

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

|                                    |   |                         |
|------------------------------------|---|-------------------------|
| LESLEY NOBLE and JUSTIN NOBLE,     | ) |                         |
|                                    | ) | Cause No. 1:24-cv-01831 |
| Plaintiffs,                        | ) |                         |
|                                    | ) |                         |
| v.                                 | ) |                         |
|                                    | ) |                         |
| PFIZER INC.,                       | ) |                         |
| and PHARMACIA & UPJOHN COMPANY LLC | ) |                         |
|                                    | ) |                         |
| Defendants.                        | ) |                         |

**COMPLAINT**

**COMES NOW**, Plaintiffs Lesley Noble and Justin Noble, 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 Hamilton County, Indiana within the Southern District of Indiana.
3. The amount in controversy exceeds \$75,000.

**THE PARTIES**

4. Plaintiff Lesley Noble (hereinafter “Lesley”) is an individual and a citizen of the State of Indiana. At all relevant times, Lesley was the lawful spouse of Plaintiff Justin Noble.
5. Plaintiff Justin Noble (hereinafter "Justin") is an individual and a citizen of the State of Indiana. At all relevant times, Justin was the lawful spouse of Lesley.
6. Lesley and Justin may hereinafter collectively be referred to as “Plaintiffs”.

7. 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. Pfizer is a citizen of the State of Delaware and is authorized to do and does business throughout the State of Indiana.
8. Defendant Pharmacia & Upjohn Company LLC (hereinafter “Upjohn”) is a for-profit corporation formed in the State of Michigan with its principal office located in the State of Michigan. Upjohn is a citizen of the State of Michigan and is authorized to do and does business throughout the State of Indiana.

### **FACTUAL ALLEGATIONS**

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

9. 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
10. Upjohn first developed Depo-Provera in the 1950s.
11. The FDA denied Upjohn’s application for Depo-Provera’s use as a contraceptive in 1967, 1978, and 1983.
12. The FDA finally approved Upjohn’s application for Depo-Provera’s use as a contraception in 1992.
13. Upjohn previously held the NDA for Depo-Provera.
14. 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.
15. Pfizer is the current NDA holder for Depo-Provera.

16. 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.
17. Pfizer's name began to appear on the label for Depo-Provera no later than 2003, alongside that of Upjohn.
18. Pfizer has solely held the NDA for Depo-Provera since 2020.
19. 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.
20. 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.
21. 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.
22. Depo-Provera is a contraceptive which contains the hormones progestin and/or progesterone.
23. Depo-Provera is administered as an injection every three months to women of childbearing age to suppress ovulation and thicken the cervical mucus.
24. "Depo-Provera" shall hereinafter refer to Depo-Provera and its generic formulations.
25. Defendants authorized and directed the instructions for how consumers, such as Lesley, were to receive Depo-Provera.

26. At all relevant times, Depo-Provera was defective, hazardous, unsafe, and dangerous.
27. Specifically, the persistent use of Depo-Provera increased the risk of developing meningioma brain tumors.
28. Meningioma is a tumor that arises in the meninges, which are the membranes that surround the brain and spinal cord.
29. 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.
30. A number of meningiomas may also become metastatic.
31. Treatment of meningiomas typically require invasive brain surgery, which carries its own risks, including those which may be life-threatening or life-altering.
32. The association between progesterone and meningioma has been known or knowable for decades.
33. 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 meningioma<sup>1</sup>.
34. In 1989, a study found that meningioma cell growth was significantly reduced by exposure to an antiprogestosterone agent.<sup>2</sup>

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<sup>1</sup> 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).

<sup>2</sup> 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).

35. In light of these studies, Defendants had a continuing duty to investigate whether Depo-Provera could cause the development of meningiomas.
36. Despite this duty, Defendants failed to conduct any such investigations.
37. In 2023, a study found “there appears to be a clear progestin meningioma syndrome associated with chronic [Depo-Provera] use.”<sup>3</sup> 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.”
38. 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 meningioma<sup>4</sup>.
39. 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.
40. Defendants knew or should have known that the discontinuing of Depo-Provera could slow the growth of meningiomas.
41. The label for Depo-Provera has had fourteen (14) iterations, with the most recent being issued in July 2024.
42. 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.

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<sup>3</sup> 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).

<sup>4</sup> 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>.

43. Defendants failed to disclose the known defects of Depo-Provera to Lesley, Lesley's health care providers, and the general public and, instead, misrepresented that Depo-Provera was safe for intended use.
44. Defendants actively concealed Depo-Provera's known defects and risks of serious harm, including the development of meningiomas.
45. 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.
46. 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. Lesley's History of Taking Depo-Provera and the Damages She Incurred as a Result Thereof.

47. Starting in January 1995, Lesley began receiving 150MG/ML intramuscular injections of Depo-Provera approximately every three months.
48. Lesley received Depo-Provera injections every three months until April 2007 when she did not receive them for approximately six (6) months.
49. Lesley then continued to receive Depo-Provera injections every three months until October 2, 2018.
50. Lesley and her physicians used and administered Depo-Provera as instructed by Defendants.
51. Neither Lesley nor her physicians misused Depo-Provera in any manner.
52. In December 2008, Lesley suffered a serious fall, which resulted in a fractured vertebra, facial lacerations (which required 17 stitches), and severe bruising.

53. Lesley suffered her fall as a result of dizziness caused by the Depo-Provera injections.

54. In Spring 2015, Lesley was forced to stop working her job as a bus monitor for Carmel Schools due to the symptoms she was suffering from as a result of the Depo-Provera injections.

55. Beginning in Fall 2015, Lesley began experiencing incontinence and her feelings of frustration, irritability, depression, and confusion began to exponentially increase.

56. Lesley also constantly suffered from dizziness and sensitivity to light.

57. In or around Fall 2016, Lesley was committed to outpatient psychological treatment at IU Health Methodist Hospital in Downtown Indianapolis.

58. By the start of 2017, Lesley began experiencing total apathy and exhaustion and slept 18-20 hours per day.

59. Lesley suffered multiple episodes of loss of control of her bowels. In her malaise, Lesley often slept through these episodes.

60. Lesley underwent testing, which determined that she had developed a large meningioma.

61. Lesley underwent surgery on July 14, 2017 to remove the meningioma.

62. Even after the meningioma was surgically removed, Lesley continued to receive injections of Depo-Provera because Defendants failed to warn her and her physicians of the risks and defects of Depo-Provera.

63. Because Defendants failed to warn Lesley and Lesley's physician of Depo-Provera's defects, Lesley's meningioma began to aggressively regrow approximately six (6) months after the initial surgery was completed to remove it.

64. In March and April 2018, Lesley underwent 36 rounds of radiation treatments to halt the growth of the meningioma.

65. Lesley continued to receive injections of Depo-Provera until October 2, 2018.
66. At no time while Lesley was administered Depo-Provera did Defendants inform Plaintiffs of any dangers associated with Depo-Provera, including the risk of developing meningiomas.
67. At no time during the above events did Plaintiffs have any knowledge that Lesley's injuries and other damages had any relation with Depo-Provera.
68. Defendants willfully, wantonly, and intentionally withheld information from Lesley, Lesley'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.
69. Due to Defendants' concealment of the risks of developing meningiomas through the use of Depo-Provera, neither Lesley nor her physicians were aware, nor could that have reasonably known through reasonable diligence, of these risks.
70. As a direct and proximate result of Defendants' negligence and the defectiveness of Depo-Provera, Plaintiffs suffered economic and noneconomic damages.
71. Despite diligent investigation by Lesley 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.
72. Given Defendants' deliberate actions and omissions regarding the risks of Depo-Provera, any statute of limitations is inapplicable.
73. Due to Defendants' acts and omissions described herein, Lesley suffered damages including, but not limited to:



- a. Meningiomas.
  - b. Fractured vertebra.
  - c. Facial lacerations.
  - d. Bruising.
  - e. Highly invasive brain surgery and radiation treatment.
  - f. Lost earnings and reduced earning capacity.
  - g. Medical expenses.
  - h. Emotional distress.
74. Justin suffered loss of consortium, loss of companionship, and other elements of an intimate relationship with Lesley, due to the injuries Lesley suffered as a result of Defendants' acts and omissions.

**COUNT I: INDIANA PRODUCTS LIABILITY ACT – STRICT LIABILITY**

**(Lesley Against All Defendants)**

75. 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).
76. Defendants are manufacturers of Depo-Provera.
77. Defendants had a duty to exercise reasonable care in the design, testing, research, manufacture, marketing, distribution, and sale of Depo-Provera.
78. Defendants placed Depo-Provera into the stream of commerce.
79. 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 Lesley, to unreasonable risk of serious bodily injury.

80. Lesley 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 Lesley.

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

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

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

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

85. As a direct result of Defendants' actions and omissions, Lesley 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**

**(Lesley Against All Defendants)**

86. 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).

87. Defendants had a duty to manufacture Depo-Provera consistent with the specifications, requirements, regulations, and conditions of approval.

88. At the time that the Depo-Provera left the control of Defendants and was administered to Lesley, it was unreasonably dangerous.

89. 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.

90. Defendants' breach of reasonable care includes, but is not limited to, its failure to employ good manufacturing practices consistent with the standards in the industry for manufacturing, monitoring, testing, and distributing Depo-Provera.

91. The Depo-Provera administered to Lesley was unreasonably defective as a result of Defendants' failure to use reasonable care.

92. Since Defendants failed to meet its duty of reasonable care, Lesley, and her treating physicians, did not know, and had no reason to know, that Depo-Provera was causing Lesley injuries.

93. As a direct result of Defendants' actions and omissions, Lesley 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**

#### **(Lesley Against All Defendants)**

94. 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).

95. Defendants expressly warranted to Lesley 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.
96. Lesley reasonably relied on the skill and judgment of Defendants and upon said express warranty, in using Depo-Provera.
97. Lesley and her physicians reasonably relied upon Defendants' representations that Depo-Provera was safe in their decision to prescribe, purchase, and/or use the drug.
98. Defendants did not have adequate proof that Depo-Provera was safe and effective.
99. Depo-Provera did not conform with the representations made by Defendants.
100. Instead of being safe and effective, as represented by Defendants, Depo-Provera was defective and cause severe side effects.
101. 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.
102. Lesley used Depo-Provera for the purpose and in the manner intended by Defendants.
103. Lesley 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.
104. The breach of warranty was a substantial factor in bringing about Lesley's injuries.
105. As a direct result of Defendants' actions and omissions, Lesley 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**

**(Lesley Against All Defendants)**

106. 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).
107. 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.
108. Defendants represented that Depo-Provera was of a particular standard and quality because of its safety and effectiveness.
109. Defendants’ sale, marketing, promotion, and distribution of Depo-Provera under the guise that it was safe and effective was unfair and/or deceptive.
110. At all relevant times, Defendants were “suppliers” as that term is defined under Ind. Code § 24-5-0.5-2(a)(3).
111. At all relevant times, Defendants’ sale of Depo-Provera to Lesley and her physicians were “consumer transactions” as the term is defined under Ind. Code § 24-5-0.5-2(a)(1).
112. At all relevant times, Lesley was a consumer of goods and services within the scope of Ind. Code § 24-5-0.5-1.
113. Depo-Provera is, in fact, not safe and/or effective making Defendants’ representations as violations of Ind. Code § 24-5-0.5-3(2).
114. Lesley reasonably relied on the skill and judgment of Defendants and upon said express warranty, in using Depo-Provera.

115. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Lesley for Depo-Provera that would not have been paid had Defendants not engaged in unfair and deceptive conduct.
116. 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.
117. Lesley 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.
118. Had Defendants not engaged in this deceptive conduct, Lesley's physicians would not have administered Depo-Provera to Lesley and Lesley would not have purchased and/or paid for Depo-Provera and, thus, would not have incurred her damages.
119. Defendants' acts were deceptive and incurable.
120. As a direct result of Defendants' actions and omissions, Leslie suffered economic and non-economic damages, including physical pain and suffering, lost wages, disability, medical expenses, and emotional distress.

#### **COUNT V: NEGLIGENCE**

##### **(Lesley Against All Defendants)**

121. 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).
122. Defendants are manufacturers of Depo-Provera.

123. Defendants had a duty to exercise reasonable care in the design, testing, research, manufacture, marketing, distribution, and sale of Depo-Provera.
124. Defendants placed Depo-Provera into the stream of commerce.
125. 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 Lesley, to unreasonable risk of serious bodily injury.
126. Prior to Lesley'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.
127. Lesley 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 Lesley.
128. Lesley used Depo-Provera in a manner for which it was intended and in a reasonable manner as anticipated.
129. The Depo-Provera that Lesley used was in a defective condition and unreasonably dangerous when used in reasonably expectable ways of handling or consumption.
130. The defects to Depo-Provera were foreseeable and Lesley's injuries and damages would not have occurred but for the use of the product.
131. Lesley was not aware of the defective condition of the Depo-Provera nor could she have reasonably discovered its defectiveness.
132. Defendants failed to exercise ordinary care in the labeling, design, manufacturing, testing, marketing, distribution, and/or sale of Depo-Provera.

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

134. 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.

135. As a direct result of Defendants' actions and omissions, Leslie 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**

**(Lesley Against All Defendants)**

136. 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).

137. 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.

138. 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.

139. 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.

140. 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.



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

142. 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 Lesley, to unreasonable risk of serious bodily injury, including the development of meningiomas.

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

144. 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.

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

146. 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."<sup>5</sup>

147. 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

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<sup>5</sup> 21 C.F.R. 201.80(e).

association of a serious hazard with [the] drug” even though “a causal relationship need not have been proved.”<sup>6</sup>

148. 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.”<sup>7</sup>

149. 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 Lesley and Lesley’s physicians’ information regarding the risks associated with both the brand name and generic versions of Depo-Provera.

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

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

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

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

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

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<sup>6</sup> *Id.*

<sup>7</sup> 21 C.F.R. § 314.70(c)(6)(iii)(A).

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

### **COUNT VII: LOSS OF CONSORTIUM**

#### **(Justin Against All Defendants)**

156. 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).

157. At all relevant times, Justin was the lawful spouse of Lesley.

158. As a proximate result of Defendants' actions and omissions as set forth above, Justin has been deprived of the services, society, and companionship of Lesley, 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: October 15, 2024

Respectfully submitted,

s/ Andrea L. Ciobanu  
Andrea L. Ciobanu, #28942-49  
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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.)

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| <b>I. (a) PLAINTIFFS</b><br>Lesley Noble and Justin Noble                                                                                                            | <b>DEFENDANTS</b><br>Pfizer Inc. and Pharmacia & Upjohn Company LLC                                           |
| <b>(b)</b> County of Residence of First Listed Plaintiff <u>Hamilton County, IN</u><br>(EXCEPT IN U.S. PLAINTIFF CASES)                                              | County of Residence of First Listed Defendant _____<br>(IN U.S. PLAINTIFF CASES ONLY)                         |
| <b>(c)</b> Attorneys (Firm Name, Address, and Telephone Number)<br>Andrea L. Ciobanu, CIOBANU LAW, P.C., 902 E. 66th Street,<br>Indianapolis, IN 46220, 317-495-1090 | NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.<br><br>Attorneys (If Known) |

|                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                            |                                         |                            |                                       |     |     |                                                                           |                                       |                            |                       |                            |                            |                                                                                               |                            |                            |                          |                            |                                       |  |                            |                            |                                         |                            |                            |
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| <b>II. BASIS OF JURISDICTION</b> (Place an "X" in One Box Only)                                                  | <b>III. CITIZENSHIP OF PRINCIPAL PARTIES</b> (Place an "X" in One Box for Plaintiff and One Box for Defendant)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                            |                                         |                            |                                       |     |     |                                                                           |                                       |                            |                       |                            |                            |                                                                                               |                            |                            |                          |                            |                                       |  |                            |                            |                                         |                            |                            |
| <input type="checkbox"/> 1 U.S. Government Plaintiff<br><br><input type="checkbox"/> 2 U.S. Government Defendant | <table><tr><td></td><td>PTF</td><td>DEF</td><td></td><td>PTF</td><td>DEF</td></tr><tr><td><input type="checkbox"/> 3 Federal Question (U.S. Government Not a Party)</td><td><input checked="" type="checkbox"/> 1</td><td><input type="checkbox"/> 1</td><td>Citizen of This State</td><td><input type="checkbox"/> 4</td><td><input type="checkbox"/> 4</td></tr><tr><td><input checked="" type="checkbox"/> 4 Diversity (Indicate Citizenship of Parties in Item III)</td><td><input type="checkbox"/> 2</td><td><input type="checkbox"/> 2</td><td>Citizen of Another State</td><td><input type="checkbox"/> 5</td><td><input checked="" type="checkbox"/> 5</td></tr><tr><td></td><td><input type="checkbox"/> 3</td><td><input type="checkbox"/> 3</td><td>Citizen or Subject of a Foreign Country</td><td><input type="checkbox"/> 6</td><td><input type="checkbox"/> 6</td></tr></table> |                            | PTF                                     | DEF                        |                                       | PTF | DEF | <input type="checkbox"/> 3 Federal Question (U.S. Government Not a Party) | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 1 | Citizen of This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 | <input checked="" type="checkbox"/> 4 Diversity (Indicate Citizenship of Parties in Item III) | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Citizen of Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |  | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Citizen or Subject of a Foreign Country | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |
|                                                                                                                  | PTF                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | DEF                        |                                         | PTF                        | DEF                                   |     |     |                                                                           |                                       |                            |                       |                            |                            |                                                                                               |                            |                            |                          |                            |                                       |  |                            |                            |                                         |                            |                            |
| <input type="checkbox"/> 3 Federal Question (U.S. Government Not a Party)                                        | <input checked="" type="checkbox"/> 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <input type="checkbox"/> 1 | Citizen of This State                   | <input type="checkbox"/> 4 | <input type="checkbox"/> 4            |     |     |                                                                           |                                       |                            |                       |                            |                            |                                                                                               |                            |                            |                          |                            |                                       |  |                            |                            |                                         |                            |                            |
| <input checked="" type="checkbox"/> 4 Diversity (Indicate Citizenship of Parties in Item III)                    | <input type="checkbox"/> 2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <input type="checkbox"/> 2 | Citizen of Another State                | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |     |     |                                                                           |                                       |                            |                       |                            |                            |                                                                                               |                            |                            |                          |                            |                                       |  |                            |                            |                                         |                            |                            |
|                                                                                                                  | <input type="checkbox"/> 3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <input type="checkbox"/> 3 | Citizen or Subject of a Foreign Country | <input type="checkbox"/> 6 | <input type="checkbox"/> 6            |     |     |                                                                           |                                       |                            |                       |                            |                            |                                                                                               |                            |                            |                          |                            |                                       |  |                            |                            |                                         |                            |                            |

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| <b>IV. NATURE OF SUIT</b> (Place an "X" in One Box Only)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Click here for: <a href="#">Nature of Suit Code Descriptions.</a> |  |
| <b>CONTRACT</b><br><input type="checkbox"/> 110 Insurance<br><input type="checkbox"/> 120 Marine<br><input type="checkbox"/> 130 Miller Act<br><input type="checkbox"/> 140 Negotiable Instrument<br><input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment<br><input type="checkbox"/> 151 Medicare Act<br><input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans)<br><input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits<br><input type="checkbox"/> 160 Stockholders' Suits<br><input type="checkbox"/> 190 Other Contract<br><input type="checkbox"/> 195 Contract Product Liability<br><input type="checkbox"/> 196 Franchise | <b>TORTS</b><br><b>PERSONAL INJURY</b><br><input type="checkbox"/> 310 Airplane<br><input type="checkbox"/> 315 Airplane Product Liability<br><input type="checkbox"/> 320 Assault, Libel & Slander<br><input type="checkbox"/> 330 Federal Employers' Liability<br><input type="checkbox"/> 340 Marine<br><input type="checkbox"/> 345 Marine Product Liability<br><input type="checkbox"/> 350 Motor Vehicle<br><input type="checkbox"/> 355 Motor Vehicle Product Liability<br><input type="checkbox"/> 360 Other Personal Injury<br><input type="checkbox"/> 362 Personal Injury - Medical Malpractice<br><b>PERSONAL INJURY</b><br><input type="checkbox"/> 365 Personal Injury - Product Liability<br><input checked="" type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability<br><input type="checkbox"/> 368 Asbestos Personal Injury Product Liability<br><b>PERSONAL PROPERTY</b><br><input type="checkbox"/> 370 Other Fraud<br><input type="checkbox"/> 371 Truth in Lending<br><input type="checkbox"/> 380 Other Personal Property Damage<br><input type="checkbox"/> 385 Property Damage Product Liability | <b>FORFEITURE/PENALTY</b><br><input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881<br><input type="checkbox"/> 690 Other<br><br><b>LABOR</b><br><input type="checkbox"/> 710 Fair Labor Standards Act<br><input type="checkbox"/> 720 Labor/Management Relations<br><input type="checkbox"/> 740 Railway Labor Act<br><input type="checkbox"/> 751 Family and Medical Leave Act<br><input type="checkbox"/> 790 Other Labor Litigation<br><input type="checkbox"/> 791 Employee Retirement Income Security Act<br><br><b>IMMIGRATION</b><br><input type="checkbox"/> 462 Naturalization Application<br><input type="checkbox"/> 465 Other Immigration Actions | <b>BANKRUPTCY</b><br><input type="checkbox"/> 422 Appeal 28 USC 158<br><input type="checkbox"/> 423 Withdrawal 28 USC 157<br><br><b>PROPERTY RIGHTS</b><br><input type="checkbox"/> 820 Copyrights<br><input type="checkbox"/> 830 Patent<br><input type="checkbox"/> 835 Patent - Abbreviated New Drug Application<br><input type="checkbox"/> 840 Trademark<br><br><b>SOCIAL SECURITY</b><br><input type="checkbox"/> 861 HIA (1395ff)<br><input type="checkbox"/> 862 Black Lung (923)<br><input type="checkbox"/> 863 DIWC/DIWW (405(g))<br><input type="checkbox"/> 864 SSID Title XVI<br><input type="checkbox"/> 865 RSI (405(g))<br><br><b>FEDERAL TAX SUITS</b><br><input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant)<br><input type="checkbox"/> 871 IRS—Third Party 26 USC 7609 | <b>OTHER STATUTES</b><br><input type="checkbox"/> 375 False Claims Act<br><input type="checkbox"/> 376 Qui Tam (31 USC 3729(a))<br><input type="checkbox"/> 400 State Reapportionment<br><input type="checkbox"/> 410 Antitrust<br><input type="checkbox"/> 430 Banks and Banking<br><input type="checkbox"/> 450 Commerce<br><input type="checkbox"/> 460 Deportation<br><input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations<br><input type="checkbox"/> 480 Consumer Credit<br><input type="checkbox"/> 490 Cable/Sat TV<br><input type="checkbox"/> 850 Securities/Commodities/Exchange<br><input type="checkbox"/> 890 Other Statutory Actions<br><input type="checkbox"/> 891 Agricultural Acts<br><input type="checkbox"/> 893 Environmental Matters<br><input type="checkbox"/> 895 Freedom of Information Act<br><input type="checkbox"/> 896 Arbitration<br><input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision<br><input type="checkbox"/> 950 Constitutionality of State Statutes |                                                                   |  |
| <b>REAL PROPERTY</b><br><input type="checkbox"/> 210 Land Condemnation<br><input type="checkbox"/> 220 Foreclosure<br><input type="checkbox"/> 230 Rent Lease & Ejectment<br><input type="checkbox"/> 240 Torts to Land<br><input type="checkbox"/> 245 Tort Product Liability<br><input type="checkbox"/> 290 All Other Real Property                                                                                                                                                                                                                                                                                                                                                                         | <b>CIVIL RIGHTS</b><br><input type="checkbox"/> 440 Other Civil Rights<br><input type="checkbox"/> 441 Voting<br><input type="checkbox"/> 442 Employment<br><input type="checkbox"/> 443 Housing/Accommodations<br><input type="checkbox"/> 445 Amer. w/Disabilities - Employment<br><input type="checkbox"/> 446 Amer. w/Disabilities - Other<br><input type="checkbox"/> 448 Education                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>PRISONER PETITIONS</b><br><b>Habeas Corpus:</b><br><input type="checkbox"/> 463 Alien Detainee<br><input type="checkbox"/> 510 Motions to Vacate Sentence<br><input type="checkbox"/> 530 General<br><input type="checkbox"/> 535 Death Penalty<br><b>Other:</b><br><input type="checkbox"/> 540 Mandamus & Other<br><input type="checkbox"/> 550 Civil Rights<br><input type="checkbox"/> 555 Prison Condition<br><input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                   |  |

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>V. ORIGIN</b> (Place an "X" in One Box Only)                                                                                                                                                                                                                                                                                                                                                                                  |
| <input checked="" type="checkbox"/> 1 Original Proceeding <input type="checkbox"/> 2 Removed from State Court <input type="checkbox"/> 3 Remanded from Appellate Court <input type="checkbox"/> 4 Reinstated or Reopened <input type="checkbox"/> 5 Transferred from Another District (specify) <input type="checkbox"/> 6 Multidistrict Litigation - Transfer <input type="checkbox"/> 8 Multidistrict Litigation - Direct File |

|                            |                                                                                                                                      |
|----------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
| <b>VI. CAUSE OF ACTION</b> | Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):<br><u>28 USC 1391</u> |
|                            | Brief description of cause:<br><u>Pharmaceutical Product Liability</u>                                                               |

|                                     |                                                                                   |                  |                                                                                                                                     |
|-------------------------------------|-----------------------------------------------------------------------------------|------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| <b>VII. REQUESTED IN COMPLAINT:</b> | <input type="checkbox"/> CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. | <b>DEMAND \$</b> | CHECK YES only if demanded in complaint:<br><b>JURY DEMAND:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |
|-------------------------------------|-----------------------------------------------------------------------------------|------------------|-------------------------------------------------------------------------------------------------------------------------------------|

|                                     |                     |             |                     |
|-------------------------------------|---------------------|-------------|---------------------|
| <b>VIII. RELATED CASE(S) IF ANY</b> | (See instructions): | JUDGE _____ | DOCKET NUMBER _____ |
|-------------------------------------|---------------------|-------------|---------------------|

|                           |                                                            |
|---------------------------|------------------------------------------------------------|
| DATE<br><u>10/15/2024</u> | SIGNATURE OF ATTORNEY OF RECORD<br><u>Andrea L Ciobanu</u> |
|---------------------------|------------------------------------------------------------|

|                            |              |                    |             |                  |
|----------------------------|--------------|--------------------|-------------|------------------|
| <b>FOR OFFICE USE ONLY</b> |              |                    |             |                  |
| RECEIPT # _____            | AMOUNT _____ | APPLYING IFP _____ | JUDGE _____ | MAG. JUDGE _____ |

AO 440 (Rev. 06/12) Summons in a Civil Action

## UNITED STATES DISTRICT COURT

for the

Southern District of Indiana

Lesley Noble and Justin Noble

---

*Plaintiff(s)*

v.

Pfizer Inc. and Pharmacia &amp; Upjohn Company LLC

---

*Defendant(s)*

Civil Action No. 1:24-cv-01831

## SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Pfizer Inc.  
 c/o C T Corporation System  
 334 N. Senate Ave.  
 Indianapolis, IN 46204

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Andrea Ciobanu  
 CIOBANU LAW, P.C.  
 902 E. 66th Street  
 Indianapolis, IN 46220

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: \_\_\_\_\_

\_\_\_\_\_  
*Signature of Clerk or Deputy Clerk*

AO 440 (Rev. 06/12) Summons in a Civil Action

## UNITED STATES DISTRICT COURT

for the

Southern District of Indiana

Lesley Noble and Justin Noble

---

*Plaintiff(s)*

v.

Pfizer Inc. and Pharmacia &amp; Upjohn Company LLC

---

*Defendant(s)*

Civil Action No. 1:24-cv-01831

## SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Pharmacia & Upjohn Company LLC  
 c/o C T Corporation System  
 334 N. Senate Ave.  
 Indianapolis, IN 46204

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Andrea Ciobanu  
 CIOBANU LAW, P.C.  
 902 E. 66th Street  
 Indianapolis, IN 46220

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: \_\_\_\_\_

\_\_\_\_\_  
*Signature of Clerk or Deputy Clerk*