

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

In Re: Depo-Provera (Depot
Medroxyprogesterone Acetate) Products
Liability Litigation

This Document Relates to:

Amy STIVERS,

Plaintiff,

v.

PFIZER INC.; VIATRIS INC.;
GREENSTONE LLC;
PHARMACIA & UPJOHN CO.
LLC; and PHARMACIA LLC,

Defendants.

Case No. 25-md-3140

Judge M. Casey Rodgers
Magistrate Judge Hope T. Cannon

Designated Forum:
District of Colorado [no Divisions]

**COMPLAINT AND DEMAND FOR
JURY TRIAL**

Plaintiff Amy Stivers, by and through Plaintiff's undersigned counsel, brings this civil action against Defendants for personal injuries and damages suffered by Plaintiff, and alleges upon information and belief as follows:

INTRODUCTION

1. This is an action for damages for Defendants' wrongful conduct related to the development, design, testing, manufacturing, labeling, packaging, promoting, advertising, marketing, distribution, and selling of the prescription drug medroxyprogesterone acetate ("MPA"), also known as depot medroxyprogesterone acetate ("DMPA"), Defendants' trade name for which is Depo-Provera® ("Depo-Provera").

2. Defendants manufacture, promote, and sell Depo-Provera as a prescription drug for contraception, to treat endometriosis, and for other indications. Depo-Provera is manufactured as an injection to be administered intramuscularly in either the upper arm or buttocks every three months.

3. Depo-Provera injured Plaintiff by causing or substantially contributing to the development of an intracranial meningioma, a type of brain tumor. Plaintiff's meningioma has caused her serious injuries.

4. For decades, Defendants knew or should have known that Depo-Provera can cause or substantially contribute to the development of meningiomas when administered and prescribed as intended.

5. Several scientific studies have established that progesterone, its synthetic analogue progestin, and Depo-Provera in particular, cause or substantially contribute to the development of intracranial meningiomas.

6. Nevertheless, Defendants failed to warn, instruct, advise, educate, or otherwise inform Depo-Provera users and prescribers about the risk of intracranial meningiomas or the need for monitoring for meningioma symptoms.

7. The European Union ("EU") and the United Kingdom ("UK") labels now list meningiomas under the "special warnings and precautions for use" section and advise EU patients to speak with their doctors before using Depo-Provera if they have any history of meningiomas.

8. Moreover, the Canadian label for Depo-Provera has listed “meningioma” among its “Post-Market Adverse Drug Reactions” since at least 2015.

9. But the U.S. label still makes no mention of the increased risk to patients of developing intracranial meningiomas.

10. As a proximate result of Defendants’ wrongful actions and inactions, Plaintiff was injured and suffered damages from Plaintiff’s use of Depo-Provera.

11. Plaintiff therefore demands judgment against Defendants and requests, among other things, compensatory damages, statutory damages, punitive damages, attorneys’ fees, and costs.

PARTIES

12. Plaintiff is a resident and citizen of Colorado.

13. 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, New York 10001, and is a citizen of Delaware and New York for the purposes of diversity under 28 U.S.C. § 1332(a).

14. Defendant VIATRIS INC. (“Viatris”) is a corporation organized under Delaware law with its principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317, and is a citizen of Delaware and Pennsylvania for the purposes of diversity under 28 U.S.C. § 1332(a).

15. Defendant GREENSTONE LLC (“Greenstone”) is a limited liability corporation organized under Delaware law with its principal place of business at 2898

Manufacturers Road, Office #112, Greensboro, North Carolina 27406, and is a citizen of Delaware and North Carolina for the purposes of diversity under 28 U.S.C. § 1332(a).

16. Defendant PHARMACIA & UPJOHN COMPANY LLC (“Pharmacia & Upjohn”) is a Delaware limited liability company with two members, Pharmacia & Upjohn LLC and Anacor Pharmaceuticals, LLC. Pharmacia & Upjohn LLC is a Delaware limited liability company, whose sole member is Pharmacia LLC. Pharmacia LLC is a Delaware limited liability company, whose sole member is Wyeth Holdings LLC, which is a Maine limited liability company. Its sole member is Anacor Pharmaceuticals, LLC, a Delaware limited liability company, whose sole member is Pfizer MAP Holding, Inc., which is organized under Delaware law and has a principal place of business in New York, New York. Defendant Pharmacia & Upjohn is therefore a citizen of Delaware and New York for the purposes of diversity under 28 U.S.C. § 1332(a).

17. Defendant PHARMACIA LLC (“Pharmacia”) is a Delaware limited liability company. As outlined above, its sole member is Wyeth Holdings LLC, and the sole member of Wyeth Holdings LLC is Anacor Pharmaceuticals, LLC. The sole member of Anacor Pharmaceuticals, LLC is Pfizer MAP Holding, Inc., which is a corporation organized under Delaware law with a principal place of business in New York, New York. Defendant Pharmacia is a citizen of Delaware and New York for the purposes of diversity under 28 U.S.C. § 1332(a).

18. Defendant Pfizer is the current New Drug Application (“NDA”) holder

for Depo-Provera and has solely held the NDA for Depo-Provera since 2020. Upon information and belief, Pfizer has effectively held the NDA since at least 2002 when it acquired Pharmacia & Upjohn—who then held the NDA— as a wholly owned subsidiary. Pfizer’s name appeared on the label alongside Pharmacia & Upjohn no later than 2003.

19. At all relevant times, Defendant Pharmacia & Upjohn was a wholly owned subsidiary of Defendant Pfizer until Upjohn was spun off in a merger in 2020 to create Defendant Viatris and the remnant—Defendant Pharmacia—was retained by Pfizer.

20. Defendant Greenstone, founded in 1993, was a wholly owned subsidiary first of Pharmacia & Upjohn and later of Pfizer, that at pertinent times was in the business of offering a product portfolio of “authorized generic” versions of Depo- Provera.

21. Defendant 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, New Jersey. 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. Consequently, Greenstone was effectively a department within Pfizer.

22. In the early 2000s, intellectual property challenges 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

23. In 2004, Pfizer executives stated that it was not only Greenstone’s precise brand-name chemical formulation of its authorized generics that would remain identical to Pfizer’s, but also, Greenstone would share every aspect 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

24. Defendants Greenstone/Pfizer sold a version of Depo-Provera that was in fact known as an “authorized generic.” Unlike standard generics, which must contain the same active ingredients and have the same pharmaceutical effect but can contain vastly different additives, “authorized generics” are *exact* replicas of the brand-name drug, with the identical chemical composition; they differ only in that they are marketed without the brand name on its label. Thus, the U.S. Food & Drug Administration (“FDA”) has stated that the term “authorized generic” is used to

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

² *Id.*

³ *Id.*

describe an approved brand-name drug that is marketed without the brand name on its label. While it does not have the brand name on its label, it is the exact same drug product as the branded product. An “authorized generic” may be marketed by the brand-name drug company, or another company with the brand company’s permission.⁴

25. As the seller of Depo-Provera in its authorized generic version, Greenstone presented itself as a distinct generic manufacturing entity but in actuality was Pfizer personnel producing the exact same product as brand-name Depo-Provera, and at Pfizer’s own facility. Indeed, Pfizer’s own website still states that “GREENSTONE Authorized Generics are manufactured to the same standards and at the same facilities as Pfizer brand-name drugs.”⁵ And Defendant Greenstone has continued to operate from the same location at Pfizer’s corporate offices in Peapack, New Jersey. In other words, Pfizer was the actual manufacturer of the authorized generic product that Greenstone distributed and sold.

26. Defendant Viatrix was formed by the merger of Upjohn, Greenstone, and Mylan N.V., in November 2020. Viatrix is the latest iteration of Upjohn and Greenstone.

27. Defendant Pfizer retained 57% ownership of Viatrix stock, making Pfizer

⁴ See <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs> (last viewed Mar. 25, 2025).

⁵ See <https://www.pfizer.com/news/press-release/press-release-detail/pfizers-greenstone-and-digital-mens-health-clinic-roman> (last viewed Mar. 25, 2005).

the majority owner of Viatris. And since Pfizer retained the remnants of Pharmacia, Pfizer effectively remains the majority owner of Defendants Pharmacia & Upjohn as well as Greenstone.

28. All Defendants do business in Colorado by, among other things, distributing, marketing, selling, and/or profiting from brand-name and/or “authorized generic” Depo-Provera in Colorado as well as throughout the United States.

29. Thus, at all times material herein, Defendants have been pharmaceutical companies involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Depo-Provera and its “authorized generic” version, in Colorado and throughout the United States.

JURISDICTION AND VENUE

30. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332, as the amount in controversy exceeds \$75,000.00 and the Parties are citizens of different States.

31. The designated forum, the United States District Court, District of Colorado [no Divisions], has personal jurisdiction over Defendants because at all relevant times, all Defendants regularly conduct business in the State of Colorado and have extensive connections to the State of Colorado that are highly relevant to the subject matter of the instant action.

32. This Court has supplemental jurisdiction over the remaining common law

and state claims pursuant to 28 U.S.C. § 1367.

33. Venue is proper in the designated forum 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 Depo-Provera to Plaintiff and Plaintiff's development, diagnosis, and treatment of her intracranial meningioma, occurred in the District of Colorado.

PLAINTIFF AMY STIVERS'S SPECIFIC ALLEGATIONS

34. Plaintiff was prescribed and administered Depo-Provera from 2000 to 2012, in Colorado and Costa Rica.

35. At all times relevant herein, Defendants represented Depo-Provera to be appropriate, safe, and suitable for contraception through the label, packaging, patient inserts, and advertising.

36. Throughout the time she was prescribed Depo-Provera, Plaintiff and her healthcare providers relied on the Defendants' representations that Depo-Provera was safe, appropriate, and suitable for contraception.

37. Beginning in approximately 2021, Plaintiff received a brain scan after an assault, and physicians discovered and diagnosed a meningioma in the right posterior frontal region of her brain.

38. Plaintiff experiences various meningioma symptoms, including headaches, dizziness, weakness, fatigue, blurry vision, difficulty speaking, and cognitive issues.

39. Plaintiff has undergone repeated MRIs to monitor growth of the meningioma.

40. As a result of Defendants' actions and inactions, Plaintiff has suffered serious injuries, including the development of an intracranial meningioma and sequelae related thereto. Plaintiff's quality of life has been significantly impacted and she continues to face the prospect of further treatment.

41. Plaintiff did not discover, and could not reasonably have discovered, the causal connection between her use of Depo-Provera and her meningiomas until early 2025.

GENERAL ALLEGATIONS

A. Intracranial Meningioma.

42. Intracranial meningioma is a medical condition in which a tumor forms in the meninges, the membranous layers surrounding the brain.

43. Although 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 severe, debilitating symptoms ranging from seizures and vision problems to weakness, difficulty speaking, and even death.

44. Moreover, a sizeable number of meningiomas do become metastatic, greatly increasing their danger.

45. Treatment of a symptomatic intracranial meningioma typically requires highly invasive brain surgery that involves the removal of a portion of the skull—known as a craniotomy—to access the brain and meninges. Oftentimes, however, meningiomas related to progesterone-based contraceptives tend to manifest in areas of the skull from

which removal is extremely challenging, increasing the risks of injuries.

46. Radiation therapy and chemotherapy also may be required, as the tumor's sensitive location in the brain—immediately proximate to critical neurovascular structures and the cortical area—can render complete removal highly risky and medically difficult.

47. Given the sensitive location of intracranial meningiomas, surgery can have severe neurological consequences. Many studies have described the potential for postoperative anxiety and depression, which in turn may require high intake of sedatives and antidepressants in the postoperative period.

48. Significantly, surgery for intracranial meningiomas can lead to seizures requiring medication to treat epilepsy.

B. Depo-Provera.

49. The FDA first approved Depo-Provera in 1992 to be used as a contraceptive, and later, with the approval of the Depo-SubQ Provera 104 variant in 2004, as a treatment for endometriosis.

50. Depo-Provera contains a high dose of progestin, a synthetic progesterone-like hormone that suppresses ovulation. It is administered as an intramuscular injection.

51. A December 2023 National Health Statistics Report notes that nearly a quarter (24.5%) of all sexually experienced women ages 15 to 49 in the United States between 2015 and 2019 have used Depo-Provera.⁶

⁶ Daniels, K *et al.*, “Contraceptive Methods Women Have Ever Used: United States, 2015-2019,” *Nat’l Health Statistics Report*, No. 195, Dec. 14, 2023.

52. According to that same report, the percentages of Depo-Provera use among U.S. women in these age brackets are even higher for Hispanic (27.2%) women and Black (41.2%) women.⁷

53. Depo-Provera is a 150 mg/mL dosage of DMPA that is injected every three 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.

54. Defendant Pfizer represents Depo-Provera to be one of the most effective contraceptives in existence. In fact, the Depo-Provera label groups injectable contraceptives like Depo-Provera alongside “Sterilization” as the most effective contraceptive methods, resulting in the fewest unintended pregnancies.

55. Among reproductive-age women who used any form of contraception from 2017 to 2019, the contraceptive injection was most often used by young women, lower-income women, and Black women.⁸

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

57. Upjohn introduced Depo-Provera as an injectable intramuscular formulation for the treatment of endometrial and renal cancer in 1960.

⁷ *Id.*

⁸ See <https://www.kff.org/womens-health-policy/fact-sheet/dmpa-contraceptive-injection-use-and-coverage/> (last viewed Mar. 25, 2025).

58. As early as 1969, Upjohn successfully received approval for Depo-Provera for contraception in international markets, including France.

59. Upjohn originally submitted the NDA for Depo-Provera for use as a contraceptive in 1967. But the FDA rejected this application.

60. Upjohn again applied to the FDA for approval to market Depo-Provera as a contraceptive in 1978. Again, the FDA rejected the application.

61. Upjohn applied to the FDA for a third time for the approval of Depo-Provera as a contraceptive in 1983. The FDA once more rejected the application.

62. The FDA eventually approved Upjohn's NDA for Depo-Provera for use as a contraceptive on or about October 29, 1992.

63. The FDA requires post-market surveillance of approved products for potential safety issues. That duty includes an obligation by NDA-holders to keep current with emerging relevant literature and, where appropriate, perform their own long-term studies and follow-up research.

64. In 1995, Upjohn merged with Swedish manufacturer Pharmacia AB to form Pharmacia & Upjohn.

65. In 2002, Defendant Pfizer acquired Pharmacia & Upjohn, thereby acquiring the Depo-Provera NDA as well as the associated responsibilities and liabilities stemming from the manufacturing, sale, and marketing of Depo-Provera.

66. Pfizer has effectively held the Depo-Provera NDA since acquiring Pharmacia & Upjohn in 2002. It has been the sole holder of the NDA since 2020, when

Upjohn was spun off to form Defendant Viatris.

67. Throughout the time Defendants marketed both variants of Depo-Provera for use as a contraceptive and for treatment of endometriosis and certain cancers, 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.

68. Defendants also failed adequately to test Depo-Provera to investigate the potential for intracranial meningiomas.

69. Defendants are also liable for the conduct of its predecessors who failed to adequately design, test, and warn of the dangers associated with use of Depo-Provera.

C. The Dangers of Depo-Provera.

70. The association between progesterone and meningiomas has been known or knowable for decades, particularly for sophisticated pharmaceutical corporations like Defendants engaging in FDA-required post-market surveillance for potential safety issues.

71. Before 1983, medical and scientific communities believed that meningioma cells, like breast cancer cells, would have a preference for estrogen receptors.

72. But a study published in 1983 in the *European Journal of Cancer and Clinical Oncology* ("EJCCO") by Blankenstein and others found the opposite: meningioma cells have a high number of progesterone receptors, especially relative to estrogen receptors, indicating that progesterone was involved in the incidence, mediation, and growth

rate of meningiomas.⁹ This finding was surprising and notable within the medical and scientific communities.

73. The EJCCO Blankenstein study was published nearly a decade before the FDA approved Depo-Provera for contraception in 1992.

74. In the nine years before Depo-Provera was approved for contraception, and in the thirty-three years since—more than forty years in total—Defendants have seemingly failed to investigate the effect of their high-dose progestin Depo-Provera on the development of meningiomas.

75. Since at least as early as 1989, researchers have also been aware of the relationship between progesterone-inhibiting agents and the growth rate of meningiomas.¹⁰ That year, Blankenstein and others published a study in the *Journal of Steroid Biochemistry* entitled, “Effect of steroids and antisteroids on human meningioma cells in primary culture.” This new study found that meningioma cell growth was significantly reduced by exposure to mifepristone, an antiprogestosterone agent.¹¹

76. In the decades since the 1983 and 1989 studies, many published studies have presented similar findings on the negative correlation between progesterone-inhibiting

⁹ 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).

¹⁰ 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).

¹¹ *Id.*

agents and meningiomas.¹² And numerous published studies have reported on the positive correlation between a progesterone and/or progestin medication and the incidence and growth rate of meningiomas.¹³

77. 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 others conducted over a span of more than thirty years, and concluded that mifepristone, an antiprogestosterone agent, had a regressive effect on meningiomas, meaning it stopped or reversed its growth.¹⁴ The authors determined that mifepristone competes with progesterone for its receptors on meningioma cells and, by blocking progesterone from binding, stems or even reverses the growth of meningiomas.

78. The aforementioned studies indicate that for decades, Defendant

¹² See, e.g., Grunberg, *et al.*, “Treatment of unresectable meningiomas with the antiprogestosterone agent mifepristone,” *J Neurosurgery*, Vol. 74, No. 6, pp. 861-66 (1991); see also Matsuda, *et al.*, “Antitumor effects of antiprogestosterones on human meningioma cells in vitro and in vivo,” *J Neurosurgery*, Vol. 80, No. 3, pp. 527-34 (1994).

¹³ 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).

¹⁴ 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>.

manufacturers and sellers of Depo-Provera and its authorized generic and generic analogues had an unassignable duty to investigate the foreseeable potential that a high-dose synthetic progesterone delivered in the deep tissue like Depo-Provera could cause the development or substantially contribute to the growth of meningiomas. Defendants were best positioned to perform such investigations. And had they done so, they would have discovered decades ago that their high-dose progestin Depo-Provera was associated with a highly increased risk of meningiomas. This would have spared Plaintiff and countless others the pain and suffering associated with meningiomas. 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.

79. Indeed, more recently, researchers have found that prolonged (more than one year) use of progesterone and progestin, and specifically Depo-Provera, is linked to a greater incidence of developing intracranial meningiomas, 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.

80. For example, in 2022, the journal *Endocrinology* published an article entitled “Estrogen and Progesterone Therapy and Meningiomas.”¹⁵ This retrospective literature review noted that a “dose-dependent relationship” has been established between

¹⁵ Hage, *et al.*, “Estrogen and progesterone therapy and meningiomas,” *Endocrinology*, Vol. 163, pp. 1-10 (2022).

at least one progestin and the incidence and growth rate of meningiomas. The authors also found that progesterone-mediated meningiomas are more likely to be multiple and require more intensive treatment.

81. In 2023, researchers reported on a direct link between Depo-Provera and meningiomas. 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.”¹⁶ The study reported on twenty-five individuals who developed one or more intracranial meningiomas related to chronic use of Depo-Provera. Of these twenty-five patients, ten were instructed to cease Depo-Provera use, after which half (five) showed “clear evidence of tumor shrinkage.” This led the authors to conclude that “there appears to be a clear progestin meningioma syndrome associated with chronic DMPA use.”¹⁷

82. In 2024, the French National Agency for Medicines and Health Products Safety, along with several French neurosurgeons, epidemiologists, clinicians, and researchers published a large case control study (“the *Roland* study”) in the *British Medical Journal* (“BMJ”), one of the premier scientific journals in the world, showing the risk of intracranial meningiomas with the use of numerous progestogens

¹⁶ 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).

¹⁷ *Id.*

among women in France.¹⁸

83. The *Roland* study stated 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.”¹⁹

84. The *Roland* study analyzed 18,061 cases of women undergoing surgery for intracranial meningiomas between 2009 and 2018. The study found that “prolonged use of . . . medroxyprogesterone acetate [Depo-Provera] . . . was found to increase the risk of intracranial meningioma.”²⁰ Specifically, the authors found that prolonged use of Depo-Provera resulted in a 555% increased risk of developing intracranial meningiomas. The study concluded “[t]he increased risk associated with the use of injectable medroxyprogesterone acetate, a widely used contraceptive,” was an important finding.²¹ The study also noted Depo-Provera is “often administered to vulnerable populations,” *i.e.*, lower-income women who have no choice but to take a subsidized option that requires action only every three months to remain effective for its intended use of preventing

¹⁸ Roland, *et al.*, “Use of progestogens and the risk of intracranial meningioma: national case-control study,” *BMJ*, Vol. 384, published online Mar. 27, 2024, <https://doi.org/10.1136/bmj-2023-078078> (last viewed Mar. 25, 2025).

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

pregnancy and endometriosis, as Depo-Provera does.²²

85. The *Roland* study analyzed the effect of several other progestogen-based medications. With regard to oral or intravaginal progesterone or percutaneous progesterone, dydrogesterone or spironolactone, the study reported that three subjects showed no excess risk of intracranial meningioma surgery, and stated that no conclusions could be drawn from two other subjects due to lack of exposure.

86. By contrast, the *Roland* study reported that medroxyprogesterone acetate (Depo-Provera) and other medications were associated with an increased risk of intracranial meningiomas, with Depo-Provera 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 meningiomas. Indeed, Depo-Provera had by far the highest risk of meningioma surgeries amongst progesterone contraceptive products studied. This makes Depo Provera far more dangerous than other drugs and treatment options designed to prevent pregnancy due to the unreasonably increased risk of injury associated with intracranial meningiomas, including but not limited to seizures, vision problems, and even death.²³

87. Further, the *Roland* study found the longer the duration of exposure to Depo-Provera, the greater the patient's risk; study results show that three quarters of the women in the case group who had been exposed for more than a year had been exposed

²² *Id.*

²³ *Id.*

for more than three years.

88. Finally, the *Roland* study noted that among cases of meningiomas observed in the study, 28.8% (5,202/18,061) of the women used antiepileptic drugs three years after the index date of intracranial surgery.

89. More recently, in September 2024, an article entitled “The Association between Medroxyprogesterone Acetate Exposure and Meningioma” was published in *Cancers*.²⁴ This large case-control study analyzed over 117,000 meningioma cases and more than one million matched controls. The study found that “injection exposure” of medroxyprogesterone acetate, *i.e.*, Depo-Provera usage, was associated with a 53% increase in the development of meningiomas. The association was specific to cerebral meningiomas and became even stronger with prolonged use.²⁵

90. In October 2024, researchers at the University of Cincinnati published an abstract in the *International Journal of Radiation Oncology Biology Physics* titled “Progesterone Contraception and Tumor-Related Visual Impairment in Premenopausal Women with Meningioma Referred for Radiation.”²⁶ This research reported on a retrospective case-control study that examined, among other things, the role of hormonal contraception in the development of intracranial-meningioma-caused visual impairment

²⁴ Griffin, “The association between medroxyprogesterone acetate exposure and meningioma,” *Cancers*, Vol. 16, No. 3362 (2024).

²⁵ *Id.*

²⁶ Bailey, *et al.*, “Progesterone contraception and tumor-related visual impairment in premenopausal women with meningioma referred for radiation,” *Int’l J of Radiation Oncology Biology Physics*, Vol. 120, No. 2 Supp., pp. E217 (2024).

in women under the age of 55. The authors concluded “progesterone use is a significant risk factor for meningioma-related visual deficits . . . , with a disproportionate number on [Depo-] Provera specifically.”²⁷

D. Defendants’ Failure to Test Depo-Provera.

91. Defendants knew or should have known of the potential impact of the drug to cause the development of intracranial meningiomas, but they failed to adequately study these adverse effects.

92. Furthermore, despite the fact that, for decades, studies have provided evidence of the meningioma-related risks and dangers of progesterone and progestins and Depo-Provera specifically, Defendants have failed to adequately investigate the threat that Depo-Provera poses to patients’ well-being or warn the medical community and patients of the risk of intracranial meningiomas and sequelae related thereto.

E. Defendants’ Continuing Failure to Disclose Depo-Provera’s Health Risks.

93. According to the Drugs@FDA website, the label for Depo-Provera has been updated on at least thirteen occasions since 2003, with the most recent update occurring in July 2024.²⁸ Although there are at least fourteen iterations of the Depo- Provera label, Defendants’ labels in the United States have not contained any warning or any information whatsoever on the increased propensity of Depo-Provera to cause severe and debilitating

²⁷ *Id.*

²⁸ See Drugs@FDA:FDA-Approved Drugs- Depo-Provera, <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020246> (last viewed Mar. 25, 2025).

intracranial meningiomas like those from which Plaintiff has suffered.

94. Despite the *Roland* study and the mountain of above-cited medical literature demonstrating the biological plausibility of the association between progesterone and meningiomas, the evidence of Depo-Provera-related cases of meningiomas, and the evidence of other high-dose progesterones causing meningiomas, Defendants still have made no change to the U.S. Depo-Provera label related to intracranial meningiomas. Furthermore, Defendants have failed to take any steps to otherwise warn the medical community and Depo-Provera users of these significant health risks, despite changing the label as recently as July 2024 to include warnings about pregnancy-related risks, and despite Defendant Pfizer stating to the newspaper *The Guardian* when the *BMJ* article was released in April 2024: “We are aware of this potential risk associated with long-term use of progestogens and, in collaboration with regulatory agencies, are in the process of updating product labels and patient information leaflets with appropriate wording.”²⁹

95. Defendant Pfizer *has* changed the label in the EU and the UK and potentially in other countries. Specifically, Defendants’ Depo-Provera 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. Depo-

²⁹ “Hormone medication could increase risk of brain tumours, French study finds,” *The Guardian*, published online Mar. 27, 2024, <https://www.theguardian.com/society/2024/mar/27/hormone-medication-brain-tumours-risk-progestogens-study> (last viewed Mar. 25, 2025).

Provera should be discontinued if a meningioma is diagnosed. Caution is advised when recommending Depo-Provera to patients with a history of meningiomas.”

96. And Defendants’ Package Leaflet in the EU, which provides patient information, states that “before using Depo-Provera[,] . . . 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).”

97. Nothing was or is stopping Defendants from adding similar language to the label and package insert for Depo-Provera in the United States. Defendants could have at any time made “moderate changes” to the label.

98. Specifically, Defendants could have filed a “Changes Being Effected” (“CBE”) supplement, under Section 314.70(c) of Title 21 of the Code of Federal Regulations provisions governing the FDCA, to make “moderate changes” to Depo-Provera’s label without any prior FDA approval. *See* 21 C.F.R. § 314.70(c).

99. Examples of moderate label changes that can be made via a CBE supplement include changes “to reflect newly acquired information” to “add or strengthen a contraindication, warning, precaution, or adverse reaction.” 21 U.S.C. § 314.70(c)(6)(3). By definition and by regulation, such changes to add a warning based on newly-acquired information—such as that imparted by newly emerging literature like the litany of studies cited above—are considered a “moderate change.” *Id.*

100. The Third Circuit recently reaffirmed a plain-text interpretation of the CBE

supplement process in a precedential decision holding that the defendant in that case, Merck, could not rely on a preemption defense based on an allegedly irreconcilable conflict between federal (FDCA) and state (civil tort) law so long as the warning could have been effected via a CBE change. *See generally In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 118 F4th 322, 357 (3d Cir. 2024) (noting “the availability of a label change via a CBE supplement is problematic for Merck, as will very often be the case for pharmaceutical companies raising an impossibility defense”).

101. Defendants also could have instructed physicians to consider its own safer alternative design, 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 104.³⁰ Indeed, studies have shown that 150 mg Depo-Provera administered intramuscularly causes a spike in blood serum levels of DMPA that is more than four times higher than the peak blood serum concentration of DMPA when that same 150 mg Depo-Provera shot is given subcutaneously; this very high intramuscular peak concentration persists for several days.³¹ In fact, 150 mg Depo-Provera administered subcutaneously has a remarkably

³⁰ See Shelton, *et al.*, “Subcutaneous DPMA: a better low dose approach,” *Contraception*, Vol. 89, pp. 341-43 (2014).

³¹ See *id.*

similar pharmacokinetic profile to Depo-SubQ Provera 104.³²

102. Nevertheless, Defendants never produced a 150 mg subcutaneous version.

103. Another study published in *Contraception: X* in 2022 concluded that not only was the lower-dose Depo-SubQ Provera 104 just as effective as 150 mg Depo-Provera when administered properly, but it could also be administered every sixteen weeks (four months) instead of every twelve weeks (three months) due to the more gradual uptake of the subcutaneous administration route.³³ That same study found that 150 mg Depo-Provera if injected subcutaneously could remain at efficacious levels in the blood for even longer, up to six months.³⁴ As with subcutaneously administered Depo-SubQ Provera 104, the study authors noted “subcutaneous administration of 150 mg Depo-Provera every 6 months would be a highly effective repurposing . . . with a similar reduction in cumulative exposure.”³⁵ The authors concluded: “The use of an unnecessarily high exposure to limit the residual chance of treatment failure would be a disservice to the vast majority of women if a lower exposure can reduce side effects, costs, or otherwise make the product more acceptable.”³⁶

104. Despite knowing that the subcutaneous administration of 150 mg Depo-Provera would have resulted in less risk of dangerous side effects like meningiomas

³² See *id.* at 342.

³³ See Taylor, *et al.*, “Ovulation suppression following subcutaneous administration of depot medroxyprogesterone acetate,” *Contraception: X*, Vol. 4 (2022).

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

while providing the same contraceptive efficacy for twice as long (and therefore would have required only half as many doses of Defendants' product per year), Defendants failed to produce a 150 mg subcutaneous version.

105. In Europe and other countries outside of the United States, this 104 mg subcutaneous dose may be self-administered by patients, obviating the need for quarterly visits to a medical practitioner.

106. Knowing that the lower-dose 104 mg Depo-SubQ Provera 104 was equally effective and 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.

107. When Depo-SubQ Provera 104, under NDA number 21-583, submitted by Defendant Pharmacia & Upjohn, a subsidiary of Defendant Pfizer, was approved by the FDA on February 17, 2004, more than two decades ago, those Defendants submitted a proposed trade name that the FDA did not approve, so instead, the proprietary name Depo-SubQ Provera 104 was deemed to be the brand name.

108. In Europe, the same dose has a more accessible trade name, "Sayana Press," unlike the unwieldy proprietary developmental name of "Depo-SubQ Provera 104."

109. But inexplicably, and presumably for commercially beneficial or contractual reasons, Defendant Pfizer consciously decided not to seek an alternative commercially

more accessible brand name, and not to endeavor to more vigorously advocate for the sale of Depo-SubQ Provera 104 to patients seeking contraception, despite knowing it had a lower, safer, more administrable, and more 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.

110. The “lowest effective dose” is a well-known concept in the field of pharmaceuticals 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 only increase the risk of unwanted and potentially dangerous side effects while providing no additional efficacy.

111. Either change—adding a warning about the risk of meningiomas based on “newly acquired information,” or, advising physicians to consider a switch to subcutaneous Depo-SubQ Provera 104—would have constituted a “moderate change” or changes justifying a simple CBE supplement that Defendants could have effectuated immediately, and then simply notified the FDA thereafter.

112. But Defendants have failed to make either change. And their failure continues to date.

113. Defendants ignored reports from patients and healthcare providers throughout the United States that indicated that Depo-Provera failed to perform as intended. Defendants also knew or should have known of the effects associated with long-term use of Depo-Provera, which led to the severe and debilitating injuries suffered by

Plaintiff and many other patients. Rather than conducting adequate testing to determine the cause of such injuries (of which they had notice) or rule out Depo-Provera's design as the cause of the injuries, Defendants continued to falsely and misleadingly market Depo-Provera as a safe and effective prescription drug for contraception and other indications.

114. Defendants' Depo-Provera is and was at all times utilized and prescribed in a manner foreseeable to Defendants, as Defendants generated the instructions for use for Plaintiff to receive Depo-Provera injections.

115. Plaintiff and Plaintiff's physicians used Depo-Provera in a foreseeable manner, and did not misuse or alter Depo-Provera in an unforeseeable manner.

116. Through their affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with Depo-Provera use.

117. Consequently, Plaintiff and Plaintiff's 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.

118. As a direct result of being prescribed and consuming Depo-Provera, Plaintiff has been permanently and severely injured, having suffered serious consequences.

119. As a direct and proximate result of her Depo-Provera use, Plaintiff has

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.

120. 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 Depo-Provera was not discovered, and through reasonable care and diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims.

**LIABILITY OF DEFENDANTS PFIZER, GREENSTONE AND VIATRIS FOR
THE "AUTHORIZED GENERICS"**

121. Defendants Greenstone and Viatris were at different times from 2004 until the present the authorized generic "manufacturer" and distributor operating under the same NDA of Depo-Provera. As such, Defendants Greenstone and Viatris had the express permission of Defendant Pfizer to make, label, distribute, sell, and market Depo-Provera without the brand name on its label—even though it is the exact same drug product as the branded Depo-Provera manufactured in some or all instances by Pfizer.

122. Accordingly, the authorized generic distributors, Defendants Greenstone and Viatris, operated as if they were the brand-name holder under the same NDA. Just like Defendant Pfizer, these Defendants could have changed the brand-name label to warn of the risks of meningiomas and the use of high-dose progestins.

123. Further, the "authorized generic" distributors Defendants Greenstone and

Viartis could have requested that Pfizer, with whom they were under contract to sell the “authorized generic,” change the brand-name label to warn of the risks of meningiomas and the use of high-dose progestins.

124. Pfizer had a duty to change the label knowing that its “authorized generic” distributors Defendants Greenstone and Viartis, with whom Pfizer was in contract and receiving revenue from the sale of the “authorized generic” DMPA, were selling the “authorized generic” without warning of meningioma risk.

125. Pfizer knew that its authorized generic manufacturers held a large market share of its manufactured Depo-Provera under a different name.

126. Pfizer was at some or all of the pertinent times the actual manufacturer of the DMPA, identical to Depo-Provera in all ways other than name, which was sold by Defendants Greenstone and Viartis, who were at different times the “authorized generic” distributor, with the express permission of Pfizer, to distribute, sell, and market Depo-Provera without the brand name on its label.

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

127. 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, Depo-Provera, particularly over extended periods of time.

128. 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, Depo-Provera, particularly over extended periods of time.

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

130. The aforementioned studies reveal that discontinuing use of high-dose progesterone and progestin, including Depo-Provera, can slow the growth of meningiomas. But Defendants failed to warn the medical community and the Plaintiff of this method to mitigate the damage of a developing meningioma.

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

132. Defendants failed to disclose a known defect and, instead, affirmatively misrepresented that Depo-Provera was safe for its intended use. Defendants disseminated labeling, marketing, promotion and sales information to Plaintiff, Plaintiff's healthcare providers, and the general public regarding the safety of Depo-Provera, knowing that such information was false, misleading, and inadequate to warn of the safety risks associated with long-term Depo-Provera use. Defendants did so willfully, wantonly, and with the intent to prevent the dissemination of information known to them concerning Depo-Provera's safety.

133. Further, Defendants actively concealed the true risks associated with the use of Depo-Provera, particularly as they relate to the risk of serious intracranial meningiomas, by affirmatively representing in numerous communications, which were disseminated to Plaintiff, Plaintiff's 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 Depo-Provera and no intracranial meningioma-related adverse side effects associated with use of Depo-Provera.

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

135. Due to the absence of any instructions for how to identify and/or monitor Depo-Provera patients for potential intracranial meningioma-related complications, Plaintiff was unaware that Depo-Provera could cause serious, intracranial meningioma-related injuries, as this danger was not known to Plaintiff, Plaintiff's healthcare providers, or the general public.

136. 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 Depo-Provera, Defendants are estopped from relying on any statute of limitations defenses.

CONDUCT WARRANTING PUNITIVE DAMAGES

137. For the reasons set forth above and addressed below, Defendant Pfizer acted with a conscious disregard of the safety of Plaintiff and other women, many of whom were young and of lower socioeconomic status, who were subjected to high-dose injections of 150 mg Depo-Provera with the known and/or knowable risk of meningioma brain tumors which was generally accepted in the scientific community, while Defendant Pfizer had available its very own safer alternative medication, Depo-SubQ Provera 104. Exemplary damages are warranted to punish and deter Defendant Pfizer and others from such conduct in the future.

COUNT I

STRICT LIABILITY – FAILURE TO WARN

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

139. At all times material 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 Depo- Provera into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendants.

140. Defendants, as manufacturers, distributors, and marketers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field. 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.

141. 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.

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

143. 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 about the risks and dangers associated with Depo-Provera, as it became or could have become available to Defendants.

144. Defendants marketed, promoted, distributed, and sold an unreasonably dangerous and defective prescription drug, Depo-Provera, to healthcare providers, who in turn were empowered to prescribe and dispense Depo-Provera to Plaintiff and other consumers without adequate warnings and other clinically relevant information and data regarding the risks of meningiomas and of unnecessarily excessive progestin exposure that was available and generally accepted within the scientific community. Through both

omission and affirmative misstatements, Defendants misled the medical community about the risk-and-benefit balance of Depo-Provera. That resulted in injury to Plaintiff.

145. Defendants knew or should have known through testing, scientific knowledge, advances in the field, published research in major peer-reviewed journals, or otherwise, that Depo-Provera created a risk of developing serious and debilitating intracranial meningiomas. At all relevant times, this information was readily available and generally accepted within the scientific community.

146. Even though Defendants knew or should have known based on information generally accepted within the scientific community that Depo-Provera, with its higher-than-necessary progestin dosage, caused unreasonable and dangerous side effects, they continue to promote and market Depo-Provera without providing adequate clinically-relevant information and data or recommending that patients be monitored.

147. Defendants knew that a safer alternative design and product existed, including its own Depo-SubQ Provera 104, which contained substantially less progestin but was equally effective in preventing pregnancy. Yet they failed to warn the medical community and the patients about the risks of the high-dose formulation, Depo-Provera, which could be somewhat mitigated by using the lower-dose alternative, Depo-SubQ Provera 104.

148. Defendants knew or should have known that consumers, and Plaintiff, specifically, would foreseeably and needlessly suffer injury as a result of Defendants' failures.

149. The Depo-Provera supplied to Plaintiff by Defendants was defective, unreasonably dangerous, and had inadequate warnings or instructions at the time it was sold, and Defendants then also acquired additional knowledge and information confirming the defective and unreasonably dangerous nature of Depo-Provera. Despite this knowledge and information, Defendants failed and neglected to issue adequate warnings that Depo-Provera causes serious and potentially debilitating intracranial meningiomas and/or instructions concerning the need for monitoring and potential discontinuation of use of Depo-Provera.

150. Defendants' failure to provide adequate warnings or instructions rendered Depo-Provera unreasonably dangerous in that it failed to perform as safely as an ordinary patient, prescriber, and/or other consumer would expect when used as intended and/or in a manner reasonably foreseeable by the Defendants, and in that the risk of danger outweighs the benefits.

151. Defendants failed to provide timely and adequate warnings to physicians, pharmacies, and consumers, including Plaintiff and Plaintiff's intermediary physicians.

152. Plaintiff's prescribing physicians would not have prescribed and administered Depo-Provera to Plaintiff had they been apprised by Defendants of the unreasonably high risk of meningiomas associated with usage of Depo-Provera.

153. Alternatively, even if Defendants had apprised Plaintiff's prescribing physicians of the unreasonably high risk of meningiomas associated with usage of

Depo- Provera, and these prescribing physicians had still recommended usage of Depo-Provera to Plaintiff, the prescribing physicians would have relayed the information concerning the risk of meningiomas to Plaintiff, and the alternative treatment of the lower-dose subcutaneous Depo-SubQ Provera 104, and Plaintiff as an objectively prudent person would not have chosen to take Depo-Provera, and/or would have opted to take safer and lower-dose Depo-SubQ Provera 104, notwithstanding Plaintiff's prescribing physicians' continued recommendation.

154. Similarly, if Defendants had warned of the unreasonably high risk of meningiomas associated with Depo-Provera use, and the availability of the safer and equally effective lower-dose Depo-SubQ Provera 104 in the Patient Information handout, Plaintiff, as an objectively prudent person, would not have chosen to take Depo-Provera, and/or would have opted to take the safer, lower, and equally effective dose of Depo-SubQ Provera 104, notwithstanding Plaintiff's prescribing physicians' recommendation.

155. Defendants failed to include adequate warnings and/or provide adequate clinically-relevant information and data that would alert Plaintiff and Plaintiff's prescribing physicians of the dangerous risks of Depo-Provera, including, among other things, the development of intracranial meningiomas.

156. Defendants failed to provide adequate post-marketing warnings and instructions after Defendants knew or should have known of the significant risks of, among other things, intracranial meningiomas.

157. Defendants continued to aggressively promote and sell Depo-Provera even after they knew or should have known of the unreasonable risks of intracranial meningiomas caused by the drug.

158. Defendants had an obligation to provide Plaintiff and Plaintiff's prescribing physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Depo-Provera, and/or that there existed safer and more or equally effective alternative drug products. They failed this obligation.

159. Because of Defendants' failure to adequately test and research harms associated with Depo-Provera and their failure to provide appropriate warnings and instructions about Depo-Provera, Plaintiff and other patients, as well as the medical community, including prescribing doctors, were inadequately informed about the true risk-benefit profile of Depo-Provera and were not sufficiently aware that serious and potentially debilitating intracranial meningiomas might be associated with the use of Depo-Provera. Nor were the medical community, patients (including Plaintiff), patients' families, or regulators appropriately informed that serious and potentially debilitating intracranial meningiomas might be a side effect of Depo-Provera and should or could be reported as an adverse event.

160. The Depo-Provera products designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective due to inadequate post-marketing surveillance and/or warnings because, even after

Defendants knew or should have known of the risks of severe and permanent intracranial meningioma-related injuries from administration of Depo-Provera, Defendants failed to provide adequate warnings to users or consumers of the products, and continued to improperly advertise, market and/or promote Depo-Provera.

161. Depo-Provera is defective and unreasonably dangerous to Plaintiff and other consumers regardless of whether Defendants exercised all possible care in its preparation and sale.

162. The foreseeable risk of serious and potentially debilitating intracranial meningiomas caused by Depo-Provera could have been reduced or avoided by Plaintiff, prescribers, or other consumers had Defendants provided reasonable instructions or warnings of these foreseeable risks of harm.

163. As a direct and proximate result of Defendants' conduct, including the inadequate warnings, dilution or lack of information, lack of adequate testing and research, and the defective and dangerous nature of Depo-Provera, 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 ability to earn money, and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer such losses in the future.

COUNT II

STRICT LIABILITY – DESIGN DEFECT

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

165. At all times material 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 Depo-Provera into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendants.

166. Defendants, as manufacturers, designers, distributors, and marketers of pharmaceutical drugs, had a duty to design a product free from a defective condition that was unreasonably dangerous to Plaintiff.

167. Depo-Provera was designed to use a higher dose of progesterone than was necessary for effective contraception, such that it posed an unreasonable risk of intracranial meningiomas, and Defendants placed and kept Depo-Provera on the market despite Depo-Provera being in a defective condition.

168. Depo-SubQ Provera 104 is a lower dosage version of Depo-Provera that contains 104 mg / 0.65mL and is injected subcutaneously every three months. According to the label, Depo-SubQ Provera 104 can be used for both contraception and treatment of endometriosis.

169. Depo-SubQ Provera 104 never attained meaningful market share, and

Defendants 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.

170. 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.

171. It has long been a tenet in the medical and toxicological community that the “dose makes the poison.” Defendants had a viable safer and lower-dose alternative in Depo-SubQ Provera 104 but failed to warn the medical community prescribing and administering Depo-Provera that Depo-SubQ Provera 104 was a safer alternative, while still maintaining requisite effectiveness.

172. Moreover, the 150 mg Depo-Provera itself could have been a viable lower effective dose if it had simply been designed, approved, and sold to be administered subcutaneously, like Depo-SubQ Provera 104, instead of intramuscularly.

173. Injections given intramuscularly are well-known to be absorbed by the body and taken up in the bloodstream at much faster rates than injections given subcutaneously because of the much higher vascularization of deep muscle tissue compared to the dermis.

174. Studies have shown that 150 mg Depo-Provera administered intramuscularly causes a spike in blood serum levels of DMPA that is more than four times higher than

the peak blood serum concentration of DMPA when that same 150 mg Depo-Provera shot is given subcutaneously; this very high intramuscular peak concentration persists for several days.³⁷ In fact, 150 mg Depo-Provera administered subcutaneously has a remarkably similar pharmacokinetic profile to Depo-SubQ Provera 104.³⁸

175. Thus, there are *two* lower effective doses of Depo-Provera—both Depo-SubQ Provera 104, *and* the very same 150 mg Depo-Provera simply given subcutaneously instead of intramuscularly.

176. Defendants wantonly and willfully failed to apprise the public, including the FDA, the medical community, Plaintiff, and Plaintiff’s physicians, of the greatly reduced risk of meningiomas when injecting 150 mg Depo-Provera subcutaneously compared to the indicated method of intramuscular injection, because Defendants did not want to raise any alarms with respect to the safety profile of Depo-Provera and did not want to lose any of its lucrative market share held in part through its contracts with “authorized generic” partners and subsidiaries.

177. Defendants knew or should have known that the Depo-Provera they developed, manufactured, labeled, marketed, sold, and/or promoted was defectively designed in that it posed a serious risk of severe and permanent intracranial-meningioma-related injuries when injected intramuscularly.

³⁷ See Shelton, *et al.*, “Subcutaneous DPMA: a better low dose approach,” *Contraception*, Vol. 89, pp. 341-43 (2014).

³⁸ See *id.* at 342.

178. Defendants have a continuing duty to design a product that is not unreasonably dangerous to users and to adequately understand, test, and monitor their product.

179. Defendants sold, marketed, and distributed a product that is unreasonably dangerous for its normal, intended, and foreseeable use.

180. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Depo-Provera, a defective product which created an unreasonable risk to the health of consumers, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

181. The Depo-Provera supplied to Plaintiff by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer or supplier, it was in an unreasonably dangerous and a defective condition because it failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendants, posing a risk of serious and potentially debilitating intracranial meningiomas to Plaintiff and other consumers.

182. The Depo-Provera ingested by Plaintiff was expected to, and did, reach Plaintiff without substantial change in the condition in which it is sold.

183. The Depo-Provera ingested by Plaintiff was in a condition not contemplated by the Plaintiff in that it was unreasonably dangerous, posing a serious risk of permanent vision and retinal injuries.

184. Depo-Provera is a medication prescribed for contraception and treatment

of endometriosis, among other uses. Depo-Provera in fact causes serious and potentially debilitating intracranial meningiomas, a type of brain tumor that can cause severe damage and require invasive surgical removal, harming Plaintiff and other consumers.

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

186. The Depo-Provera supplied to Plaintiff by Defendants was 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 meningiomas to Plaintiff and other consumers.

187. 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 meningiomas posed by the drug. Given Depo-Provera's utility and the risk involved in its use, the product's design makes it unreasonably dangerous.

188. Depo-Provera's design is more dangerous when used in its intended or reasonably foreseeable manner than a reasonably prudent consumer would expect.

189. Depo-Provera's design was more dangerous than Plaintiff expected.

190. The intended or actual utility of Depo-Provera is not of such benefits to justify the risk of intracranial meningiomas which may cause severe and permanent

injuries, thereby rendering the product unreasonably dangerous.

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

192. 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 meningiomas and sequelae related thereto.

193. Depo-Provera is defective and unreasonably dangerous to Plaintiff and other consumers in that, despite early indications and concerns that Depo-Provera use could result in vision issues, Defendants failed to adequately test or study the drug, including but not limited to: pharmacokinetics and pharmacodynamics of the drug, its effects on the development of brain tumors like intracranial meningiomas, the potential effects and risks of long-term use, the potential for inter-patient variability, and/or the potential for a safer effective-dosing regimen.

194. Defendants knew or should have known that consumers, and Plaintiff specifically, would foreseeably and needlessly suffer injury because of Depo-Provera's defective design.

195. Depo-Provera is defective and unreasonably dangerous to Plaintiff and other consumers even if Defendants had exercised all possible care in the preparation and

sale of Depo-Provera.

196. As a direct and proximate result of Defendants' conduct and defective design, including inadequate testing and research, and the defective and dangerous nature of Depo-Provera, Plaintiff suffered bodily injuries that resulted in 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 ability to earn money, and other economic losses. The losses are either permanent or continuing, and Plaintiff will suffer losses in the future.

COUNT III
NEGLIGENCE

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

198. At all times relevant herein, it was the duty of Defendants to use reasonable care in the design, labeling, manufacturing, testing, marketing, distribution, and/or sale of Depo-Provera.

199. 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.

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

201. In disregard of their 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 negligently 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 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 whose use of Depo-Provera was reasonably foreseeable;

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 meningiomas 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.

p. A reasonable manufacturer, designer, distributor, promoter, or seller under

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

202. As a direct and proximate result of the Defendants' 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 meningiomas, 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.

203. As a direct and proximate result of one or more of the above-stated negligent 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 ability to earn money, and other economic losses. The losses are either permanent or continuing, and Plaintiff will suffer losses in the future.

COUNT IV

NEGLIGENT FAILURE TO WARN

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

205. 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 warning and post-sale warning 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.

206. Defendants' duty of care was that which a reasonably careful designer, manufacturer, seller, importer, distributor and/or supplier would use under the same or similar circumstances.

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

208. At all times material herein, Defendants failed to exercise reasonable care and knew, or in the exercise of reasonable care should have known, that Depo-Provera had inadequate instructions and/or warnings.

209. 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:

a. 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;

b. Disseminating information to Plaintiff and Plaintiff's physicians that was

negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff;

c. Failing to provide warnings or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks;

d. Failing to adequately test 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;

e. Failure to adequately warn of the risks that Depo-Provera could cause the development of intracranial meningiomas and sequelae related thereto;

f. Failure to adequately warn of the risk of serious and potentially irreversible injuries related to the development of intracranial meningiomas, a brain tumor;

g. Failure to instruct patients, prescribers, and consumers of the need for monitoring when taking Depo-Provera for symptoms potentially related to the development of intracranial meningiomas;

h. 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 meningiomas;

i. Failing to provide instructions on ways to safely use Depo-Provera to avoid injury, if any;

j. Failing to explain the mechanism, mode, and types of adverse events associated with Depo-Provera;

k. Failing to provide adequate training or information to medical care providers

for appropriate use of Depo-Provera and patients taking Depo-Provera;

l. Representing to physicians, including but not limited to Plaintiff's prescribing physicians, that this drug was safe and effective for use;

m. Failing to warn that there is a safer feasible alternative with a lower effective dose of progestin; and

n. 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.

210. Defendants knew or should have known of the risk and danger of serious bodily harm from 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.

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

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

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

214. The warnings, or lack thereof, that were given by Defendants failed to properly warn prescribing physicians, including Plaintiff's prescribing physicians, of the known and knowable risk of serious and potentially irreversible injuries related to the development of intracranial meningiomas, and failed to instruct prescribing

physicians to test and monitor for the presence of the injuries and to discontinue use when symptoms of a meningioma manifest.

215. The warnings that were given by Defendants failed to properly warn Plaintiff and prescribing physicians of the correlation between intracranial meningiomas and sequelae related thereto.

216. Plaintiff and Plaintiff's prescribing physicians reasonably relied on 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.

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

218. As a direct and proximate result of Defendants' negligent 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 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 V
NEGLIGENT DESIGN DEFECT

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

220. 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.

221. 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.

222. 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, negligently and carelessly:

- a. 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;

b. Failing to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Depo-Provera;

c. 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

d. 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.

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

224. 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.

225. 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 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

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

227. 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.

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

229. 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 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.

230. 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 meningiomas and sequelae related thereto.

231. 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 meningiomas and sequelae related thereto.

232. 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.

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

234. 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 fewer milligrams 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.

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

permanent injuries.

236. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Plaintiff and Plaintiff's prescribing 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 prescribing 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 Defendants.

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

238. 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.

239. When Plaintiff was prescribed and administered Depo-Provera, Plaintiff and her Physicians were unaware of Defendants' negligent misrepresentations and omissions.

240. 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 Defendants negligently misrepresented Depo-Provera's significant risk of unreasonable and dangerous adverse side effects.

241. Plaintiff and Plaintiff's prescribing physicians reasonably relied upon the

misrepresentations and omissions made by Defendants, where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of Depo-Provera.

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

243. 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 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 VII

FRAUDULENT MISREPRESENTATION

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

245. Defendants falsely and fraudulently have represented and continue to represent to the medical and healthcare community, Plaintiff and her physicians, and the public in general, that Depo-Provera has been appropriately tested and was found to be safe and effective.

246. At all times material herein, Defendants misrepresented to consumers and

physicians, including Plaintiff and Plaintiff's physicians and the public in general, that Depo-Provera is safe for use as a contraceptive and for other indications.

247. Defendants knew or should have known of the falsity of such a representation to consumers, physicians, and the public in general, since Depo-Provera is far from the only contraceptive approved by the FDA, and it is not the only contraception option. Nevertheless, Defendants' marketing of Depo-Provera falsely represented Depo-Provera to be a safe and effective contraceptive option with no increased risk of intracranial meningiomas and sequelae related thereto.

248. The representations were, in fact, false. When Defendants made these representations, they knew or had reason to know that those representations were false, and Defendants willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of Depo-Provera.

249. Prior to Plaintiff's use of Depo-Provera, Defendants knew or should have known of adverse event reports indicating the development of intracranial meningiomas in individuals who had taken Depo-Provera.

250. These representations were made by Defendants with the intent of defrauding and deceiving the medical community, Plaintiff and Plaintiff's prescribing physicians, and the public, and also inducing the medical community, Plaintiff, Plaintiff's prescribing physicians, or the public, to recommend, prescribe, dispense, and purchase Depo-Provera for use as a contraceptive and other treatment indications while concealing the drug's known propensity to cause serious and debilitating intracranial meningiomas and

sequelae related thereto.

251. Despite the fact that Defendants knew or should have known of Depo-Provera's propensity to cause serious and potentially debilitating injuries due to the development of intracranial meningiomas and sequelae related thereto, the label did not contain any of this information in the "Warnings" section. In fact, the label for Depo-Provera has been updated at least a dozen times over the past twenty years. But at no point did Defendants provide any of the foregoing information in the "Warnings" section. To date, the Depo-Provera label still does not include any warnings whatsoever that indicate the dangers of intracranial meningiomas and sequela related thereto after using Depo-Provera.

252. In representations to Plaintiff and/or to her healthcare providers, including Plaintiff's prescribing physicians, Defendants fraudulently stated that Depo-Provera was safe and omitted warnings related to intracranial meningiomas.

253. In representations to Plaintiff and/or to her Physicians, Defendants fraudulently stated that Depo-Provera was safe and concealed and intentionally omitted material information from the Depo-Provera product labeling in existence at the time Plaintiff was prescribed Depo-Provera.

254. Defendants were under a duty to disclose to Plaintiff and her physicians the defective nature of Depo-Provera, including but not limited to, the propensity to cause the development of intracranial meningiomas, and consequently, its ability to cause debilitating and permanent injuries.

255. Defendants had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiff, and/or her physicians.

256. Defendants knew or had reason to know of the dangerous side effects of Depo-Provera as a result of information from case studies, clinical trials, literature, and adverse event reports available to the Defendants at the time of the development and sale of Depo-Provera, as well as at the time of Plaintiff's prescription.

257. Defendants' concealment and omissions of material facts concerning the safety of the Depo-Provera were made purposefully, willfully, wantonly, and/or recklessly to mislead Plaintiff, Plaintiff's physicians, surgeons, and healthcare providers and to induce them to purchase, prescribe, and/or use the drug.

258. Plaintiff and her physicians were unaware of the falsehood of these representations.

259. In reliance upon these false representations, Plaintiff was induced to, and did, use Depo-Provera, thereby causing severe, debilitating, and potentially permanent personal injuries and damages to Plaintiff. Defendants knew or had reason to know that the Plaintiff had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of Depo-Provera as described in detail herein.

260. In comporting with the standard of care for prescribing physicians, Plaintiff's prescribing physicians relied on the labeling for Depo-Provera in existence at

the date of prescription that included the aforementioned fraudulent statements and omissions.

261. These representations made by Defendants were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

262. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations and omissions of Defendants, nor could Plaintiff with reasonable diligence have discovered the true facts about Defendants' misrepresentations at the time when Depo-Provera was prescribed to her.

263. As a direct and proximate result of reliance upon Defendants' fraudulent 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 ability to earn money, and other economic losses. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

264. Defendants have engaged in willful, malicious conduct and/or conduct so careless that it demonstrates a wanton disregard for the safety of others, including Plaintiff, such that the imposition of punitive damages is warranted here.

COUNT VIII

BREACH OF EXPRESS WARRANTY

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

266. 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.

267. Defendants expressly warranted to Plaintiff, Plaintiff's prescribing 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.

268. 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.

269. 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.

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

271. Plaintiff and Plaintiff's physicians justifiably relied on Defendants' representations regarding the safety of Depo-Provera, and Defendants' representations became part of the basis of the bargain.

272. Plaintiff and Plaintiff's prescribing physicians justifiably relied on Defendants' representations that Depo-Provera was safe and well-tolerated in their decision to ultimately prescribe, purchase and use the drug.

273. Plaintiff's prescribing 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, and Plaintiff justifiably relied on Defendants' representations in deciding to purchase and use the drug.

274. 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 meningiomas.

275. 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 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 IX

BREACH OF IMPLIED WARRANTY

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

277. 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.

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

279. When 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.

280. 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.

281. 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 or to treat endometriosis safely and effectively, among other uses.

282. 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.

283. 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.

284. 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 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.

DEMAND FOR JURY TRIAL

285. Plaintiff demands a trial by jury on all Counts and as to all issues.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court:

286. Award Plaintiff compensatory and punitive exemplary damages in an amount to be determined at trial, and also including, but not limited to:

a. General Damages for severe physical pain, mental suffering, inconvenience, and loss of the enjoyment of life; and

b. Special Damages, including all expenses, incidental past and future expenses, medical expenses, and loss of earnings and earning capacity.

287. Award interest as permitted by law;

288. Award reasonable attorneys' fees and costs, as provided for by law; and

289. Grant such other and further relief as the Court deems just and proper.

Dated: June 17, 2025

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