

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION**

MISTY ALBANESE,

Plaintiff,

vs.

**PFIZER INC., PHARMACIA & UPJOHN
COMPANY, LLC, PHARMACIA LLC,
GREENSTONE LLC, and VIATRIS INC,**

Case No. 25-md-3140

Judge M. Casey Rodgers
Magistrate Judge Hope T. Cannon

Designated Forum: Southern District of
Ohio

**COMPLAINT AND
DEMAND FOR JURY TRIAL**

Plaintiff MISTY ALBANESE, by and through Plaintiff's undersigned counsel, brings this Complaint and Jury Trial Demand seeking judgment against Defendants Pfizer Inc., Pharmacia & Upjohn Company LLC, and Pharmacia LLC (collectively, "Pfizer Defendants"), and Greenstone LLC and Viatris Inc. (collectively, "Greenstone Defendants" and with the Pfizer Defendants, collectively, "Defendants") for personal injuries and sequelae thereto sustained from Defendants' unreasonably dangerous product, the drug depot medroxyprogesterone acetate sold by the Pfizer Defendants under the brand name "Depo-Provera" and, by the Greenstone Defendants as a Depo-Provera authorized generic (in either Brand or authorized generic form, "DMPA").

At all relevant times, Defendants created, designed, assembled, manufactured, constructed, produced, tested, packaged, labeled, marketed, advertised, promoted, made, distributed, supplied, and/or sold DMPA.

INTRODUCTION

1. Plaintiff submits this Complaint to recover damages arising from development of a meningioma and sequelae thereto caused by DMPA.

2. Plaintiff was initially prescribed Depo-Provera for contraception. Plaintiff received injections of DMPA over a period of many years, from her first shot in 1999 through her latest shot

in 2023.

3. During the period of Plaintiff's use of DMPA, the Pfizer Defendants developed, designed, tested, manufactured, labeled, packaged, promoted, advertised, marketed, distributed, and sold DMPA under the brand name Depo-Provera.

4. DMPA a prescription drug used for contraception, among other indications. Depo-Provera is manufactured as an injection to be administered intramuscularly every three (3) months in either the upper arm or buttocks.

5. From 2004-2020, Greenstone, then a subsidiary of Pfizer, was also responsible for development, design, testing, manufacturing, labeling, packaging, promoting, advertising, marketing, distribution, and selling of DMPA as an "authorized generic" version of Depo-Provera. The authorized generic DMPA is identical to Depo-Provera. An authorized generic identical the brand-name drug in all respects other than the name on the label, and is sold under the NDA for the brand name drug.

6. Alternatively, Greenstone distributed Depo-Provera, without using the brand name, that was developed, designed, tested, manufactured, labeled, packaged, promoted, advertised, marketed, and sold by Pfizer.

7. Alternatively, Greenstone was an alter-ego of Pfizer from 2004-2020.

8. Viatrix Inc. is the successor to Greenstone's liabilities.

9. Plaintiff received injections of DMPA manufactured and sold by the Pfizer Defendants and the Greenstone Defendants.

10. Defendants knew or should have knows of the defects and risks of DMPA but nonetheless supplied this dangerously defective product to Plaintiff, and millions of women in the United States and abroad, for more than 30 years without Plaintiff having any knowledge of those defects and risks.

11. As a result of the dangerously defective design of DMPA, Plaintiff's use of DMPA

caused or substantially contributed to the development of a meningioma, a brain tumor.

12. For decades prior to Plaintiff's use of DMPA, Defendants knew or should have known that DMPA, when administered and prescribed as labeled, can cause or substantially contribute to the development of meningiomas.

13. For decades, multiple scientific studies have established that progesterone, its synthetic analogue progestin, and DMPA in particular, cause or substantially contribute to the development of meningioma, a type of brain tumor.

14. Defendants knew or should have known that meningiomas have receptors for female sex hormones, including progesterone, and that use of DMPA poses significant health risks for individuals who have meningioma.

15. Defendants failed to warn or instruct Plaintiff or her prescribing physicians of the defects and risks related to the use of DMPA.

16. As a direct and proximate result of Defendants' wrongful actions and inactions, Plaintiff was injured and suffered damages from Plaintiff's use DMPA.

17. Plaintiff therefore demands trial by jury and judgment against Defendants and requests, among other things, compensatory damages, statutory damages, punitive damages, attorneys' fees, and costs.

PARTIES

18. Plaintiff in this individual action is MISTY ALBANESE, a resident and citizen of Morengo, Ohio.

19. Defendant Pfizer Inc. ("Pfizer") is a corporation organized under Delaware law with its principal place of business at The Spiral, 66 Hudson Boulevard East, New York, NY 10001. Pfizer is a citizen of Delaware and New York for diversity of citizenship purposes.

20. Defendant Pharmacia & Upjohn Company, LLC (Pharmacia & Upjohn") is a Delaware limited liability company with a principal place of business in Kalamazoo, Michigan.

Pharmacia & Upjohn Company LLC has two members: Pharmacia & Upjohn LLC and Anacor Pharmaceuticals, LLC. Pharmacia & Upjohn LLC is a Delaware limited liability company with a principal place of business in Kalamazoo, Michigan. Its sole member is Pharmacia LLC. Pharmacia LLC is a Delaware limited liability company with a principal place of business in New York, New York. Its sole member is Wyeth Holdings LLC. Wyeth Holdings LLC is a Maine limited liability company with its principal place of business in New York, New York. Its sole member is Anacor Pharmaceuticals, LLC. Anacor Pharmaceuticals, LLC is a Delaware limited liability company with a principal place of business in New York, New York. Its sole member is Pfizer MAP Holding, Inc. Pfizer MAP Holding, Inc. is organized under Delaware law and has a principal place of business in New York, New York. Pfizer is the ultimate parent of the limited liability company Pharmacia & Upjohn. Pharmacia & Upjohn is a citizen of New York and Delaware for diversity of citizenship purposes.

21. Defendant Pharmacia LLC is a Delaware limited liability company with a principal place of business in New York, New York. Its sole member is Wyeth Holdings LLC. Wyeth Holdings LLC is a Maine limited liability company with its principal place of business in New York, New York. Its sole member is Anacor Pharmaceuticals, LLC. Anacor Pharmaceuticals, LLC is a Delaware limited liability company with a principal place of business in New York, New York. Its sole member is Pfizer MAP Holding, Inc. Pfizer MAP Holding, Inc. is organized under Delaware law and has a principal place of business in New York, New York. Pharmacia's ultimate parent is Pfizer. For diversity of citizenship purposes, Pharmacia is a citizen of Delaware and New York.

22. Defendant Greenstone, LLC ("Greenstone") is a limited liability company organized under the law of Delaware. Greenstone LLC has one member, Upjohn US 2 LLC, a limited liability company organized under the law of Delaware. Upjohn US 2 LLC has one member Upjohn US Holdings Inc., which is a corporation organized and existing under the law of Delaware with its principal place of business in Pennsylvania. Starting in 2020, the ultimate parent of Greenstone has

been Viatrix. Prior to 2020, Pfizer was the ultimate parent of Greenstone. For diversity of citizenship purposes, Greenstone is a citizen of Delaware and Pennsylvania.

23. Defendant Viatrix Inc. (“Viatrix”) is a corporation organized under Delaware law with its principal place of business at 1000 Mylan Boulevard, Canonsburg, PA 15317. For diversity of citizenship purposes, Viatrix is a citizen of Delaware and Pennsylvania.

JURISDICTION AND VENUE

24. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a).

25. Plaintiffs alleges the existence of subject matter jurisdiction, and absent any objection, there is complete diversity among Plaintiff and Defendants, and the amount in controversy exceeds \$75,000, exclusive of interest and costs.

26. A substantial part of the events, actions, or omissions giving rise to Plaintiff’s cause(s) of action occurred in the Southern District of Ohio, the forum where Plaintiff initially filed her complaint.

27. Venue is proper in the Southern District of Ohio pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim, including the distribution, sale and administration of DMPA to Plaintiff and Plaintiff’s development and treatment of meningioma, all occurred in the Southern District of Ohio.

28. Defendants have significant contacts with the Southern District of Ohio and regularly conduct business in Ohio, the location where Plaintiff was prescribed and administered DMPA and diagnosed with a meningioma, such that Defendants are subject to the personal jurisdiction of the courts in that district.

29. Specifically, Defendants engaged in the following contacts in each of the Ohio:

- a. conducted business in the state;
- b. regularly solicited business in the state;
- c. specifically transacted and conducted business with respect to DMPA in the state;

- d. targeted physicians and health care providers in that district for the marketing, sale, and use of DMPA to be given to patients within the state;
- e. engaged in substantial and continuing contact with the state;
- f. derived substantial revenue from goods used and consumed within the state;
- g. purposefully directed their business activities, particularly with respect to DMPA to the state;
- h. purposely placed DMPA into the stream of commerce in the state;
- i. expected or reasonably should have expected that DMPA would reach the state
- j. anticipated or reasonably should have anticipated that DMPA would reach the state and be prescribed to and used by individuals in the state;
- k. engaged in a persistent course of conduct in the state with respect to DMPA;
- l. committed a tort in whole or in part in the state;
- m. reasonably expected or should have expected their acts to have consequences within the state; and/or
- n. intended to serve the market of that state and therefore purposely availed themselves of jurisdiction there.

FACTUAL ALLEGATIONS

Defendants' development of DMPA

30. Depo-Provera or DMPA is a 150 mg/mL dosage of depot medroxyprogesterone that is injected every three (3) months into the deep tissue musculature of either the buttocks or the upper arm, with present labelling recommending alternating the injection site at each injection.

31. DMPA is administered as a contraceptive injection that contains a high dose of progestin, a synthetic progesterone-like hormone that suppresses ovulation.

32. Depo-Provera was first developed by Upjohn (later acquired by Pfizer) in the 1950s.

33. Upjohn introduced Depo-Provera as an injectable intramuscular formulation for the

treatment of endometrial and renal cancer in 1960.

34. The New Drug Application (“NDA”) for DMPA for use as a contraceptive was originally submitted to the FDA by Upjohn in 1967; however, this application was rejected.

35. Upjohn again unsuccessfully applied to the FDA for approval to market DMPA for contraceptive use in both 1978 and 1983.

36. As early as 1969, Upjohn successfully received approval for DMPA for contraception in international markets, including France.

37. Upjohn’s NDA for DMPA for use as a contraceptive was eventually approved by the FDA on or about October 29, 1992.

38. Upjohn merged with Swedish manufacturer Pharmacia AB to form Pharmacia & Upjohn in 1995.

39. Pfizer acquired Pharmacia & Upjohn in 2002, thereby acquiring the DMPA NDA as well as the associated responsibilities and liabilities stemming from the manufacturing, sale, and marketing of DMPA.

40. Pfizer has effectively held the DMPA NDA since acquiring Pharmacia & Upjohn in 2002.

41. Under the NDA, the Pfizer Defendants created, designed, assembled, manufactured, constructed, produced, tested, packaged, labeled, marketed, advertised, promoted, made, distributed, supplied, and/or sold DMPA.

42. Greenstone, founded in 1993, was a wholly owned subsidiary of Pfizer, that from 2004 until 2020 distributed “authorized generic” medicines, including an authorized generic of Depo-Provera.

43. From 2004-2020, Greenstone also was responsible for development, design, testing, manufacturing, labeling, packaging, promoting, advertising, marketing, distribution, and selling of DMPA as an “authorized generic” version of Depo-Provera. The authorized generic DMPA is

identical to Depo-Provera and is sold pursuant to the same NDA.

44. Alternatively, Greenstone distributed DMPA that was otherwise developed, designed, tested, manufactured, labeled, packaged, promoted, advertised, marketed, and sold by Pfizer.

45. Intellectual property challenges in the early 2000s to Pfizer's portfolio of brand name pharmaceuticals including Depo-Provera presented a "watershed moment at Pfizer by setting [Pfizer's] new Greenstone generic strategy into play."¹ Pfizer began to utilize Greenstone as part of its patent protection tactics, with the company president at the time stating: "[B]eing able to launch our own Pfizer quality Greenstone generic let's [sic] us continue our market presence in the face of generic competition."²

46. Pfizer executives stated in 2004 it was not just Greenstone's precise brand-name chemical formulation of its authorized generics that would remain identical to Pfizer's, but every facet of Pfizer's business operations, from manufacture to sale: "By Pfizer quality I mean not just the medication itself, but our reliable supply chain, our organizational ability to support our medicine both branded and generic."³

47. Pharmacia & Upjohn was a wholly owned subsidiary of Pfizer from 2002 until 2020.

48. In 2020 Upjohn and Greenstone were spun off from Pfizer in a merger with a company called Mylan Laboratories. The entity created by the merger of Mylan with Upjohn and Greenstone is Viatris. The Pharmacia was retained by Pfizer.

49. As a result of the merger, Viatris is the successor to all Greenstone liabilities from its time as direct subsidiary, and totally dominated department, of Pfizer.

50. Even after the merger, Defendant Greenstone has continued to rely on Pfizer for

¹ Pfizer Analyst Meeting Transcript, *Fair Disclosure Wire* (Nov. 30, 2004), at 6.

² *Id.*

³ *Id.*

operational needs.

Greenstone Is An Alter Ego of Pfizer

51. Alternatively, Greenstone was an alter-ego of Pfizer from 2004-2020. Greenstone is a company that until November 2020 was styled as a wholly owned subsidiary of Pfizer but was in fact exclusively staffed with Pfizer personnel who reported to Pfizer's HR department, were on Pfizer's payroll, and shared the same corporate space with Pfizer in Peapack, NJ. Pfizer also managed Greenstone's key business functions, including financial and sales analysis, business technology, customer service, legal matters, intellectual property, and supply chain operations. Thus, Greenstone was effectively a department within Pfizer. In other words, Greenstone was an alter ego for Pfizer until it was spun off in November 2020. Even after the Viatris spin-off, Greenstone has continued to operate from the same location at Pfizer's corporate offices in Peapack, NJ

The Dangers of DMPA

52. DMPA is associated with an increase in the growth and development of meningiomas, a central nervous system tumor. The association becomes stronger with longer duration of DMPA use.

53. The association between progesterone and meningioma has been known or knowable for decades, particularly for sophisticated pharmaceutical corporations like Defendants.

54. Defendants are required to engage in post-market surveillance of their products for potential safety issues. That duty includes an obligation to keep current with emerging relevant literature and where appropriate, perform their own long-term studies and follow-up research.

55. Since at least 1983, the medical and scientific communities have been aware of the high number of progesterone receptors on meningioma cells, especially relative to estrogen

receptors.⁴

56. This finding was surprising and notable within the medical and scientific communities because it had previously been thought that meningioma cells, like breast cancer cells, would show a preference for estrogen receptors.⁵ Researchers publishing in the *European Journal of Cancer and Clinical Oncology* instead found the opposite, indicating progesterone was involved in the incidence, mediation, and growth rate of meningiomas.⁶ Defendants at all times failed to adequately investigate the effect of their high-dose progesterone Depo-Provera on the development of meningioma.

57. Since at least as early as 1989, studies have shown the relationship between progesterone-inhibiting agents and the growth rate of meningioma.⁷ That year, a study published in the *Journal of Steroid Biochemistry* entitled, “Effect of steroids and antisteroids on human meningioma cells in primary culture,” concluded that meningioma cell growth was significantly reduced by exposure to mifepristone, an antiprogesterone agent.⁸

58. Numerous studies published in the decades since have presented similar findings on the negative correlation between progesterone-inhibiting agents and meningioma.⁹

⁴ See Blankenstein, et al., “Presence of progesterone receptors and absence of oestrogen receptors in human intracranial meningioma cytosols,” *Eur J Cancer & Clin Oncol*, Vol. 19, No. 3, pp. 365-70 (1983).

⁵ See *id.*

⁶ See *id.*

⁷ See 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).

⁸ See *id.*

⁹ See, e.g., Grunberg, et al., “Treatment of unresectable meningiomas with the antiprogesterone agent mifepristone,” *J Neurosurgery*, Vol. 74, No. 6, pp. 861-66 (1991); see also Matsuda, et al., “Antitumor effects of antiprogesterones on human meningioma cells in vitro and in vivo,” *J Neurosurgery*, Vol. 80, No. 3, pp. 527-34 (1994).

59. Relatedly, a number of studies published in have reported on the positive correlation between a progesterone and/or progestin medication and the incidence and growth rate of meningioma.¹⁰

What Is A Meningioma

60. An intracranial meningioma is a medical condition in which a tumor forms in the meninges, the membranous layers surrounding the brain and spinal cord.

61. Although the tumor formed by an intracranial meningioma is typically histologically benign (meaning it usually does not metastasize), the growing tumor can nevertheless press against the sensitive surrounding tissues, i.e., the brain, and thereby cause a number of severe and debilitating symptoms ranging from seizures and vision problems to weakness, difficulty speaking, and even death, among others. Moreover, a sizeable number of meningiomas (15-20%) do become metastatic, greatly increasing their danger.

62. Treatment of a symptomatic intracranial meningioma typically requires highly invasive brain surgery that involves the removal of a portion of the skull, i.e., a craniotomy, in order to access the brain and meninges. Radiation therapy and chemotherapy may also be required as the sensitive location of the tumor in the brain can render complete removal highly risky and technically difficult.

63. Due to the sensitive location of an intracranial meningioma immediately proximate to critical neurovascular structures and the cortical area, surgery can have severe neurological consequences. Many studies have described the potential for postoperative anxiety and depression

¹⁰ See, e.g., 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, pp. 965-68 (2011); see also Bernat, et al., “Growth stabilization and regression of meningiomas after discontinuation of cyproterone acetate: a case series of 12 patients,” *Acta Neurochir (Wien)*. Vol. 157, No. 10, pp. 1741-46 (2015); see also Kalamarides, et al., “Dramatic shrinkage with reduced vascularization of large meningiomas after cessation of progestin treatment,” *World Neurosurg*. Vol. 101, pp 814.e7-e10 (2017).

and an attendant high intake of sedatives and antidepressants in the postoperative period. Surgery for intracranial meningioma can also lead to seizures requiring medication to treat epilepsy. Moreover, meningiomas related to progesterone-based contraceptives tend to manifest at the base of the skull where removal is even more challenging, further increasing the risks of injuries.

Defendants Knew Or Should Have Known Of Meningioma Risk

64. At all relevant times, Defendants had the ability to add warnings to the DMPA products sold pursuant to the DMPA NDA, including authorized generic versions of DMPA sold by Greenstone.

65. Throughout the time Defendants marketed Depo-Provera, Defendants failed to provide adequate warnings to patients and the medical community, including Plaintiff's prescribing physicians, of the risks associated with using the drug.

66. Defendants also failed to adequately test Depo-Provera to investigate the potential for meningioma.

67. Defendants are also liable for the conduct of their predecessors who failed to adequately design, test, and warn of the dangers associated with use DMPA.

68. In 2015, a retrospective literature review published in the peer-reviewed journal *BioMed Research International* by Cossu, et al. surveyed the relevant literature including many of the studies cited above and concluded that mifepristone, an antiprogesterone agent, had a regressive effect on meningioma, meaning it stopped or reversed its growth.¹¹ Reviewing the Blankenstein studies as well as many others conducted over a span of more than 30 years, the authors concluded that mifepristone competes with progesterone for its receptors on meningioma cells and, by blocking progesterone from binding, stems or even reverses the growth of

¹¹ See Cossu et al., "The Role of Mifepristone in Meningiomas Management: A Systematic Review of the Literature" *BioMed Res. Int.* 267831 (2015), <https://doi.org/10.1155/2015/267831>

meningioma.

69. In light of these studies, and the science known for several decades, the Defendants had an unassignable duty to investigate the foreseeable potential that synthetic progesterone could cause the development or substantially contribute to the growth of meningioma.

70. Defendants had an ongoing duty to warn, and to ensure that warning remain adequate as long as DMPA remains on the market. Defendants were obligated to and also best positioned to perform investigations into the risks of meningioma associated with DMPA.

71. Had Defendants conducted proper investigations, they would have discovered decades ago that their high dose progestin DMPA was associated with a highly increased risk of meningioma and would have spared Plaintiff and countless others the pain and suffering associated with meningioma. Instead, Defendants did nothing, and therefore willfully failed to apprise the medical community, and the women patients receiving quarterly high dose injections, of this dangerous risk.

72. Indeed, many researchers have found that prolonged use (greater than one year) of progesterone and progestin, and specifically DMPA, is linked to a greater incidence of developing intracranial meningioma, as would be expected based on all the aforementioned studies and recognition of the relationship between dose and duration of use and the development of adverse events well recognized in the fields of pharmacology, toxicology, and medicine.

73. In 2023, researchers reported on a direct link between DMPA and meningioma. That year a case series was published in the *Journal of Neurological Surgery Part B: Skull Base* titled “Skull Base Meningiomas as Part of a Novel Meningioma Syndrome Associated with Chronic Depot Medroxyprogesterone Acetate Use.”¹² The abstract reported on 25 individuals who

¹² 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).

developed one or more intracranial meningiomas related to chronic use of DMPA. Of the 25 patients, 10 were instructed to cease Depo-Provera use, after which 5 of those patients had “clear evidence of tumor shrinkage,” leading the authors to conclude “there appears to be a clear progestin meningioma syndrome associated with chronic DMPA use.”

74. Solidifying the findings of prior studies, in 2024, the French National Agency for Medicines and Health Products Safety along with several French neurosurgeons, epidemiologist, clinicians, and researchers published a large case control study in the *British Medical Journal* (*BMJ*), one of the premier scientific journals in the world, to assess the risk of intracranial meningioma with the use of numerous progestogens among women in France, hereinafter referred to as the *Roland* study.¹³

75. By way of history, the *Roland* study noted that concerns over meningiomas associated with high dose progestogen medications resulted in the recent discontinuation of three such medications in France and the EU. Specifically, there were “postponements in the prescription of chlormadinone acetate, norgestrel acetate, and cyproterone acetate, following the French and European recommendations to reduce the risk of meningioma attributable to these progestogens in 2018 and 2019.”¹⁴

76. The study analyzed 18,061 cases of women undergoing surgery for intracranial meningioma between 2009 and 2018. The study found that “prolonged use of ... medroxyprogesterone acetate [DMPA] ... was found to increase the risk of intracranial meningioma.” Specifically, the authors found that prolonged use of DMPA resulted in a 555 times increased risk of developing intracranial meningioma. The study authors concluded “[t]he

¹³ Roland, et al., “Use of progestogens and the risk of intracranial meningioma: national case-control study,” *BMJ*, Vol. 384, published online Mar. 27, 2024 at <https://doi.org/10.1136/bmj-2023-078078>.

¹⁴ See *id.*

increased risk associated with the use of injectable medroxyprogesterone acetate, a widely used contraceptive,” was an important finding.

77. The authors also noted DMPA is “often administered to vulnerable populations,” i.e., lower-income women who have no other choice but to take the subsidized option which only requires action every three months to remain effective for its intended use of preventing pregnancy.

78. The 2024 *Roland* study published in *BMJ* studied the effect of several other progestogen-based medications. Three study subjects showed no excess risk of intracranial meningioma surgery with exposure to oral or intravaginal progesterone or percutaneous progesterone, dydrogesterone or spironolactone, while no conclusions could be drawn for two others due to lack of exposed cases. The other medications, including medroxyprogesterone acetate (DMPA), were found to be associated with an increased risk of intracranial meningioma, with DMPA having by far the second highest increased risk, surpassed only by the product cyproterone acetate, which had already been withdrawn from the market due to its association with meningioma.

79. DMPA had by far the highest risk of meningioma surgeries amongst progesterone contraceptive products studied, rendering Depo-Provera more dangerous than other drugs and treatment options designed to prevent pregnancy due to the unreasonably increased risk of injury associated with intracranial meningioma, including but not limited to seizures, vision problems, and even death.

80. Since 1992, Defendants knew or should have known of the potential impact of DMPA to contribute to the development of intracranial meningioma but failed to adequately study these adverse effects.

Defendants’ Ability To Warn

81. According to the Drugs@FDA website, the label for DMPA has been updated on at

least thirteen (13) occasions since 2003, with the most recent update coming in July 2024.¹⁵

82. Nothing was or is stopping Defendants from warning about the risk of meningioma associated with DMPA use.

83. Defendants could have at any time added warnings about the risk of meningioma associated with DMPA to the label of Brand Depo-Provera and authorized generic versions of DMPA.

84. Pfizer has changed the label in the EU and the UK and potentially in other countries. Specifically, Pfizer's DMPA label in the EU now contains the following addition under the section titled "**Special warnings and precautions for use**": "Meningioma: Meningiomas have been reported following long term administration of progestogens, including medroxyprogesterone acetate. [DMPA] should be discontinued if a meningioma is diagnosed. Caution is advised when recommending [DMPA] to patients with a history of meningioma."

85. Additionally, Defendants' Package Leaflet in the EU which provides information for the patient states that "before using [DMPA]... it is important to tell your doctor or healthcare professional if you have, or have ever had in the past ... a meningioma (a usually benign tumor that forms in the layers of tissue that cover your brain and spinal cord)."

86. The Pfizer Defendants could have provided warnings and instructions for use the to have addressed the unreasonable dangers posed by DMPA in the absence of adequate warnings and instructions.

87. It was possible for the Pfizer Defendants to comply both with FDA regulations and the state law product liability claims raised by Plaintiff in this Complaint.

88. It was also possible for Greenstone to provide adequate warnings and instructions for DMPA. Alternatively, the Pfizer defendants are liable for Greenstone's failure to warn because

¹⁵ See Drugs@FDA:FDA-Approved Drugs- Depo-Provera, <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020246> (last visited Apr. 29, 2024).

Greenstone acted merely as a distributor of Pfizer manufactured DMPA.

89. Defendants have ignored reports from patients and health care providers throughout the United States which indicated that DMPA failed to perform as intended.

90. Defendants also knew or should have known of the effects associated with long term use of DMPA, which led to the severe and debilitating injuries suffered by Plaintiff and numerous other patients. Rather than conducting adequate testing to determine the cause of these injuries for which it had notice or rule out DMPA's design as the cause of the injuries, Defendants continued to falsely and misleadingly market DMPA as a safe and effective prescription drug for contraception and other indications.

Defendants Failed To Warn Of Meningioma Risk

91. Defendants have failed to warn about the risks of meningioma associate with DMPA use.

92. The FDA would not have rejected any and all warnings that would have satisfied state law.

93. Defendants' labels have not contained any warning or any information whatsoever on the increased propensity of Depo- Provera to cause severe and debilitating intracranial meningioma like that suffered by Plaintiff.

94. Despite the aforementioned article in the *BMJ* and all the preceding medical literature cited above demonstrating the biological plausibility of the association between progesterone and meningioma, evidence of DMPA related cases of meningioma and the evidence of other high dose progesterone causing meningiomas, Defendants have still made no change to the DMPA label related to intracranial meningioma.

95. Defendants have also failed to take any steps to otherwise warn the medical community and DMPA users of these significant health risks.

Depo-SubQ Provera 104

96. Pfizer also developed, manufactures, and sells a drug called Depo-SubQ Provera 104, another form of medroxyprogesterone acetate, for birth control.

97. Depo-SubQ Provera 104 has been FDA-approved since 2004.

98. Defendants could have also instructed physicians and provided warning to physicians and patients that any patient considering DMPA should instead consider Depo-SubQ Provera 104, a lower dose medroxyprogesterone acetate injected subcutaneously instead of the more invasive and painful intramuscular injection method. Studies going back at least ten years have shown that the 150 mg dose of Depo-Provera—when administered subcutaneously, instead of intramuscularly—is absorbed by the body at a similarly slower rate as the lower dose 104 mg Depo-SubQ Provera 104 version.¹⁶ Nevertheless, Defendants never produced a 150 mg subcutaneous version.

99. Knowing that the lower dose 104 mg Depo-SubQ Provera 104 was equally effective and was easier to administer since it involved a smaller needle being injected only below the skin and not all the way into the muscle, Defendants could have educated the gynecology community that it had a safer alternative product to Depo-Provera which was more well known to prescribers and patients.

100. Inexplicably, and presumably for commercially beneficial or contractual reasons, Pfizer made a conscious decision to not actively promote the sale and use of Depo-SubQ Provera 104 to patients seeking contraception, despite knowing it had a lower safer and effective dosage which would mitigate the potential for adverse reactions engendered by a high dose progestin, including the risk of developing or worsening meningioma tumors.

101. The “lowest effective dose” is a well-known concept in the field of pharmaceuticals

¹⁶ See Shelton, et al., “Subcutaneous DPMA: a better low dose approach,” *Contraception*, Vol. 89, pp. 341-43 (2014).

wherein a drug-maker should seek to find the lowest possible dose at which the drug of interest is efficacious for the intended use, as any additional dosage on top of that lowest effective dose is inherently superfluous and can increase the risk of unwanted side effects.

Fraudulent Concealment

102. At all times material hereto, Defendants committed a continuing fraud in obfuscating and failing to disclose facts that were known to them relating to their inadequate testing of the DMPA and defective design of the product—facts that were not discovered and could not have been discovered by any person or Plaintiff undertaking reasonable due diligence.

103. Plaintiff did not and could not have discovered with reasonable diligence the veritable facts regarding Defendants' misrepresentations, omissions, faulty testing, and the defective design of DMPA.

104. Nor could Plaintiff have discovered that Defendants' DMPA caused their meningioma and/or sequelae thereto.

105. Defendants willfully, wantonly, and intentionally conspired, and acted in concert, to withhold information from Plaintiff, Plaintiff's healthcare providers, and the general public concerning the known hazards associated with the use of, and exposure to, DMPA, particularly over extended periods of time.

106. Defendants willfully, wantonly, and intentionally conspired, and acted in concert, to withhold safety-related warnings from the Plaintiff, and the general public concerning the known hazards associated with the use of, and exposure to, DMPA, particularly over extended periods of time.

107. Defendants willfully, wantonly, and intentionally conspired, and acted in concert, to withhold instructions from the Plaintiff, her family members, and the general public concerning how to identify, mitigate, and/or treat known hazards associated with the use of, and exposure to, DMPA, particularly over extended periods of time.

108. The aforementioned studies reveal that discontinuing use of high dose progesterone and progestin, including DMPA, can retard the growth of meningiomas, but failed to warn the medical community and the Plaintiff of this method to mitigate the damage of a developing meningioma.

109. Defendants willfully, wantonly, and intentionally conspired, and acted in concert, to ignore relevant safety concerns and to deliberately not study the long-term safety and efficacy of DMPA, particularly in chronic long-term users of DMPA.

110. Defendants failed to disclose a known defect and, instead, affirmatively misrepresented that DMPA was safe for its intended use.

111. Defendants disseminated labeling, marketing, promotion and/or sales information to Plaintiff, her healthcare providers and prescribers, and the general public regarding the safety of DMPA knowing such information was false, misleading, and/or inadequate to warn of the safety risks associated with long-term DMPA use. Defendants did so willfully, wantonly, and with the intent to prevent the dissemination of information known to them concerning DMPA's risks.

112. Further, Defendants actively concealed the true risks associated with the use of DMPA, particularly as they relate to the risk of serious intracranial meningioma, by affirmatively representing in numerous communications, which were disseminated to Plaintiff, her healthcare providers, and which included, without limitation, the Package Insert and the Medication Guide, that there were no warnings required to safely prescribe and take DMPA and no intracranial meningioma-related adverse side effects associated with use of DMPA.

113. Due to the absence of any warning by the Defendants as to the significant health and safety risks posed by DMPA, Plaintiff was unaware that DMPA could cause the development of a serious and debilitating intracranial meningioma, as this danger was not known to Plaintiff, Plaintiff's healthcare providers, or the general public.

114. Due to the absence of any instructions for how to identify and/or monitor DMPA

patients for potential intracranial meningioma-related complications, Plaintiff was unaware that DMPA could cause serious, intracranial meningioma-related injuries, as this danger was not known to Plaintiff, Plaintiff's healthcare providers, or the general public.

115. Given Defendants' conduct and deliberate actions designed to deceive Plaintiff, Plaintiff's healthcare providers, and the general public, with respect to the safety and efficacy of DMPA, Defendants are estopped from relying on any statute of limitations defenses.

116. Defendants are jointly and severally liable to Plaintiffs for their individual and collective tortious acts.

Plaintiff's Use Of DMPA and Injury

117. Plaintiff was born July 31, 1970.

118. In or around 1999, at the age of 29, Plaintiff was first administered Depo-Provera for contraception. At that time, only brand-DMPA, or Depo-Provera, was available.

119. At all times relevant herein, Defendants represented DMPA to be appropriate, safe, and suitable for such purposes through the label, packaging, patient inserts, and advertising.

120. Plaintiff relied on the Defendants' representations that DMPA was safe and suitable for the use for which she received injections.

121. Plaintiff would not have taken DMPA had she been aware of the risk of meningioma.

122. Plaintiff regularly received DMPA injections starting in 1999 and continuing through 2023.. Her injections were of both branded-DMPA, Depo-Provera, and Greenstone distributed DMPA.

123. Over time, while receiving DMPA injections, Plaintiff developed painful and disturbing symptoms including severe headache and twitching in the arm. An MRI was performed in 2023, and Plaintiff was subsequently diagnosed with a meningioma at the age of 53.

124. In March 2023, Plaintiff underwent a bifrontal craniotomy for resection of the meningioma.

125. Pathology results showed the meningioma was a grade 2 tumor.

126. Despite being diagnosed with a meningioma, because Depo-Provera failed to include any warning about the risks of DMPA to users with meningioma, Plaintiff continued to receive DMPA injections after her meningioma diagnosis.

127. Plaintiff relied on the Defendants' omissions regarding to the risks of DMPA to individuals with meningioma as she continued received injections.

128. As a result of Defendants' actions and inactions, Plaintiff has suffered serious injuries and damages due to Plaintiff's development of an intracranial meningioma, surgery and sequelae related thereto.

129. Plaintiff was unaware until very recently, following publicity associated with a large case control study in France published in March 2024, that Depo-Provera had any connection to her meningioma.

130. Defendants' DMPA was at all times used by Plaintiff and prescribed in a manner foreseeable to Defendants, as Defendants generated the instructions for use for Plaintiff to receive Depo-Provera injections.

131. Plaintiff and Plaintiff's physicians foreseeably used DMPA, and did not misuse or alter DMPA in an unforeseeable manner.

132. Through its affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff and her physicians the true and significant risks associated with DMPA use.

133. As a result of Defendants' actions, Plaintiff and her physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff would be exposed to the risks identified in this Complaint and that those risks were the direct and proximate result of Defendants' conduct.

134. As a direct result of being prescribed and consuming DMPA, Plaintiff has been permanently and severely injured, having suffered serious consequences.

135. As a direct and proximate result of her DMPA use, Plaintiff suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress, along with economic loss including past and future medical expenses.

136. Despite diligent investigation by Plaintiff into the cause of these injuries, including consultations with medical providers, the nature of Plaintiff's injuries and damages and their relationship to DMPA was not discovered, and through reasonable care and diligence could not have been discovered until September 2024.

137. Defendants acted with malice, wanton disregard, and a reckless intent and complete disregard of the safety of Plaintiff and all the other women, many who were young and of lower socioeconomic status, who were subjected to high dose injections of 150 mg DMPA with the known and/or knowable risk of meningioma brain tumors which was generally accepted in the scientific community. New York law should apply and punitive damages are warranted to punish and deter Defendant Pfizer and others from such conduct in the future.

CAUSE OF ACTION
COUNT I
NEGLIGENCE
(Against All Defendants)

138. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

139. Defendants failed to exercise ordinary care in the labeling, design, manufacturing, testing, marketing, distribution and/or sale of Depo-Provera in that Defendants knew or should have known that Depo-Provera created a high risk of unreasonable harm to Plaintiff and other users.

140. Defendants breached its duty of care to the Plaintiff and her physicians, in the testing, monitoring, and pharmacovigilance of Depo-Provera.

141. In disregard of its duty, Defendants committed one or more of the following negligent acts or omissions:

- a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and distributing Depo-Provera without thorough and adequate pre- and post-market testing of the product;
- b. Manufacturing, producing, promoting, advertising, formulating, creating, developing, and designing, and distributing Depo-Provera while recklessly and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of Depo-Provera;
- c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Depo-Provera was safe for its intended use;
- d. Failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendants knew and had reason to know that Depo-Provera was indeed unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users;
- e. Failing to warn Plaintiff, the medical and healthcare community, and consumers of the known and knowable product's risk of harm which was unreasonable and that there were safer and effective

alternative products available to Plaintiff and other consumers;

- f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would use Depo-Provera;
- g. Advertising, marketing, and recommending the use of Depo-Provera, while concealing and failing to disclose or warn of the dangers known and knowable by Defendants to be connected with, and inherent in, the use of Depo-Provera;
- h. Representing that Depo-Provera was safe for its intended use when in fact Defendants knew and should have known the product was not safe for its intended purpose;
- i. Continuing to manufacture and sell Depo-Provera with the knowledge that Depo-Provera was unreasonably unsafe and dangerous;
- j. Failing to use reasonable and prudent care in the design, research, testing, manufacture, and development of Depo-Provera so as to avoid the risk of serious harm associated with the use of Depo-Provera;
- k. Failing to design and manufacture Depo-Provera so as to ensure the drug was at least as safe and effective as other similar products;
- l. Failing to ensure the product was accompanied by proper and accurate warnings about monitoring for potential symptoms related to intracranial meningioma associated with the use of Depo-Provera;
- m. Failing to ensure the product was accompanied by proper and accurate warnings about known and knowable adverse side effects associated with the use of Depo-Provera and that use of Depo-Provera created a high risk of severe injuries;
- n. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Depo-Provera; and
- o. Failing to sell a product with the lowest effective dose knowing that there were safer lower effective dose formulations.

142. A reasonable manufacturer, designer, distributor, promoter, or seller under the same

or similar circumstances would not have engaged in the aforementioned acts and omissions.

143. As a direct and proximate result of the Defendants' reckless and negligent testing, monitoring, and pharmacovigilance of Depo-Provera, Defendants introduced a product that they knew or should have known would cause serious and permanent injuries related to the development of intracranial meningioma, and Plaintiff has been injured tragically and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

144. As a direct and proximate result of one or more of the above-stated reckless acts by Defendants, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of consortium, loss of ability to earn money and other economic losses. The losses are either permanent or continuing, and Plaintiff will suffer losses in the future.

COUNT II
STRICT LIABILITY – FAILURE TO WARN – O.R.C., § 2307.76
(Against All Defendants)

145. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

146. Under Ohio law, a product is defective if the manufacturer fails to give effective warnings of the product's dangers that were known or should have been known, or failed to provide warnings that a manufacturer exercising reasonable care would have provided in light of the likelihood that the product would cause that type of harm.

147. Defendants failed to properly and adequately warn and instruct Plaintiff and her health care providers as to the dangers and risks associated with use of Depo-Provera. Defendants failed to properly package or label their products to give reasonable warnings of danger about

148. Depo-Provera to Plaintiff and her health care providers.

149. Defendants were reckless in their failure to warn Plaintiff and her doctor(s) regarding adverse reactions that were known at the time Plaintiff was prescribed and injected with their Depo-Provera products.

150. Defendants had a duty to warn Plaintiff, Plaintiff's physicians, and consumers of Depo-Provera of the known and/or knowable dangers and serious side effects, including serious and potentially debilitating intracranial meningioma, as it was reasonably foreseeable to Defendants that Depo-Provera could cause such injuries.

151. Defendants, as manufacturers, distributors, and marketers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known based on information that was available and generally accepted in the scientific community that warnings and other clinically relevant information and data which they distributed regarding the risks associated with the use of Depo-Provera were inadequate.

152. As the only manufacturer with the ability under FDA regulations to initiate labeling changes and/or report to the FDA findings, such as those that led to the foreign label changes, Defendants Pfizer, Pharmacia & Upjohn, and Pharmacia had a duty to all users of drugs marketed under the FDA-approved label, including users of generic equivalents.

153. Brand-name manufacturers, like Defendants Pfizer, Pharmacia & Upjohn, and Pharmacia, that control the contents of the label on a generic drug owes a duty to consumers of that generic drug not to act in reckless disregard of an unreasonable risk of death or grave bodily injury. Defendants did, in fact, act with reckless disregard by failing to update the label for Depo-Provera and its generic equivalents to warn about the risk of meningioma with its use.

154. Defendants Viatriis, Greenstone did not provide an adequate warning

regarding the side effects of Depo-Provera at the time Plaintiff was prescribed and injected with the brand-name and generic medication.

155. Defendants acted or intentionally failed to act—in breach of their duty to Plaintiff regarding warning of the risks associated with Depo-Provera—knowing or having reason to know of facts which would lead a reasonable man to realize, not only that his conduct creates an unreasonable risk of physical harm to another, but also that such risk is substantially greater than that which is necessary to make his conduct negligent.

156. Plaintiff and Plaintiff's treating physicians did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information or data was communicated to Plaintiff or to Plaintiff's treating physicians.

157. Defendants had and continue to have a duty to provide adequate warnings and instructions for Depo-Provera, to use reasonable care to design a product that is not unreasonably dangerous to users, and to adequately understand, test, and monitor their product.

158. Defendants had and continue to have a duty to provide consumers, including Plaintiff and Plaintiff's physicians, with warnings and other clinically relevant information and data generally accepted within the scientific community regarding the risks and dangers associated with Depo-Provera, as it became or could have become available to Defendants.

159. At all times material herein, Defendants acted with reckless disregard and knew, or in the exercise of reasonable care should have known, that Depo-Provera had inadequate instructions and/or warnings.

160. Each of the following acts and omissions herein alleged was negligently and carelessly performed by Defendants, resulting in a breach of the duties set forth above. These acts and omissions include, but are not restricted to:

- p. Failing to accompany their product with proper and adequate warnings, labeling, or instructions concerning the potentially dangerous, defective, unsafe, and deleterious propensity of Depo-Provera and of the risks associated with its use, including the severity and potentially irreversible nature of such adverse effects;
- q. Disseminating information to Plaintiff and Plaintiff's physicians that was recklessly and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff;
- r. Failing to provide warnings or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks;
- s. Failing to adequately test and/or warn about the use of Depo-Provera, including, without limitations, the possible adverse side effects and health risks caused by the use of Depo-Provera;
- t. Failure to adequately warn of the risks that Depo-Provera could cause the development of intracranial meningioma and sequelae related thereto;
- u. Failure to adequately warn of the risk of serious and potentially irreversible injuries related to the development of intracranial meningioma, a brain tumor;
- v. Failure to instruct patients, prescribers, and consumers of the need for all monitoring when taking Depo-Provera for symptoms potentially related to the development of intracranial meningioma;
- w. Failure to instruct patients, prescribers, and consumers of the need to discontinue Depo-Provera in the event of symptoms potentially related to the development of intracranial meningioma;
- x. Failing to provide instructions on ways to safely use Depo-Provera to avoid injury, if any;
- y. Failing to explain the mechanism, mode, and types of adverse events associated with Depo-Provera;
- z. Failing to provide adequate training or information to medical care providers for appropriate use of Depo-Provera and patients taking Depo-Provera;
- aa. Representing to physicians, including but not limited to Plaintiff's prescribing physicians, that this drug was safe and effective for use;
- bb. Failing to warn that there is a safer feasible alternative with a lower

effective dose of progestin; and

- cc. Failing to warn that the 150 mg dosage of progestin injected intramuscularly was an excessive and thus toxic dose capable of causing and or substantially contributing to the development and growth of meningioma tumors.

161. Defendants knew or should have known of the risk and danger of serious bodily harm from the use of Depo-Provera but failed to provide an adequate warning to patients and prescribing physicians for the product, including Plaintiff and Plaintiff's prescribing physicians, despite knowing the product could cause serious injury.

162. Plaintiff was prescribed and used Depo-Provera for its intended purpose.

163. Plaintiff could not have known about the dangers and hazards presented by Depo-Provera.

164. The warnings given by Defendants were not accurate, clear, or complete, and/or were ambiguous.

165. The warnings, or lack thereof, that were given by Defendants failed to properly warn prescribing physicians, including Plaintiff's prescribing physician, of the known and knowable risk of serious and potentially irreversible injuries related to the development of intracranial meningioma, and failed to instruct prescribing physicians to test and monitor for the presence of the injuries and to discontinue use when symptoms of meningioma manifest.

166. The warnings that were given by the Defendants failed to properly warn Plaintiff and prescribing physicians of the prevalence of intracranial meningioma and sequelae related thereto.

167. Plaintiff and Plaintiff's prescribing physicians reasonably relied upon the skill, superior knowledge, and judgment of Defendants. Defendants had a continuing duty to warn Plaintiff and prescribing physicians of the dangers associated with Depo-Provera. Had Plaintiff

received adequate warnings regarding the risks of Depo-Provera, Plaintiff would not have used the product.

168. Defendants' reckless disregard for the information disseminated regarding the dosing information, marketing, testing, and warnings of Depo-Provera was a proximate cause of Plaintiff's injuries and damages.

169. The risk of meningioma was reasonably foreseeable at the time of sale and could have been discovered by way of reasonable testing prior to marketing the product. Defendants recklessly failed to conduct such reasonable testing.

170. Defendants intentionally failed to inform the public, including Plaintiff and her implanting surgeon, of the risk of meningioma with use of Depo-Provera.

171. Instead, Defendants chose to over-promote the safety, efficacy, and benefits of the Products.

172. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of Depo-Provera, she would not have purchased, used, consented to, or relied on the information given regarding Depo-Provera.

173. As a direct and proximate result of Defendants' reckless failure to warn, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of consortium, loss of ability to earn money and other economic losses. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

COUNT III
PRODUCTS LIABILITY – DESIGN DEFECT- O.R.C., § 2307.75
(Against Defendants Pfizer, Pharmacia & Upjohn, and Pharmacia)

174. Plaintiff incorporates by reference each and every preceding paragraph as though

fully set forth herein.

175. Under Ohio law, a product is defectively designed if the foreseeable risks associated with its design or formulation exceeded the benefits associated with that designation or formulation, or the product is more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

176. Plaintiff, ordinary consumers, and prescribers would not expect a contraceptive drug designed, marketed, and labeled for contraception to cause intracranial meningioma.

177. The dozens of Depo-Provera injections supplied to Plaintiff by Defendants were defective in design or formulation in that, when it left the hands of the manufacturer or supplier, it had not been adequately tested, was in an unreasonably dangerous and defective condition, provided an excessive dose of progestin for its purpose and posed a risk of serious and potentially debilitating intracranial meningioma to Plaintiff and other consumers.

178. The Depo-Provera supplied to Plaintiff by Defendants was defective in design or formulation in that its effectiveness as a contraceptive did not outweigh the risks of serious and potentially debilitating intracranial meningioma posed by the drug. In light of the utility of the drug and the risk involved in its use, the design of the Depo-Provera drug makes the product unreasonably dangerous.

179. Depo-Provera's design is more dangerous than a reasonably prudent consumer would expect when used in its intended or reasonably foreseeable manner. It was more dangerous than Plaintiff expected and the risks far outweighed the benefits.

180. Feasible and suitable alternative designs have existed at all times relevant as compared to Defendants' 150mg Depo-Provera.

181. Depo-SubQ Provera 104 is a lower dosage version of Depo-Provera that contains

104 mg / 0.65mL and is injected subcutaneously every three (3) months. According to the label, Depo-SubQ Provera 104 can be used for both contraception.

182. Depo-SubQ Provera 104 never attained meaningful market share, and Defendant failed to promote the product to the medical community as a safer and equally effective method of contraception for women choosing to receive quarterly injections.

183. Defendants failed to promote and encourage conversion of the prescribing gynecological community to Depo-SubQ Provera 104, fearing that doing so could instill a concern of safety as to the risks of its high dose progesterone long standing product, Depo-Provera.

184. The intended or actual utility of Depo-Provera is not of such benefits to justify the risk of intracranial meningioma which may cause severe and permanent injuries, thereby rendering the product unreasonably dangerous.

185. The design defects render Depo-Provera more dangerous than other drugs and therapies designed for contraception and causes an unreasonable increased risk of injury, including, but not limited, to potentially debilitating intracranial meningioma and sequelae related thereto.

186. Defendants knew or should have known through testing, generally accepted scientific knowledge, advances in the field, published research in major peer-reviewed journals, or other means, that Depo-Provera created a risk of serious and potentially debilitating intracranial meningioma and sequelae related thereto.

187. Defendants' actions, when viewed objectively from Defendants' standpoint at the time of the occurrence, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants had an actual, subjective awareness of the risk involved but nevertheless intentionally and recklessly proceeded with conscious

indifference to the rights, safety, or welfare of others.

188. Defendants acted or intentionally failed to act—in breach of their duty to Plaintiff regarding designing Depo-Provera in a way that does not render it unreasonably dangerous—knowing or having reason to know of facts which would lead a reasonable man to realize, not only that his conduct creates an unreasonable risk of physical harm to another, but also that such risk is substantially greater than that which is necessary to make his conduct negligent.

189. Each of the following acts and omissions herein alleged was negligently and carelessly performed by Defendants, resulting in a breach of the duties set forth above. These acts and omissions include, but are not restricted to recklessly and carelessly:

- dd. Failing to use due care in developing, testing, designing, and manufacturing Depo-Provera so as to avoid the aforementioned risks to individuals when Depo-Provera was being used for contraception and other indications;
- ee. Failing to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Depo-Provera;
- ff. Designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable use, which Defendants knew or should have known could cause injury to Plaintiff; and
- gg. Failing to use due care in developing, testing, designing, and manufacturing Depo-Provera with the lowest effective dose as a safer alternative which clearly existed at all relevant times so as to avoid the aforementioned risks to individuals when high dose progestin Depo-Provera was being used for contraception.

190. Defendants' recklessness and Depo-Provera's failures arise under circumstances precluding any other reasonable inference other than a defect in Depo-Provera.

191. At all times material herein, Defendants had a duty to exercise reasonable care and had the duty of an expert in all aspects of the design, formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, promotion, advertising, sale, testing,

and research to assure the safety of Depo-Provera when used as intended or in a way that Defendants could reasonably have anticipated, and to assure that the consuming public, including Plaintiff and Plaintiff's physicians, obtained accurate information and adequate instructions for the safe use or non-use of Depo-Provera.

192. At all times material herein, Defendants failed to exercise reasonable care and the duty of an expert and knew, or in the exercise of reasonable care should have known, that Depo-Provera was not properly manufactured, designed, compounded, tested, inspected, packaged, distributed, marketed, advertised, formulated, promoted, examined, maintained, sold, prepared, or a combination of these acts.

193. Defendants' failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Depo-Provera was a proximate cause of Plaintiff's injuries and damages.

194. Defendants' reckless disregard for the design of Depo-Provera was a proximate cause of Plaintiff's injuries and damages.

195. The risk of meningioma was reasonably foreseeable at the time of sale and could have been discovered by way of reasonable testing prior to marketing the product. Defendants recklessly failed to conduct such reasonable testing.

196. As a direct and proximate result of Defendants' negligence, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of consortium, loss of ability to earn money and other economic losses. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

COUNT VI
NEGLIGENT MISREPRESENTATION
(Against All Defendants)

197. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

198. At all relevant times, Defendants negligently provided Plaintiff, her healthcare providers, and the general medical community with false or incorrect information or omitted or failed to disclose material information concerning Depo-Provera, including, but not limited to, misrepresentations regarding the safety and known risks of Depo-Provera.

199. The information distributed by the Defendants to the public, the medical community, Plaintiff, and her Prescribing and Administering Health Care Providers, including advertising campaigns, labeling materials, print advertisements, commercial media, was false and misleading and contained omissions and concealment of truth about the dangers of Depo-Provera.

200. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff and Plaintiff's Prescribing and Administering Health Care Providers; to falsely assure them of the quality of Depo-Provera and induce the public and medical community, including Plaintiff and her Prescribing physicians.

201. The Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, medical device manufacturers, Plaintiff, her Prescribing and Administering Health Care Providers and the public, the known risks of Depo-Provera, including its propensity to cause intracranial meningioma and sequelae related thereto.

202. Defendants made continued omissions in the Depo-Provera labeling, including promoting it as safe and effective while failing to warn of its propensity to cause intracranial meningioma and sequelae related thereto.

203. Defendants made additional misrepresentations beyond the product labeling by representing Depo-Provera as safe and effective for contraception and other indications with only minimal risks.

204. Defendants misrepresented and overstated the benefits of Depo-Provera to Plaintiff, Plaintiff's Prescribing and Administering Health Care Providers, and the medical community without properly advising of the known risks associated with intracranial meningioma and sequelae related thereto.

205. Defendants misrepresented and overstated that the Depo-Provera dosage was needed to protect against pregnancy when Defendants knew that a safer alternative existed with forty-six (46) fewer mg per dose of the powerful progestin being ingested quarterly in women, and when Defendants could have warned and recommended usage of Depo-SubQ Provera 104 instead.

206. In reliance upon the false and negligent misrepresentations and omissions made by the Defendants, Plaintiff and Plaintiff's Prescribing and Administering Health Care Providers were induced to, and did use Depo-Provera, thereby causing Plaintiff to endure severe and permanent injuries.

207. In reliance upon the false and negligent misrepresentations and omissions made by the Defendants, Plaintiff and Plaintiff's Prescribing and Administering Health Care Providers were unable to associate the injuries sustained by Plaintiff with her Depo-Provera use, and therefore unable to provide adequate treatment. Defendants knew or should have known that the Plaintiff, Plaintiff's Prescribing and Administering Health Care Providers, and the general medical community did not have the ability to determine the true facts which were intentionally and/or negligently concealed and misrepresented by the Defendants.

208. Plaintiff and her Prescribing and Administering Health Care Providers would not have used or prescribed Depo-Provera had the true facts not been concealed by the Defendants.

209. Defendants had sole access to many of the material facts concerning the defective nature of Depo-Provera and its propensity to cause serious and dangerous side effects.

210. At the time Plaintiff was prescribed and administered Depo-Provera, Plaintiff and her Prescribing and Administering Health Care Providers were unaware of Defendants' negligent misrepresentations and omissions.

211. The Defendants failed to exercise ordinary care in making representations concerning Depo-Provera while they were involved in their manufacture, design, sale, testing, quality assurance, quality control, promotion, marketing, labeling, and distribution in interstate commerce, because the Defendants negligently misrepresented Depo-Provera's significant risk of unreasonable and dangerous adverse side effects.

212. Plaintiff and Plaintiff's Prescribing and Administering Health Care Providers reasonably relied upon the misrepresentations and omissions made by the Defendants, where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of Depo-Provera.

213. Plaintiff and Plaintiff's Prescribing and Administering Health Care Providers' reliance on the foregoing misrepresentations and omissions was the direct and proximate cause of Plaintiff's injuries.

214. As a direct and proximate result of reliance upon Defendants' negligent misrepresentations, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and

treatment, loss of earnings, loss of consortium, loss of ability to earn money and other losses. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

COUNT V
MATERIAL MISREPRESENTATION/FRAUDULENT MISPRESENTATION
(Against All Defendants)

215. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

216. At all relevant times, Defendants provided Plaintiff, her healthcare providers, and the general medical community with false or incorrect information or omitted or failed to disclose material information concerning Depo-Provera, including, but not limited to, misrepresentations regarding the safety and known risks of Depo-Provera.

217. The information distributed by the Defendants to the public, the medical community, Plaintiff, and her physicians, including advertising campaigns, labeling materials, print advertisements, commercial media, was false and misleading and contained material omissions and concealment of truth about the dangers of Depo-Provera.

218. For example, as stated above, the United States label for Depo-Provera does not contain a warning for the risk of meningioma, while the Canadian label for Depo-Provera does include such a warning.

219. Defendants' intent and purpose in making these misrepresentations or omissions was to deceive and defraud the public and the medical community, including Plaintiff and her physicians; to falsely assure them of the quality of Depo-Provera and induce the public and medical community, including Plaintiff and her physicians to request, recommend, purchase, and prescribe Depo-Provera.

220. The Defendants had a duty to accurately and truthfully represent to the medical and

healthcare community, medical device manufacturers, Plaintiff, her physicians, and the public, the known risks of Depo-Provera, including its propensity to cause intracranial meningioma and sequelae related thereto.

221. Defendants made continued material omissions in the Depo-Provera labeling, including promoting it as safe and effective while failing to warn of its propensity to cause intracranial meningioma and sequelae related thereto.

222. Defendants made additional misrepresentations beyond the product labeling by representing Depo-Provera as safe and effective for contraception and other indications with only minimal risks.

223. Defendants misrepresented and overstated the benefits of Depo-Provera to Plaintiff, Plaintiff's physicians, and the medical community without properly advising of the known risks associated with intracranial meningioma and sequelae related thereto.

224. Defendants misrepresented and overstated that the Depo-Provera dosage was needed to protect against pregnancy when Defendants knew that a safer alternative existed with forty-six (46) fewer mg per dose of the powerful progestin being ingested quarterly in women, and when Defendants could have warned and recommended usage of Depo-SubQ Provera 104 instead.

225. In reliance upon the false and negligent misrepresentations and omissions made by the Defendants, Plaintiff and Plaintiff's physicians were induced to, and did use Depo-Provera, thereby causing Plaintiff to endure severe and permanent injuries.

226. In reliance upon the false and negligent misrepresentations and omissions made by the Defendants, Plaintiff and Plaintiff's physicians were unable to associate the injuries sustained by Plaintiff with her Depo-Provera use, and therefore unable to provide adequate treatment. Defendants knew or should have known that the Plaintiff, Plaintiff's physicians, and the general

medical community did not have the ability to determine the true facts which were intentionally and/or negligently concealed and misrepresented by the Defendants.

227. Plaintiff and her physicians would not have used or prescribed Depo-Provera had the true facts not been concealed by the Defendants.

228. Defendants had sole access to many of the material facts concerning the defective nature of Depo-Provera and its propensity to cause serious and dangerous side effects.

229. At the time Plaintiff was prescribed and administered Depo-Provera, Plaintiff and her physicians were unaware of Defendants' negligent misrepresentations and omissions.

230. Defendants owed a duty to Plaintiff not to knowingly act in reckless disregard of an unreasonable risk of death or grave bodily injury.

231. Plaintiff and her physicians reasonably relied upon the misrepresentations and omissions made by the Defendants, where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of Depo-Provera.

232. Plaintiff and her physicians' reliance on the foregoing misrepresentations and omissions was the direct and proximate cause of Plaintiff's injuries.

233. As a direct and proximate result of reliance upon Defendants' negligent misrepresentations, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of consortium, loss of ability to earn money and other economic losses. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

COUNT VI
BREACH OF EXPRESS WARRANTY (O.R.C. 1302.26)
(Against All Defendants)

234. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

235. At all relevant times herein, Defendants engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Depo-Provera, and placed it into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendants.

236. Plaintiff and/or her prescribing physicians were at all relevant times in privity with Defendants.

237. Defendants expressly warranted to Plaintiff, Plaintiff's physicians, and the general public, by and through Defendants and/or their authorized agents or sales representatives, in publications, labeling, the internet, and other communications intended for physicians, patients, Plaintiff, and the general public, that Depo-Provera was safe, effective, fit and proper for its intended use.

238. Depo-Provera materially failed to conform to those representations made by Defendants, in package inserts and otherwise, concerning the properties and effects of Depo-Provera, which Plaintiff purchased and consumed via intramuscular injection in direct or indirect reliance upon these express representations. Such failures by Defendants constituted a material breach of express warranties made, directly or indirectly, to Plaintiff concerning Depo-Provera as sold to Plaintiff.

239. Defendants expressly warranted that Depo-Provera was safe and well-tolerated.

However, Defendants did not have adequate proof upon which to base such representations, and, in fact, knew or should have known that Depo-Provera was dangerous to the well-being of Plaintiff and others.

240. Depo-Provera does not conform to those express representations because it is defective, is not safe, and has serious adverse side effects.

241. Defendants' Depo-Provera was expected to reach and did in fact reach consumers, including Plaintiff and her prescribing physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

242. Defendants breached various express warranties with respect to Depo-Provera including the following particulars:

- a) Defendants represented to Plaintiff and her physicians and healthcare providers through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Depo-Provera was safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with being injected with Depo-Provera;
- b) Defendants intentionally omitted information regarding feasible and suitable alternative designs to Defendants' 150mg Depo-Provera. Depo-SubQ Provera 104 is a lower dosage version of Depo-Provera that contains 104 mg / 0.65mL and is injected subcutaneously every three (3) months;
- c) Defendants represented to Plaintiff and her physicians and healthcare providers that Depo-Provera was as safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that Depo-Provera was not safer than alternatives available on the market; and
- d) Defendants represented to Plaintiff and her physicians and healthcare providers that Depo-Provera was more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy of Depo-Provera.

243. Plaintiff's physicians justifiably relied on Defendants' representations through Defendants' marketing and sales representatives in deciding to prescribe Depo-Provera over other

alternative treatments on the market, like Depo-SubQ Provera 104, and Plaintiff justifiably relied on Defendants' representations in deciding to purchase and use the drug.

244. Plaintiff purchased and ingested Depo-Provera without knowing that the drug is not safe and well-tolerated, but that Depo-Provera instead causes significant and irreparable damage through the development of debilitating intracranial meningioma.

245. As a direct and proximate result of Defendants' breaches of warranty, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, past and future medical care and treatment, loss of earnings, loss of consortium, loss of ability to earn money and other economic losses, and other damages. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

COUNT VII
BREACH OF IMPLIED WARRANTY (O.R.C. 1302.27)
(Against All Defendants)

246. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

247. At all relevant times herein, Defendants engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Depo-Provera, and placed it into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendants.

248. Defendants were the sellers of Depo-Provera and sold Depo-Provera to be taken for contraception. Plaintiff was prescribed and purchased Depo-Provera for these intended purposes.

249. The risk of meningioma was reasonably foreseeable at the time of sale and could have been discovered by way of reasonable testing prior to marketing the product. Defendants

failed to conduct such reasonable testing.

250. Plaintiff and/or her physicians were at all relevant times in privity with Defendants.

251. Defendants were the sellers of the Depo-Provera and sold Depo-Provera to be taken for contraception, among other indications. Plaintiff was prescribed and purchased Depo-Provera for these intended purposes.

252. When the Depo-Provera was prescribed by Plaintiff's physicians and taken by Plaintiff, the product was being prescribed and used for the ordinary purpose for which it was intended.

253. Defendants impliedly warranted their Depo-Provera product, which they manufactured and/or distributed and sold, and which Plaintiff purchased and ingested, to be of merchantable quality and fit for the common, ordinary, and intended uses for which the product was sold.

254. Defendants' Depo-Provera was expected to reach and did in fact reach consumers, including Plaintiff and her prescribing physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

255. Defendants breached various express warranties with respect to Depo-Provera including the following particulars:

- e) Defendants represented to Plaintiff and her physicians and healthcare providers through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Depo-Provera was safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with being injected with Depo-Provera;
- f) Defendants represented to Plaintiff and her physicians and healthcare providers that Depo-Provera was as safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that Depo-Provera was not safer than alternatives available on the market; and

- g) Defendants represented to Plaintiff and her physicians and healthcare providers that Depo-Provera was more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy of Depo-Provera.

256. Defendants breached their implied warranties of the Depo-Provera product because the Depo-Provera sold to Plaintiff was not fit for its ordinary purpose as a contraceptive safely and effectively, among other uses.

257. The Depo-Provera would not pass without objection in the trade; is not of fair average quality; is not fit for its ordinary purposes for which the product is used; was not adequately contained, packaged and labeled; and fails to conform to the promises or affirmations of fact made on the container or label.

258. Defendants' breach of their implied warranties resulted in the intramuscular administration of the unreasonably dangerous and defective product into Plaintiff, which placed Plaintiff's health and safety at risk and resulted in the damages alleged herein.

259. As a direct and proximate result of reliance upon Defendants' breaches of warranty, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, past and future medical care and treatment, loss of earnings, loss of consortium, loss of ability to earn money and other economic losses, and other damages. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

WHEREFORE, Plaintiff demands judgment against Defendants and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

JURY DEMAND

Plaintiff hereby demands a trial by jury as to all claims in this action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests:

- i. That process issue according to law;
- ii. That Defendants be duly served and cited to appear and answer herein, and that after due proceedings are had, that there be judgment in favor
- iii. of Plaintiff and against Defendants for the damages set forth below, along with court costs and pre-judgment and post-judgment interest at the legal rate;
- iv. Pain and suffering (past and future);
- v. Wage loss (past and future);
- vi. Loss of earnings and loss of earning capacity;
- vii. Medical expenses (past and future);
- viii. Loss of enjoyment of life (past and future);
- ix. Mental anguish and distress (past and future);
- x. Disfigurement (past and future);
- xi. Physical impairment (past and future);
- xii. Costs and expenses incurred in this litigation, including but not limited to expert fees and reasonable attorneys' fees;
- xiii. Any and all applicable statutory and civil penalties, as allowed by law;
- xiv. Punitive or exemplary damages in such amounts as may be proven at trial;
- xv. Pre- and post-judgment interest on any amounts awarded, as allowed by

law; and

xvi. Any such other and further relief as the Court deems just and proper.

Dated: March 20, 2025

Respectfully submitted,

By: /s/ Christopher A. Seeger

Christopher A. Seeger

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