UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

IN RE: DEPO-PROVERA (DEPOT MEDROXYPROGESTERONE ACETATE) PRODUCT LIABILITY LITIGATION	Case No. 3:25-md-3140
This Document Relates to: **SANDRA SOMARAKIS**, Plaintiff, vs. **PFIZER INC.; PHARMACIA & UPJOHN CO. LLC; PHARMACIA LLC; GREENSTONE LLC,** Defendants.	Judge M. Casey Rodgers Magistrate Judge Hope T. Cannon **Designated Forum: U.S. District Court for the District of Oregon**

COMPLAINT

Plaintiff, SANDRA SOMARAKIS, by and through the undersigned counsel, brings this civil action against Defendants for personal injuries and damages suffered by Plaintiff and alleges as follows upon information and belief:

THRESHOLD ALLEGATIONS

1. Plaintiff is a resident and citizen of the state of Oregon.

2. 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 of New York for the purposes of diversity under 28 U.S.C. § 1332(a).

3. Defendant Greenstone LLC ("Greenstone") is a limited liability company organized and existing under the law of Delaware. Greenstone LLC has one member, Upjohn US 2 LLC, which is a limited liability company organized and existing under the law of Delaware. Upjohn US 2 LLC has one member, Upjohn US Holdings Inc., which is a corporation organized and existing under the law of Delaware with its principal place of business in Pennsylvania. For purposes of jurisdiction based on diversity under 28 U.S.C. § 1332(a), therefore, Greenstone LLC is a citizen of Delaware and Pennsylvania.

4. 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).

5. 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).

6. The Designated Forum (the federal district in which the Plaintiff would have filed his or her case in the absence of direct filing in the MDL Court) is the U.S. District Court for the District of Oregon.

7. Plaintiff was administered the prescription drug depot medroxyprogesterone acetate ("DMPA"). The brand name for this prescription drug is Depo-Provera® ("Depo-Provera").

8. Plaintiff has been diagnosed with intracranial meningioma that resulted from or was exacerbated by Plaintiff's use of Depo-Provera.

JURISDICTION AND VENUE

9. Based on the threshold allegations above, this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) because there is complete diversity among Plaintiff and Defendants, and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

10. As mentioned herein, in the absence of Direct Filing, venue is proper in the U.S. District Court for the District of Oregon 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, administration of DPMA, and Plaintiff's diagnosis and treatment of her meningioma all occurred within the State of Oregon.

11. Furthermore, Defendants have significant contacts with the State of Oregon and regularly conduct business in Oregon, the location where Plaintiff was prescribed and administered DMPA and diagnosed with a meningioma, such that Defendants are subject to the personal jurisdiction of the courts in that district. Specifically, Defendants engaged in the following:

a) conducted business in the state;

b) regularly solicited business in the state;

c) specifically transacted and conducted business with respect to DMPA in the state;

d) targeted physicians and health care providers in that district for the marketing, sale, and use of DMPA to be given to patients within the state;

e) engaged in substantial and continuing contact with the state;

f) derived substantial revenue from goods used and consumed within the state;

g) purposefully directed their business activities, particularly with respect to DMPA to the state;

h) purposely placed DMPA into the stream of commerce in the state;

i) expected or reasonably should have expected that DMPA would reach the state

j) anticipated or reasonably should have anticipated that DMPA would reach the state and be prescribed to and used by individuals in the state;

k) engaged in a persistent course of conduct in the state with respect to DMPA;

l) committed a tort in whole or in part in the state;

m) reasonably expected or should have expected their acts to have consequences within the state; and/or

n) intended to serve the market of that state and therefore purposely availed themselves of jurisdiction there.

INTRODUCTION

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

13. Defendants manufacture, promote, and sell Depo-Provera as a prescription drug used for contraception or to treat endometriosis, among other indications. Depo-Provera is manufactured as an injection to be administered intramuscularly every three (3) months in either the upper arm or buttocks.

14. Plaintiff SANDRA SOMARAKIS (hereinafter "Plaintiff") received injections of DMPA manufactured and sold by the Defendants.

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

16. As a result of its dangerously defective design, Plaintiff's use of DMPA directly caused or significantly contributed to Plaintiff suffering severe injuries, including the development of an intracranial meningioma, a specific type of brain tumor that required extensive medical treatment, along with severe associated side effects. As a result, Plaintiff must undergo lifelong medical monitoring due to a substantially increased risk of developing new or recurrent tumors and other serious health complications in the future.

17. The relationship between sex hormones and meningioma tumors has been known since the 1920s, and the presence of progesterone receptors in meningioma tissue has been reported since the 1970s.

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

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

20. Since at least 2015, Defendants' Product Monographs for DMPA distributed with Defendants' products in Canada have specifically identified "meningioma" among the "Post-Market Adverse Drug Reactions." In addition, the Canadian Monographs for DMPA contraindicate the drug in "women with… known or suspected progestin-dependent neoplasia" which by definition includes meningioma.

21. Similarly, Defendants' DMPA labeling in the European Union (EU) and the United Kingdom specifically list "meningioma" in the "special warnings and precautions for use" section and advise EU patients to speak with their doctors before using DMPA if they have any history of meningioma.

22. On September 6, 2024, the Pharmacovigilance Risk Assessment Subcommittee of the European Medicines Agency [PRAC] "recommended measures to minimize the risk of meningioma, a type of brain tumor, with medicines containing medroxyprogesterone acetate…. The committee's recommendations

followed a review of data from epidemiological studies, case studies from the medical literature and cases reported in the pharmacovigilance database of the European Union.... PRAC recommended that, in patients who have a meningioma or have had one in the past, medicines containing high-dose medroxyprogesterone acetate must not be used, unless medroxyprogesterone acetate is needed for the treatment of an oncological indication. PRAC also recommended that patients taking high doses of medroxyprogesterone should be monitored for symptoms of meningioma, which can include change in vision, hearing loss or ringing in ears, loss of smell, headaches, memory loss, seizures and weakness in arms and legs. If a patient treated for a non-oncological indication is diagnosed with meningioma, treatment with high-dose medroxyprogesterone acetate must be stopped." [1]

23. On February 25, 2025, Pfizer issued an official Important Safety Communication to healthcare professionals in South Africa informing them that, "The product information for [DMPA] will be updated… meningioma will be added as an adverse reaction[.]" Defendants explicitly stated that DMPA "is contraindicated in patients with a history of meningioma" and advised healthcare professionals to discontinue treatment if meningioma is diagnosed in patients using DMPA for contraception. Additionally, South African healthcare providers were

[1] www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-2-5-september-2024

instructed to monitor patients for meningioma symptoms and counsel them on the potential risks associated with Depo-Provera.

24. However, Defendants' labeling in the United States for their DMPA products remains entirely devoid of any reference to meningioma, including the post-marketing occurrence of these tumors in patients using DMPA and the risk of developing these tumors posed by its use. Neither does Defendants' U.S. labeling contraindicate the use of DMPA in women suffering symptoms of meningioma or with a known or suspected history of meningioma and lacks any information or guidance to healthcare providers on screening patients for meningioma before prescribing or while using DMPA.

25. To this day, Defendants have failed to warn, instruct, advise, educate, or otherwise inform patients and healthcare providers in the United States about the risk of intracranial meningioma or the need for monitoring for resultant symptoms.

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

27. As a direct and proximate result of the Defendants' wrongful actions and inactions, Plaintiff sustained injuries, including disability, disfigurement, neurological impairment, scarring, loss of capacity for enjoyment of life, aggravation and exacerbation of preexisting conditions, inconvenience, mental and

physical pain and suffering, cost of medical, surgical and hospital and other care and treatment, and the losses and injuries are ongoing and continuing in nature.

28. Plaintiff, therefore, demands judgment against Defendants and requests, among other things, compensatory damages, statutory damages, punitive damages, pre- and post-judgment interest, attorneys' fees, and costs.

PLAINTIFF SANDRA SOMARAKIS' SPECIFIC FACTS

29. From approximately 1995 until 2010, Plaintiff SANDRA SOMARAKIS was administered DMPA via intramuscular injections as prescribed by her physicians.

30. At least thirteen (13) of those injections consisted of Greenstone/Pfizer's "authorized generic" Depo-Provera which is identical to brand-name Depo-Provera.

31. At all times relevant, Plaintiff and Plaintiff's physicians relied on the Defendants' representations that Depo-Provera was safe, appropriate, and suitable for use as a contraceptive and Defendants represented Depo-Provera to be appropriate, safe, and suitable for such purpose through the label, packaging, patient inserts, and advertising.

32. However, following Plaintiff's prolonged exposure to DMPA, Plaintiff developed concerning neurological complications and deficits including but

not limited to frequent and debilitating headaches, a protruding left eye, and progressively worsening visual disturbances.

33. In 2008, Plaintiff underwent an MRI that revealed the presence of a meningioma. Due to the tumor's critical location and its pressure on the left eye socket, Plaintiff underwent an extensive and highly invasive pterional craniotomy in August 2008. This procedure included resection of the tumor and removal of portions of the greater wing of the sphenoid, the posterolateral wall of the orbit, and the anterior squamosal temporal bone.

34. The tumor was subsequently identified in a post-surgical Pathological report to be a WHO Grade I meningioma.

35. Following surgery, Plaintiff experienced a prolonged and debilitating recovery period. She remained incapacitated for months due to severe mobility issues, imbalance, and neurological impairments. Her head remained swollen at the surgical site, and her left eye continued to protrude. She endured relentless headaches and chronic discomfort.

36. A subsequent MRI revealed the presence of residual meningioma tissue. As a result, Plaintiff was required to undergo a second intracranial surgical procedure in 2010 to address the remaining tumor mass.

37. To prevent recurrence of the tumor, Plaintiff underwent 29 fractions of radiation therapy over a six-week and six-day period. This treatment was

excruciatingly painful and resulted in several adverse side effects, including permanent hearing loss in her left ear.

38. Plaintiff continued to receive DMPA even after her diagnosis and during the course of treatment for her meningioma, as Plaintiff and Plaintiff's Prescribing and Administering Health Care Providers were unaware that Depo-Provera could cause serious, intracranial meningioma-related injuries.

39. As a direct result of Plaintiff's prolonged usage of DMPA/ Depo-Provera and the subsequent development of a large intracranial meningioma at a relatively young age, Plaintiff's current condition requires ongoing, close medical surveillance through regular MRI imaging and CT scans to assess any further progression.

40. Plaintiff remains at a high risk of developing worsening neurological symptoms and other medical complications.

41. Such uncertainty surrounding Plaintiff's condition has caused and will continue to cause Plaintiff serious psychological injuries and emotional distress.

42. Notwithstanding, Plaintiff continues to suffer from daily and persistent life altering and debilitating neurological deficits or symptoms as a direct consequence of her prolonged usage of DMPA and the subsequent development of

an intracranial meningioma to which she required intracranial surgeries and radiation therapy.

43. As a result of Defendant's actions and omissions, Plaintiff was made to suffer serious injuries and damages, specifically, the development of an intracranial meningioma requiring extensive medical treatment and surveillance for recurrence, and sequelae thereto.

44. Plaintiff and her prescribing health care providers relied on the Defendants' omissions regarding the risks of meningioma to individuals who use DMPA for contraception.

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

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

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

48. As a result of Defendants' actions, Plaintiff and her physicians were unaware, and could not have reasonably known or have learned through reasonable

diligence, that Plaintiff would be exposed to the risks identified in this Complaint and that those risks were the direct and proximate result of Defendants' conduct.

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

50. As a direct and proximate result of the Defendants' wrongful actions and inactions, Plaintiff sustained severe physical and emotional injuries, including disability, neurological impairment, loss of capacity for enjoyment of life, aggravation and exacerbation of preexisting conditions, inconvenience, mental and physical pain and suffering, cost of medical, surgical and hospital and other care and treatment, and the losses and injuries are ongoing and continuing in nature.

GENERAL ALLEGATIONS

A. Intracranial Meningioma

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

52. Although the tumor formed by an intracranial meningioma is typically histologically benign (meaning it usually does not metastasize), the growing tumor can nevertheless press against the sensitive surrounding tissues, i.e., the brain, and thereby cause a number of severe and debilitating symptoms ranging from seizures and vision problems to weakness, difficulty speaking, and even death, among others.

Moreover, a sizeable number of meningiomas (15-20%) do become metastatic, greatly increasing their danger.

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

54. Due to the sensitive location of an intracranial meningioma immediately proximate to critical neurovascular structures and the cortical area, surgery can have severe neurological consequences. Many studies have described the potential for postoperative anxiety and depression and an attendant high intake of sedatives and antidepressants in the postoperative period. Surgery for intracranial meningioma can also lead to seizures requiring medication to treat epilepsy. Moreover, meningiomas related to progesterone-based contraceptives tend to manifest at the base of the skull where removal is even more challenging, further increasing the risks of injuries.

B. Depo-Provera

55. Depo-Provera (depot medroxyprogesterone acetate, hereinafter "DMPA") was first approved by the FDA 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.

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

57. According to a recent National Health Statistics Report published in December 2023, nearly a quarter (24.5%) of all sexually experienced women in the United States between 2015 and 2019 had ever used Depo-Provera.[2]

58. According to that same report, those proportions increase even further for Hispanic (27.2%) women and Black (41.2%) women who had ever used Depo-Provera.[3]

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

60. In 1954, Upjohn (later acquired by Pfizer) initiated research into medroxyprogesterone acetate (MPA) as a synthetic progestin hormone for treating endometriosis, uterine cancer, and hormone imbalances.

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[2] Daniels, K et al., "Contraceptive Methods Women Have Ever Used: United States, 2015-2019", *Nat'l Health Statistics Report*, No. 195, Dec. 14, 2023.
[3] *Id.*

61. In 1956, Upjohn began conducting clinical trials testing the use of MPA for habitual or threatened miscarriages and endometriosis.

62. Between 1957 and 1959, animal testing demonstrated that MPA effectively suppressed ovulation, leading Upjohn to pivot its research toward long-acting contraception. Early toxicology tests focused on endocrine disruption and cancer risk, yet data gaps remained on long-term effects.

63. On June 18, 1959, Upjohn introduced MPA in oral tablet form branded as "Provera" in the United States for treating conditions like amenorrhea and metrorrhagia.

64. In 1960, Upjohn branded DMPA as "Depo-Provera" and introduced it as an injectable intramuscular formulation for treating endometrial and renal cancer. However, concerns over its hormonal impact on fetal development soon arose. By the mid-1960s, scientists warned of potential congenital disabilities in children exposed in utero.

65. In 1963, Upjohn submitted an Investigational New Drug (IND) application to the FDA, initiating clinical trials for contraceptive use.

66. By 1964, U.S. clinical trials had begun, disproportionately targeting marginalized women, including incarcerated women and psychiatric patients, who were not adequately informed of the risks. Many of these women were unaware they were participating in a medical experiment.

67. Between 1965 and 1966, large-scale international trials commenced in Jamaica, Thailand, and Mexico under the guise of population control programs. These studies failed to meet ethical standards for informed consent, as many women were unaware they were receiving an experimental drug.

68. On February 27, 1967, Upjohn submitted a Supplemental New Drug application to the FDA for approval of the intramuscular injection of Depo-Provera as a contraceptive agent in humans. This supplemental application sought approval for a "general marketing" license for the drug in the United States. Given the lack of long-term safety data, the FDA refused approval and mandated additional studies before considering market authorization. Specifically, the FDA required long-term animal studies to determine the carcinogenic potential of DMPA before it could be considered for widespread use in humans. FDA's denial and demand for long-term animal studies for Depo-Provera was driven by early evidence of mammary tumors in beagle dogs exposed to another progestogen, the absence of sufficient human safety data, and growing concerns about the carcinogenicity of synthetic hormones.

69. In 1969, Upjohn successfully received approval for Depo-Provera for contraception in international markets, including France.

70. However, in 1974, the FDA rejected the NDA, citing findings from long-term animal studies demonstrating increased cancer risks and serious flaws and

ethical violations in Upjohn's clinical trials, including the lack of informed consent among vulnerable populations.

71. Throughout the mid-1970s, women's rights activists, medical ethicists, and lawmakers began demanding investigations into Depo-Provera's unethical testing, rampant off-label use, and potential carcinogenic effects.

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

73. In 1978, after a second beagle dog study confirmed increased mammary carcinomas, the FDA formally declared Depo-Provera "not approvable."

74. Upjohn contested this decision, leading to a Public Board of Inquiry (PBI) hearing in 1983, where the company presented misleading data to downplay cancer risks.

75. In 1984, the PBI concluded that Depo-Provera's risks had not been adequately studied, yet the drug continued to be used internationally under population control initiatives.

76. Upjohn’s NDA for Depo-Provera for use as a contraceptive was eventually approved by the FDA on or about October 29, 1992.

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

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

79. Pfizer has effectively held the Depo-Provera NDA since acquiring Pharmacia & Upjohn in 2002 and has solely held the NDA since 2020, when Upjohn was spun off to form Viatris Inc. (hereinafter "Viatris").

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

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

82. Defendants also failed to adequately test Depo-Provera to investigate the safest lowest dose which could have mitigated its risks, including the development of meningioma.

83. 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

84. The association between progesterone and meningioma has been known and knowable for decades, particularly for sophisticated pharmaceutical corporations like Defendants engaging in FDA-required post-market surveillance of their products for potential safety issues. That duty includes an obligation to keep current with emerging relevant literature and where appropriate, perform their own long- term studies and follow-up research.

85. Since 1938, the gender and thus hormonal connection to meningioma was appreciated with Dr. Harvey Cushing noting, "we have noted for many years a definite predominance in the incidence of meningiomas in females over males, the proportion being 60–40…still more striking is the fact that in our series tumors of certain loci are largely restricted to women… Meningiomas in not a few instances appear to have been incited by unusual activity, or at least to have shown their first recognizable symptoms soon after a recent pregnancy."[4]

86. Since at least 1983, the medical and scientific communities have been aware of the high number of progesterone receptors on meningioma cells, especially relative to estrogen receptors.[5]

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[4] Cushing H (1938) Meningiomas: their classification, regional behavior, life history, and surgical end result. Springfield Charles C Thomas 111:735.

[5] *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).

87. This finding was surprising and notable within the medical and scientific communities because it had previously been thought that meningioma cells, like breast cancer cells, would show a preference for estrogen receptors.[6] Researchers publishing in the *European Journal of Cancer and Clinical Oncology* instead found the opposite, indicating progesterone was involved in the incidence, mediation, and growth rate of meningiomas.[7]

88. Since at least as early as 1989, researchers have also been aware of the relationship between progesterone-inhibiting agents and the growth rate of meningioma.[8] That year, the same authors published a study in the *Journal of Steroid Biochemistry* entitled, "Effect of steroids and antisteroids on human meningioma cells in primary culture," finding that meningioma cell growth was significantly reduced by exposure to mifepristone, an antiprogesterone agent.[9]

89. Numerous studies published in the decades since have presented similar findings on the negative correlation between progesterone-inhibiting agents and meningioma.[10]

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[6] *See id.*
[7] *See id.*
[8] *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).
[9] *See id.*
[10] *See*, *e.g.*, Grunberg, et al., "Treatment of unresectable meningiomas with the antiprogesterone agent mifepristone," *J Neurosurgery*, Vol. 74, No. 6, pp. 861-66 (1991); *see also* Matsuda, et al., "Antitumor effects of antiprogesterones on human meningioma cells in vitro and in vivo," *J Neurosurgery*, Vol. 80, No. 3, pp. 527-34 (1994).

90. Relatedly, a number of studies published in the interim have reported on the positive correlation between a progesterone and/or progestin medication and the incidence and growth rate of meningioma.[11] The studies highlighted throughout this Complaint are a non-exhaustive list.

91. In light of the aforementioned studies, for several decades the manufacturers and sellers of Depo-Provera and its authorized generic and generic analogues, Defendants, had an unassignable duty to investigate the foreseeable potential that a high dose synthetic progesterone delivered in the deep tissue could cause the development or substantially contribute to the growth of meningioma. Defendants were also best positioned to perform such investigations. Had Defendants done so, they would have discovered decades ago that their high dose progestin Depo-Provera was associated with a highly increased risk of meningioma and would have spared Plaintiff and countless others the pain and suffering associated with meningioma. Instead, Defendants did nothing, and therefore willfully failed to apprise the medical community, and the women patients receiving quarterly high dose injections, of this dangerous risk.

[11] *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).

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

93. In 2023, researchers reported on a direct link between Depo-Provera and meningioma. That year a case series was published in the *Journal of Neurological Surgery Part B: Skull Base* titled "Skull Base Meningiomas as Part of a Novel Meningioma Syndrome Associated with Chronic Depot Medroxyprogesterone Acetate Use."[12] The abstract reported on 25 individuals who developed one or more intracranial meningiomas related to chronic use of Depo-Provera. Of the twenty-five (25) patients, ten (10) were instructed to cease Depo-Provera use, after which five (5) of those patients had "clear evidence of tumor shrinkage," leading the authors to conclude "there appears to be a clear progestin meningioma syndrome associated with chronic DMPA use."

94. In 2024, the French National Agency for Medicines and Health Products Safety along with several French neurosurgeons, epidemiologist,

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

clinicians, and researchers published a large case control study in the *British Medical Journal* (*BMJ*), one of the premier scientific journals in the world, to assess the risk of intracranial meningioma with the use of numerous progestogens among women in France, hereinafter referred to as the *Roland* study.[13]

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

96. The 2024 *Roland* study published in *BMJ* studied the effect of several other progestogen-based medications. Three study subjects showed no excess risk of intracranial meningioma surgery with exposure to oral or intravaginal progesterone or percutaneous progesterone, dydrogesterone or spironolactone, while no conclusions could be drawn for two others due to lack of exposed cases. The other medications, including medroxyprogesterone acetate (Depo-Provera), were found to

[13] Roland, et al., "Use of progestogens and the risk of intracranial meningioma: national case-control study," *BMJ*, Vol. 384, published online Mar. 27, 2024 at https://doi.org/10.1136/bmj-2023-078078 (last accessed Apr. 21, 2024).

[14] *See id.*

be associated with an increased risk of intracranial meningioma, 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 meningioma.

97. The study analyzed 18,061 cases of women undergoing surgery for intracranial meningioma between 2009 and 2018. The study found that "prolonged use of ... medroxyprogesterone acetate [Depo-Provera] ... was found to increase the risk of intracranial meningioma." Specifically, the authors found that current use of Depo-Provera was associated with a 5.55-fold heightened risk of developing meningioma requiring intracranial surgery, which increased further to a 5.62-fold heightened risk associated with prolonged use (greater than one year) of Depo-Provera. The study authors concluded "[t]he increased risk associated with the use of injectable medroxyprogesterone acetate, a widely used contraceptive," was an important finding. The authors also noted Depo-Provera is "often administered to vulnerable populations," i.e., lower-income women who have no other choice but to take the subsidized option.

98. Depo-Provera had by far the highest risk of meningioma surgeries amongst progesterone contraceptive products studied, rendering Depo-Provera more dangerous than other drugs and treatment options designed to prevent pregnancy due

to the unreasonably increased risk of injury associated with intracranial meningioma, including but not limited to seizures, vision problems, and even death.

99. More recently, in September 2024, an article entitled "The Association between Medroxyprogesterone Acetate Exposure and Meningioma" was published in *Cancers*. This large case-control study analyzed over 117,000 meningioma cases and more than one million matched controls and found that "injection exposure" of medroxyprogesterone acetate, i.e. Depo-Provera usage, was associated with a 53% increase in the development of meningioma. The association was specific to cerebral meningiomas and became even stronger with prolonged use.[15]

100. 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." This paper reported on a retrospective case-control study that examined, *inter alia*, the role of hormonal contraception in the development of intracranial meningioma causing visual impairment in women under the age of 55. The authors concluded

[15] Griffin, "The association between medroxyprogesterone acetate exposure and meningioma," *Cancers*, Vol. 16, No. 3362 (2024).

"progesterone use is a significant risk factor for meningioma-related visual deficits ..., with a disproportionate number on [Depo-] Provera specifically."[16]

D. Defendants' Failure to Test Depo-Provera

101. Defendants knew or should have known of the potential impact of the drug to cause the development of intracranial meningioma but failed to adequately study these adverse effects.

102. Furthermore, despite the fact that studies have emerged over the course of decades providing 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 meningioma and sequelae related thereto.

103. E. Defendants' Continuing Failure to Disclose Depo-Provera's Health RisksAccording to the Drugs@FDA website, the label for Depo-Provera has been updated on at least thirteen (13) occasions since 2003, with the most recent update coming in July 2024.[17] Despite the fact there are at least fourteen (14) iterations of

[16] 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).

[17]Drugs@FDA:FDA-ApprovedDrugs-Depo-Provera, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020246 (last visited Apr. 29, 2024).

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

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

105. Additionally, Defendants' Package Leaflet in the EU which provides information for the patient 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)."

106. Defendants could have also 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 version and never exceeds more than a small fraction of the dangerously high serum levels seen in the first several days with intramuscular administration of 150 mg Depo-Provera.[18] Nevertheless, Defendants never produced a 150 mg subcutaneous version.

107. 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 16 weeks instead of every 12 weeks due to the more gradual uptake of the subcutaneous administration route. 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 (6) months.[19]

108. 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." The authors concluded: "The use of an unnecessarily high

[18] *See* Shelton, et al., "Subcutaneous DPMA: a better low dose approach," *Contraception*, Vol. 89, pp. 341-43 (2014).

[19] *See* Taylor, et al., "Ovulation suppression following subcutaneous administration of depot medroxyprogesterone acetate," *Contraception: X*, Vol. 4 (2022).

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."[20]

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

110. 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 already had a safer alternative product to 150 mg Depo-Provera, which was more well known to prescribers and patients.

111. In Europe and other countries outside of the United States, this 104 mg subcutaneous dose has a more accessible trade name, "Sayana Press", unlike the unwieldy proprietary developmental name of "Depo-SubQ Provera 104". Sayana

[20] *Id.*

Press as sold in Europe may be self-administered by patients, obviating the need for quarterly visits to a medical practitioner.

112. When Depo-SubQ Provera 104, under NDA number 21-583, submitted by Pharmacia & Upjohn, a subsidiary of 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.

113. Inexplicably, and presumably for commercially beneficial or contractual reasons, Pfizer made a conscious decision to not seek an alternative commercially more accessible brand name, and to not endeavor to more vigorously advocate for the sale of Depo-SubQ Provera 104 to patients seeking contraception, despite knowing it had a lower safer and effective dosage which would somewhat mitigate the potential for adverse reactions engendered by a high dose progestin, including the risk of developing or worsening meningioma tumors.

114. The "lowest effective dose" is a well-known concept in the field of pharmaceutics 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.

115. Defendants ignored reports from patients and health care providers throughout the United States which 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 numerous other patients. Rather than conducting adequate testing to determine the cause of these injuries for which it 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.

116. Defendants' Depo-Provera 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.

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

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

119. As a result of Defendants' actions, 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.

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

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

122. 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 PFIZER AND GREENSTONE FOR THE "AUTHORIZED GENERICS"

123. Defendant Pfizer is the current New Drug Application (hereinafter "NDA") holder for Depo-Provera. Pfizer has effectively held the NDA since at least 2002, when it acquired Pharmacia & Upjohn, then the NDA holder, as a wholly owned subsidiary. No later than 2003 did Pfizer's name appear on the label alongside Pharmacia & Upjohn.

124. In November 2020, Defendant Greenstone became a subsidiary of Viatris Inc. pursuant to the spin-off.

125. Defendant Greenstone was from 2004 until 2020 the "authorized generic manufacturer" and distributor operating under the same NDA of Depo-Provera, with the express permission of 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.

126. Unlike standard generics, "authorized generics" are exact replicas of the brand-name drug and are manufactured by or under the authority of the NDA holder while marketed without the brand name on the label.

127. The FDA has stated that the term "authorized generic" drug is most commonly used to describe an approved brand name drug that is marketed without the brand name on its label. Other than the fact that 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.[21]

[21] *See* https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs (last accessed March 13, 2025).

128. For instance, 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." [22]

129. 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" medicines, including Depo-Provera.

130. From 2004 until approximately November 2020, Defendant Greenstone sold an "authorized generic" version of Depo-Provera ("Greenstone DMPA"). Unlike standard generics, which must contain only the same active ingredients and have the same pharmaceutic effect but can otherwise contain vastly different additives, Greenstone's DMPA as an "authorized generic" was an exact replica of the brand name drug, with the identical chemical composition, simply marketed without the brand-name on its label.

131. In other words, Greenstone was presenting itself as a distinct generic manufacturing entity when it was in fact Pfizer personnel producing the exact same brand-name Depo-Provera at Pfizer's own facility.

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[22] *See* https://www.pfizer.com/news/press-release/press-release-detail/pfizers-greenstone-and-digital-mens-health-clinic-roman (last accessed March 13, 2025).

132. In addition, Greenstone was not a separate and independent corporate entity, but an alter ego of Pfizer. Greenstone was exclusively staffed with Pfizer personnel who reported to Pfizer's Human Resources department, were on Pfizer's payroll, and operated out of Pfizer's corporate headquarters in Peapack, New Jersey. Pfizer managed Greenstone's core business functions, including financial and sales analysis, business technology, customer service, legal matters, intellectual property, and supply chain operations.

133. In effect, Greenstone functioned as a mere department within Pfizer such that the corporate veil should be pierced to hold Pfizer liable for Greenstone's actions related to the marketing, sale, and distribution of Greenstone DMPA.

134. Even after the November 2020 spin-off of Greenstone to Viatris Inc., the company continued to operate from Pfizer's corporate offices in Peapack, New Jersey, further evidencing the lack of separation between the two entities.

135. Likewise, Pfizer had responsibility for investigating and monitoring adverse reactions, other related pharmacovigilance duties, and reporting adverse events of patients using Greenstone's DMPA to the FDA.

136. Pfizer on several occasions submitted label changes to the FDA to revise and/or update the labeling for both the brand name and "authorized generic" Greenstone version of Depo-Provera.

137. Accordingly, since 2004 until the present the authorized generic distributors Greenstone operated as if it was the brand name holder under the same NDA and could and should have changed the brand name label to warn of the risks of meningioma and the use of high dose progestins.

138. At all times relevant, Pfizer knew that its authorized generic manufacturers held a large market share of its manufactured Depo-Provera under a different name.

139. Pfizer was at some or all of the pertinent times the actual manufacturer of the DMPA, identical to Depo-Provera other than its name, which was sold by Greenstone who was an "authorized generic" distributor based on the express permission of Pfizer to distribute, sell, and market Depo-Provera without the brand name on its label.

140. The "authorized generics" distributor Greenstone could and should have requested that Pfizer, with whom it was under contract to sell the "authorized generic" to change the brand name label to warn of the risks of meningioma and the use of high dose progestins.

141. Consequently, Pfizer had an independent duty to change the label knowing that its "authorized generic" distributor Greenstone, with whom they were in contract with and receiving revenue from the sale of the "authorized generic" DMPA, were selling the "authorized generic" without warning of meningioma risk.

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

142. Defendants willfully, wantonly, and intentionally conspired, and acted in concert, to withhold information from Plaintiff, Plaintiff's Prescribing and Administering Health Care 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.

143. 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.

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

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

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

147. 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/or sales information to Plaintiff, Plaintiff's Prescribing and Administering Health Care Providers, and the general public regarding the safety of Depo-Provera knowing such information was false, misleading, and/or 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.

148. Further, Defendants actively concealed the true risks associated with the use of Depo-Provera, particularly as they relate to the risk of serious intracranial meningioma, by affirmatively representing in numerous communications, which were disseminated to Plaintiff, Plaintiff's Prescribing and Administering Health Care Providers, 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.

149. Due to the absence of any warning by the Defendants as to the significant health and safety risks posed by Depo-Provera, Plaintiff was unaware that Depo-Provera could cause the development of a serious and debilitating intracranial meningioma, as this danger was not known to Plaintiff, Plaintiff's Prescribing and Administering Health Care Providers, or the general public.

150. 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 Prescribing and Administering Health Care Providers, or the general public.

151. Given Defendants' conduct and deliberate actions designed to deceive Plaintiff, Plaintiff's Prescribing and Administering Health Care 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

152. For the reasons set forth above and addressed below, Defendant Pfizer acted with a conscious disregard of the safety of Plaintiff and all the other women,

many who were young and of lower socioeconomic status, who were subjected to high dose injections of 150 mg Depo-Provera with the known and/or knowable risk of meningioma brain tumors which was generally accepted in the scientific community, while Pfizer had available its very own safer alternative medication, Depo-SubQ Provera 104. Exemplary damages are warranted to punish and deter Pfizer and others from such conduct in the future.

COUNT I

STRICT LIABILITY – FAILURE TO WARN

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

154. 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.

155. Defendants, as manufacturers, distributers, and marketers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known based on information that was available and generally accepted in the scientific community that warnings and other

clinically relevant information and data which they distributed regarding the risks associated with the use of Depo-Provera were inadequate.

156. Plaintiff and Plaintiff's Prescribing and Administering Health Care Providers 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 Prescribing and Administering Health Care Providers.

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

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

159. Defendants marketed, promoted, distributed and sold an unreasonably dangerous and defective prescription drug, Depo-Provera, to health care providers empowered to prescribe and dispense Depo-Provera, to consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data regarding the risk of meningioma and the risks of unnecessarily excessive

progestin exposure which 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, which resulted in injury to Plaintiff.

160. 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 meningioma. At all relevant times this information was readily available and generally accepted within the scientific community.

161. Despite the fact that Defendants knew or should have known based on information generally accepted within the scientific community that Depo-Provera with its higher than needed 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 patients be monitored.

162. 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, but failed to warn the medical community and the patients about the risks of the high dose which could be somewhat mitigated by using the lower dose formulation, Depo-SubQ Provera 104.

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

164. 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 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 meningioma and/or instructions concerning the need for monitoring and potential discontinuation of use of Depo-Provera.

165. 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.

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

167. Plaintiff's various prescribing physicians, nurse practitioners, physician assistants, and nurses (hereinafter collectively referred to as "Plaintiff's Prescribing and Administering Health Care Providers") would not have prescribed and administered Depo-Provera to Plaintiff had they been apprised by Defendants of the unreasonably high risk of meningioma associated with usage of Depo-Provera.

168. Alternatively, even if Defendants had apprised Plaintiff's Prescribing and Administering Health Care Providers of the unreasonably high risk of meningioma associated with usage of Depo-Provera and these Prescribing and Administering Health Care Providers had still recommended usage of Depo-Provera to Plaintiff, the Prescribing and Administering Health Care Providers would have relayed the information concerning the risk of meningioma 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 Physician and Administering Health Care Providers' continued recommendation.

169. Similarly, if Defendants had warned of the unreasonably high risk of meningioma associated with the usage of Depo-Provera, 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 and Administering Health Care Providers' recommendation.

170. Defendants failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Plaintiff and Plaintiff's Prescribing and Administering Health Care Providers of the dangerous risks of Depo-Provera including, among other things, the development of intracranial meningioma.

171. 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 meningioma.

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

173. Defendants had an obligation to provide Plaintiff and Plaintiff's Prescribing and Administering Health Care Providers 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.

174. By failing to adequately test and research harms associated with Depo-Provera, and by failing to provide appropriate warnings and instructions about Depo-Provera use, patients and 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 meningioma might be associated with use of Depo-Provera. Nor were the medical community, patients, patients' families, or regulators appropriately informed that serious and potentially debilitating intracranial meningioma might be a side effect of Depo-Provera and should or could be reported as an adverse event.

175. 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 ingesting 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.

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

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

178. 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 the losses in the future.

COUNT II
STRICT LIABILITY – DESIGN DEFECT

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

180. 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.

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

182. Depo-Provera was designed in such a way, using such a high dose of progesterone not necessary for effective contraception, that it posed an unreasonable risk of intracranial meningioma and by placing and keeping Depo-Provera on the market despite Depo-Provera being in a defective condition.

183. Depo-SubQ Provera 104 is a lower dosage version of Depo-Provera that contains 104 mg / 0.65mL and is injected subcutaneously every three (3) months. According to the label, Depo-SubQ Provera 104 can be used for both contraception and treatment of endometriosis.

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

185. 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.

186. Defendants failed to advocate Depo-SubQ Provera 104, the safer lower dose, approved by the FDA in 2004, for financial reasons because it could impact their business revenue and contractual relations with its authorized generic market for the 150 mg dose formulation.

187. 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.

188. 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 is administered, instead of intramuscularly.

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

190. Studies have shown that 150 mg Depo-Provera administered intramuscularly causes a spike in blood serum levels of DMPA that is more than four (4) times higher than the peak blood serum concentration of DMPA when that same 150 mg Depo-Provera shot is given subcutaneously, and that very high intramuscular peak concentration persists for several days.[23] In fact, 150 mg Depo-Provera administered subcutaneously has a remarkably similar pharmacokinetic profile to Depo-SubQ Provera 104.[24]

191. 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.

192. Defendants wantonly and willfully failed to apprise the public, including the FDA, the medical community, Plaintiff, Planned Parenthood, and Plaintiff's physicians, of the greatly reduced risk of meningioma 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

[23] *See* Shelton, et al., "Subcutaneous DPMA: a better low dose approach," *Contraception*, Vol. 89, pp. 341-43 (2014).

[24] *See id.* at 342.

lucrative market share held in part through its contracts with "authorized generic" partners and subsidiaries.

193. 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.

194. 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.

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

196. 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.

197. 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 meningioma to Plaintiff and other consumers.

198. The Depo-Provera injected into Plaintiff was expected to, and did, reach Plaintiff without substantial change in the condition in which it is sold.

199. The Depo-Provera injected into Plaintiff was in a condition not contemplated by Plaintiff in that it was unreasonably dangerous, posing a serious risk of meningioma, a severe and permanent injury.

200. 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 meningioma, a brain tumor that can cause severe damage and require invasive surgical removal, harming Plaintiff and other consumers.

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

202. 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 meningioma to Plaintiff and other consumers.

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

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

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

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

207. Defendants knew or should have known through testing, generally accepted scientific knowledge, advances in the field, published research in major

peer-reviewed journals, or other means, that Depo-Provera created a risk of serious and potentially debilitating intracranial meningioma and sequelae related thereto.

208. 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 meningioma tumors, 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 meningioma, 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.

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

210. 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.

211. 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

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

213. 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.

214. 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.

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

216. Defendants introduced a product that they knew or should have known would cause serious and permanent injuries related to the development of intracranial meningioma, and Plaintiff has been injured tragically and sustained severe and permanent injuries. In disregard of its duty, Defendants committed one or more of the following negligent acts or omissions:

a) Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and distributing Depo-Provera without thorough and adequate pre- and post-market testing of the product;

b) Manufacturing, producing, promoting, advertising, formulating, creating, developing, and designing, and distributing Depo-Provera while 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 the regulatory agencies, the medical community, and consumers that Defendants knew and had reason to know that Depo-Provera was indeed unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users;

e) Failing to warn Plaintiff, the medical and healthcare community, and consumers of the known and knowable product's risk of harm which was unreasonable and that there were safer and effective alternative products available to Plaintiff and other consumers;

f) Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would use Depo-Provera;

g) Advertising, marketing, and recommending the use of Depo-Provera, while concealing and failing to disclose or warn of the dangers known and knowable by Defendants to be connected with, and inherent in, the use of Depo-Provera;

h) Representing that Depo-Provera was safe for its intended use when in fact Defendants knew and should have known the product was not safe for its intended purpose;

i) Continuing to manufacture and sell Depo-Provera with the knowledge that Depo-Provera was unreasonably unsafe and dangerous;

j) Failing to use reasonable and prudent care in the design, research,

testing, manufacture, and development of Depo-Provera so as to avoid the risk of serious harm associated with the use of Depo-Provera;

k) Failing to design and manufacture Depo-Provera so as to ensure the drug was at least as safe and effective as other similar products;

l) Failing to ensure the product was accompanied by proper and accurate warnings about monitoring for potential symptoms related to intracranial meningioma associated with the use of Depo-Provera;

m) Failing to ensure the product was accompanied by proper and accurate warnings about known and knowable adverse side effects associated with the use of Depo-Provera and that use of Depo-Provera created a high risk of severe injuries;

n) Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Depo-Provera; and

o) Failing to sell a product with the lowest effective dose knowing that there were safer lower effective dose formulations.

217. A reasonable manufacturer, designer, distributor, promoter, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

218. 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 meningioma, and Plaintiff has been injured tragically and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

219. 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

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

221. 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.

222. Defendants duty of care was that a reasonably careful designer, manufacturer, seller, importer, distributor and/or supplier would use under like circumstances.

223. 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 meningioma, as it was reasonably foreseeable to Defendants that Depo-Provera could cause such injuries.

224. 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.

225. 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 and/or warn about the use of Depo-Provera, including, without limitations, the possible adverse side effects and health risks caused by the use of Depo-Provera;

e) Failure to adequately warn of the risks that Depo-Provera could cause the development of intracranial meningioma and sequelae related

thereto;

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

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

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 meningioma;

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.

226. Defendants knew or should have known of the risk and danger of serious bodily harm from the use of Depo-Provera but failed to provide an adequate warning to patients and prescribing physicians for the product, including Plaintiff

and Plaintiff's prescribing physicians, despite knowing the product could cause serious injury.

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

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

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

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

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

232. Plaintiff and Plaintiff's prescribing physicians reasonably relied upon the skill, superior knowledge, and judgment of Defendants. Defendants had a continuing duty to warn Plaintiff and prescribing physicians of the dangers

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

233. 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.

234. 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

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

236. 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.

237. 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.

238. 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;

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;

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

f) 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.

239. 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

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

241. At all relevant times, Defendants negligently provided Plaintiff, her Prescribing and Administering Health Care 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.

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

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

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

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

246. 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.

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

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

249. Defendants knew or should have known that equal efficacy for contraception and less risk could have been achieved with fewer doses administered.

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

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

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

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

253. 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.

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

255. The Defendants failed to exercise ordinary care in making representations concerning Depo-Provera while they were involved in their manufacture, design, sale, testing, quality assurance, quality control, promotion, marketing, labeling, and distribution in interstate commerce, because the Defendants

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

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

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

258. 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

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

260. The Defendants falsely and fraudulently have represented and continue to represent to the medical and healthcare community, Plaintiff and her Prescribing and Administering Health Care Providers, and the public in general that Depo-Provera has been appropriately tested and was found to be safe and effective.

261. 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.

262. 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 meningioma and sequelae related thereto.

263. The representations were, in fact, false. When the Defendants made these representations, it knew and/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.

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

265. These representations were made by the Defendants with the intent of defrauding and deceiving the medical community, Plaintiff , and the public, and also inducing the medical community, Plaintiff, Plaintiff's Prescribing and Administering Health Care Providers, and/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 meningioma and sequelae related thereto.

266. Despite the fact that the Defendants knew or should have known of Depo-Provera's propensity to cause serious and potentially debilitating injuries due to the development of intracranial meningioma 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 20 years, yet 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 meningioma and sequela related thereto after using Depo-Provera.

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

268. In representations to Plaintiff and/or to her Prescribing and Administering Health Care Providers, 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.

269. 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 meningioma, and consequently, its ability to cause debilitating and permanent injuries.

270. The 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.

271. The 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.

272. 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 and her Prescribing and Administering Health Care Providers to induce them to purchase, prescribe, and/or use the drug.

273. At the time these representations were made by Defendants, and at the time Plaintiff and/or her Prescribing and Administering Health Care Providers used Depo-Provera, Plaintiff and/or her Prescribing and Administering Health Care Providers were unaware of the falsehood of these representations.

274. 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. The Defendants knew or had reason to know that the Plaintiff had no way to determine the truth behind the Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of Depo-Provera as described in detail herein.

275. 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.

276. 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.

277. 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 the Defendants, nor could Plaintiff with reasonable diligence have discovered the true facts about the Defendants' misrepresentations at the time when Depo-Provera was prescribed to her.

278. 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.

279. 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

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

281. 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.

282. Defendants expressly warranted to Plaintiff, Plaintiff's Prescribing and Administering Health Care Providers, 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.

283. 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.

284. 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.

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

286. 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.

287. Plaintiff and Plaintiff's Prescribing and Administering Health Care Providers justifiably relied on Defendants' representations that Depo-Provera was safe and well-tolerated in their decision to ultimately prescribe, purchase and use the drug.

288. Plaintiff's Prescribing and Administering Health Care Providers 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.

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

290. 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

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

292. 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.

293. Defendants were the sellers of the 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.

294. When the Depo-Provera was prescribed by Plaintiff's Prescribing and Administering Health Care Providers and taken by Plaintiff, the product was being prescribed and used for the ordinary purpose for which it was intended.

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

296. 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.

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

298. 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.

299. 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court:

1. 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;
   b. Special Damages, including all expenses, incidental past and future expenses, medical expenses, and loss of earnings and earning capacity;
2. Award interest as permitted by law;
3. Award reasonable attorneys' fees and costs, as provided for by law; and
4. Grant such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

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

Dated: May 23, 2025

Respectfully Submitted,

By: /s/ *Ellen Relkin*

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