Stuart C. Talley (SBN 180374)
stuart@ktblegal.com
KERSHAW TALLEY BARLOW PC
401 Watt Avenue, Suite 1
Sacramento, CA 95864
Telephone: (916) 520-6639

Ashleigh Raso (*pro hac vice application to be submitted*)
Ava Cavaco (*pro hac vice application to be submitted*)
araso@nighgoldenberg.com
acavaco@nighgoldenberg.com
NIGH GOLDENBERG RASO & VAUGHN
60 S. 6th St. Floor 28
Minneapolis, MN 55402
Telephone: (202) 792-7927-10
Facsimile: (202) 792-7927

Attorneys for Plaintiff Mayra Valencia

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

MAYRA VALENCIA, Plaintiff, vs. **PFIZER INC.; VIATRIS INC.; GREENSTONE LLC; PRASCO, LLC d/b/a PRASCO LABS.; PHARMACIA & UPJOHN CO. LLC**; **and PHARMACIA LLC**, Defendants.	**Case No.: _____** **COMPLAINT AND DEMAND FOR JURY TRIAL**

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

INTRODUCTION

1. This is an action for damages 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").

2. 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.

3. Depo-Provera injured Plaintiff Mayra Valencia (hereinafter "Plaintiff") by causing or substantially contributing to the development of an intracranial meningioma, i.e., brain tumor, which required significant and invasive treatment and have resulted in serious injuries.

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

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

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

7. To date, the U.S. label for Depo-Provera still makes no mention of the increased risk to patients of developing intracranial meningiomas despite the fact that the European Union (EU) and the United Kingdom labels now list meningioma under the "special warnings and precautions for use" section and advise EU patients to speak with their doctors before using Depo-Provera if they have any history of meningioma.

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

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

10. Plaintiff therefore demands judgment against Defendants and requests, among

other things, compensatory damages, statutory damages, punitive damages, attorneys' fees, and costs.

PARTIES

11. At all relevant times hereto, Plaintiff Mayra Valencia (hereinafter "Plaintiff") was and is a resident and citizen of Fresno, California.

12. Defendant PFIZER INC. (hereinafter "Pfizer") is a corporation organized under Delaware law with its principal place of business at The Spiral, 66 Hudson Boulevard East, New York, NY 10001.

13. Pfizer has a registered agent for service of process, CT Corp., at 330 North Brand Boulevard in Glendale, California.

14. Defendant VIATRIS INC. (hereinafter "Viatris") is a corporation organized under Delaware law with its principal place of business at 1000 Mylan Boulevard, Canonsburg, PA 15317.

15. Viatris has a registered agent for service of process, CT Corp., at 330 North Brand Boulevard in Glendale, California.

16. Defendant GREENSTONE, LLC (hereinafter "Greenstone") is a limited liability corporation organized under Delaware law with its principal place of business at 2898 Manufacturers Road, Office #112, Greensboro, NC 27406.

17. Greenstone has a registered agent for service of process, CT Corp., at 5098 Washington Street West, Suite 407, Charleston, WV 25313.

18. Defendant PRASCO, LLC d/b/a PRASCO LABS. (hereinafter "Prasco") is a corporation organized under Ohio law with its principal place of business at 6125 Commerce Court, Mason, OH 45040.

19. Prasco has a registered agent for service of process, CT Corp., at 330 North Brand Boulevard in Glendale, CA.

20. Defendant PHARMACIA & UPJOHN CO. LLC (hereinafter "Pharmacia & Upjohn" or "Upjohn") is or was a corporation organized under Michigan law and headquartered at 7171 Portage Road, Kalamazoo, MI 49002.

21. Pharmacia & Upjohn has a registered agent for service of process, CT Corp., at 330 North Brand Boulevard in Glendale, CA.

22. Defendant PHARMACIA LLC (hereinafter "Pharmacia") is a corporation organized under Delaware law and headquartered at Pfizer Peapack Campus, 100 Route 206 North, Peapack, NJ 07977.

23. Pharmacia has a registered agent for service of process, CT Corp., at 820 Bear Tavern Road, West Trenton, NJ 08628.

24. Defendant Pfizer is the current New Drug Application (hereinafter "NDA") holder for Depo-Provera and has solely held the NDA for Depo-Provera since 2020. Upon information and belief, Pfizer has effectively held the NDA since at least 2002 when it acquired Pharmacia & Upjohn—who then held the NDA—as a wholly owned subsidiary. No later than 2003 did Pfizer's name appear on the label alongside Pharmacia & Upjohn.

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

26. Defendant Greenstone, founded in 1993, was a wholly owned subsidiary of Pfizer, that at pertinent times was in the business of offering a product portfolio of "authorized generic" medicines, including Depo-Provera.

27. Defendant Greenstone is a company that until November 2020 was styled as a wholly owned subsidiary of Pfizer but was in fact exclusively staffed with Pfizer personnel who reported to Pfizer's HR department, were on Pfizer's payroll, and shared the same corporate space with Pfizer in Peapack, NJ. Pfizer also managed Greenstone's key business functions including financial and sales analysis, business technology, customer service, legal matters, intellectual property, and supply chain operations. Thus, Greenstone was effectively a department within Pfizer.

28. Defendants Greenstone/Pfizer sold a "generic" version of Depo-Provera that was in fact what is known as an "authorized generic." Unlike standard generics, which must contain only the same active ingredients and have the same pharmaceutic effect but can otherwise

contain vastly different additives, "authorized generics" are exact replicas of the brand name drug, with the identical chemical composition, simply marketed without the brand-name on its label. 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.

29. 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.[1]

30. Indeed, Pfizer's own website still states that "GREENSTONE Authorized Generics are manufactured to the same standards and at the same facilities as Pfizer brand-name drugs."[2]

31. Pfizer was the actual manufacturer of the authorized generic product that Greenstone distributed and sold.

32. Defendant Viatris was formed by the merger of Upjohn, Greenstone, and another company, Mylan N.V., in November 2020. Viatris is thus merely the latest iteration of Upjohn and Greenstone.

33. Even after the merger, Defendant Greenstone has continued to operate from the same location at Pfizer's corporate offices in Peapack, NJ.

34. Additionally, Defendant Pfizer retained 57% ownership of Viatris stock, making Pfizer the majority owner of Viatris, and since Pfizer retained the remnants of Pharmacia, Pfizer effectively remains the majority owner of Defendants Pharmacia & Upjohn and Greenstone.

35. Defendant Prasco is another "authorized generic" manufacturer of Depo-Provera, meaning Prasco simply takes brand-name Depo-Provera manufactured by Defendants

[1] *See* https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs (last accessed Sept. 30, 2024).

[2] *See* https://www.pfizer.com/news/press-release/press-release-detail/pfizers-greenstone-and-digital-mens-health-clinic-roman (last accessed Sept. 26, 2024).

Greenstone and/or Pfizer and distributes it as its own generic product.

36. Defendant Prasco consistently maintains a sizeable percentage of the market share for Depo-Provera sales in the US.

37. Pfizer is the actual manufacturer of the authorized generic product that Prasco distributes and sells. Pfizer packages and labels the product with the Prasco name on the label under the Pfizer NDA.

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

39. At all times material herein, Defendants were, and still are, pharmaceutical companies involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Depo-Provera and its "authorized generic" version, in California, and throughout the United States.

JURISDICTION AND VENUE

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

41. All Defendants regularly conduct business in California.

42. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

43. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim, including the distribution, sale, and administration of Depo-Provera to Plaintiff and Plaintiff's development and treatment of meningiomas, all occurred in the Eastern District of California.

44. Defendant Pfizer has extensive connections to the State of California that are highly relevant to the subject matter of the instant action.

45. For example, Pfizer maintains the Pfizer La Jolla Research Site, a 25-acre "campus" complete with a 500,000-square-foot state-of-the-art facility devoted to the study of

oncology, drug safety, and pharmacokinetics.[3]

46. As of December 2018, Defendant Pfizer's La Jolla campus is home to more than 900 scientists and clinicians studying, *inter alia*, the effects of drugs on the development of tumors.[4]

47. According to Pfizer's website, the "Pfizer La Jolla campus is an important part of California's life sciences community and partners with academic institutions and other research organizations to advance scientific understanding and deliver new medicines."[5]

48. Pfizer's website states: "In 2011, Pfizer announced that it is partnering with the University of California, San Diego Health Sciences and Sanford-Burnham Medical Research Institute through [Pfizer's] Centers for Therapeutic Innovation (CTI)." Pfizer's website explains "CTI is a network of collaborative partnerships with top-tier life science research institutions in California, Massachusetts and New York that aims to accelerate and transform drug discovery and development. In San Diego, CTI's home base is located on the Pfizer La Jolla campus."[6]

49. CTI was launched by Pfizer in 2010 as "an entrepreneurial network of partnerships with leading academic medical centers to transform research and development by accessing leading translational researchers."[7]

50. The University of California, San Francisco was "the first collaboration in the network."[8]

51. Pfizer's senior vice president of Worldwide BioTherapeutics Research and Development stated at the time of the announcement, "UCSF is a world-class academic medical

---

[3] https://www.pfizer.com/la-jolla-california (Last accessed Oct. 13, 2024).

[4] *See* https://www.sandiegouniontribune.com/2018/12/11/pfizer-adds-100-to-cancer-research-center-in-la-jolla/ (Dec. 11, 2018) (Last accessed Oct. 13, 2024).

[5] https://www.pfizer.com/la-jolla-california (Last accessed Oct. 13, 2024).

[6] *Id.*

[7] https://www.pfizer.com/news/press-release/press-release-detail/pfizer_launches_global_centers_for_therapeutic_innovation_a_network_of_research_partnerships_with_university_of_california_san_francisco (Nov. 16, 2010) (Last accessed Oct. 13, 2024).

[8] *Id.*

center with a strong focus on both basic science and clinical research, which is why Pfizer is partnering with them on this initiative. Ultimately, we believe this could create significant benefit for the patient."[9]

52. Pfizer has thus deliberately created strong connections not just to the consumers and patients of California but also to the life and health sciences communities and the State educational institutions of California as well.

53. Moreover, Defendants Pfizer, Viatris, Upjohn & Pharmacia, and Prasco are all registered to do business in the State of California and can be served at their registered agent for service of process, CT Corp., at 330 North Brand Boulevard in Glendale, CA.

54. All Defendants at different periods of time had a contractual and/or sales relationship directly or through intermediaries to sell Depo-Provera to Kaiser Permanente Health System knowing that health care providers at Kaiser Permanente in California would be injecting Depo-Provera into patients.

55. At various points of time, Defendant Pfizer sponsored continuing education courses, seminars, and meetings to promote the use of Depo-Provera to Plaintiff's health care providers and the Kaiser Permanente Health System in California.

PLAINTIFF MAYRA VALENCIA SPECIFIC FACTS

56. In 2001, at the age of 16, Plaintiff Myra Valencia was first administered Depo-Provera for contraception.

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

58. From 2001 to September 2024, Plaintiff regularly received Depo-Provera injections pursuant to her physicians' prescriptions, which amounts to roughly ninety-five (95) injections.

59. Over time, Plaintiff developed alarming symptoms, including blurred vision, eye bulging, and persistent headaches. After numerous medical visits and testing procedures, Plaintiff

[9] *Id.*

was diagnosed with an intracranial meningioma.

60. Specifically, in June of 2024 at the age of 39, Plaintiff underwent an MRI which revealed a possible meningioma measuring 6 mm.

61. On August 14, 2024, Plaintiff underwent a right orbitozygomatic craniotomy at Community Regional Medical Center to remove the meningioma.

62. During the procedure, Plaintiff's head was shaved and an incision was made down to her skull. Small holes were then drilled into Plaintiff's skull. The surgeon then "osteotomized the zygoma as well as the superior, the skull base, just all the way to the superior orbital fissure and the inferior orbital fissure laterally". The surgeon then removed the superior and lateral orbital walls which "were quite diseased". The Plaintiff's periorbita structures were retracted and more holes were drilled into the Plaintiffs skull down to the mass. The surgeon removed the mass.

63. After removing the mass, the surgeon placed orbital mesh to cover the dural defect and reconstructed the orbital walls.

64. Plaintiff spent three nights in the hospital in recovery.

65. Plaintiff will continue to be monitored for reoccurrence of the Meningioma.

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

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

GENERAL ALLEGATIONS

A. Intracranial Meningioma

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

69. 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.

70. 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.

71. 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

72. 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.

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

74. 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.[10]

75. According to that same report, those proportions increase even further for

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

Hispanic (27.2%) women and Black (41.2%) women who had ever used Depo-Provera.[11]

76. 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 labelling recommending alternating the injection site at each injection.

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

78. Among reproductive age women who used any form of contraception from 2017-2019, the contraceptive injection was most often used by young women, lower-income women, and Black women.[12]

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

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

81. The NDA for Depo-Provera for use as a contraceptive was originally submitted to the FDA by Upjohn in 1967; however, this application was rejected.

82. Upjohn again applied to the FDA for approval to market Depo-Provera as a contraceptive in 1978 but was again rebuffed.

83. Upjohn applied to the FDA for a third time for the approval of Depo-Provera as a contraceptive in 1983, but the FDA once again rejected the application.

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

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

---

[11] *Id.*

[12] *See* https://www.kff.org/womens-health-policy/fact-sheet/dmpa-contraceptive-injection-use-and-coverage/ (last accessed Sept. 30, 2024).

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

87. 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.

88. 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 Defendant Viatris.

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

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

91. 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

92. The association between progesterone and meningioma has been known or 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.

93. 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.[13]

94. This finding was surprising and notable within the medical and scientific communities because it had previously been thought that meningioma cells, like breast cancer

[13] *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).

cells, would show a preference for estrogen receptors.[14] 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.[15] This particular study was published nearly a decade before the FDA approved Depo-Provera for contraception in 1992. In those nine (9) years before Depo-Provera was approved for contraception, and in the thirty-two (32) years since—more than forty (40) years in all—Defendants have seemingly failed to investigate the effect of their high-dose progesterone Depo-Provera on the development of meningioma.

95. 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.[16] 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.[17]

96. Numerous studies published in the decades since have presented similar findings on the negative correlation between progesterone-inhibiting agents and meningioma.[18]

97. 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.[19]

---

[14] *See id.*

[15] *See id.*

[16] *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).

[17] *See id.*

[18] *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).

[19] *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

98. In 2015, a retrospective literature review published in the peer-reviewed journal *BioMed Research International* by Cossu, et al. surveyed the relevant literature including many of the studies cited above and concluded that mifepristone, an antiprogesterone agent, had a regressive effect on meningioma, meaning it stopped or reversed its growth.[20] Reviewing the Blankenstein studies as well as many others conducted over a span of more than thirty (30) years, the authors concluded that mifepristone competes with progesterone for its receptors on meningioma cells and, by blocking progesterone from binding, stems or even reverses the growth of meningioma.

99. 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.

100. 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

---

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).

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

medicine.

101. In 2022, an article was published in the journal *Endocrinology* entitled "Estrogen and Progesterone Therapy and Meningiomas."[21] This retrospective literature review noted that a "dose-dependent relationship" has been established between at least one progestin and the incidence and growth rate of meningioma. The study authors further noted that progesterone-mediated meningiomas appear to be located most often in the anterior and middle base of the skull and are more likely to be multiple and require more intensive treatment.

102. 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."[22] 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."

103. In 2024, the French National Agency for Medicines and Health Products Safety along with several French neurosurgeons, epidemiologist, clinicians, and researchers published a large case control study in the *British Medical Journal* (*BMJ*), one of the premier scientific journals in the world, to assess the risk of intracranial meningioma with the use of numerous progestogens among women in France, hereinafter referred to as the *Roland* study.[23]

104. By way of history, the *Roland* study noted that concerns over meningiomas

[21] Hage, et al., "Estrogen and progesterone therapy and meningiomas," *Endocrinology*, Vol. 163, pp. 1-10 (2022).

[22] 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).

[23] 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).

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."[24]

105. 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 prolonged use of Depo-Provera resulted in a 555% increased risk of developing intracranial meningioma. 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 which only requires action every three months to remain effective for its intended use of preventing pregnancy, and, in the case of the subcutaneous variant, treating endometriosis.

106. 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 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.

107. Depo-Provera had by far the highest risk of meningioma surgeries amongst progesterone contraceptive products studied, rendering Depo-Provera more dangerous than other

[24] *See id.*

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.

108. Further, the *Roland* study found the longer duration of exposure had a greater risk noting the results show that three quarters of the women in the case group who had been exposed for more than a year had been exposed for more than three years.

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

D. Defendants' Failure to Test Depo-Provera

110. 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.

111. 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.

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

112. According 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.[25] Despite the fact there are at least fourteen (14) iterations of 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.

113. Despite the aforementioned article in the *BMJ* and all the preceding medical

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

literature cited above demonstrating the biological plausibility of the association between progesterone and meningioma, evidence of Depo-Provera related cases of meningioma and the evidence of other high dose progesterones causing meningiomas, Defendants have still made no change to the U.S. Depo-Provera label related to intracranial meningioma. Furthermore, Defendants have failed to take any steps to otherwise warn the medical community and Depo-Provera users of these significant health risks, despite changing the label as recently as July 2024 to include warnings about pregnancy-related risks, and despite Defendant Pfizer stating to The Guardian when the *BMJ* article was released in April 2024: "We are aware of this potential risk associated with long-term use of progestogens and, in collaboration with regulatory agencies, are in the process of updating product labels and patient information leaflets with appropriate wording."[26]

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

115. 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)."

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

[26] "Hormone medication could increase risk of brain tumours, French study finds," The Guardian, published online Mar. 27, 2024 (available at https://www.theguardian.com/society/2024/mar/27/hormone-medication-brain-tumours-risk-progestogens-study) (last accessed Sept. 12, 2024).

117. Specifically, Defendants could have filed a "Changes Being Effected" ("CBE") supplement under Section 314.70(c) of the FDCA to make "moderate changes" to Depo-Provera's label without any prior FDA approval.

118. Examples of moderate label changes that can be made via a CBE supplement explicitly include changes "to reflect newly acquired information" in order to "add or strengthen a contraindication, warning, precaution, or adverse reaction." By definition and by regulation such changes to add a warning based on newly acquired information—such as that imparted by newly emerging literature like the litany of studies cited above—are considered a "moderate change." § 340.70(c)(6)(iii).

119. Recently, the Third Circuit reaffirmed that plain text interpretation of the CBE supplement process in a precedential decision holding that the defendant in that case, Merck, could not rely on a preemption defense based on an allegedly irreconcilable conflict between federal (FDCA) and state (civil tort) law so long as the warning could have been effected via a CBE change. *See generally In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, Case No. 22-3412, D.I. 82 at 73 on the docket (J. Jordan) (3d Cir. Sept. 20, 2024) (noting "the availability of a label change via a CBE supplement is problematic for Merck, as will very often be the case for pharmaceutical companies raising an impossibility defense").

120. 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.[27] Nevertheless, Defendant never produced a 150 mg subcutaneous version.

121. Knowing that the lower dose 104 mg Depo-SubQ Provera 104 was equally effective and was easier to administer since it involved a smaller needle being injected only below

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

the skin and not all the way into the muscle, Defendants could have educated the gynecology community that it had a safer alternative product to Depo-Provera which was more well known to prescribers and patients.

122. In Europe and other counties 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 Press sold in Europe may be self-administered by patients, obviating the need for quarterly visits to a medical practitioner.

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

124. Inexplicably, and presumably for commercially beneficial or contractual reasons, Defendant 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 mitigate the potential for adverse reactions engendered by a high dose progestin, including the risk of developing or worsening meningioma tumors.

125. 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 increase the risk of unwanted side effects.

126. Either change—adding a warning about the risk of meningioma based on "newly acquired information" or advising physicians to consider a switch to subcutaneous Depo-SubQ Provera 104—either on its own or taken together, would have constituted a "moderate change" or changes justifying a simple CBE supplement that Defendants could have effectuated immediately, and then simply notified the FDA thereafter. Yet, Defendants have failed to do so, and that failure continues to date.

127. 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.

128. 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.

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

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

131. 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.

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

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

134. 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, GREENSTONE, VIATRIS, AND PRASCO FOR THE "AUTHORIZED GENERICS"

135. Defendants Greenstone, Viatris and Prasco were at different times from 2004 until the present 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.

136. Accordingly, the authorized generic distributors Greenstone, Viatris, and Prasco operated as if they were the brand name holder under the same NDA and could have changed the brand name label to warn of the risks of meningioma and the use of high dose progestins.

137. Further, the "authorized generics" distributors Greenstone, Viatris, and Prasco could have requested that Pfizer, with whom they were 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.

138. Pfizer had a duty to change the label knowing that its "authorized generic" distributors Greenstone, Viatris, and Prasco, with whom they were in contract and receiving revenue from the sale of the "authorized generic" DMPA were selling the "authorized generic" without warning of meningioma risk.

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

140. 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 Defendants Greenstone, Viatris, and Prasco who were at different times the "authorized generic" distributor, with the express permission of Pfizer, to distribute, sell, and market Depo-Provera without the brand name on its label.

/ / /

/ / /

INNOVATOR LIABILITY UNDER CALIFORNIA LAW

141. In October of 2002, Defendant Pfizer's patent for Depo-Provera expired. Following this, the FDA approved various generic versions of Depo-Provera for sale in the United States. Despite the availability of generics, Pfizer has continued to manufacture, market, and distribute the brand-name Depo-Provera across the United States, including in California.

142. A manufacturer wishing to market a generic version of an FDA-approved drug can submit an Abbreviated New Drug Application (ANDA). This allows the generic manufacturer to rely on the NDA filed by the brand-name manufacturer by demonstrating that the generic version contains the same active ingredients and is biologically equivalent to the brand-name drug.[28]

143. As part of the NDA, the brand-name manufacturer must propose the exact text of the label, subject to FDA approval.[29] For generics, the ANDA process mandates that the safety and efficacy labeling must be identical to that of the brand-name drug.[30]

144. While the brand-name manufacturer bears responsibility for the accuracy and adequacy of the drug label, generic manufacturers are only required to ensure that their labels mirror the brand-name version.[31] The California Supreme Court has reasoned that because a brand-name manufacturer is responsible for the content of a drug's warning label, it "knows to a legal certainty ... that any deficiencies in the label for its drug will be perpetrated in the label for its generic bioequivalent."[32] As a result, the content of the generic labels for Depo-Provera bioequivalents is entirely dictated by the brand-name manufacturer Defendant Pfizer's label. Thus, California law liability for failure to warn can extend to Defendant Pfizer, even when the consumer is prescribed only the generic version.

145. Because generic manufacturers must replicate the brand-name label exactly, Defendant Pfizer exerted exclusive control over the contents of the labels used by generic

[28] *See* 21 U.S.C. § 355(j)(2)(A)(ii), (iv).

[29] *See* 21 U.S.C. § 355; *see also* 21 C.F.R. § 314.105(b).

[30] *See* 21 U.S.C.A. § 355(j); *see also PLIVA, Inc. v. Mensing,* 564 U.S. 604, 612-13 (2011).

[31] *See generally* 21 U.S.C. § 355; *see also* 21 C.F.R. § 314.105(b).

[32] *T.H. v. Novartis Pharm. Corp.,* 4 Cal. 5th 145, at 166 (2017).

versions of Depo-Provera that Plaintiff may have been prescribed and administered. Consequently, any deficiencies or omissions in Defendant Pfizer's label would have been reflected in the generic labels.

146. As the brand-name manufacturer of Depo-Provera, Defendant Pfizer had and continues to have a duty to ensure that the labeling for Depo-Provera remains accurate and adequate "as soon as there is reasonable evidence of an association of a serious hazard with a drug," regardless of whether a causal relationship has been established.[33] Defendant Pfizer was not only in the best position to provide warnings regarding Depo-Provera's risks but was also the only entity legally authorized to update the label unilaterally under federal law.

147. Defendant Pfizer knew or should have known that any failure to adequately warn of Depo-Provera's risks would be replicated in the labels of its generic bioequivalents, directly affecting the information available to physicians and patients regarding both the brand-name and generic drugs. Accordingly, it is foreseeable that the warnings included or omitted on the brand-name drug label would influence dispensing of the generic drug and the decision-making of unsuspecting doctors and patients, like Plaintiff and Plaintiff's physicians, as to whether to take a generic equivalent of Depo-Provera and/or brand-named Depo-Provera for contraception.

148. As the brand-name manufacturer of Depo-Provera, Defendant Pfizer could have, at any time, unilaterally updated the Depo-Provera label without waiting for FDA preapproval in order to "add or strengthen a contraindication, warning, precaution, or adverse reaction" under the CBE regulation.[34] As the brand name manufacturer of Depo-Provera, Defendant Pfizer had a duty to give information about Depo-Provera to the medical community and public at large.

149. Despite having the ability and obligation to provide timely and adequate warnings, Defendant Pfizer failed to take such action, contributing to the harm suffered by Plaintiff.

150. Thus, to the extent that any of the approximately sixty-four (64) doses of Depo-Provera administered to Plaintiff were generic, Defendant Pfizer is additionally liable for any resultant harm to Plaintiff from those generic doses under California's well-established doctrine

[33] *See* 21 C.F.R. § 201.80(e).

[34] *See* 21 C.F.R. § 314.70(c)(6)(iii)(A).

of innovator fendliability.

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

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

152. 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.

153. 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.

154. 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.

155. 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.

156. 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, her healthcare 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.

157. 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, her healthcare providers, and which included, without limitation, the Package Insert and the Medication Guide, that there were no warnings required to safely prescribe and take Depo-Provera and no intracranial meningioma-related adverse side effects associated with use of Depo-Provera.

158. 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 healthcare providers, or the general public.

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

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

CONDUCT WARRANTING PUNITIVE DAMAGES

161. 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 Defendant Pfizer had available its very own safer alternative medication, Depo Sub-Q Provera 104. Exemplary damages are warranted to punish and deter Defendant Pfizer and others from such conduct in the future.

/ / /

/ / /

COUNT I

STRICT LIABILITY – FAILURE TO WARN

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

163. 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.

164. 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.

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

166. 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.

167. 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.

168. 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.

169. 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.

170. 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.

171. 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 mitigated by using the lower dose formulation, Depo-SubQ Provera 104.

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

173. 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.

174. 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.

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

176. 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.

177. 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.

178. 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.

179. 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.

180. 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.

181. 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.

182. 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.

183. 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.

184. 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.

185. 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.

186. 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.

187. 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

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

189. 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.

190. 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.

191. 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.

192. 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.

193. 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.

194. Defendant 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.

195. 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.

196. 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.

197. 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.

198. 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.[35]

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

In fact, 150 mg Depo-Provera administered subcutaneously has a remarkably similar pharmacokinetic profile to Depo-SubQ Provera 104.[36]

199. 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.

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

201. 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.

202. 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.

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

204. 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.

205. 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

[36] *See id.* at 342.

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.

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

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

208. 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.

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

210. 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.

211. 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.

212. 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.

213. 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.

214. 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.

215. 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.

216. Depo-Provera is defective and unreasonably dangerous to Plaintiff and other consumers in that, despite early indications and concerns that Depo-Provera use could result in vision issues, Defendants failed to adequately test or study the drug, including but not limited to: pharmacokinetics and pharmacodynamics of the drug, its effects on the development of brain tumors like intracranial 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.

217. 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.

218. 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.

219. 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

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

221. 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.

222. 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.

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

224. 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; and

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

o. Failing to sell a product with the lowest effective dose knowing that

there were safer lower effective dose formulations.

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

226. 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.

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

COUNT IV

NEGLIGENT FAILURE TO WARN

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

229. 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.

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

231. 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.

232. 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.

233. 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 al 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; and

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.

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.

234. 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.

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

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

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

238. 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.

239. 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.

240. 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.

241. 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.

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

COUNT V

NEGLIGENT DESIGN DEFECT

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

244. 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.

245. 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.

246. 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; and

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.

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

248. 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.

249. As a direct and proximate result of Defendants' negligence, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for

the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of consortium, loss of ability to earn money and other economic losses. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

COUNT VI

NEGLIGENT MISREPRESENTATION

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

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

252. 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.

253. 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.

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

255. 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.

256. 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.

257. 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.

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

259. 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.

260. 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.

261. 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.

262. 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.

263. 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.

264. 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.

265. 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.

266. 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.

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

COUNT VII

FRAUDULENT MISREPRESENTATION

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

269. 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.

270. 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.

271. 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.

272. 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.

273. 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.

274. 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.

275. 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.

276. 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.

277. 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 in 2005.

278. 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.

279. 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.

280. 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.

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

282. 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.

283. 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.

284. 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.

285. 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.

286. 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.

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

288. 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

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

fully set forth herein.

290. 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.

291. 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.

292. 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.

293. 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.

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

295. 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.

296. 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.

297. 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.

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

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

COUNT IX

BREACH OF IMPLIED WARRANTY

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

301. 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.

302. 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.

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

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

305. 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.

306. 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.

307. 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.

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

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: November 4, 2024

Respectfully Submitted,

KERSHAW TALLEY BARLOW

By: */s/Stuart C. Talley*

Stuart C. Talley
401 Watt Avenue, Suite 1
Sacramento, CA 95864
Telephone: (916) 779-7000
stuart@ktblegal.com

Ashleigh Raso (MN #0393353)
Ava Cavaco (MN #0400683)
PHV Forthcoming
NIGH GOLDENBERG RASO & VAUGHN
60th S 6th St., Floor 2800
Minneapolis, MN 55402
araso@nighgoldenberg.com
acavaco@nighgoldenberg.com
(202) 792-7927

Attorneys for Plaintiff Mayra Valencia