UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

REESCI GILLESPIE, individually and as parent and natural guardian of R.G., minor,	:	**Case No. 3:17-cv-1063**
PLAINTIFFS,	:	
v.	:	
ABBOTT LABORATORIES	:	**COMPLAINT AND JURY DEMAND**
and	:	
ABBVIE INC.,	:	
DEFENDANTS.	:	

Plaintiff, Reesci Gillespie, individually and as mother and natural guardian of R.G., a minor, by their attorneys Burg Simpson Eldredge Hersh & Jardine, P.C., for this Complaint and Jury Demand, allege as follows:

PARTIES, JURISDICTION AND VENUE

1. Plaintiffs Reesci Gillespie and R.G. were residents and citizens of Texas when the transactions and occurrences described herein occurred.

2. Reesci Gillespie and R.G. currently are residents and citizens of Galveston County, TX

3. Defendant Abbott Laboratories is an Illinois corporation with its principal place of business in Illinois.

4. Defendant AbbVie Inc. is a Delaware corporation with its principal place of business in Illinois.

5. Defendant Abbvie Inc. is described on Abbott's website as a new, independent biopharmaceutical company composed of Abbott's former proprietary pharmaceutical business. On information and belief, Abbvie, Inc., is the successor in interest to one or more divisions of Abbott Laboratories that were in existence prior to its incorporation.

6. Abbvie Inc. was incorporated on April 10, 2012, and began operations as the owner and operator of Abbott's proprietary pharmaceutical business in January of 2013.

7. Plaintiffs allege damages in excess of $75,000.00, exclusive of interest and costs.

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332, as complete diversity exists between Plaintiffs and Defendants, and the amount in controversy exceeds $75,000.00.

9. This Court has personal jurisdiction over Defendants because said Defendants have regularly and purposefully transacted business and engaged in commercial activities within the State of Illinois and this District.

10. Venue is proper within this district pursuant to 28 U.S.C. §1391(b)(1) and (d), because defendants are residents of the State of Illinois and have had such contacts within this District that would be sufficient to subject it to personal jurisdiction if this District were a state.

FACTUAL BACKGROUND

11. Defendants manufacture, market and distribute medications containing the active ingredient valproate, valproic acid, and valproate sodium as prescription name brand pharmaceutical products.

12. Defendants first introduced Depakene, an immediate-release formulation of valproate, to the United States market in 1978 for the treatment of seizures.

13. Defendants subsequently introduced Depakote, an enteric coated, stable coordination complex of valproic acid and valproate sodium, to the United States market in 1983 for the treatment of seizures. Depakote was later approved for the additional indications of bipolar disorder and migraines.

14. Defendants subsequently introduced several other strengths and formulations of valproate, valproic acid, and valproate sodium [hereinafter referred to as "valproate"] over the ensuing decades under the brand names Depakene and Depakote, and held the New Drug Applications ["NDAs"] for all dosages and formulations of Depakene and Depakote until at least 2013.

15. On or about January of 2013, Defendant Abbott Laboratories transferred ownership of most or all of the Depakene and Depakote NDAs to Defendant Abbvie.

16. Plaintiff Reesci Gillespie consistently ingested Depakote in tablet form for the indication of control of her seizure disorder. Plaintiff Reesci Gillespie ingested Depakote during her pregnancy with R.G.

17. Plaintiff R.G. was born in August 2003, and suffers significant physical malformations and cognitive impairments.

18. Valproate is a human teratogen, which is an agent that causes birth defects.

19. Defendants knew or should have known by the time of Plaintiff Reesci Gillespie's pregnancy in 2002-2003 that valproate was a human teratogen and should not be prescribed to pregnant women, or women of childbearing years who are likely to

become pregnant.

20. In fact, the first report of valproate teratogenicity was published in the medical literature in 1980, within two years of the initial introduction of valproate to the market.

21. In 1982, the association between valproate and neural tube defects was first documented. By 1983, a twenty-fold increase in the rate of spina bifida among infants exposed to valproate during fetal development was reported in the medical literature.

22. In 1984, “fetal valproate syndrome” became a defined term in the medical literature. Defects associated with fetal valproate syndrome include characteristic facial features, major malformations, learning disabilities and central nervous system dysfunction, among other disorders.

23. In particular, the occurrence of neural tube defects (such as spina bifida) from fetal exposure to valproate is estimated to be as high as 5% of all births, compared to approximately 0.1% in the general population.

24. Other congenital defects characteristic of exposure to valproate during early pregnancy include cleft palates, cardiac defects, hypospadias and skeletal abnormalities.

25. Craniofacial abnormalities caused by valproate exposure in utero include such features as trigonocephaly (triangular shaped head due to premature fusion of metopic suture), a tall forehead with bilateral narrowing, flat nasal bridge, broad nasal root, anteverted nostrils, small jaw, abnormalities of the lip and philtrum, epicanthic folds, and midface hypoplasia.

26. Skeletal defects caused by valproate exposure in utero include radial ray and tibial ray defects (deformation of bones in forearm and lower leg), multiple, missing, overlapping, or deformed fingers and toes, extremely elongated fingers or toes, as well as talipes equinovarus (club foot).

27. Abnormalities of the eyes caused by valproate exposure in utero include such defects as bilateral congenital cataract, optic nerve hypoplasia and other defects of the iris and cornea.

28. Congenital heart defects caused by valproate exposure in utero include such defects as ventricular septal defects, aortic and/or pulmonary stenosis, coarctation of the aorta, and atrial septal defect.

29. Defendants knew or should have known that women would ingest valproate as prescribed - on a daily basis – for chronic conditions, and therefore would be exposed to valproate throughout pregnancy.

30. Many other drugs are approved for treatment of bipolar disorder, seizure disorders, and migraine, which present a lower risk of teratogenicity than valproate.

31. Valproate increases the risk of fetal malformation compared to other seizure medications, as well as other medications for the treatment of bipolar disorder and migraine to a statistically significant degree.

32. Valproate also increases the risk of fetal malformations compared to no use of medications to a statistically significant degree.

33. Despite the fact that valproate is a teratogen, Defendants claimed in the product labeling from 1978 until 2006 that any potential increase in birth defects from Depakote, Depakene, and other valproate products was only a possibility, and that the

risk was common to the entire class of antiepileptic drugs.

34. Defendants failed to warn that the risk of adverse fetal outcome was 25% or greater in mothers that used valproate at doses of approximately 1000 mg/day or more during pregnancy.

35. Defendants even denied in the product labeling for Depakote, Depakene, and other valproate products that a cause-and-effect relationship between use of valproate and birth defects had been proven, and claimed instead that the increased incidence in birth defects could be attributed to methodological problems in the data, genetic causes, or to risks arising from the epileptic condition itself.

36. Valproate causes an increased incidence of behavioral dysfunction in comparison to other anti-seizure and bipolar medications or no use of medication.

37. Valproate causes an increased incidence of cognitive dysfunction in comparison to other anti-seizure and bipolar medications or no use of medication.

38. Valproate causes an increased incidence of lower IQ in comparison to other anti-seizure and bipolar medications or no use of medication.

39. Valproate causes an increased incidence of attention deficit in comparison to other anti-seizure and bipolar medications or no use of medication.

40. Valproate causes an increased incidence of autism and autism spectrum disorders in comparison to other anti-seizure and bipolar medications or no use of medication.

41. Defendants provided no warning of these behavioral and cognitive risks to Plaintiff Reesci Gillespie at the time she ingested Depakote during her pregnancy with the minor Plaintiff.

42. In fact, Defendants did not warn of a risk of cognitive impairment until a label change in 2011. Even then, Defendants still did not warn that Depakote should be a drug of last resort or completely contraindicated in women of childbearing potential.

43. On July 15, 2013, almost 10 years after R.G.'s birth AbbVie issued a Dear Doctor Letter entitled "**Important Drug Warning,**" in which Abbvie announced major safety labeling changes for Depakote, Depakene and other valproate products.

44. In particular, Abbvie announced "**Changes to Boxed Warning,**" as well as "**Important Limitations of Use in Women of Childbearing Potential"** and "**Pregnancy Category X for Prophylaxis of Migraine Headaches"** for all valproate products.

45. As part of the label change, Abbvie strengthened and clarified the **BLACK BOX** warning in regard to teratogenicity as follows:

> **Fetal Risk**
>
> Valproate can cause major congenital malformations, particularly neural tube defects (e.g., spina bifida). In addition, valproate can cause decreased IQ scores following in utero exposure.
>
> Depakote and Depakote ER are therefore contraindicated in pregnant women treated for prophylaxis of migraine. Valproate should only be used to treat pregnant women with epilepsy or bipolar disorder if other medications have failed to control their symptoms or are otherwise unacceptable.
>
> Depakote Sprinkle Capsules should only be used to treat pregnant women with epilepsy if other medications have failed to control their symptoms or are otherwise unacceptable.
>
> Valproate should not be administered to a woman of childbearing potential unless the drug is essential to the management of her medical condition. This is especially important when valproate use is considered for a condition not usually associated with permanent injury or death (e.g. migraine). Women should use effective contraception while using valproate.

46. As a result of this warning, Depakote, Depakene and other valproate products are labeled as **Category X** for pregnancy for the indication of migraine. They remain **Category D** for bipolar disorder and seizure disorder, but may only be used in pregnancy as drugs of last resort.

47. In addition Defendants revised the **WARNINGS AND PRECAUTIONS** sections in the labels of Depakote, Depakene, and other valproate products as follows:

Birth Defects

- Valproate can cause fetal harm when administered to a pregnant woman. Pregnancy registry data show that maternal valproate use can cause neural tube defects and other structural abnormalities (e.g., craniofacial defects, cardiovascular malformations and malformations involving various body systems). The rate of congenital malformations among babies born to mothers using valproate is about four times higher than the rate among babies born to epileptic mothers using other anti-seizure monotherapies. Evidence suggests that folic acid supplementation prior to conception and during the first trimester of pregnancy decreases the risk for congenital neural tube defects in the general population.

Decreased IQ Following *in utero* Exposure

- Valproate can cause decreased IQ scores following *in utero* exposure. Published epidemiological studies have indicated that children exposed to valproate *in utero* have lower cognitive test scores than children exposed *in utero* to either another antiepileptic drug or to no antiepileptic drugs. The largest of these studies is a prospective cohort study conducted in the United States and United Kingdom that found that children with prenatal exposure to valproate (n=62) had lower IQ scores at age 6 (97 [95% C.I. 94-101]) than children with prenatal exposure to the other antiepileptic drug monotherapy treatments evaluated: lamotrigine (108 [95% C.I. 105–110]), carbamazepine (105 [95% C.I. 102–108]), and phenytoin (108 [95% C.I. 104–112]). It is not known when during pregnancy cognitive effects in valproate-exposed children occur. Because the women in this study were exposed to antiepileptic drugs throughout pregnancy, whether the risk for decreased IQ was related to a particular time period during pregnancy could not be assessed.

- Although all of the available studies have methodological limitations, the weight of the evidence supports the conclusion that valproate exposure *in utero* can cause decreased IQ in children.

- In animal studies, offspring with prenatal exposure to valproate had malformations similar to those seen in humans and demonstrated neurobehavioral deficits.

- Valproate is contraindicated during pregnancy in women being treated for prophylaxis of migraine headaches. Women with epilepsy or bipolar disorder who are pregnant or who plan to become pregnant should not be treated with valproate unless other treatments have failed to provide adequate symptom control or are otherwise unacceptable. In such women, the benefits of treatment with valproate may still outweigh the risks.

Use in Women of Childbearing Potential

- …It is not known whether the risk of neural tube defects or decreased IQ in the offspring of women receiving valproate is reduced by folic acid supplementation. Dietary folic acid supplementation both prior to conception and during pregnancy should be routinely recommended for patients using valproate.

48. Thus Defendants waited 30 years to warn that Depakote is a drug of last resort during pregnancy, and that it is completely contraindicated during pregnancy for the treatment of migraine.

49. However, other less hazardous anti-seizure drugs have included this warning since the early 1980s, including Defendant's own anti-seizure drugs, trimethadione (Tridione) and paramethadione (Paradion), which contained a **BLACK BOX** warning stating,

> **"BECAUSE OF ITS POTENTIAL TO PRODUCE FETAL MALFORMATIONS AND SERIOUS SIDE EFFECTS, [drug name] SHOULD ONLY BE UTILIZED WHEN OTHER LESS TOXIC DRUGS HAVE BEEN FOUND INEFFECTIVE…"**

50. Other anti-seizure drugs approved prior to 1997 clearly warned that due to potential serious side effects, they should be prescribed only when patients' conditions had proven refractory to treatment with other drugs. Examples include:

> 1) phenacemide (Phenurone) - indicated only for seizures "refractory to other drugs" or when "other available antiepileptics have been found to be ineffective in satisfactorily controlling seizures;"

2) mephenytoin (Mesantoin) - indicated for seizures "in those patients who have been refractory to less toxic anticonvulsants"; "should be used only after safer anticonvulsants have been given an adequate trial and have failed;"

3) methsuximide (Celontin) - indicated for control of absence (petit mal) seizures that are refractory to other drugs;" and,

4) felbamate (Felbatol) - "recommended for use only in those patients who respond inadequately to alternative treatments".

51. Yet not until 2013 did Defendants revise the labels for Depakote and other valproate products to warn that they should not be a first line medication during pregnancy for treatment of seizure disorder.

52. Defendants failed to warn for over thirty years that valproate should be completely contraindicated and/or a drug of last resort during pregnancy because Defendants sought to exploit the marketing potential for valproate products, and did not want to risk secondary status for the marketing segment of women of childbearing years. In particular, Defendants fought to maintain market share during the three decades that valproate in its various formulations had no generic competition, heedless of the risk of teratogenicity when prescribed to women of childbearing years.

53. With an adequate warning, Plaintiff Reesci Gillespie and her physicians would have pursued a safer, more practical, alternative treatment option to treat her seizure disorder, including but not limited to lamotrigine (Lamictal) and carbamazepine (Tegretol), which pose much less risk of teratogenicity with comparable or better efficacy.

54. Moreover, had Plaintiff Reesci Gillespie, who ingested Depakote during her pregnancy with R.G., been warned of the increased risk posed by higher doses of valproate, she would have exercised other treatment options.

55. Plaintiff R.G. was born in August 2003. Since then, Plaintiff R.G. has been diagnosed with severe physical, cognitive, and behavioral abnormalities.

56. Plaintiff R.G.'s physical impairments include, but are not limited to, deviation of penis requiring surgery, strabismus requiring surgery, and bi-lateral congenital renal cyst. R.G. As a result of Plaintiff R.G. s physical abnormalities, he has received physical therapy.

57. Plaintiff R.G.'s cognitive and behavioral impairments include, but are not limited to: developmental delays, reduced I.Q., autism spectrum disorder, episodic mood disorder, anxiety, aggressive behavior, and Tourette syndrome and As a result of Plaintiff R.G. 's cognitive impairments, he has received special education services and individual education services. R.G. also received therapy for speech and occupational therapy. Plaintiff R.G. will continue to require these services in the future.

58. Due to the injuries caused by his in utero exposure to Depakote, Plaintiff R.G. may not be able to live independently and may be dependent upon Plaintiff Reesci Gillespie throughout his life.

THE FEDERAL REQUIREMENTS

59. Pursuant to federal law, the introduction of a drug that is adulterated or misbranded into interstate commerce is prohibited. See, 21 U.S.C. § 331.

60. Pursuant to federal law, a drug is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods,

facilities or controls used for its manufacture packing, storage or installation are not in conformity with federal requirements. See, 21 U.S.C. § 351.

61. Pursuant to federal law, a drug is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular, or if it is dangerous to health when used in the dosage or manner prescribed, recommended or suggested in the labeling thereof. See, 21 U.S.C. § 352.

62. Pursuant to federal law, a drug is deemed to be misbranded, unless its labeling bears adequate directions for use and adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users. See, 21 U.S.C. § 352(f).

63. Pursuant to federal law, if a drug is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal material facts with respect to consequences which may result from the use of the drug in the manner prescribed for use in the labeling or advertisement. See, 21 U.S.C. § 321(n).

64. Pursuant to FDA regulation, all advertisements for any prescription drug shall present a true statement of information in brief summary relating to side effects, contraindications (including side effects, warnings, precautions, and contraindications and include any such information under such headings as cautions, special

considerations, important notes, etc.) and effectiveness (except for those exempted by paragraph (e)(2) which are limited to reminder advertisements, advertisements for bulk-sale drugs, and advertisements of prescription-compounding drugs). 21 CFR § 202.1(e)(1).

65. Pursuant to FDA regulation, an advertisement does not satisfy the requirement that it present a "true statement" of information in brief summary relating to side effects, contraindications, and effectiveness if it is false or misleading with respect to side effects, contraindications, or effectiveness; if it fails to present a fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug; or if it fails to reveal material facts regarding consequences from use recommended or suggested in the advertisement. 21 CFR § 202.1(e)(5).

66. Pursuant to FDA regulation, an advertisement for a prescription drug is false, lacking in fair balance, or misleading if, among other reasons, it represents or suggests in a manner not approved or permitted for use in the labeling that drug is better, more effective, useful in a broader range of conditions or patients safer, has fewer or less serious side effects or contraindications than has been demonstrated by substantial evidence or clinical experience; contains a drug comparison that represents a drug is safer or more effective than the other when it has not been demonstrated to be by substantial evidence or clinical experience; contains information previously regarded as valid but which has been proven invalid by contrary and more credible recent information; or represents or suggests that a drug is safer than it has been

demonstrated to be by selective information from any source in a way that makes the drug appear to be safer than has been demonstrated. 21 CFR § 202.1(e)(6).

67. Pursuant to FDA regulation, adverse events associated with a drug must be reported to the FDA as soon as possible but no later than 15 days after the initial receipt by the manufacturer of the adverse drug experience that is both serious and unexpected (15-day Alert Report). Manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. 21 CFR § 310.305; 21 CFR § 314.80.

68. Pursuant to FDA regulation, manufacturers must promptly investigate all serious, unexpected adverse drug experiences that are the subject of the 15-day Alert Reports and shall submit follow-up reports within 15 calendar days of receipt of new information or as requested by the FDA. 21 CFR § 310.305; 21 CFR § 314.80.

69. Pursuant to FDA regulation, if additional information is not obtainable, records should be maintained of the unsuccessful steps taken to seek additional information. 21 CFR § 310.305; 21 CFR § 314.80.

70. Pursuant to FDA regulation, each report submitted must identify its contents such as “15-day Alert report,” or “15-day Alert report followup.” 21 CFR § 310.305; 21 CFR § 314.80.

71. Pursuant to FDA regulation, in the case of post marketing reporting of adverse drug experiences, the manufacturer must report each adverse drug experience at quarterly intervals for three (3) years from the date of approval of the application, and then at annual intervals. 21 CFR § 314.80.

72. Pursuant to FDA regulation, each periodic report is required to contain (*a*) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval (*b*) an Adverse Reaction Report for each adverse drug experience not reported already reported under 21 CFR § 314.80 paragraph (c)(1)(i) (Post marketing 15-day Alert report) and (*c*) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated). 21 CFR § 314.80.

73. Pursuant to FDA regulation, a 15-day Alert based on information from the scientific literature is required to be accompanied by a copy of the published article. The 15-day reporting requirements of 21 CFR § 314.80 paragraph (c)(1)(i) (i.e., serious, unexpected adverse drug experiences) apply to reports found in scientific and medical journals either as case reports of as the result of a formal clinical trial.

74. Pursuant to FDA regulation, the labeling for human prescription drugs must be informative and accurate and neither promotional in tone nor false or misleading in any particular. The labeling must also be updated when new information becomes available that causes the labeling to become inaccurate, false, or misleading. 21 CFR § 201.56(a).

75. Pursuant to FDA regulation, the contraindications section of the label shall describe those situations in which the drug should not be used because any risk of use clearly outweighs any possible benefit. 21 CFR § 201.80(d).

76. Pursuant to FDA regulation, the warnings section of the label shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be

revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved. 21 CFR § 201.80(e).

FIRST CAUSE OF ACTION

Strict Products Liability
Design Defect

77. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

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

79. The Depakote manufactured, designed, marketed, distributed and sold by Defendants was expected to and did reach consumers, including Plaintiff Reesci Gillespie, without any alterations or changes.

80. 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, the foreseeable risks of the product exceeded the benefits associated with its design or formulation.

81. 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.

82. 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 nature of resulting harm to the fetus.

83. The fact that harm such as that suffered by Plaintiff R.G. will occur from use of Depakote by women of childbearing age is completely foreseeable because (1) Depakote is a known teratogen; (2) Defendants have not prohibited Depakote's use in women of childbearing years; (3) Defendants did not warn against use during pregnancy or limit its use to a drug of last resort; and (4) half of all pregnancies in the United States are unplanned, and few contraception measures are 100% effective.

84. 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.

85. 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, neurological and behavioral dysfunction.

86. At the time Defendants manufactured, designed, marketed, distributed, and sold Depakote to Plaintiff Reesci Gillespie, safer, more practical, alternative treatment options were available to treat her seizure disorder, including but not limited to prescription drug alternatives such as lamotrigine (Lamictal) and carbamazepine (Tegretol), both of which pose less risk of teratogenicity with comparable or better efficacy.

87. The Depakote manufactured, designed, marketed, distributed, and sold by Defendants was not unavoidably unsafe, as alternative formulations for anti-seizure

disorder medications were available with comparable or better efficacy that did not pose the same teratogenic risk.

88. Moreover, the Depakote manufactured, designed, marketed, distributed, and sold by Defendants was not unavoidably unsafe, because no use of any anti-seizure disorder medication during pregnancy is safer than use of Depakote, and thus the teratogenic risks of Depakote could be avoided entirely during pregnancy.

89. Based upon the foregoing, the Depakote manufactured, designed, marketed, distributed and sold by Defendants was defective in design at the time it left the Defendants' control.

90. As a direct and proximate result of the defective design of Depakote consumed by Plaintiff Reesci Gillespie and/or the Defendants' failure to comply with applicable federal requirements, Plaintiff R.G. 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.

91. In addition, as a direct and proximate result of the defective design of Depakote consumed by Plaintiff Reesci Gillespie and /or the Defendants' failure to comply with applicable federal requirements, Plaintiff Reesci Gillespie has suffered individual damages, including but not limited to economic harm, emotional distress, and inconvenience due to the injuries caused to Plaintiff R.G., and will continue to suffer said damages in the future.

92. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence, and evidenced reckless indifference to Plaintiff's rights, so as to warrant the imposition of punitive damages.

SECOND CAUSE OF ACTION

Strict Products Liability
Defect Due To Inadequate Warning

93. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

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

95. It was reasonably foreseeable that women of childbearing years, such as Plaintiff Reesci Gillespie, 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.

96. The Depakote manufactured, designed, marketed, distributed and sold by Defendants was defective due to inadequate warning or instruction because at the time it left the control of Defendants and was supplied to Plaintiff Reesci Gillespie, 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 disorder.

97. 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 disorder, 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 Reesci Gillespie's product use that the association between Depakote and birth defects was causal.

98. The Depakote manufactured and supplied by Defendants was defective due to inadequate warning or instruction because at the time it left the control of Defendants and was supplied to Plaintiff Reesci Gillespie, 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, such as the Depakote ingested daily by Plaintiff, substantially and significantly increases the risk of teratogenic effects compared to lower doses.

99. 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 (such as doses under 1000 mg/day), 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.

100. The Depakote manufactured and supplied by Defendants was defective due to inadequate warning or instruction because at the time it left the control of Defendants and was supplied to Plaintiff Reesci Gillespie, 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, lower IQ, attention deficit and behavioral disorders, and autism and autistic spectrum disorders.

101. Despite the fact that Defendants knew or should have known about the increased risk of impaired cognitive function, lower IQ, attention deficit and behavioral disorders, and 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's product use.

102. The Depakote manufactured and supplied by Defendants was defective due to inadequate warning or instruction because at the time it left the control of Defendants and was supplied to Plaintiff Reesci Gillespie, 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 (often before the existence of the pregnancy is known), more than half of all pregnancies in the United States are unplanned, and Depakote cannot be readily discontinued without causing adverse withdrawal effects.

103. 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 using 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.

104. The Depakote manufactured and supplied by Defendants was also defective due to inadequate warning or instruction because at the time it left the control of Defendants and was supplied to Plaintiff Reesci Gillespie, 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, when compared to no treatment for seizures during pregnancy. 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."

105. Despite the fact that Defendants knew or should have known that using Depakote during pregnancy created a substantially greater risk to the fetus than no treatment for seizure disorder, Defendants failed to exercise reasonable care to adequately warn women and their doctors of the unreasonable risk posed by use of Depakote during pregnancy.

106. The Depakote manufactured and supplied by Defendants was also defective due to inadequate warning or instruction because at the time it left the control of Defendants and was supplied to Plaintiff Reesci Gillespie, Defendants knew or should have known that their product was unreasonably dangerous and should be completely contraindicated during pregnancy, or should be a drug of last resort to be used during pregnancy only if all other available medications had been found to be ineffective in controlling seizures.

107. The Depakote manufactured and supplied by Defendants was also defective 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 no use of anti-seizure medications, or 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 Reesci Gillespie or her physicians of the increased risk of cognitive impairment, lower IQ, attention deficit and behavioral disorders, and autism and autistic spectrum disorders, that alternative safer options were available, and that Depakote should not be ingested by women of childbearing years or only when all other treatment options had failed.

108. 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.

109. As a direct and proximate result of the use of Depakote as manufactured, designed, marketed, distributed, and sold by Defendants and/or their failure to comply with applicable federal requirements, Plaintiff R.G. 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.

110. In addition, as a direct and proximate result of the use of defective Depakote and/or the Defendants' failure to comply with applicable federal requirements, Plaintiff Reesci Gillespie has suffered individual damages, including but not limited to economic harm, emotional distress, and inconvenience due to the injuries caused to R.G., and will continue to suffer said damages in the future.

111. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence, and evidenced reckless indifference to Plaintiff's rights, so as to warrant the imposition of punitive damages.

THIRD CAUSE OF ACTION

Negligence

112. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

113. Defendants had a duty to exercise reasonable care in the manufacture, design, distribution, marketing, labeling and sale of Depakote, including a duty to ensure that Depakote did not pose a significantly increased risk of bodily harm and adverse events.

114. Defendants failed to exercise ordinary care in the design, formulation, manufacture, design, distribution, marketing, labeling and sale of Depakote in that Defendants knew, or should have known, that their products caused such significant bodily harm or death and was not safe for use by consumers.

115. Defendants also failed to exercise ordinary care in the labeling of Depakote, and failed to issue to consumers and/or their health care providers adequate warnings of the increased risk of serious bodily injury or death due to the use of Depakote as compared to other alternative treatments.

116. Despite the fact that Defendants knew or should have known that Depakote posed a serious and increased risk of bodily harm to consumers, Defendants continued to manufacture and market Depakote for use by consumers, including women of childbearing years such as Plaintiff Reesci Gillespie, and continued to knowingly withhold critical safety information, such as the increased risk at higher doses, the increased risk compared to other treatment options, the increased risk compared to no treatment for seizures, and the increased risk of cognitive and neuropsychological disorders. Further Defendants failed to warn that Depakote should either be completely contraindicated during pregnancy or used only when all other treatment options had proven ineffective in controlling seizures.

117. Defendants knew or should have known that consumers, such as Plaintiff Reesci Gillespie, would foreseeably ingest Depakote during pregnancy and that their children would suffer injury as a result of Defendants' failure to exercise reasonable care as described above.

118. As a direct and proximate result of Defendants' negligence and/or the failure to comply with applicable federal requirements, Plaintiffs Reesci Gillespie and R.G. 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.

119. In addition, as a direct and proximate result of Defendants' negligence and/or the failure to comply with applicable federal requirements, Plaintiff Reesci Gillespie has suffered individual damages, including but not limited to economic harm, emotional distress, and inconvenience due to the injuries caused to R.G., and will continue to suffer said damages in the future.

120. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence, and evidenced reckless indifference to Plaintiff's rights, so as to warrant the imposition of punitive damages.

FOURTH CAUSE OF ACTION

Negligent Misrepresentation and Fraud

121. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

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

123. Defendants have a duty not to deceive consumers and their physicians, including Plaintiff Reesci Gillespie, about Depakote.

124. Defendants made representations to Plaintiff Reesci Gillespie and her physicians regarding the character and/or quality of Depakote for guidance in their decision to select Depakote for Plaintiff's use.

125. Specifically, Defendants represented that their products were just as safe or even safer than other prescription drugs for treatment of seizure disorder available on the market.

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

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

128. 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.

129. 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 arose from intrinsic methodological problems,

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

130. 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.

131. Defendants had actual or constructive knowledge based upon studies, published reports, and clinical experience of the dangerous teratogenic effects of Depakote, and of the fact that these risks were substantially greater than risks associated with other anti-seizure treatments or no treatment at all.

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

133. In supplying this false information, Defendants failed to exercise reasonable care or competence in obtaining safety information concerning Depakote and in communicating this information to their intended recipients, including Plaintiff Reesci Gillespie and her physicians.

134. Defendants had a duty to disclose to Plaintiff Reesci Gillespie and her physicians, as well as to the public, that Depakote was not safe for use by women of childbearing years due to its teratogenic effects, or should only be used when all other treatment options had proven ineffective.

135. Defendants also had a duty to disclose the dose-response relationship between Depakote and birth defects and the increased risk of cognitive deficits, lower IQ, attention deficit and behavioral disorders, and autism and autistic spectrum disorders caused by use of Depakote.

136. Defendants did not disclose any of the above information to Plaintiffs.

137. Plaintiff Reesci Gillespie and her physicians reasonably relied to Plaintiff's detriment upon Defendants' misrepresentations and/or omissions concerning the serious risks posed by Depakote in the product's labeling, advertisements and promotions. Plaintiff and her physicians reasonably relied to her detriment upon Defendants' representations that Depakote was just as safe and effective as other methods of treating and preventing seizures, or just as safe as no treatment of seizures during pregnancy.

138. Defendants' representations that Defendants' labeling, advertisements and promotions fully and accurately described all known risks of the product were false.

139. Had Plaintiff Reesci Gillespie or her physicians 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 or no use of anti-seizure medications—Plaintiff would not have been prescribed or used Depakote.

140. As a direct and proximate result of Defendants' negligent or intentional misrepresentations and/or the failure to comply with applicable federal requirements, Plaintiff R.G. 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.

141. In addition, as a direct and proximate result of Defendants' negligent or intentional misrepresentation and/or the failure to comply with applicable federal requirements, Plaintiff Reesci Gillespie has suffered individual damages, including but not limited to economic harm, emotional distress, and inconvenience due to the injuries caused to R.G., and will continue to suffer said damages in the future.

142. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence, and evidenced reckless indifference to Plaintiff's rights, so as to warrant the imposition of punitive damages.

FIFTH CAUSE OF ACTION

Breach of Express Warranty

143. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

144. Defendants expressly warranted that the relationship between Depakote and birth defects "cannot be regarded as a cause-and-effect relationship."

145. The Depakote manufactured and sold by Defendants did not conform to this express representation because Depakote clearly is a human teratogen when taken in the recommended dosages.

146. As a direct and proximate result of Defendants' breach of express warranty and/or the failure to comply with applicable federal requirements, Plaintiff R.G. 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.

147. In addition, as a direct and proximate result of Defendants' breach of express warranty and/or the failure to comply with applicable federal requirements, Plaintiff Reesci Gillespie has suffered individual damages, including but not limited to economic harm, emotional distress, and inconvenience due to the injuries caused to R.G., and will continue to suffer said damages in the future.

148. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence, and evidenced reckless indifference to Plaintiff's rights, so as to warrant the imposition of punitive damages.

SIXTH CAUSE OF ACTION

Breach of Implied Warranty of Merchantability (Treatment of Seizure Disorder During Pregnancy)

149. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

150. At the time Defendants manufactured, marketed, sold, distributed, and/or supplied Depakote, Defendants impliedly warranted that the Depakote was just as safe for the treatment of seizures during pregnancy as any other drugs in the anti-seizure class.

151. At the time Defendants manufactured, marketed, sold, distributed, and/or supplied Depakote, Defendants knew or should have known that treatment of seizures during pregnancy was within the ordinary purpose for which Depakote was to be used.

152. Defendants impliedly warranted Depakote to be merchantable and safe for such use during pregnancy by claiming that the teratogenicity risks of Depakote were presumed to be the same as with other anti-seizure medications, when in fact the risks with Depakote were substantially greater.

153. Contrary to these implied warranties of merchantability, Depakote was not of merchantable quality or safe for its intended use during pregnancy, because Depakote is unreasonably dangerous as described herein.

154. As a direct and proximate result of Defendants' breach of implied warranty of merchantability and failure to comply with applicable federal requirements, R.G. 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.

155. In addition, as a direct and proximate result of Defendants' breach of implied warranty of merchantability and failure to comply with applicable federal requirements, Plaintiff Reesci Gillespie has suffered individual damages, including but not limited to economic harm, emotional distress, and inconvenience due to the injuries caused to R.G., and will continue to suffer said damages in the future.

156. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence, and evidenced reckless indifference to Plaintiff's rights, so as to warrant the imposition of punitive damages.

SEVENTH CAUSE OF ACTION

Breach of Implied Warranty of Fitness

157. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

158. At the time Defendants manufactured, designed, marketed, sold, and/or distributed Depakote, Defendants had actual or constructive knowledge that consumers would choose Defendants' product, not only for its ordinary purpose (the treatment of seizure disorder), but also for the particular purpose of treating seizures during pregnancy.

159. Defendants impliedly warranted Depakote to be just as fit and safe for this particular purpose as any other anti-seizure medication.

160. Contrary to this implied warranty of fitness, Depakote was not fit or safe for Plaintiff's particular use, because Depakote was unreasonably dangerous compared to other available anti-seizure medications as previously described.

161. As a direct and proximate result Defendants' breach of implied warranty of fitness and/or failure to comply with applicable federal requirements, Plaintiff R.G. 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.

162. In addition, as a direct and proximate result of Defendants' breach of implied warranty of fitness and/or failure to comply with applicable federal requirements, Plaintiff Reesci Gillespie has suffered individual damages, including but not limited to economic harm, emotional distress, and inconvenience due to the injuries caused to R.G., and will continue to suffer said damages in the future.

163. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence, and evidenced reckless indifference to Plaintiff's rights, so as to warrant the imposition of punitive damages.

EIGHTH CAUSE OF ACTION

Medical and Related Expenses

164. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

165. 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, and/or failure to comply with applicable federal requirements, as fully described above, Plaintiff Reesci Gillespie, as the parent and natural guardian of R.G., has incurred significant economic harm, including but not limited to medical and medication expenses, caregiving expenses, and lost earnings,

due to the injuries suffered by R.G. from in utero exposure to Depakote, and will continue to suffer such damages in the future.

166. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence, and evidenced reckless indifference to Plaintiff's rights, so as to warrant the imposition of punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendants on each of the above-referenced claims and Causes of Action and further demand as follows:

i. Compensatory damages in excess of the minimum jurisdictional amount, including but not limited to compensation for injury, pain, suffering, mental anguish, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined by the trier of fact in this action;

ii. Economic damages in the form of medical expenses, out-of-pocket expenses, child care expenses, life care expenses, lost earnings, and other economic damages in an amount to be determined by the trier of fact in this action;

iii. Attorneys' fees, expenses, and costs of this action;

iv. Punitive damages; and

v. Such further relief as this Honorable Court deems necessary, just, and proper.

RESPECTFULLY SUBMITTED,

/s/ Janet G. Abaray
Janet G. Abaray (General Admission)
BURG SIMPSON ELDREDGE HERSH & JARDINE, P.C.
312 Walnut Street, Suite 2090
Cincinnati, OH 45202
Phone: (513) 852-5600
Fax: (513) 852-5611
E-mail: jabaray@burgsimpson.com

COUNSEL FOR PLAINTIFFS

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury as to all issues so triable.

/s/ Janet G. Abaray
Janet G. Abaray

JS 44 (Rev. 06/17)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

Reesci Gillespie, Individually and as parent and natural guardian of R.G., Minor

(b) County of Residence of First Listed Plaintiff Galveston, TX
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Janet G. Abaray, Esq., Burg Simpson Eldredge Hersh & Jardine, 312 Walnut Street, Suite 2090, Cincinnati, OH 45202; (513) 852-5600

DEFENDANTS

Abbott Laboratories, Inc.

County of Residence of First Listed Defendant Cook County, IL
(IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys *(If Known)*

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

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

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☒ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

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

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

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

☒ 1 Original Proceeding | ☐ 2 Removed from State Court | ☐ 3 Remanded from Appellate Court | ☐ 4 Reinstated or Reopened | ☐ 5 Transferred from Another District *(specify)* | ☐ 6 Multidistrict Litigation - Transfer | ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

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

Brief description of cause:
Personal Injury - Product Liability

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ >75,000.00

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Williams DOCKET NUMBER 12-cv-52-NJR-SCW

DATE 10/03/2017

SIGNATURE OF ATTORNEY OF RECORD /s/ Janet G. Abaray

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

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