause unreasonable or unnecessary injury.

81. Defendants breached their duty of care to Plaintiffs through its negligent acts and omissions. Defendants did not exercise reasonable care in the warning, design, manufacture, sale, testing, labeling and/or distribution into the stream of commerce of the Depakote in that

Defendants knew or should have known that Depakote could cause serious birth defects if taken by pregnant women.

82. Defendants were negligent in the design, manufacture, sale, testing, and/or distribution of Depakote in that it: (a) failed to use due care in designing, formulating, developing, testing, and manufacturing Depakote so as to avoid or warn against the described risks to consumers who used Depakote; (b) placed an unsafe product into the stream of commerce; and (c) failed to discover or warn of the dangers associated with the use of Depakote despite having actual and/or constructive knowledge of such dangers.

83. Defendants knew or should have known that Plaintiff could foreseeably suffer injuries as a result of Defendants' failure to exercise ordinary care as described above.

84. As a direct and proximate result of Defendants' negligence, Plaintiff Christin Hutchens ingested Depakote throughout her pregnancy, and Plaintiff Z.H. suffered damages, including but not limited to personal injury, bodily harm, emotional distress, pain and suffering, permanent physical, mental, neurologic, cognitive and behavioral injuries, loss of enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries, distress, pain and suffering, harm, damages and economic loss in the future.

85. In addition, as a direct and proximate result of Defendants' negligence, Plaintiff Christin Hutchens ingested Depakote throughout her pregnancy with Z.H., and as a result Plaintiffs Kevin Hutchens and Christin Hutchens have suffered individual damages, including but not limited to economic harm and loss of consortium due to the injuries caused to their son Z.H., and will continue to suffer said damages, harm and loss of consortium in the future.

86. Defendants' conduct as alleged in this Complaint shows that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiffs' rights, so as to warrant the imposition of punitive damages.

87. As a direct and proximate result of Defendants' negligence, Plaintiffs suffered injuries and damages as described, in excess of $75,000.00.

COUNT V

Gross Negligence

88. Plaintiffs incorporate the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

89. Each of the foregoing acts or omissions by Defendants, when viewed objectively from its standpoint at the time, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to Plaintiffs and others.

90. Defendants acted with conscious indifference to the rights, safety or welfare of Plaintiff and others. Their deceptive and inadequate labeling and marketing, misrepresentation of the risks of Depakote to doctors and women of child bearing potential, and refusal to engage in proper safety evaluation and investigation, both before and after Depakote was first sold, were undertaken in the callous pursuit of market advantage and without regard for the safety of those exposed to Depakote, whether directly or in utero.

91. Therefore, in addition to actual damages, Plaintiffs are entitled to recovery of exemplary damages against Defendants as a penalty or by way of punishment and to deter Defendants from similar conduct in the future. Defendants' conduct as alleged in this Complaint shows that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiffs' rights, so as to warrant the imposition of punitive damages.

92. As a direct and proximate result of Defendants' gross negligence, Plaintiffs suffered injuries and damages as described, in excess of $75,000.00.

COUNT VI

Negligent Misrepresentation and Fraud

93. Plaintiffs incorporate the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

94. Defendants manufacture, design, market, label, distribute and sell Depakote.

95. Defendants have a duty not to deceive consumers and their physicians, including Plaintiff Christin Hutchens, about Depakote.

96. Defendants made representations to Plaintiff Christin Hutchens and her physician regarding the character and/or quality of Depakote for guidance in their decision to select Depakote for Plaintiff's use.

97. Specifically, Defendants represented that Depakote was just as safe or even safer than other prescription drugs for treatment of seizure available on the market.

98. Defendants knew, or should have known that such statements were false.

99. Defendants stated that any risk of teratogenicity with Depakote was a class wide risk common to anti-seizure medications in general.

100. Defendants knew or should have known that this statement was false, and that Depakote posed a dramatically increased risk of teratogenicity compared to other anti-seizure drugs.

101. Further, Defendants denied that the relationship between Depakote and birth defects was causal, and instead claimed that the association between Depakote and birth defects in the medical literature was not causal, but rather arose from intrinsic methodological problems,

and that genetic risks and the risks posed by epilepsy itself were of greater teratogenicity concern than Depakote.

102. Defendants knew or should have known that these statements were false, and that the relationship between Depakote and birth defects was causal, and that genetic factors and epilepsy itself did not create a greater risk of teratogenicity than Depakote.

103. Defendants had actual or constructive knowledge based upon studies, published reports, and clinical experience of the dangerous teratogenic effects of Depakote.

104. Defendants negligently and/or intentionally misrepresented this information in Depakote's labeling, promotions and advertisements, in order to avoid losses and sustain profits in their sales to consumers and instead labeled, promoted and advertised their product as just as safe and effective as other anti-seizure medications.

105. In supplying the false information, Defendants failed to exercise reasonable care or competence in obtaining safety information concerning Depakote and in communicating this information to the intended recipients, including Plaintiff Christin Hutchens and her physician. Further, Defendants were aware that without such safety information it could not accurately make the above described representations. Defendants knew about Depakote's relative risks and the true extent of its risks to women of childbearing age but chose to include false and misleading representations regarding those risks in its labeling, which were relied on by Plaintiffs and their doctors and proximately caused harm to Plaintiffs.

106. Defendants had a duty to disclose to Plaintiff Christin Hutchens, her physician, and the public that Depakote was not safe for use by women of childbearing years due to its teratogenic effects.

107. Defendants also had a duty to disclose the dose relationship between Depakote and birth defects, the increased risk of birth defects when Depakote was used in polytherapy, and the increased risk of cognitive deficits, neurodevelopmental delay, behavioral disorders, autism and autistic spectrum disorder caused by use of Depakote.

108. Defendants did not disclose any of the above information to Plaintiff Christin Hutchens.

109. Plaintiff Christin Hutchens and her physician reasonably relied to her detriment upon Defendants' misrepresentations and/or omissions concerning the serious risks posed by Depakote in the product's labeling, advertisements and promotions. Plaintiff Christin Hutchens and her physician reasonably relied to her detriment upon Defendants' representations that Depakote was just as safe and effective as other methods of treating and preventing seizures during pregnancy.

110. Plaintiff Christin Hutchens and her physician reasonably relied to her detriment upon Defendants' representations that Defendants' labeling, advertisements and promotions fully and accurately described all known risks of the product

111. Had Plaintiff Christin Hutchens or her physician known of Defendants' concealment of the true facts—that Depakote was more dangerous for use by women of childbearing years than other anti-seizure medications—Plaintiff Christin Hutchens would not have been prescribed or used Depakote.

112. As a direct and proximate result of Defendants' negligent and/or intentional misrepresentations, Plaintiff Christin Hutchens ingested Depakote throughout her pregnancy, and Plaintiff Z.H. suffered damages, including but not limited to personal injury, bodily harm, emotional distress, pain and suffering, permanent physical, mental, neurologic, cognitive and

behavioral injuries, loss of enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries, distress, pain and suffering, harm, damages, and economic loss in the future.

113. In addition, as a direct and proximate result of Defendants' negligent and/or intentional misrepresentations, Plaintiffs Kevin Hutchens and Christin Hutchens have suffered individual damages, including but not limited to economic harm and loss of consortium due to the injuries caused to their son Z.H., and will continue to suffer said damages, harm and loss of consortium in the future.

114. Defendants' conduct as alleged in this Complaint shows that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiff's rights, so as to warrant the imposition of punitive damages.

115. As a direct and proximate result of Defendants' negligent and/or intentional misrepresentations, Plaintiffs suffered injuries and damages as described, in excess of $75,000.00.

COUNT VII

Breach of Implied Warranty

116. Plaintiffs incorporate the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

117. Defendants were merchant sellers with respect to Depakote.

118. In order to induce the purchase and/or use of Depakote, Defendants impliedly warranted to potential users of Depakote that Depakote was safely tested and manufactured and was safe for the uses for which it was designed and/or advertised to be used.

119. Defendants breached this warranty in that Depakote was not safe for the uses for which it was manufactured and/or advertised.

120. Plaintiff was injured as a result of detrimental reliance upon Defendants' implied warranties.

121. As a direct and proximate result of Defendants' breach of warranty, Plaintiff Christin Hutchens ingested Depakote throughout her pregnancy, and Z.H. suffered damages, including but not limited to personal injury, bodily harm, emotional distress, pain and suffering, permanent physical, mental, neurologic, cognitive and behavioral injuries, loss of enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries, distress, pain and suffering, harm, damages and economic loss in the future.

122. In addition, as a direct and proximate result of Defendants' breach of warranty, Plaintiff Christin Hutchens ingested Depakote throughout her pregnancy with Z.H., and as a result Plaintiffs Kevin Hutchens and Christin Hutchens have suffered individual damages, including but not limited to economic harm and loss of consortium due to the injuries caused to their son Z.H., and will continue to suffer said damages, harm and loss of consortium in the future.

123. Defendants' conduct as alleged in this Complaint shows that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiffs' rights, so as to warrant the imposition of punitive damages.

124. As a direct and proximate result of one or more of the foregoing breaches of implied warranty, Plaintiffs suffered injuries and damages as described, in excess of $75,000.00.

COUNT VIII

Breach of Express Warranty

125. Plaintiffs incorporate the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

126. Defendants were merchants and sellers with respect to Depakote.

127. In order to induce the purchase and/or use of Depakote, Defendants expressly warranted to potential users of Depakote that Depakote was safely tested and manufactured and was safe for the uses for which it was designed and/or advertised to be used. Express warranties were contained in direct to consumer advertising and other promotional and marketing campaigns, Depakote product information sheets given to patients with their prescriptions, the product labeling, and other public communications and representations.

128. Defendants breached said warranty in that Depakote was not safe to be used for the purposes for which it was manufactured and/or advertised.

129. Plaintiff was injured as a result of detrimental reliance upon Defendants' express warranties.

130. As a direct and proximate result of Defendants' breach of warranty, Plaintiff Christin Hutchens ingested Depakote throughout her pregnancy, and Plaintiff Z.H. suffered damages, including but not limited to personal injury, bodily harm, emotional distress, pain and suffering, permanent physical, mental, neurologic, cognitive and behavioral injuries, loss of enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries, distress, pain and suffering, harm, damages and economic loss in the future.

131. In addition, as a direct and proximate result of Defendants' breach of warranty, Plaintiff Christin Hutchens ingested Depakote throughout her pregnancy with Z.H., and as a

result Plaintiffs Kevin Hutchens and Christin Hutchens have suffered individual damages, including but not limited to economic harm and loss of consortium due to the injuries caused to their son Z.H., and will continue to suffer said damages, harm and loss of consortium in the future.

132. Defendants' conduct as alleged in this Complaint shows that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiffs' rights, so as to warrant the imposition of punitive damages.

133. As a direct and proximate result of one or more of the foregoing breaches of express warranty, Plaintiffs suffered injuries and damages as described, in excess of $75,000.00.

COUNT IX

Intentional Infliction of Emotional Distress

134. Plaintiffs incorporate the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

135. Defendants' intentional, reckless and extreme conduct foreclosed any opportunity to adequately measure the level of risk related to Defendants' Depakote product. By withholding information of known design and manufacturing defects and concealing those fatal problems, Defendants created a false sense of security regarding the safety of Defendants' Depakote product.

136. Defendants' conduct of intentional omission, concealment and failure to warn of the design and manufacturing defects caused Plaintiff to suffer injuries, harm and economic loss as alleged herein, including permanent and substantial injuries, and expenses attributable to Defendants' conduct.

137. Defendants' conduct as alleged in this Complaint shows that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiffs' rights, so as to warrant the imposition of punitive damages.

138. The injuries described above entitle Plaintiffs to compensatory damages in excess of $75,000.00 and equitable and declaratory relief, along with all appropriate other damages according to proof.

COUNT X

Negligent Infliction of Emotional Distress

139. Plaintiffs incorporate the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

140. Defendants intentionally and willfully failed to disclose or warn of the inherent risks and defects of Depakote, while knowingly concealing design, manufacturing and safety defects, and misrepresenting the risks of severe side effects, quality, safety and efficacy of the drug.

141. Defendants' willful conduct inflicted Plaintiff with severe emotional distress.

142. Defendants' conduct of willful omission and concealment of design, manufacturing and safety defects in order to induce ingestion of the drug caused Plaintiff severe emotional distress.

143. As a direct result of Defendants' careless and negligent conduct, Plaintiff has suffered and will continue to suffer injury, harm and economic loss as alleged herein, including permanent and substantial injuries, and expenses attributable to his injuries.

144. Defendants' conduct as alleged in this Complaint shows that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiffs' rights, so as to warrant the imposition of punitive damages.

145. The injuries described above entitle Plaintiff to compensatory damages in excess of $75,000.00 and equitable and declaratory relief, along with all other appropriate damages according to proof.

COUNT XI

Loss of Consortium
Medical and Related Expenses

146. Plaintiffs incorporate the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

147. As a direct and proximate result of the defective condition of Defendants' product, Depakote, Defendants' wrongful conduct, negligence, breach of warranties, negligent misrepresentation and fraud, as fully described above, Plaintiffs Kevin Hutchens and Christin Hutchens, as parents and natural guardians of Z.H., have incurred significant economic harm, including but not limited to medical expenses, caregiving expenses, and lost earnings due to the injuries suffered by their son as a result of *in utero* exposure to Depakote, and will continue to suffer such damages in the future.

148. As a direct and proximate result of the defective condition of Defendants' product, Depakote, Defendants' wrongful conduct, negligence, breach of warranties, negligent misrepresentation and fraud, as fully described above, Plaintiffs Kevin Hutchens and Christin Hutchens, as parents and natural guardians of Z.H., have incurred a loss of filial consortium, including but not limited to the loss of the society, companionship, comfort, love and solace of

their son, Z.H., due to the injuries he suffered from *in utero* exposure to Depakote, and will continue to suffer such losses in the future.

149. As a direct and proximate result of the actions by Defendants as described above which evidence that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiffs' rights, Plaintiffs are entitled to punitive damages.

DAMAGES

150. Plaintiffs incorporate the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

151. The facts set out above demonstrate that, as a direct and proximate result of Defendants' conduct, Plaintiffs have suffered and will continue to suffer severe economic and non-economic losses and injuries for which they are entitled to recover damages in excess of $75,000.00, including without limitation the following:

(a) bodily injury, disfigurement, conscious pain, suffering, mental anguish, mental suffering, embarrassment, shame, loss of enjoyment of life, shortened life expectancy, loss of association, loss of earnings, loss of profits, loss of salary, loss of consortium;

(b) the reasonable and necessary expenses for the medical treatment rendered to Plaintiff in the past and that will be medically probable in the future;

(c) compensation for Plaintiff Z.H.'s permanent mental and physical impairment;

(d) all other actual damages available under applicable law;

(e) punitive damages;

(f) future economic damages during the age of minority and beyond the age of 18, including lost wages of Plaintiff;

(g) costs of this suit.

PRAYER

WHEREFORE, Plaintiffs ask that Defendants Abbott Laboratories, Inc. and AbbVie Inc. be cited to appear and answer herein. That upon final trial, Plaintiff has judgment against Defendants Abbott Laboratories, Inc. and AbbVie Inc. in excess of this Court's jurisdictional requisite for actual damages, costs of court, and any other relief that will fairly and adequately compensate for the losses herein alleged.

Respectfully submitted,

BY: */s/ Brian K. Balser*
Brian K. Balser
Brian K. Balser Co., LPA
5311 Meadow Lane Court
Elyria, Ohio 44035
Telephone: (440) 934-0044
Brian@balserlaw.com

Ralph D. McBride
Phillip L. Sampson
Heath A. Novosad
Blair R. Loocke
Nancy R. McEvily
BRACEWELL & GIULIANI LLP
711 Louisiana Street, Suite 2300
Houston, Texas 77002
Phone: (713) 223-2300
Fax: (713) 221-1212
Ralph.McBride@bgllp.com
Phillip.Sampson@bgllp.com
Heath.Novosad@bgllp.com
Blair.Loocke@bgllp.com
Nancy.McEvily@bgllp.com

Jennifer M. Salim Richards
BRACEWELL & GIULIANI LLP
1445 Ross Avenue, Suite 3800
Dallas, Texas 75202
Phone: (214) 468-3800

Fax: (214) 468-3888
Jennifer.Richards@bgllp.com

Jeff Meyer
THE MEYER LAW FIRM, P.C.
6363 Woodway Drive, Suite 720
Houston, Texas 77057
Phone: (713) 974-4100
Fax: (713) 974-0225
Jeff@themeyerlawfirm.com

Robert L. Salim
SALIM-BEASLEY, LLC
1901 Texas Street
Natchitoches, Louisiana 71457
Phone: (318) 352-5999
Fax: (318) 352-5998
Skeeter@cp-tel.net

ATTORNEYS FOR PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was served on the following counsel of record on September 1, 2014:

Seth J. Linnick
John Q. Lewis
TUCKER ELLIS LLP
950 Main Ave., Suite 1100
Cleveland, Ohio 44113
Seth.Linnick@TuckerEllis.com
John.Lewis@TuckerEllis.com

Dino Sangiamo
Jason Sayers
VENABLE LLP
750 East Pratt Street, Suite 900
Baltimore, Maryland 21202
DSSangiamo@Venable.com
JSayers@Venable.com

/s/ Nancy R. McEvily
Nancy R. McEvily