

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION**

KATHRYN PAULSEN and)	
DANIEL PAULSEN,)	
)	Cause No. 1:24-cv-02191
Plaintiff,)	
)	
v.)	
)	
PFIZER INC.)	
and PHARMACIA & UPJOHN COMPANY LLC,)	
)	
Defendants.)	

COMPLAINT

COMES NOW, Plaintiffs Kathryn Paulsen and Daniel Paulsen, by counsel, Andrea L. Ciobanu of CIOBANU LAW, P.C., complaining of Defendants Pfizer Inc. and Pharmacia & Upjohn Company LLC and state to this Court as follows:

JURISDICTION

1. This Court has diversity jurisdiction over this action under 28. U.S.C. § 1332.
2. Venue is proper under 28 U.S.C. § 1391 in that the claim alleged herein arose in Marion County, Indiana within the Southern District of Indiana.
3. The amount in controversy exceeds \$75,000.

THE PARTIES

4. Plaintiff Kathryn Paulsen (hereinafter “Kathryn”) is an individual and a citizen of the State of Indiana.
5. Plaintiff Daniel Paulsen (hereinafter “Daniel”) is an individual and a citizen of the State of Indiana.
6. Kathryn and Daniel began their relationship in 2015 and were legally married in 2019.

7. Kathryn and Daniel may collectively be referred to hereinafter as “Plaintiffs”.
8. Defendant Pfizer Inc. (hereinafter “Pfizer”) is a for-profit corporation formed in the State of Delaware with its principal office located in the State of New York. All members of Pfizer are citizens of the State of New York. Pfizer is authorized to do and does business throughout the State of Indiana.
9. Defendant Pharmacia & Upjohn Company LLC (hereinafter “Upjohn”) is a foreign limited liability company formed in the State of Michigan with its principal office located in the State of Michigan. Upjohn’s members include Colum Lane and Andre B. Petrunoff, both of whom are citizens of the State of Michigan. Upjohn is authorized to do and does business throughout the State of Indiana.

FACTUAL ALLEGATIONS

A. Background of Depo-Provera and its Known Risks.

10. At all relevant times, Pfizer and/or Upjohn held the New Drug Application (NDA) for the drug medroxyprogesterone acetate, which is currently sold under the brand name Depo-Provera
11. Upjohn first developed Depo-Provera in the 1950s.
12. The FDA denied Upjohn’s application for Depo-Provera’s use as a contraceptive in 1967, 1978, and 1983.
13. The FDA finally approved Upjohn’s application for Depo-Provera’s use as a contraception in 1992.
14. Upjohn previously held the NDA for Depo-Provera.

15. Pfizer acquired Upjohn as a wholly owned subsidiary in 2002, thereby acquiring the NDA for Depo-Provera as well as the associated responsibilities and liabilities from the manufacturing, sale, and marketing of Depo-Provera.
16. Pfizer is the current NDA holder for Depo-Provera.
17. Pfizer has officially held the NDA for Depo-Provera since 2020 and, upon information and belief, effectively held the NDA for Depo-Provera since 2002 when it acquired Upjohn.
18. Pfizer's name began to appear on the label for Depo-Provera no later than 2003, alongside that of Upjohn.
19. Pfizer has solely held the NDA for Depo-Provera since 2020.
20. At all relevant times, Defendants engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, labelling, selling, and marketing its products, including the drug medroxyprogesterone acetate, which is sold under the brand name Depo-Provera.
21. Defendants researched, tested, formulated, patented, designed, licensed, labeled, manufactured, marketed, sold, and distributed the drug Depo-Provera and its generic forms to the general public and licensed healthcare providers for human use and consumption.
22. At all relevant times, Defendants authorized and directed and/or participated in the promotion and sale of Depo-Provera when they knew, or, with the exercise of reasonable care, should have known, of the increased risks, hazards, and unreasonable dangerous propensities of Depo-Provera.
23. Depo-Provera is a contraceptive which contains the hormones progestin and/or progesterone.

24. Depo-Provera is administered as an injection every three months to women of childbearing age to suppress ovulation and thicken the cervical mucus.
25. “Depo-Provera” shall hereinafter refer to Depo-Provera and its generic formulations.
26. Defendants authorized and directed the instructions for how consumers, such as Kathryn, were to receive Depo-Provera.
27. At all relevant times, Depo-Provera was defective, hazardous, unsafe, and dangerous.
28. Specifically, the persistent use of Depo-Provera increased the risk of developing meningioma brain tumors.
29. Meningioma is a tumor that arises in the meninges, which are the membranes that surround the brain and spinal cord.
30. Although usually noncancerous, meningiomas may compress or squeeze the brain, nerves, and vessels, resulting in various symptoms, including, but not limited to, changes in vision, headaches, hearing loss, memory loss, loss of smell, seizures, and weakness.
31. A number of meningiomas may also become metastatic.
32. Treatment of meningiomas typically require invasive brain surgery, which carries its own risks, including those which may be life-threatening or life-altering.
33. The association between progesterone and meningioma has been known or knowable for decades.
34. Although the FDA approved Depo-Provera for contraception in 1992, numerous studies have been published that have presented findings on the positive correlation between a

progesterone and/or progestin medication and the incidence and growth rate of meningioma¹.

35. In 1989, a study found that meningioma cell growth was significantly reduced by exposure to an antiprogestosterone agent.²

36. In light of these studies, Defendants had a continuing duty to investigate whether Depo-Provera could cause the development of meningiomas.

37. Despite this duty, Defendants failed to conduct any such investigations.

38. In 2023, a study found “there appears to be a clear progestin meningioma syndrome associated with chronic [Depo-Provera] use.”³ During that study, ten (10) participants were instructed to cease injections of Depo-Provera, five (5) of whom later had “clear evidence of tumor shrinkage.”

39. In 2024, a study in the *British Medical Journal* found that Depo-Provera had an increased risk of intracranial meningioma, second only to cyproterone acetate, which had already been withdrawn from the market due to its association with meningioma⁴.

40. Defendants knew or should have known of the potential risks of Depo-Provera, including the risk of developing meningiomas, but failed to adequately study these risks.

41. Defendants knew or should have known that the discontinuing of Depo-Provera could slow the growth of meningiomas.

¹ Grunberg, et al., “Treatment of unresectable meningiomas with the antiprogestosterone agent mifepristone,” *J Neurosurgery*, Vol. 74, No. 6, pp. 861-66 (1991); Matsuda, et al., “Antitumor effects of antiprogestosterones on human meningioma cells in vitro and in vivo,” *J Neurosurgery*, Vol. 80, N. 3, pp. 527-34 (1994).

² Blankenstein, et al., “Effect of steroids and antisteroids on human meningioma cells in primary culture,” *J Steroid Biochem*, Vol. 34, No. 1-6, pp. 419-21 (1989).

³ Abou-Al-Shaar, et al., “Skull base meningiomas as part of a novel meningioma syndrome associated with chronic depot medroxyprogesterone acetate use,” *J Neurol Surg Part B Skull Base*, Vol. 84:S1-344 (2023).

⁴ Roland, et al., “Use of progestogens and the risk of intracranial meningioma: national case-control study,” *British Medical Journal*, Vol. 384, published online Mar. 27, 2024 at <https://doi.org/10.1136/bmj-2023-078078>.

42. The label for Depo-Provera has had fourteen (14) iterations, with the most recent being issued in July 2024.
43. None of the labels for Depo-Provera in the United States have contained any warning regarding its risks of causing meningiomas even though such warnings have appeared on labels issued by Pfizer in the European Union.
44. Defendants failed to disclose the known defects of Depo-Provera to Kathryn, Kathryn's health care providers, and the general public and, instead, misrepresented that Depo-Provera was safe for intended use.
45. Defendants actively concealed Depo-Provera's known defects and risks of serious harm, including the development of meningiomas.
46. Instead of conducting the reasonable and appropriate testing regarding the risks associated with Depo-Provera, Defendants continued to falsely and misleadingly market the defective Depo-Provera as a safe and effective contraceptive.
47. Defendants knew, or should have known, that any failure to adequately study the risks of Depo-Provera and make the appropriate warnings of these risks would be replicated in the labels of Depo-Provera's generics.

B. Kathryn's History of Taking Depo-Provera and the Damages She Incurred as a Result Thereof.

48. Starting in 1998, Kathryn began receiving 150MG/ML intramuscular injections of Depo-Provera approximately every three months.
49. Kathryn received Depo-Provera injections every three months from approximately 1998 through 2000.
50. Kathryn and her physicians used and administered Depo-Provera as instructed by Defendants.

51. Neither Kathryn nor her physicians misused Depo-Provera in any manner.
52. In or around 2003 Kathryn began experiencing negative health effects, including headaches, which became progressively worse over the intervening years.
53. Starting in 2015, Kathryn began suffering neuropathic pains in her feet and legs, as well as back spasms and shooting pain around her spine.
54. On June 16, 2020, Kathryn had an MRI taken of her spine which alluded to a possible meningioma, schwannoma, tumor, or cyst.
55. On June 25, 2020, Kathryn underwent another MRI of her spine, which again alluded to possible schwannoma, neurofibroma, meningioma, or other tumor. This MRI also shown a likely bronchogenic cyst. Due to the results of this MRI, it was recommended that Kathryn undergo an MRI of her brain.
56. On October 14, 2020, Kathryn underwent an MRI of her brain, which confirmed that she had developed a small meningioma. Another MRI of Kathryn spine again suggested a schwannoma or meningioma and a bronchogenic cyst.
57. On October 27, 2021, Kathryn underwent another MRI of her brain which showed the meningioma first observed on October 14, 2020. The meningioma was now measured to be 6 x 10 mm. Another MRI of Kathryn's spine showed a nodule which likely represented a schwannoma or meningioma and a lesion which likely represented a bronchogenic cyst.
58. On November 14, 2022, Kathryn underwent another MRI of her brain, which again showed the meningioma. The meningioma was now measured to be 1.0 x 0.6 cm. An MRI of Kathryn's spine again showed what was now presumed to be a meningioma and bronchogenic cyst.

59. On November 13, 2024, Kathryn underwent another MRI of her brain, which showed that the meningioma in her brain had grown. An MRI of her Kathryn's spine again suggested a bronchogenic cyst and a meningioma which had increased in size.
60. Kathryn will require an MRI every one or two years for the remainder of her life.
61. Kathryn may require brain surgery if her symptoms worsen and/or the meningioma continues to grow.
62. At no time while Kathryn was administered Depo-Provera did Defendants inform Plaintiffs of any dangers associated with Depo-Provera, including the risk of developing meningiomas.
63. At no time during the above events did Kathryn have any knowledge that her injuries and other damages had any relation with Depo-Provera.
64. Defendants willfully, wantonly, and intentionally withheld information from Kathryn, Kathryn's physicians, and the general public regarding the known risks associated with Depo-Provera, including the development of meningiomas, and how such risks can be mitigated.
65. Due to Defendants' concealment of the risks of developing meningiomas though the use of Depo-Provera, neither Kathryn nor her physicians were aware, nor could that have reasonably known through reasonable diligence, of these risks.
66. As a direct and proximate result of Defendants' negligence and the defectiveness of Depo-Provera, Plaintiffs suffered economic and non-economic damages.
67. Despite diligent investigation by Kathryn and her physicians into the cause of her injuries, the nature and cause of these injuries and their relationship with Depo-Provera could not

be discovered until a date within the applicable statute of limitations for filing these claims against Defendants.

68. Given Defendants' deliberate actions and omissions regarding the risks of Depo-Provera, any statute of limitations is inapplicable.

69. Due to Defendants' acts and omissions described herein, Kathryn suffered damages including, but not limited to:

- a. Meningiomas.
- b. Lost earnings and reduced earning capacity.
- c. Medical expenses.
- d. Physical pain from headaches and neuropathic pain.
- e. Loss of sleep.
- f. Emotional distress.

70. Daniel suffered loss of consortium, loss of companionship, and other elements of an intimate relationship with Kathryn, due to the injuries Kathryn suffered as a result of Defendants' acts and omissions.

COUNT I: INDIANA PRODUCTS LIABILITY ACT – STRICT LIABILITY

(Kathryn Against All Defendants)

71. Plaintiffs incorporate by reference the preceding paragraphs of this complaint as fully set forth herein. Pursuant to the federal notice pleading standard, this complaint contains a factual allegations section, pleaded with sufficient factual matter, which demonstrates that Plaintiffs are entitled to relief. Fed. R. Civ. P. 8(a)(2).

72. Defendants are manufacturers of Depo-Provera.

73. Defendants had a duty to exercise reasonable care in the design, testing, research, manufacture, marketing, distribution, and sale of Depo-Provera.
74. Defendants placed Depo-Provera into the stream of commerce.
75. Defendants knew, or should have known, from the time of its manufacture, distribution, and sale of Depo-Provera and prior to the incidents underlying this Complaint, that Depo-Provera was unreasonably dangerous and would subject users and consumers, such as Kathryn, to unreasonable risk of serious bodily injury.
76. Kathryn was a consumer of Depo-Provera because she was in a class of persons that Defendants should have reasonably foreseen as being subject to harm at the time its products were used by Kathryn.
77. Kathryn used Depo-Provera in a manner for which it was intended and in a reasonable manner as anticipated.
78. The Depo-Provera that Kathryn used was in a defective condition and unreasonably dangerous when used in reasonably expectable ways of handling or consumption.
79. The defects to Depo-Provera were foreseeable and Kathryn's injuries and damages would not have occurred but for the use of the product.
80. Kathryn was not aware of the defective condition of the Depo-Provera nor could she have reasonably discovered its defectiveness.
81. As a direct result of Defendants' actions and omissions, Kathryn suffered economic and non-economic damages, including physical pain and suffering, lost wages, disability, medical expenses, and emotional distress.

**COUNT II: INDIANA PRODUCTS LIABILITY ACT –NEGLIGENT
MANUFACTURING**

(Kathryn Against All Defendants)

82. Plaintiffs incorporate by reference the preceding paragraphs of this complaint as fully set forth herein. Pursuant to the federal notice pleading standard, this complaint contains a factual allegations section, pleaded with sufficient factual matter, which demonstrates that Plaintiffs are entitled to relief. Fed. R. Civ. P. 8(a)(2).
83. Defendants had a duty to manufacture Depo-Provera consistent with the specifications, requirements, regulations, and conditions of approval.
84. At the time that the Depo-Provera left the control of Defendants and was administered to Kathryn, it was unreasonably dangerous.
85. Defendants breached their duty of due care by failing to exercise the degree of reasonable care that was expected of a reasonably prudent manufacturer of medical products, such as Depo-Provera, under similar circumstances.
86. Defendants' breach of reasonable care includes, but it no limited to, its failure to employ good manufacturing practices consistent with the standards in the industry for manufacturing, monitoring, testing, and distributing Depo-Provera.
87. The Depo-Provera administered to Kathryn was unreasonably defective as a result of Defendants' failure to use reasonable care.
88. Since Defendants failed to meet its duty of reasonable case, Kathryn, and her treating physicians, did not know, and had no reason to know, that Depo-Provera was causing Kathryn injuries.

89. As a direct result of Defendants' actions and omissions, Kathryn suffered economic and non-economic damages, including physical pain and suffering, lost wages, disability, medical expenses, and emotional distress.

COUNT III: BREACH OF EXPRESS WARRANTY

(Kathryn Against All Defendants)

90. Plaintiffs incorporate by reference the preceding paragraphs of this complaint as fully set forth herein. Pursuant to the federal notice pleading standard, this complaint contains a factual allegations section, pleaded with sufficient factual matter, which demonstrates that Plaintiffs are entitled to relief. Fed. R. Civ. P. 8(a)(2).

91. Defendants expressly warranted to Kathryn and the general public that Depo-Provera was safe, non-defective, and fit and proper for its intended use as a contraceptive, through Pfizer and/or its authorized agents, in publications, labeling, the internet, and other communications.

92. Kathryn reasonably relied on the skill and judgment of Defendants and upon said express warranty, in using Depo-Provera.

93. Kathryn and her physicians reasonably relied upon Defendants' representations that Depo-Provera was safe in their decision to prescribe, purchase, and/or use the drug.

94. Defendants did not have adequate proof that Depo-Provera was safe and effective.

95. Depo-Provera did not conform with the representations made by Defendants.

96. Instead of being safe and effective, as represented by Defendants, Depo-Provera was defective and caused severe side effects.

97. Defendants' warranty and representations were untrue in that Depo-Provera was unsafe, hazardous, and unsuited for the use for which it was intended and marketed.

98. Kathryn used Depo-Provera for the purpose and in the manner intended by Defendants.

99. Kathryn and her physicians could not have discovered through the use of reasonable care

Defendants' breach of warranty and Depo-Provera's hidden risks and unreasonable dangers.

100. The breach of warranty was a substantial factor in bringing about Kathryn's injuries.

101. As a direct result of Defendants' actions and omissions, Kathryn suffered economic and non-economic damages, including physical pain and suffering, lost wages, disability, medical expenses, and emotional distress.

COUNT IV: VIOLATION OF INDIANA'S CONSUMER SALES ACT

(Kathryn Against All Defendants)

102. Plaintiffs incorporate by reference the preceding paragraphs of this complaint as fully set forth herein. Pursuant to the federal notice pleading standard, this complaint contains a factual allegations section, pleaded with sufficient factual matter, which demonstrates that Plaintiffs are entitled to relief. Fed. R. Civ. P. 8(a)(2).

103. Defendants had a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Depo-Provera.

104. Defendants represented that Depo-Provera was of a particular standard and quality because of its safety and effectiveness.

105. Defendants' sale, marketing, promotion, and distribution of Depo-Provera under the guise that it was safe and effective was unfair and/or deceptive.

106. At all relevant times, Defendants were "suppliers" as that term is defined under Ind. Code § 24-5-0.5-2(a)(3).

107. At all relevant times, Defendants' sale of Depo-Provera to Kathryn and her physicians were "consumer transactions" as the term is defined under Ind. Code § 24-5-0.5-2(a)(1).

108. At all relevant times, Kathryn was a consumer of goods and services within the scope of Ind. Code § 24-5-0.5-1.

109. Depo-Provera is, in fact, not safe and/or effective making Defendants' representations as violations of Ind. Code § 24-5-0.5-3(2).

110. Kathryn reasonably relied on the skill and judgment of Defendants and upon said express warranty, in using Depo-Provera.

111. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Kathryn for Depo-Provera that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

112. Upon information and belief, Defendants had actual knowledge of the defective and unreasonably dangerous condition of Depo-Provera and failed to take any action to ensure that such defective and dangerous conditions were cured.

113. Kathryn was induced to purchase and use Depo-Provera for personal use by relying upon Defendants' statements, representations, and material omissions which were false, misleading, and deceptive.

114. Had Defendants not engaged in this deceptive conduct, Kathryn's physicians would not have administered Depo-Provera to Kathryn and Kathryn would not have purchased and/or paid for Depo-Provera and, thus, would not have incurred her damages.

115. Defendants' acts were deceptive and incurable.

116. As a direct result of Defendants' actions and omissions, Kathryn suffered economic and non-economic damages, including physical pain and suffering, lost wages, disability, medical expenses, and emotional distress.

COUNT V: NEGLIGENCE

(Kathryn Against All Defendants)

117. Plaintiffs incorporate by reference the preceding paragraphs of this complaint as fully set forth herein. Pursuant to the federal notice pleading standard, this complaint contains a factual allegations section, pleaded with sufficient factual matter, which demonstrates that Plaintiffs are entitled to relief. Fed. R. Civ. P. 8(a)(2).

118. Defendants are manufacturers of Depo-Provera.

119. Defendants had a duty to exercise reasonable care in the design, testing, research, manufacture, marketing, distribution, and sale of Depo-Provera.

120. Defendants placed Depo-Provera into the stream of commerce.

121. Defendants knew, or should have known, from the time of its manufacture, distribution, and sale of Depo-Provera and prior to the incidents underlying this Complaint, that Depo-Provera was unreasonably dangerous and would subject users and consumers, such as Kathryn, to unreasonable risk of serious bodily injury.

122. Prior to Kathryn's knowledge of her injuries, Defendants had information concerning Depo-Provera's harmful and dangerous effects as of other lawsuits, claims, complaints, and other sources.

123. Kathryn was a consumer of Depo-Provera because she was in a class of persons that Defendants should have reasonably foreseen as being subject to harm at the time its products were used by Kathryn.

124. Kathryn used Depo-Provera in a manner for which it was intended and in a reasonable manner as anticipated.

125. The Depo-Provera that Kathryn used was in a defective condition and unreasonably dangerous when used in reasonably expectable ways of handling or consumption.

126. The defects to Depo-Provera were foreseeable and Kathryn's injuries and damages would not have occurred but for the use of the product.

127. Kathryn was not aware of the defective condition of the Depo-Provera nor could she have reasonably discovered its defectiveness.

128. Defendants failed to exercise ordinary care in the labeling, design, manufacturing, testing, marketing, distribution, and/or sale of Depo-Provera.

129. Defendants breached its duty of care to Kathryn and her physicians in the testing, monitoring, and distribution of Depo-Provera.

130. As a direct result of Defendants' negligent testing, monitoring, and distribution of Depo-Provera, Pfizer introduced a product they knew or should have known would cause serious and permanent injuries, including meningioma.

131. As a direct result of Defendants' actions and omissions, Kathryn suffered economic and non-economic damages, including physical pain and suffering, lost wages, disability, medical expenses, and emotional distress.

COUNT VI: INDIANA PRODUCTS LIABILITY ACT – FAILURE TO WARN

(Kathryn Against All Defendants)

132. Plaintiffs incorporate by reference the preceding paragraphs of this complaint as fully set forth herein. Pursuant to the federal notice pleading standard, this complaint contains a factual allegations section, pleaded with sufficient factual matter, which demonstrates that Plaintiffs are entitled to relief. Fed. R. Civ. P. 8(a)(2).

133. At all relevant times, Pfizer and/or Upjohn were the NDA holders for the drug medroxyprogesterone acetate, which is sold under the brand name Depo-Provera.

134. At all relevant times, Pfizer and Upjohn engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and promoting the brand name version of Depo-Provera.

135. At all relevant times, Pfizer and Upjohn placed the brand name version of Depo-Provera into the stream of commerce in a defective and unreasonably dangerous condition.

136. Pfizer and Upjohn had a duty to exercise reasonable care in the design, testing, research, manufacture, marketing, distribution, and sale of the brand name Depo-Provera.

137. Pfizer and Upjohn had a duty to provide Kathryn and Kathryn's physicians with adequate information and warnings regarding the risks associated with brand name Depo-Provera, including the risk of developing meningiomas.

138. Pfizer and Upjohn knew, or should have known, from the time of its manufacture, distribution, and sale of Depo-Provera and prior to the incidents underlying this Complaint, that Depo-Provera was unreasonably dangerous and would subject users and consumers, such as Kathryn, to unreasonable risk of serious bodily injury, including the development of meningiomas.

139. Pfizer and Upjohn had a continuing duty to provide Kathryn and her physicians with warnings and other clinically relevant information regarding the risks and dangers associated with Depo-Provera.

140. As the NDA holders of brand name Depo-Provera, Pfizer and Upjohn were the only entities legally authorized to update the labelling of Depo-Provera under federal law.

141. Pfizer and Upjohn failed to issue adequate warnings that Depo-Provera causes serious and debilitating meningiomas.

142. As the NDA holders of brand name Depo-Provera, Pfizer and Upjohn had a duty to provide labeling for brand name Depo-Provera which “describe[d] serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.”⁵

143. As the NDA holders, Pfizer and Upjohn had a continuing duty to revise the labeling of Depo-Provera “to include a warning as soon as there is reasonable evidence of an association of a serious hazard with [the] drug” even though “a causal relationship need not have been proved.”⁶

144. As the NDA holders, Pfizer and Upjohn had the ability to update the Depo-Provera label without FDA preapproval in order to “add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the label.”⁷

145. As the NDA holders, Pfizer and Upjohn’s failure to adequately provide warnings of brand name Depo-Provera’s risks was replicated in the labels of the drug’s generic counterparts, with affected Kathryn and Kathryn’s physicians’ information regarding the risks associated with both the brand name and generic versions of Depo-Provera.

146. Kathryn used Depo-Provera in a manner for which it was intended and in a reasonable manner as anticipated.

⁵ 21 C.F.R. 201.80(e).

⁶ *Id.*

⁷ 21 C.F.R. § 314.70(c)(6)(iii)(A).

147. The Depo-Provera that Kathryn used was in a defective condition and unreasonably dangerous when used in reasonably expectable ways of handling or consumption.

148. If Pfizer and Upjohn had provided adequate warning to Kathryn and her physicians regarding the unreasonably high risk of meningiomas associated with Depo-Provera, Kathryn and her physicians would have opted to take a safer and non-defective contraceptive alternative.

149. The defects to Depo-Provera were foreseeable to Pfizer and Upjohn and Kathryn's injuries and damages would not have occurred but for the use of the product.

150. Kathryn was not aware of the health risks associated with Depo-Provera nor could she have reasonably discovered its defectiveness.

151. As a direct result of Pfizer and Upjohn's actions and omissions, Kathryn suffered economic and non-economic damages, including physical pain and suffering, lost wages, disability, medical expenses, and emotional distress.

COUNT VII: LOSS OF CONSORTIUM

(Daniel Against All Defendants)

152. Plaintiffs incorporate by reference the preceding paragraphs of this complaint as fully set forth herein. Pursuant to the federal notice pleading standard, this complaint contains a factual allegations section, pleaded with sufficient factual matter, which demonstrates that Plaintiffs are entitled to relief. Fed. R. Civ. P. 8(a)(2).

153. At all relevant times, Daniel was the lawful spouse of Kathryn.

154. As a proximate result of Defendants' actions and omissions as set forth above, Daniel has been deprived of the services, society, and companionship of Kathryn, his comfort and

happiness has been impaired, and this deprivation and impairment will necessarily continue in the future.

PRAYER FOR RELIEF

Plaintiffs pray that a judgement be entered on their behalf and against Defendants on all Counts of this Complaint.

RESERVATION OF RIGHTS

Plaintiffs reserve the right to proceed with any and all claims which the facts averred in this complaint support, pursuant to the notice pleading requirement of F.R.C.P. 8.

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment in favor of Plaintiffs on all counts of this Complaint, award compensatory damages, and punitive damages, as well as litigation costs, and grant such other and further relief as this Court deems just under the circumstances, including, but not limited to, a public apology, attorney's fees, and pre and post-judgment interest.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury of all issues so triable.

Date: December 12, 2024

Respectfully submitted,

s/ Andrea L. Ciobanu _____
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