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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF FLORIDA

PENSACOLA DIVISION

IN RE: DEPO-PROVERA (DEPOT MEDROXYPROGESTERONE ACETATE)) PRODUCTS LIABILITY ACTION	Case No.: 3:25-md-3140 **PLAINTIFF'S COMPLAINT AND JURY DEMAND** Judge M. Casey Rodgers Magistrate Judge Hope T. Cannon
This Document Relates to: *Ashley Smith v. Pfizer, Inc.; Pharmacia & Upjohn Co. LLC*	DESIGNATED FORUM: Eastern District of Wisconsin

Plaintiff, Ashley Smith, through her counsel, Schwaba Law Firm, brings this products liability action and alleges and avers as follows:

INTRODUCTION

1. This is a products liability action against the makers and distributors of Depo-Provera, a pharmaceutical drug marketed as a contraceptive that was injected into women approximately every 3 months by their physician. Depo-Provera's active ingredient is medroxyprogesterone acetate, a derivative of progesterone, which purportedly inhibits the secretion of gonadotropins, which in turn, prevents follicular

maturation and ovulation and results in endometrial thinning, producing a contraceptive effect.

2. The use of Depo-Provera poses an excess increased risk of intracranial meningioma, a slow-growing tumor that compresses surrounding tissue, causing pain and lack of function. Defendants knew or should have known that Depo-Provera posed the increased risk of meningioma, but failed to warn the Plaintiff, her physicians, and the wider medical community of the connection between Depo-Provera and intracranial meningioma, although Defendants knew or should have known of the increased risk, and/or failed to perform sufficient testing of the risks, despite knowing that an increased risk of intracranial testing was required since at least 1983.

3. This action is brought on behalf of the Plaintiff who was injected with Depo-Provera from 2000 to 2012 and again in 2014 to September 2015. Plaintiff was originally diagnosed with an intracranial meningioma in 2009 which increased in symptoms in October 2024. Plaintiff was never warned of the excess risk of meningioma from Depo-Provera injections and would never have received the injections had she known of the risk. Her Complaint alleges claims of negligence and negligent failure to warn, strict products liability, negligent misrepresentation and punitive damages for Defendant's failure to warn the Plaintiff of the dangers of Depo-Provera.

PARTIES, JURISDICTION, AND VENUE

4. Plaintiff, Ashley Smith, is an adult resident citizen of Jefferson County, Wisconsin.

5. Defendant Pfizer Inc. is a corporation existing under the laws of Delaware with its principal place of business located at 66 Hudson Boulevard East, New York, NY 10001. At all times material, Defendant Pfizer Inc., was involved in the design, research, development, manufacture, marketing, sale and distribution of the pharmaceutical drug Depo-Provera and/or its generic equivalent in this District and throughout the United States.

6. Defendant Pharmacia & Upjohn Company is a corporation existing under the laws of Michigan with its principal place of business located at 7171 Portage Road, Kalamazoo, MI 49002. At all times material, Defendant Pharmacia & Upjohn Company was involved in the design, research, development, manufacture, marketing, sale and distribution of the pharmaceutical drug Depo-Provera and/or its generic equivalent in this District and throughout the United States.

7. Jurisdiction is proper in this Court under 28 U.S.C. § 1332 because the claims in this case involve parties from different states, Plaintiff from Wisconsin and the Defendants from New York and Michigan.

8. Plaintiff would show the Court that venue would be proper in the Eastern District of Wisconsin absent direct filing into this MDL. Venue is proper in this MDL pursuant to Pre-Trial Order #10 [ECF 268]. Venue is proper in the Eastern District of Wisconsin under 28 U.S.C. § 1391(b) because the Plaintiff resides in this district and a substantial part of the actions giving rise to the claim occurred in the Eastern District, including the prescription and ingestion of Depo-Provera, her resulting medical treatment for meningioma, and the sale, marketing and use of Depo-Provera by the Defendant in this District.

FACTUAL BACKGROUND

9. Depo-Provera, also known as depot medroxyprogesterone acetate is an injectable contraceptive that was first formulated by scientists at Upjohn Company in 1954. It is a hormonal medication of the progestin type that is an artificial progestogen which activates progesterone receptor. It decreases the body's release of gonadotropins and works as a form of birth control by preventing ovulation.

10. Depo-Provera is also used in menopausal hormone therapy to prevent endometrial hyperplasia and cancer that would otherwise be induced by prolonged estrogen therapy.

11. As a contraceptive, Depo-Provera is most often given by intramuscular or subcutaneous injection, usually into the thigh, buttock or deltoid muscle and is released

over a period of several months. The shot is then repeated every 11 to 13 weeks to remain effective. It is given in doses of 150mg/mL for contraception.

12. Depo-Provera was first used as a treatment for endometriosis and uterine fibroids when it was discovered in 1956.

13. In 1960, Upjohn submitted its first New Drug Application (NDA) regarding Depo-Provera to the FDA for approval as a contraceptive, but the application was denied due to concerns it increased the risk of cancer.

14. After years of clinical trials, the United States Food and Drug Administration (FDA) approved Depo-Provera as a contraceptive in the United States, but only for use in women who were not able to use other methods of contraception. In 1978, the FDA revoked its approval, again due to concerns about the increased risk of breast cancer. Another New Drug Application (NDA) was rejected by the FDA in 1983 for the same reasons.

15. In 1992, the FDA re-approved Depo-Provera for use as a contraceptive in the United States. Upon information and belief, Defendants failed to advise the FDA of the association between medroxyprogestogen acetate and intracranial meningioma the association between prostegerone receptors and meningioma generally.

DEPO-PROVERA CAUSES INTRACRANIAL MENINGIOMA

16. For years and at least beginning in the 1980's, Defendants knew or should have known of the relationship between progesterone and meningiomas. Such an association required the Defendant to research, investigate, document and advise physicians and patients of the hazards, risks and dangers of the development of intracranial meningiomas after use of Depo-Provera.

17. For example, a 1983 study in the European Journal of Cancer and Clinical Oncology found progesterone receptors on meningioma cells.[1]

[1] Blankenstein, et al. "Presence of progesterone receptors and absence of oestrogen receptors in human intracranial meningioma cystosols," *Eur. J. Cancer & Clin. Oncol*., Vol. 19, No. 3, p. 365-70 (1983).

18. Progesterone-inhibiting agents have also been reported since 1989, beginning with a 1989 article in the Journal of Steroid Biochemistry finding exposure to mifepristone, an antiprogesterone agent, significantly reduced meningioma cell growth.[2]

19. In 2022, an article in the European Journal of Neurology found that progesterone exposure increased the risk of meningiomas for all histological grades and anatomical sites, particularly for the anterior and middle skull base. The article concluded that a strong association between prolonged exposure to potent progestogens and surgery for meningioma was observed. The article advised that individuals should be informed of that heightened risk.[3]

20. A 2024 study in the British Medical Journal (BMJ) confirmed the findings in the 2022 Hoisnard study. The BMJ article was a national case control study of 108,366 women overall, with 18,061 women who had intracranial surgery for meningioma and 90,305 controls between 2009 and 2018. The analysis showed an excess risk of intracranial meningioma with use of medroxyprogesterone acetate.[4]

21. Medroxyprogesterone acetate was confirmed to cause intracranial meningioma in another 2024 study in the journal Cancers. The author used a large commercial insurance database to study identified meningioma cases using ICD-10 codes from hospital data and medroxyprogesterone acetate exposure from pharmaceutical claims data. The study found injected exposure to medroxyprogesterone acetate was associated with a 53% increased odds of being a case

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[2] Blankenstein, et al., Effect of Steroids and antisteroids on Human Meningioma Cells in Primary Culture, J. Steroid Biochem., Vol. 34, No. 1-6, p. 419-21 (1989). *See also*, Grunberg, et al., Treatment of Unresectable Meningiomas With the AntiProgesterone Agent Mifepristone," *J. Neurosurgery*, Vol. 74, No. 6, p. 861-66 (1991); Matsuda, et al., Antitumor Effects of Antiprogesterones on Human Meningioma Cells in Vitro and in Vivo," *J. Neurosurgery*, Vol. 80, No. 3, p. 527-34 (1994); Gil, et al., Risk of Meningioma Among Users of High Doses of Cyproterone Acetate as Compared With the General Population: Evidence From A Population-Based Cohort Study, Br. J. Clin Pharmacol, Vol. 72, No. 6, p. 965-68 (2011).

[3] Hoisnard, et al., Risk of Intracranial Meningioma With Three Potent Progestogens: A Population Based Case-Control Study" *Eur J. Neurol*, Vol. 29, p. 2801-2809 (2022).

[4] Roland, et al., Use of Progestogens and the Risk of Intracranial Meningioma: National Case-Control Study, *BMJ* Vol. 384 (2024).

specific to cerebral meningioma. Importantly, the longer duration of use of injected medroxyprogesterone the stronger association with cerebral meningioma occurred.[5]

DEFENDANTS FAILURE TO INVESTIGATE AND WARN

22. Upon its release and sale to the public, the Defendants listed contraindications of Depo-Provera with other existing conditions including migraine headaches, deep vein thrombosis or pulmonary embolus, vaginal bleeding, and a history of stroke among others.

23. Listed side effects identified by the defendants in the use of Depo-Provera have included breast tenderness, lowered libido, stomach pain, weight gain with diabetes and edema, and irregular or unpredictable bleeding.

24. From the initial sale of Depo-Provera in the United States, the Defendants have failed to provide proper and adequate warnings to physicians and patients of the hazards, risks and dangers associated with use of the drug, including the dangers of intracranial meningioma.

25. The most recent, July 2024, Depo-Provera Physician Information label includes contraindications related to use during pregnancy, vaginal bleeding, liver dysfunction and other concerns. However, the Depo-Provera label fails to provide any contraindications, warnings, or other information regarding an association between medroxyprogestogen acetate and intracranial meningioma specifically or the association between prostegerone receptors and meningiomas generally.

26. The label includes warnings related to bleeding irregularities, breast and cervical cancers, ocular disorders and unexpected pregnancies among other concerns. However, the Depo-Provera label fails to provide any warnings or other information regarding an association between medroxyprogestogen acetate and intracranial meningioma specifically or the association between prostegerone receptors and meningioma generally.

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[5] Griffin, R.L., The Association Between Medroxyprogesterone Acetate Exposure and Meningioma, *Cancers*, Vol. 16, p. 3362 (2024).

27. The label includes adverse reactions related to menstrual irregularities, abdominal pain, dizziness, headaches, breast pain, and arthralgias among other concerns.

28. The Depo-Provera label fails to provide any notice of contraindications, adverse reaction, warnings or other information regarding an association between prostegerone receptors and meningioma generally or the association between medroxyprogestogen acetate and intracranial meningioma specifically.

29. Beginning in 2003, Depo-Provera's label has changed at least 13 times according to Drugs@FDA.gov, including its most recent change in July of 2024. None of those changes provided additional language or provided any warnings or other information regarding an association between medroxyprogestogen acetate and intracranial meningioma specifically or the association between prostegerone receptors and meningioma generally.

30. Each label change beginning in 2003 included sections related to Warnings and Precautions, Adverse Reactions, and Contraindications. None of those sections of the labels provided any warnings or other information regarding an association between medroxyprogestogen acetate and intracranial meningioma specifically or the association between prostegerone receptors and meningioma generally.

31. Each label change beginning in 2010 also included sections related to Clinical Pharmacology and Clinical Studies, yet these sections specifically and the label as a whole failed to report the association between medroxyprogestogen acetate and intracranial meningioma specifically or the association between prostegerone receptors and meningioma generally, including the Blankenstein, Hoisnard, Roland and Griffin articles discussed in the preceding paragraphs above.

32. Each label change beginning in 2010 included sections related to Post-Market Experience, but those sections failed to advise consumers and physicians of the association between medroxyprogestogen acetate and intracranial meningioma

specifically or the association between prostegerone receptors and meningioma generally, including the Blankenstein, Hoisnard, Roland and Griffin articles discussed in the preceding paragraphs above.

33. Defendants have also failed to test, research, investigate, advise and warn patients and physicians of information to potentially manage intracranial meningiomas upon their diagnosis with use of mifepristone, an antiprogesterone agent, which reportedly stops or reverses the growth of intracranial meningiomas.[6]

34. Defendants have never filed a Changes Being Effected (CBE) supplement to the FDA which allows them to make changes to Depo-Provera's label without prior approval to reflect newly acquired information to strengthen the label.

35. Defendants failed to adequately test Depo-Provera to research, investigate, document, and advise physicians and patients of the hazards, risks and dangers of the development of intracranial meningioma following use of the drug.

PLAINTIFF'S USE OF DEPO-PROVERA

36. Plaintiff, Ashley Smith, received injections of Depo-Provera from 2000 to 2012 and again from 2014 to September, 2015 from clinics around Jefferson, Wisconsin, receiving injections approximately every 10 weeks during that timeframe.

37. At the time of her injections with Depo-Provera, the Defendants represented Depo-Provera to be a safe and effective contraceptive, with no representations that Depo-Provera could or would cause meningioma.

38. At the time of her injections, Plaintiff was never advised that Depo-Provera could or would cause meningiomas in any form. Had she been advised and/or warned of the increased risk of meningiomas from the use of Depo-Provera, she would not have taken the injections.

[6] See Cossu et al. "The Role of Mifepristone in Meningiomas Management: A Systematic Review of the Literature" *BioMed Res. Int*. 267831 (2015).

39. In 2009, Plaintiff experienced migraines and headaches. In 2009, Plaintiff was referred to Dean Health in Fort Atkinson, Wisconsin. CT scans and MRI scans indicated that she had a meningioma in the left frontal parietal region of her brain.

40. Subsequent exams as a result of her worsening condition in October, 2024 confirmed her meningioma.

41. Plaintiff still suffers from headaches, cognitive loss, and pain. Plaintiff must continue to monitor the meningioma and is required to undergo MRI procedures to monitor the same every six months for the rest of her life.

42. Only after Plaintiff no longer required the injections did she learn of the association between Depo-Provera and intracranial meningioma.

43. Plaintiff's diagnosis of meningioma consists of a latent disease such that any statute of repose is inapplicable pursuant to Wis.Stat. § 895.047(5).

COUNT I

NEGLIGENCE AND NEGLIGENT FAILURE TO WARN

44. Plaintiff incorporates, reasserts and realleges the allegations set forth above as if fully set forth herein below.

45. Defendants negligently promoted, sold, allowed to be sold and marketed Depo-Provera as being safe for patients including Plaintiff.

46. The Depo-Provera was negligently designed and/or manufactured and/or marketed in violation of federal regulations, various state statutes and common law.

47. Defendants also failed to train physicians in how to use Depo-Provera, because they failed to alert and warn physicians of the dangers of Depo-Provera, specifically the dangers of meningioma. Because of this, Defendants failed to provide any instructions whatsoever that would alert physicians to recommend and use other contraceptives, even though it actively promoted and marketed Depo-Provera for use through its sales representatives.

48. Defendants breached their duties of reasonable care to Plaintiff by the actions detailed above, including, but not limited to, failing to warn Plaintiff and the

medical community of the true risks of Depo-Provera, misrepresenting the true safety of Depo-Provera, failing to update the medical community and patients when it learned or discovered new information about the risks and safety of Depo-Provera, and otherwise failing to update its labeling, Instructions for Use or the chemical composition in a timely manner.

49. Defendants' breach of their duties caused Plaintiff's injuries.

50. Depo-Provera was distributed and/or manufactured in violation of regulations specifically designed to protect patients against the type of harm Plaintiff suffered.

51. Defendants consistently under-reported and withheld information about the likelihood of meningioma after use of Depo-Provera, and have misrepresented the efficacy and safety of Depo-Provera, actively misleading the medical community, patients, the public at large, and Plaintiff.

52. Defendants knew, and continue to know, that their disclosures to the public and Plaintiff were and are incomplete and misleading; and that Defendants' Depo-Provera were and are causing numerous patients severe injuries and complications. Defendants suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the medical community, health care providers, and patients.

53. As a result, Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers, and patients, into believing that Depo-Provera was safe and effective, leading to the prescription for and injection into patients such as Plaintiff.

54. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of Depo-Provera. As compared to other alternatives, feasible and suitable alternative designs, procedures, and contraceptives have existed at all times relevant.

55. The Depo-Provera was used and injected in a manner foreseeable to Defendants. Defendants failed to warn and provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing Depo-Provera, thereby increasing the sales of the products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

56. Subsequently, injecting Depo-Provera into Plaintiff caused and/or contributed to the severe and permanent injuries sustained and endured by Plaintiff. As a direct and proximate result, Plaintiff endured pain and suffering and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; both past and future wage loss; both past and future non-economic damages including, but not limited to physical and mental pain and suffering, inconvenience, emotional distress and impairment of the quality of her life; and permanent impairment and disfigurement.

57. Under Wisconsin law, Defendants owed a foreseeable, legal duty to Plaintiff to comply with the regulations and laws governing pharmaceutical drugs and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty was the actual and proximate cause of the Plaintiff's injuries as described herein.

58. Under Wisconsin law, Defendants' violations of federal statutes and regulations establish a *prima facie* case of negligence.

59. Wisconsin law treats violations of federal statutes and regulations, among other things, as evidence of common law negligence.

60. Defendants undertook a duty to comply with the terms of the NDA and update its labels and warnings pursuant to 21 C.F.R. § 201.80 and 21 C.F.R. § 314.70 among others, but failed to comply with these provisions.

61. In addition to the details set forth above, upon information and belief, Defendants breached their duties by:

a. failing to correctly monitor its products to ensure that it complied with appropriate quality control procedures and to track nonconforming products;

b. failing to conduct regular risk analysis of Depo-Provera, including failing to include and consider known complications from the drug as part of its risk analysis processes and failing to exercise appropriate post-market quality controls;

c. failing to provide the FDA with timely post-approval reports pursuant to its schedules for the NDA;

d. failing to comply with applicable federal and state regulations;

e. failing to monitor the sale and use of Depo-Provera; discover defects associated with its use; and warn the government, doctors, and users about those defects;

f. failing to adequately train Defendants' employees and sales representatives who provided recommendations and advice to physicians who performed injections into patients;

g. failing to provide truthful and accurate information in its voluntary statements to the medical community outside the labeling;

h. failing to update the medical community as it learned of new or additional risks;

i. failing to update the medical community with information about the real- world risks of developing meningiomas after injection of Depo-Provera;

j. failing to properly train and educate physicians on the use and correct dosage of Depo-Provera. Defendants accepted a duty even to the Plaintiff's physicians to train them to correctly select the right dosage.

62. These simple common law negligence duties are parallel to the duties under federal law, and are not preempted by any federal law.

63. Defendants's breach of these duties caused Plaintiff's injuries.

64. Defendants for years made voluntary statements outside the labeling and directly to physicians and patients, including Plaintiff, that Depo-Provera was safe. This message was delivered explicitly and implicitly, was designed to convey that the product was safe, went beyond mere descriptive puffery and was a material factor in patients choosing Depo-Provera and/or choosing to agree to their doctor's recommendation (which was also secured by Defendants through false and misleading representations beyond the FDA-approved labeling) to undergo injection with Depo-Provera.

65. Had Defendants been truthful in their statements to patients, and included material information, patients would not have chosen Depo-Provera and would have chosen a safer option for their contraception.

66. Plaintiff and/or Plaintiff's physicians did in fact reasonably rely on Defendants' negligent misrepresentations, as Defendants intended. Specifically, Plaintiff would have never used Depo-Provera had they been aware of the falsity of the representations.

67. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

68. Had Defendants exercised ordinary care, and complied with the then existing standards of care, Plaintiff would not have been injured.

69. As a direct and proximate result of Defendants' aforementioned actions, Plaintiff was injured by Depo-Provera.

COUNT II

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

70. Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

71. Defendants' Depo-Provera was defective and unreasonably dangerous when it left the control of the Defendant in that it contained warnings inadequate to alert consumers, including Plaintiff, of the dangerous risks and reactions associated with use of the product, including but not limited to the risks of developing serious and dangerous side effects, intracranial meningioma, as well as the need for additional resection surgeries notwithstanding Defendant's knowledge of an increased risk of these injuries and side effects over other contraceptives.

72. Defendants' Depo-Provera reached the Plaintiff, without substantial change in the condition in which it was sold.

73. At the time of Plaintiff's use of Depo-Provera, Plaintiff used it in a manner and purpose for which it was normally intended.

74. Plaintiff could not, by the exercise of reasonable care, have discovered the defects herein mentioned and perceived their danger.

75. Defendant, as manufacturer and/or distributor of Depo-Provera could have discovered the defects herein mentioned and perceived their danger.

76. Defendant, as manufacturer and distributor of Depo-Provera are held to the level of knowledge of an expert in the field.

77. The warnings that were given by the Defendant were inadequate and were not accurate, clear and/or were ambiguous.

78. The warnings that were given by the Defendant failed to properly warn physicians of the increased risks, subjecting Plaintiff to risks that exceeded the benefits of Depo-Provera, including but not limited to the dangerous risks and reactions associated with use of the product, including but not limited to the risks of developing serious and dangerous side effects, meningiomas, as well as the need for additional resection surgeries notwithstanding Defendant's knowledge of an increased risk of these injuries and side effects over other contraceptives.

79. The above described harm could have been reduced or avoided by the provision of reasonable instructions or warnings by the Defendant and the omission of proper instructions or warnings rendered Depo-Provera not reasonably safe.

80. Plaintiff, individually and through Plaintiff's physician, reasonably relied upon the skill, superior knowledge, and judgment of the Defendant.

81. Defendant had a continuing duty to warn Plaintiff of the dangers associated with the use of Depo-Provera.

82. Had Plaintiff received adequate warnings of the risks of the use of Depo-Provera, Plaintiff would not have allowed use of the product in her surgery.

83. In failing to properly warn the Plaintiff and her surgeon of the risks of using Depo-Provera, the Defendants violated Wis. Stat. § 895.047.

84. As a direct and proximate result of Defendant's failure to warn and Plaintiff's subsequent use of Depo-Provera, and Plaintiff's reliance on Defendant's representations, Plaintiff suffered serious physical injury, harm, damages and economic loss, and will continue to suffer such harm, damages and economic loss in the future.

85. Defendant's actions and omissions as alleged in this Complaint demonstrate a malicious and/or intentional disregard for the rights of the Plaintiff, which warrants the imposition of punitive damages.

86. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

COUNT III

NEGLIGENT MISREPRESENTATION

87. Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

88. Defendants had a duty to accurately and truthfully represent to the medical community, Plaintiff, and the public that Depo-Provera had not been adequately tested

and found to be safe and effective. Instead, the representations made by Defendants were false.

89. Defendants also had a duty under the law of Wisconsin and a parallel federal duty as described above to accurately and truthfully represent to the FDA, the medical community, Plaintiff, and the public the facts about the safety of Depo-Provera. Instead, the representations made by Defendants were false, misleading, omitted material information or otherwise left a false impression about the safety of Depo-Provera.

90. Defendants consistently under-reported and withheld information about the likelihood of Depo-Provera to cause meningioma, and has misrepresented the efficacy and safety of the same products, actively misleading the FDA, medical community, patients, the public at large, and Plaintiff.

91. Defendants negligently misrepresented to the medical community, Plaintiff, and the public that Depo-Provera did not have a high risk of dangerous adverse side effects such as meningioma. Defendant made this misrepresentation by consistently underreporting adverse events for Depo-Provera, delaying reporting of adverse events, not reporting adverse events, and promoting Depo-Provera as if it were a safe and effective contraceptive.

92. Had Defendant accurately and truthfully represented to the medical community, Plaintiff, and the public the material facts relating to the risks of Depo-Provera, Plaintiff and/or Plaintiff's healthcare providers would not have used Depo-Provera for Plaintiff's treatment.

93. Defendants effectively deceived and misled the scientific and medical communities and consumers regarding the risks and benefits of Depo-Provera by intentionally and surreptitiously marketing Depo-Provera as being safe and effective, despite knowledge of the hazards of Depo-Provera.

94. Defendants, through its voluntary statements made outside the labeling, negligently misled and continue to mislead the public, including the medical

community, health care providers, and patients, into believing that the products were and are safe and effective, leading to the prescription for and injection of the products into patients such as Plaintiff.

95. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of Depo-Provera. Feasible and suitable alternative designs, procedures, for injection and treatment for contraception and similar other conditions have existed at all times relevant.

96. Defendants' drug was at all times utilized and injected in a foreseeable manner. Defendants failed to warn and provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the products, thereby increasing the sales of Depo-Provera, and also leading to the dissemination of inadequate and misleading information to patients.

97. Defendants' failure to comply with the above-stated duties for Depo-Provera is evident through the non-exhaustive facts detailed above of malfeasance, misfeasance, and/or nonfeasance on the part of Defendant. Subsequently, Depo-Provera injected in Plaintiff caused meningioma and/or contributed to the severe and permanent injuries sustained and endured by Plaintiff. As a direct and proximate result, Plaintiff endured pain and suffering and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; both past and future wage loss; both past and future non-economic damages including, but not limited to, physical and mental pain and suffering, inconvenience, emotional distress and impairment of the quality of her life; and permanent impairment and disfigurement.

98. Plaintiff is pursuing this parallel state common law claim for negligent misrepresentation based upon Defendants' violations of the applicable federal regulations as described above, or based on acts and omissions by Defendants that are not explicitly or impliedly preempted by federal law.

99. Prior to, on, and after the date the drug was injected in Plaintiff, and at all relevant times, Defendants negligently and carelessly represented to Plaintiff, their health care providers, and the general public that certain material facts were true.

100. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff has sustained severe damages and injuries as described elsewhere in this Complaint.

COUNT IV

PUNITIVE DAMAGES

101. Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

102. At all times material hereto, the Defendant knew or should have known that the use of Depo-Provera was dangerous and hazardous to patients, but continued to market and sell Depo-Provera at the expense of health and safety of the public, including Plaintiff, in conscious disregard of Plaintiff's rights.

103. The Defendant's intentional and/or reckless and malicious failure to warn deprived Plaintiff and her physician of necessary information to enable them to weigh the true risks of using the subject product against its benefits.

104. As a direct result of the Defendant's malicious and/or intentional disregard of the Plaintiff's rights, Plaintiff suffered severe and permanent physical injuries as set forth above.

105. The aforesaid conduct of Defendant was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiff thereby entitling Plaintiff to punitive damages in an amount appropriate to punish the Defendant and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against the defendants in an amount to justly compensate the Plaintiff for past and future medical expenses, past and future wage losses, past and future pain and suffering and loss of enjoyment of life; punitive

damages and, for such other relief, legal and equitable, as the Court deems appropriate under the circumstances.

JURY DEMAND

Plaintiff demands a trial by jury of twelve (12) persons.

Dated this 22nd day of April, 2025.

By: */s/ Andrew J. Schwaba*
Andrew J. Schwaba, J.D.
Wisconsin State Bar No: 1021967

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