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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MAKISHIA GREENO, individually and on behalf of all others similarly situated,

Plaintiff,

v.

PFIZER, INC., PHARMACIA & UPJOHN CO., LLC, PHARMACIA, LLC, PRASCO, LLC, d/b/a PRASCO LABS, GREENSTONE, LLC, and VIATRIS, INC.,

Defendants.

Case No. 2:25-cv-607

CLASS ACTION COMPLAINT FOR MEDICAL MONITORING

DEMAND FOR JURY TRIAL

1. Strict Liability—Product Defect
2. Strict Liability—Failure to Warn
3. Negligence
4. Negligent Failure to Warn
5. Negligent Design Defect
6. Negligent Misrepresentation
7. Fraudulent Misrepresentation
8. Breach of Express Warranty
9. Breach of Implied Warranty

Plaintiff Makishia Greeno, individually and on behalf of all others similarly situated, by and through her undersigned counsel, alleges as follows:

I. NATURE OF THE ACTION

1. This is an action for damages related to Defendants' development, manufacturing, marketing, and distribution of medroxyprogesterone acetate ("MPA"), more commonly known by Pfizer, Inc.'s ("Pfizer") trade name, Depo-Provera® ("Depo-Provera").

2. Depo-Provera is a progestin, *i.e.*, a synthetic progesterone hormone, prescribed for several indications, including endometriosis, hormone replacement, and prevention of uterine and cervical cancers. The most common use of Depo-Provera in the United States is as an injectable contraceptive administered once every three (3) months.

3. Medical researchers have known for decades of a plausible biological mechanism to associate progesterone and its synthetic analogue progestin—the primary active ingredient in Depo-Provera—with increased incidences of intracranial meningioma, *i.e.*, brain tumors.

4. Recent medical studies have confirmed that Depo-Provera, when prescribed and administered as an injectable contraceptive, causes a dramatic increase in the incidence of intracranial meningioma.

5. Intracranial meningioma, even when benign, typically causes a range of painful and debilitating physical symptoms and requires invasive surgical treatment. Moreover, up to twenty percent of intracranial meningioma cases become malignant and can metastasize, presenting risk to other regions of the body.

6. The risk of intracranial meningioma is particularly high for consumers who take Depo-Provera injections for more than a year, *i.e.*, at least four doses of the drug.

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

8. Despite this knowledge, Defendants continued to manufacture, market, promote, distribute, and sell Depo-Provera to the public, and moreover failed to warn or otherwise inform Depo-Provera users and health care providers about the risk of intracranial meningioma or reasonable steps to minimize such risk.

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9. Plaintiff and Class Members (defined below) were prescribed and received Depo-Provera injections for at least a year. Consequently, Plaintiff and Class Members face a dramatically increased risk of developing intracranial meningioma.[1]

10. Had Plaintiff known that taking Depo-Provera increased her risk of developing severe brain tumors, she would not have used it.

11. Plaintiff, individually and on behalf of all others similarly situated, seeks an order requiring Defendants to establish a program of medical monitoring, and seeks compensatory and punitive damages from Pfizer for breach of express warranty, breach of the implied warranty of merchantability, product defect, failure to warn, negligent or fraudulent misrepresentation, and violations of California consumer protection statutes. Plaintiff in this Medical Monitoring Class Action Complaint does not allege that she has suffered personal injury attributable to Depo-Provera.

II. PARTIES

12. Plaintiff Makishia Greeno is a natural person residing in Los Angeles County, California. Plaintiff is a citizen of California.

13. Defendant Pfizer was and is a corporation organized under Delaware law with its primary place of business in the borough of Manhattan, New York. Pfizer is a citizen of Delaware and New York. Pfizer has a registered agent for service of process, CT Corp., at 330 North Brand Boulevard in Glendale, California. At all relevant times as herein alleged, Pfizer was and is authorized to do business, and was and is doing business, in California.

14. Defendant Pharmacia & Upjohn Co., LLC ("Pharmacia & Upjohn") was and is a limited liability company organized under Michigan law with its primary place of business in Kalamazoo, Michigan. Pharmacia & Upjohn is a citizen of Michigan. Pharmacia & Upjohn has a registered agent for service of process, CT Corp., at 330 North Brand Boulevard in Glendale, California. At all relevant times as herein alleged,

[1] Roland *et al.*, *Use of progestogens and the risk of intracranial meningioma: national case-control study*, BMJ, Vol. 384, Mar. 27, 2024, https://doi.org/10.1136/bmj-2023-078078 (finding an increased 555% risk of developing a surgically treated intracranial meningioma with exposure to medroxyprogesterone acetate.)

Pharmacia & Upjohn was and is authorized to do business, and was and is doing business, in California.

15. Defendant Pharmacia, LLC ("Pharmacia") was and is a limited liability company organized under Delaware law with its primary place of business in Peapack, New Jersey. Pharmacia is a citizen of Delaware and New Jersey. Pharmacia has a registered agent for service of process, CT Corp., at 820 Bear Tavern Road, West Trenton, New Jersey. At all relevant times as herein alleged, Pharmacia was and is authorized to do business, and was and is doing business, in California.

16. Defendant Prasco, LLC, d/b/a Prasco Labs ("Prasco") was and is a limited liability company organized under Ohio law with its primary place of business in Mason, Ohio. Prasco is a citizen of Ohio. Prasco has a registered agent for service of process, CT Corp., at 330 North Brand Boulevard in Glendale, California. At all relevant times as herein alleged, Prasco was and is authorized to do business, and was and is doing business, in California.

17. Defendant Greenstone, LLC ("Greenstone") was and is a limited liability company organized under Michigan law with its primary place of business in Peapack, New Jersey. Greenstone is a citizen of Michigan and New Jersey. Greenstone has a registered agent for service of process, CT Corp., at 5098 Washington Street West, Suite 407, Charleston, West Virginia. At all relevant times as herein alleged, Greenstone was and is authorized to do business, and was and is doing business, in California.

18. Defendant Viatris, Inc. ("Viatris") was and is a corporation organized under Delaware law with its primary place of business in Canonsburg, Pennsylvania. Viatris is a citizen of Delaware and Pennsylvania. Viatris has a registered agent for service of process, CT Corp., at 330 North Brand Boulevard in Glendale, California. At all relevant times as herein alleged, Viatris was and is authorized to do business, and was and is doing business, in California.

19. Pfizer is the current New Drug Application ("NDA") holder for Depo-Provera and has solely held the NDA for Depo-Provera since 2020. Upon information and belief,

Pfizer has effectively held the NDA since at least 2002 when it acquired Pharmacia & Upjohn—who then held the NDA—as a wholly owned subsidiary. No later than 2003 did Pfizer's name appear on the label alongside Pharmacia & Upjohn.

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

21. 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.

22. 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.[2]

23. Greenstone manufactures authorized generic equivalents of Depo-Provera. 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."[3]

24. 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.

25. Even after the merger, Greenstone has continued to operate from the same location at Pfizer's corporate offices in Peapack, New Jersey.

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[2] *See* https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs (last accessed Jan. 23, 2025).

[3] *See* https://www.pfizer.com/news/press-release/press-release-detail/pfizers-greenstone-and-digital-mens-health-clinic-roman (last accessed Jan. 23, 2025).

26. Additionally, 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.

27. Prasco is another "authorized generic" manufacturer of Depo-Provera, meaning Prasco simply takes brand-name Depo-Provera manufactured by Defendants Greenstone and/or Pfizer and distributes it as its own generic product.

28. Prasco consistently maintains a sizeable percentage of the market share for Depo-Provera sales in the U.S.

29. 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.

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

31. At all relevant times, 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, in California, and throughout the United States.

III. JURISDICTION AND VENUE

32. This Court has personal jurisdiction over all Defendants. All Defendants regularly conduct business activities in California, and thus purposefully avail themselves of California law. Plaintiff's claims arise directly from the Defendants' specific activities in California, *i.e.*, Defendants' marketing, promoting, selling, and distributing Depo-Provera. All Defendants were and are engaged in substantial business in this forum, thereby purposefully directing themselves at the forum state in such a manner that the exercise of jurisdiction is reasonable.

33. This Court has subject matter jurisdiction pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d). Diversity exists because Plaintiff is a citizen of California, and Defendants are citizens of Delaware, Michigan, New Jersey, New York, Ohio, and Pennsylvania. The amount in controversy in this matter exceeds $5,000,000.

34. 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 Plaintiff's claim occurred in this district. Namely, Plaintiff obtained a prescription for Depo-Provera, purchased and used Depo-Provera, and was exposed to unreasonable risk of physical injury in this district.

IV. FACTUAL ALLEGATIONS

A. Facts Specific to Plaintiff and Class Members

35. Plaintiff Makishia Greeno was first prescribed Depo-Provera in March 1996.

36. Plaintiff Greeno received the Depo-Provera shot consecutively from the time of her first use until approximately 2014 and then again from approximately 2015 to 2019.

37. As of the filing of this Complaint, Plaintiff Greeno has not received and is not receiving any medical monitoring for the detection of meningiomas.

38. At all relevant times, Defendants represented to Plaintiff and Class Members that Depo-Provera was safe and suitable for the purpose of contraception. Defendants made these representations on the product label, packaging, patient inserts, and advertising.

39. Plaintiff and Class Members relied on Defendants' representations about the safety and suitability of Depo-Provera when they elected to use it.

40. At all relevant times, Defendants represented to Plaintiff's and Class Members' health care providers that Depo-Provera was safe and suitable to prescribe to patients for contraception. Defendants made these representations on the product label, packaging, patient inserts, and advertising. Upon information and belief, Defendants also made these representations in promotional materials specifically targeted to health care professionals.

41. Upon information and belief, Plaintiff's and Class Members' health care providers relied on Defendants' representations about the safety and suitability of Depo-Provera when they prescribed it to Plaintiff and the Class.

42. Recently, following publicity related to medical research published in journals *BMJ* and *Cancers* in 2024, as described below, it became known that Depo-Provera is connected to the development of intracranial meningiomas.

B. Intracranial Meningioma

43. Intracranial meningioma is a medical condition where a tumor grows in the meninges, the protective membrane that surrounds the brain and spinal cord just inside the skull.

44. Around eighty percent of meningiomas are benign, *i.e.*, they are not cancerous and do not spread from the origin site to other parts of the body. Even when a meningioma is benign, the constant pressure it applies to the surrounding brain tissue can cause multiple severe, painful, and debilitating physical symptoms by pressing constantly against brain tissue.

45. Physical symptoms can vary based on the precise location of the meningioma and the specific bodily functions regulated by the adjacent brain tissue. The most common symptoms of meningioma are headaches, seizures, blurred vision or vision loss, hearing loss, weakness and numbness, memory loss, changes in personality and behavior, and speech difficulties.

46. Up to twenty percent of meningiomas become malignant. These meningiomas grow quickly and can metastasize, *i.e.*, spread cancer to other parts of the brain and throughout the body.

47. It is rare for people under the age of 35 to develop meningioma. The incidence of meningioma increases with age and rises sharply after the age of 65.

48. Meningiomas are rarely diagnosed before a patient begins to show symptoms. When symptoms indicate the possibility of a meningioma, an MRI or CT scan of the brain can detect the tumor and determine its location and size. To determine whether a

meningioma is benign or malignant, a neurosurgeon performs a biopsy, by drilling into the patient's skull in order to extract a piece of tissue from the tumor.

49. Invasive surgery to remove the tumor is the usual course of treatment for patients with malignant meningioma, or patients whose benign meningioma is causing severe symptoms such as seizures, blurred vision, hearing loss, weakness or numbness in limbs, or severe headaches.

50. To remove meningioma, neurosurgeons first perform a craniotomy, *i.e.*, remove a piece of bone from the skull near the location of the tumor. The surgeon then removes as much of the tumor as possible, before replacing the bone that was removed in the craniotomy.

51. 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 risk of sedatives and antidepressants in the postoperative period.

52. Surgery for intracranial meningioma can also lead to seizures requiring medication to treat epilepsy.

53. Meningiomas related to progesterone-based contraceptives tend to manifest at the base of the skull where surgical removal is even more challenging, further increasing the risk of postoperative injuries.

54. Radiation therapy and chemotherapy may also be required if the sensitive location of the meningioma renders complete removal highly risky and technically difficult.

C. Depo-Provera

55. Depo-Provera (depot medroxyprogesterone acetate, hereinafter "DMPA") was first approved by the FDA in 1992 as a contraceptive and, later, with the approval of the Depo-SubQ Provera 104 variant in 2004, as a treatment for endometriosis.

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

57. According to a recent National Health Statistics Report published in December 2023, nearly a quarter (24.5%) of all sexually experienced women in the United States between 2015 and 2019 had ever used Depo-Provera.[4]

58. According to that same report, those proportions increase even further for Hispanic women (27.2%) and Black women (41.2%) who had ever used Depo-Provera.[5]

59. DMPA was developed by Upjohn, later acquired by Pfizer, in the 1950s. Upjohn filed a NDA with the Food & Drug Administration ("FDA") in 1967, seeking approval to market DMPA as a contraceptive.

60. The FDA rejected Upjohn's first NDA in 1967 and rejected two more NDAs in 1978 and 1983.

61. On its fourth application in 1992, Upjohn received the NDA for DMPA use as a prescription contraceptive and began marketing the drug as Depo-Provera in the United States.

62. Depo-Provera and its generic equivalents are 150 mg/mL dosages of DMPA that are delivered via intramuscular injection every three months.

63. Pfizer acquired Upjohn's NDA in 2002 and continued marketing the drug as Depo-Provera for use as an injectable contraceptive.

64. Generic versions of Depo-Provera are or have been manufactured by Defendants Greenstone, Prasco, and Viatris.

65. On the Depo-Provera label, Pfizer represents that injectable contraceptives like Depo-Provera are, along with sterilization, the most effective contraceptive methods available.

66. Depo-Provera, along with its generic equivalents, are currently used as a contraceptive by up to 25 percent of women in the United States aged 18 to 49.

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

[5] *Id.*

67. Pfizer also produces Depo-SubQ Provera 104 ("SubQ-104"), a DMPA product that is administered subcutaneously and with a lower 104 mg dose of DMPA.

68. Injections given intramuscularly, like Depo-Provera, are absorbed by the body at much faster rates than injections given subcutaneously, like SubQ-104.

69. 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 when that same shot is given subcutaneously.[6]

70. Though SubQ-104 delivers a much lower dose of progestin than Depo-Provera, studies show it is no less effective at maintaining blood serum levels of DMPA above the presumptive contraceptive threshold.[7] Remarkably, researchers reported that the SubQ-104 formulation "promises considerably longer efficacy, perhaps 6 months."[8]

71. In other words, medical evidence published a decade ago shows that SubQ-104 performs as well as Depo-Provera as an injectable contraceptive, for a potentially longer period of time, all while delivering far less of the active ingredient, progestin, known to be associated with increased incidences of meningioma.

72. SubQ-104, if it had been designed and approved for subcutaneous use, would be a lower dose alternative to Depo-Provera.

73. Depo-Provera, in its 150 mg dosage, if designed and approved for subcutaneous use, would also have been a lower dose alternative to the version of that Defendants currently market as an injectable contraceptive.

D. <u>Progesterone and Meningioma</u>

74. The association between progesterone and meningioma has been known or knowable for decades to sophisticated pharmaceutical corporations like Defendants, who engage in FDA-required post-market surveillance of their products for potential safety

[6] *See* Shelton, *et al.*, *Subcutaneous DMPA: a better low dose approach*, 89 Contraception 341 (2014).

[7] Shelton at 342.

[8] *Id*; *see also* Taylor, *et al.*, *Ovulation suppression following subcutaneous administration of depot medroxyprogesterone acetate*, Contraception: X, Volume 4, 100073 (2022), https://doi.org/10.1016/j.conx.2022.100073.

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.

75. Medical researchers have known for decades that women have a higher incidence of meningioma than men and that there exists a biologically plausible link between progesterone and intracranial meningioma.

76. The biologically plausible link between progesterone and intracranial meningiomas has been known in the scientific community since at least 1983, when researchers discovered a high number of progesterone receptors on meningioma cells, especially as compared to estrogen receptors.[9]

77. The same researchers published an article in 1989, demonstrating that meningioma cell growth was significantly reduced by exposure to mifepristone, an antiprogestrone agent.[10] The 1989 study provided further support for a link between progesterone and meningiomas.

78. Numerous studies published in the decades since the 1980s have presented similar findings on the correlation between progesterone and the incidence and growth of meningioma. Studies that have explored the effects of antiprogesterone agents have found that their use is negative correlated with meningioma size and frequency.[11]

[9] *See* Blankenstein, *et al.*, *Presence of progesterone receptors and absence of oestrogen receptors in human intracranial meningioma cytosols*, 19 Eur. J. Cancer & Clinical Oncology 365 (1983).

[10] *See* Blankenstein, *et al.*, *Effects of steroids and antisteroids on human meningioma cells in primary culture*, 34 J. Steroid Biochemistry 419 (1989).

[11] *See, e.g.,* Grunberg, *et al.*, *Treatment of unresectable meningiomas with the antiprogesterone agent mifepristone*, 74 J. Neurosurgery 861 (1991); *see also* Matsuda, et al., *Antitumor effects of antiprogesterones on human meningioma cells in vitro and in vivo*, 80 J. Neurosurgery 527 (1994); *see also* Wigertz, et al., *Swedish Interphone Study Group. Risk of brain tumors associated with exposure to exogenous female sex hormones*, Am J Epidemiol, 164(7), 629-36 (2006); Cossu, *et al.*, *The Role of Mifepristone in Meningiomas Management: A Systematic Review of the Literature*, Biomedical Rsch. Int'l 267831 (2015), available at https://doi.org/10.1155/2015/267831.

79. During the same time period, studies that have explored the effects of progesterone and progestins have found they are positively correlated with meningioma size and frequency.[12]

80. 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.[13] 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.

81. Furthermore, according to the FDA Adverse Events Reporting System ("FAERS"), thirty (30) reports of meningioma have been documented in connection with the use of medroxyprogesterone acetate from 2001 through April 2024.[14]

82. The extensive body of research exploring the relationships between antiprogesterone agents, progesterone levels, progestin-based medications, and meningioma size and frequency, were well known to pharmaceutical manufacturers like Defendants, who have the scientific and technical expertise required to research, develop,

[12] *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*, 72 Brit. J. Clinical Pharmacology 965 (2011); Bernat, et al., *Growth stabilization and regression of meningiomas after discontinuation of cyproterone acetate: a case series of 12 patients*, 157 Acta Neurochirurgia 1741 (2015); Kalamarides, *et al.*, *Dramatic shrinkage with reduced vascularization of large meningiomas after cessation of progestin treatment*, 101 World Neurosurgery 814 (2017).

[13] *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

[14] *See* Exhibit A, Food and Drug Administration (FDA), FDA Adverse Event Reporting System (FAERS), Combined Reports # 3811409; 3714569; 7760392; 23742669; 23728319; 23718188; 22953845; 22803447; 22683749; 21854560; 20840122; 20840121; 20838571; 20835846; 20833691; 20833665; 20833664; 6072532; 6027112; 5840064; 5730997; 5730548; 7052414; 7039176; 6945193; 9850172; 14292957; 16463664; 15318474; and 23787778.

design, produce, market, distribute, and sell progesterone or progestin-based prescription medications.

83. Conversely, this body of research was unknown and inaccessible to Plaintiff and her physicians, who lack scientific and technical expertise in biomedical and pharmaceutical research.

84. Defendants thereby have had an unassignable duty since the 1980s to investigate the foreseeable potential that a high dose synthetic progesterone delivered in the deep tissue, like Depo-Provera, could cause or substantially contribute to the growth of intracranial meningioma. Defendants were also best positioned to perform such investigations in the regular course of their biomedical and pharmaceutical research. If Defendants had performed this investigation, they would have discovered that Depo-Provera was associated with an increased risk of meningioma and could have informed physicians and patients of this risk.

85. Instead, Defendants failed to investigate links between Depo-Provera and meningioma, even though decades of medical research indicated that links were foreseeable or even probable.

86. Indeed, recent studies have shown that use of Depo-Provera for more than a year—*i.e.*, four quarterly injections—is associated with increased incidences of intracranial meningioma, as would be expected based on all the aforementioned studies and recognition of the relationship between dose and duration of use and the development of adverse events well recognized in the fields of pharmacology, toxicology, and medicine.

87. A 2022 study in the journal *Endocrinology* reported a clear association between the progestin cyproterone acetate ("CPA") and meningiomas. This relationship was "dose-dependent," *i.e.*, meningiomas were "more common with a longer duration of treatment."[15]

88. A similar direct link between Depo-Provera and meningioma was reported in 2023, when researchers published a case series in the *Journal of Neurological Surgery Part*

[15] Hage, *Estrogen and progesterone therapy and meningiomas*, 163 Endocrinology 1 (2022).

B: Skull Base. This article studied twenty-five (25) individuals who developed intracranial meningioma related to chronic use of Depo-Provera. Of the twenty-five (25) individuals, ten (10) were instructed to cease Depo-Provera use, after which five (5) of those patients showed "clear evidence of tumor shrinkage." This evidence led the study's authors to conclude that "there appears to be a clear progestin meningioma syndrome associated with chronic DMPA [Depo-Provera] use."[16]

89. In March 2024, the French National Agency for Medicines and Health Products Safety published a national case-control study ("*Roland* study") in the British Medical Journal (BMJ). The *Roland* study assessed the risk of intracranial meningioma associated with the use of selected progestogens, including injectable medroxyprogesterone acetate, *i.e.*, DMPA.[17]

90. The *Roland* study noted that concerns over meningiomas associated with high dose progestogen medications resulted in the recent discontinuation of three such medications in France and the EU. Specifically, there were "postponements in the prescription of chlormadinone acetate, nomegestrol acetate, and cyproterone acetate, following the French and European recommendations to reduce the risk of meningioma attributable to these progestogens in 2018 and 2019."[18]

91. The *Roland* study analyzed 18,061 cases of women undergoing surgery for intracranial meningioma between 2009 and 2018. The study found that use of injectable MPA [Depo-Provera] for longer than one year increased the risk of intracranial meningioma by 555 percent.[19]

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[16] Abou-Al-Shaar, *et al.*, *Skull Base Meningiomas as Part of a Novel Meningioma Syndrome Associated with Chronic Depot Medroxyprogesterone Acetate Use*, 84 J. Neurological Surgery B: Skull Base S1 (2023), BMJ, Vol. 384, Mar. 27, 2024, https://doi.org/10.1055/s-0043-1762201; *see also* Hoisnard, *et al.*, *Risk of Intracranial Meningioma With Three Potent Progestogens: A population-based case-control study*, Eur J Neurol. 29, 2901-2809 (2022).

[17] Roland, *et. al.*, *Use of progestogens and the risk of intracranial meningioma: national case-control study*, BMJ, Vol. 384, Mar. 27, 2024, https://doi.org/10.1136/bmj-2023-078078.

[18] *Id.* at 9.

[19] *Id.* at 1, 8 (finding an increased risk of surgery-requiring meningioma from injection exposure).

92. The study authors also noted that Depo-Provera is "often administered to vulnerable populations," *i.e.*, lower-income women who have no other choice but to take subsidized, inexpensive, or easily administrable medication options to prevent pregnancy or treat endometriosis.[20]

93. The *Roland* study also examined the effect of several other progestogen-based medications. Several medications showed increased risk of intracranial meningioma, with Depo-Provera having the second highest increased risk, surpassed only by cyproterone acetate, which is not approved for use in the United States and has been withdrawn from the market in the EU due to its association with meningioma.

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

95. Further, the *Roland* study noted that among cases of meningioma observed in the study, 28.8 percent (5,202 of 18,061) of patients used antiepileptic drugs three years after the index date of intracranial surgery.

96. In September 2024, a study in the journal *Cancers* explored links between Depo-Provera and meningioma using a large data set collected in the United States between 2006 and 2022. This large case-control study analyzed over 117,000 meningiomas and more than one million matched controls and found that injection exposure of medroxyprogesterone acetate, *i.e.*, Depo-Provera usage, was associated with a 53% increase in the development of meningioma. The association was specific to cerebral meningioma and became even stronger with prolonged use.[21]

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[20] *Id.* at 11 (in 2020 in the United States, injected medroxyprogesterone acetate was used in more than 2 million prescriptions, and more than one of five sexually active American women report having used it in their lifetime).

[21] Griffin, *The Association between Medroxyprogestrone Acetate Exposure and Meningioma*, 16 Cancers (2024), https://doi.org/10.3390/cancers16193362 (finding a 68% increased risk).

97. Like the prior published research, the *Cancers* study found a dose-dependent relationship between Depo-Provera and meningioma. Compared to the control group of patients who had no exposure to Depo-Provera, patients who had less than one year of Depo-Provera injections had a 23 percent higher risk of meningioma; in contrast, patients who had more than three years of Depo-Provera injections were two and a half times more likely to develop meningioma than the control group.[22]

98. The *Cancers* study noted that "[t]hough meningiomas are often benign . . . the first line of treatment is often surgery, and the meningiomas can decrease the quality of life through impaired neurologic function and potential for malignant behavior, particularly following surgery."[23]

99. In October 2024, researchers at the University of Cincinnati reported on a retrospective case-control study that examined, *inter alia*, the role of hormonal contraception in the development of intracranial meningioma causing visual impairment in women under the age of 55. The authors concluded "progesterone use is a significant risk factor for meningioma-related visual deficits . . . with a disproportionate number on [Depo-] Provera specifically.[24]

E. Defendants' Failure to Test Depo-Provera

100. 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.

101. 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

[22] *Id.* at 6.

[23] *Id.* at 9 (discussing a 2018 study reporting a 30-fold increase in odds of developing meningioma).

[24] Bailey, *et al.*, "Progesterone contraception and tumor-related visual impairment in premenopausal women with meningioma referred for radiation," 120 *Int'l J of Radiation Oncology Biology Physics* E217 (2024).

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.

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

102. The aforementioned medical literature demonstrates that a causal link between progesterone and meningioma is biologically plausible, and that high dose progestin medications, including Depo-Provera, are associated with increased levels of meningioma. Despite this evidence, Defendants have still made no change to Depo-Provera labels in the United States related to intracranial meningioma.

103. Further, Defendants have failed to take any steps to otherwise warn the medical community and Depo-Provera users of these significant health risks.

104. 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.

105. 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."

106. 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

[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 Jan. 23, 2025).

meningioma (a usually benign tumor that forms in the layers of tissue that cover your brain and spinal cord)."

107. Nothing was or is stopping Defendants from adding similar language to the label and package insert for Depo-Provera in the United States.

108. Specifically, Defendants could have filed a "Changes Being Effected" ("CBE") supplement under 21 C.F.R. § 314.70(c) to make "moderate changes" to the Depo-Provera label without seeking prior FDA approval. Examples of moderate label changes that may be made via a CBE supplement 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." § 314.70(c)(6)(iii).

109. 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 affected via a CBE change. *See In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 118 F.4th 322, 357 (3d Cir. 2024) (noting "the availability of a label change via a CBE supplement is problematic for Merck, as will very often be the case for pharmaceutical companies raising an impossibility defense").

110. Defendants could have also instructed physicians to consider its own safer alternative design, specifically 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 than the lower dose 104 mg Depo-SubQ Provera 104 version and never exceeds more than a small fraction of the dangerously high serum levels seen in the

first several days after intramuscular administration of 150-mg Depo-Provera.[26] Nevertheless, Defendants never produced a 150 mg subcutaneous version.

111. Another study published in *Contraception: X* in 2022 concluded that not only was the lower dose Depo-SubQ Provera 104 just as effective as 150 mg Depo-Provera when administered properly, but it could also be administered every 16 weeks instead of every 12 weeks due to the more gradual uptake of the subcutaneous administration route. That same study found that 150 mg Depo-Provera if injected subcutaneously could remain at efficacious levels in the blood for even longer, up to six (6) months.[27]

112. As with subcutaneously administered Depo-SubQ Provera 104, the study authors noted "subcutaneous administration of 150 mg Depo-Provera every 6 months would be a highly effective repurposing ... with a similar reduction in cumulative exposure." The authors concluded: "The use of an unnecessarily high exposure to limit the residual chance of treatment failure would be a disservice to the vast majority of women if a lower exposure can reduce side effects, costs, or otherwise make the product more acceptable." [28]

113. Despite knowing the subcutaneous administration of 150 mg Depo-Provera would have resulted in less risk of dangerous side effects like meningioma while providing the same contraceptive efficacy for twice as long (and therefore would have required only half as many doses of Defendants' product per year), Defendants failed to produce a 150 mg subcutaneous version.

114. Knowing that the lower dose Depo-SubQ Provera 104 was equally effective and easier to administer since it involved a smaller needle injected below the skin and not deep into the muscle, Defendants could have educated the gynecology community that it

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

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

[28] *Id.*

already had a safer alternative product to 150 mg Depo-Provera, which was more well known to prescribers and patients.[29]

115. In Europe and other countries outside 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 as sold in Europe may be self-administered by patients, obviating the need for quarterly visits to a medical practitioner.

116. 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.

117. 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 somewhat mitigate the potential for adverse reactions engendered by a high dose progestin, including the risk of developing or worsening meningioma tumors.

118. 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 while providing no additional efficacy.

119. 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—on its own or taken together, would have constituted a

[29] Gollub EL, *et al.*, *The Need for Policy Change Regarding Progestin-Only Injectable Contraceptives*, J Womens Health (Larchmt), 28(9), 1180-1184 (2018).

"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.

120. 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. 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 market Depo-Provera, misleading the public that it was a safe and effective prescription drug for contraception and other indications.

121. 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 and the Class to receive Depo-Provera injections.

122. Plaintiff and the Class Members, as well as their healthcare providers, foreseeably used Depo-Provera, and did not misuse or alter Depo-Provera in an unforeseeable manner.

123. Through their affirmative misrepresentations and omissions, Defendants actively concealed from the public and physicians the true and significant risks associated with Depo-Provera use.

124. As a result of Defendants' actions, Plaintiff and the Class, as well as their health care providers, were unaware and could not have reasonably known or have learned through reasonable diligence, that they would be exposed to the risks identified in this Complaint and that those risks were the direct and proximate result of Defendants' conduct.

125. As a direct result of being prescribed and consuming Depo-Provera, Plaintiff and the Class have suffered a harmful exposure to Depo-Provera in sufficient quantity to materially increase their risk of developing intracranial meningioma.

126. Plaintiff did not discover the risks of Depo-Provera, and through reasonable care and diligence could not have discovered such risks, until a date within the applicable statute of limitations for filing these claims.

G. Medical Monitoring

127. Plaintiff and the Class have been exposed to Depo-Provera in a measured quantity and over a specific period of time that has been shown to cause a significant increased risk in developing intracranial meningioma.

128. Intracranial meningioma is a serious medical condition that can cause severe and debilitating symptoms, such as headaches, seizures, blurred vision, numbness, weakness, loss of balance, memory loss, and hearing loss.[30]

129. Patients with intracranial meningiomas are usually diagnosed only after they suffer from some or all of these symptoms.[31] However, intracranial meningiomas can be detected before patients are symptomatic if they undergo magnetic resonance imaging (MRI) or similar scanning technologies.

130. The current best practice for patients with asymptomatic tumors is to undergo serial imaging. For example, the European Association of Neuro-Oncology recommends annual MRI scans for high-risk patients for five years, then an MRI scan every two years thereafter.[32]

131. Some neurological researchers propose positron emission tomography ("PET") as an alternative to MRI scans and suggest that PET may have a greater capacity to distinguish between benign and malignant meningiomas.[33]

132. The benefits of preemptive screening for meningiomas were confirmed in a recent French study published in the *Journal of Neuro-Oncology*. Researchers analyzed a systematic MRI screening program of asymptomatic patients that had been exposed to

[30] *Meningioma*, Johns Hopkins Medicine, https://www.hopkinsmedicine.org/health/conditions-and-diseases/meningioma (last visited Jan. 23, 2025).

[31] *Id*.

[32] Roland Goldbrunner et al., *EANO Guideline on the Diagnosis and Management of Meningiomas*, 23 Neuro-Oncology 1821, 1825 (2021).

[33] K. Mariam Slot, *et al.*, *Prediction of Meningioma WHO Grade Using PET Findings: A Systematic Review and Meta-Analysis*, 31 J. Neuroimaging 6 (2021).

excess progestin and concluded that screening "uncovers small and multiple meningiomas, which can be managed conservatively," *i.e.*, without invasive surgery, radiation therapy, or chemotherapy.[34]

133. If and when a meningioma grows to an extent that requires invasive surgery, the fundamental goal of the surgery is to remove as much of the tumor mass as possible without endangering neurological or cognitive function. Surgeons generally aim for "gross total resection," *i.e.*, removal of the entire tumor mass, which greatly reduces the risk that the meningioma will recur.[35]

134. However, a gross total resection is inadvisable if it would threaten core neurological functions, as is often the case where the tumor has grown too large or too close to critical brain tissue or has become too intertwined with critical neurovascular structures. In cases where gross total resection is not indicated, surgeons perform a "subtotal resection," which leaves residual meningioma tissue in the brain and poses a higher risk of recurrence. Patients who undergo subtotal resections must often seek further radiological therapy to treat the residual meningioma.[36]

135. These studies and clinical guidelines demonstrate the benefits of intracranial meningioma screening for high-risk patients. A screening program can detect meningiomas at an early stage and monitor them, such that if invasive surgery becomes necessary, it may be performed before tumors grow large or complex enough to contraindicate gross total resection.

136. A medical monitoring program thus gives high-risk patients, including Plaintiff and Class Members, the resources they need to detect developing meningiomas and treat them early, using the most effective and least intrusive methods available.

137. Medical monitoring is appropriate given the significance and extent of Plaintiff's and Class Members' measured exposure to Depo-Provera; Depo-Provera's

[34] Thomas Samoyeau, *et al.*, *Meningioma in Patients Exposed to Progestin Drugs: Results from a Real-Life Screening Program*, 160 J. Neuro-Oncology 127 (2022).
[35] Goldbrunner at 1825.
[36] *Id.*

demonstrated link to intracranial meningioma establishing its toxicity; the seriousness of meningioma, for which Plaintiff and the Class are now at a substantial increased risk of developing; the relative increase in Plaintiff's and Class Members' chances of developing meningioma, compared to the general public and to their own chances of developing meningioma had they not been exposed and that they would not have this increased risk but for exposure to Depo-Provera; and the demonstrated clinical value of and availability of early detection and diagnosis, in the form of serial imaging, that the general public does not generally or routinely receive. Diagnostic testing and early detection will equip Plaintiff and Class Members, along with their health care providers, with the knowledge they require to take steps to obtain proper treatment, mitigate the effect of their exposure to Depo-Provera, and protect themselves from worsening future harm. Plaintiff and Class Members should not be forced to bear the burden of this diagnostic testing caused by exposure to Defendants' toxic Depo-Provera.

H. Liability of Pfizer, Greenstone, Viatris, and Prasco for the "Authorized Generics"

138. 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.

139. 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.

140. 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.

141. 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.

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

143. Pfizer was at some or all of the pertinent times the actual manufacturer of the DMPA, identical to Depo-Provera other than its name, which was sold by Greenstone, 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.

I. Innovator Liability

144. In October of 2002, 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.

145. 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.[37]

146. As part of the NDA, the brand-name manufacturer must propose the exact text of the label, subject to FDA approval.[38] For generics, the ANDA process mandates that the safety and efficacy labeling must be identical to that of the brand-name drug.[39]

147. 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

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

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

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

labels mirror the brand-name version.[40] 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."[41] As a result, the content of the generic labels for Depo-Provera bioequivalents is entirely dictated by the brand-name manufacturer Pfizer's label. Thus, under California law, liability for failure to warn can extend to Pfizer, even when the consumer is prescribed only the generic version.

148. Because generic manufacturers must replicate the brand-name label exactly, Pfizer exerted exclusive control over the contents of the labels used by generic versions of Depo-Provera that Plaintiff and Class Members may have been prescribed and administered. Consequently, any deficiencies or omissions in Pfizer's label were reflected in the generic labels.

149. As the brand-name manufacturer of Depo-Provera, 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.[42] 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.

150. 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.

151. 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

[40] *See generally* 21 U.S.C. § 355; *see also* 21 C.F.R. § 314.105(b).
[41] *T.H. v. Novartis Pharm. Corp.*, 4 Cal. 5th 145, 166 (2017).
[42] *See* 21 C.F.R. § 201.80(e).

whether to take a generic equivalent of Depo-Provera and/or brand-named Depo-Provera for contraception.

152. As the brand-name manufacturer of Depo-Provera, Pfizer at any time could have 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.[43] As the brand name manufacturer of Depo-Provera, Pfizer had a duty to give information about Depo-Provera to the medical community and public at large.

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

154. Thus, to the extent that any of the doses of Depo-Provera administered to Plaintiff and the Class were generic, Pfizer is additionally liable for the substantial increased risk of harm to Plaintiff and the Class, thus requiring the medical monitoring sought herein, from those generic doses under California's well-established doctrine of innovator liability.

J. Equitable Tolling of the Statute of Limitations

155. Defendants willfully, wantonly, and intentionally conspired, and acted in concert, to withhold information from Plaintiff, the Class, their health care providers, and the general public concerning the known hazards associated with the use of, and exposure to, Depo-Provera, particularly over extended periods of time.

156. Defendants willfully, wantonly, and intentionally conspired, and acted in concert, to withhold safety-related warnings from the Plaintiff, the Class, their health care providers, and the general public concerning the known hazards associated with the use of, and exposure to, Depo-Provera, particularly over extended periods of time.

157. Defendants willfully, wantonly, and intentionally conspired, and acted in concert, to withhold instructions from the Plaintiff, the Class, their health care providers,

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

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.

158. 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, or Plaintiff or Class Members, of this method to mitigate the damage of a developing meningioma.

159. 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.

160. 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 and the Class, as well as their health care providers, 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.

161. 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 and her physicians, 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.

162. 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, her physicians, or the general public.

163. Due to the absence of any instructions for how to identify and/or monitor Depo-Provera patients for potential intracranial meningioma-related complications, Plaintiff and the Class were unaware that Depo-Provera could cause serious, intracranial meningioma-related injuries, as this danger was not known to them, their physicians, or the general public.

164. Given Defendants' conduct and deliberate actions designed to deceive Plaintiff, the Class, the medical community, 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.

V. CLASS ACTION ALLEGATIONS

165. Plaintiff brings this action pursuant to Fed. R. Civ. P. 23, on behalf of herself and all other persons similarly situated. The proposed Class is hereby defined as follows:

> All persons within the state of California who received four (4) or more injections of Depo-Provera, or a generic equivalent, from October 1992 to the present.

166. Specifically excluded from the Class are Defendants, Defendants' officers, directors, agents, trustees, principals, or entities controlled by Defendants.

167. Subject to additional information obtained through further investigation and discovery, Plaintiff reserves the right to amend, narrow, or expand the Class definition.

168. **Numerosity**: The Class is so numerous that joinder of all members is impracticable. Class Members may be notified of the pendency of this action by recognized, Court-approved notice dissemination methods, which may include U.S. Mail, electronic mail, Internet postings, and/or published notice.

169. **Commonality**: There are questions of law and fact common to the members of the Class including, without limitation:

a. whether and when Defendants knew that progesterone and progestin-based medications were associated with higher incidence of intracranial meningioma;

b. whether Defendants had a duty to investigate the association between Depo-Provera and the development of intercranial meningioma;

c. whether Defendants had a duty to warn the medical community and the general public, including Class Members and their physicians, about the known associations between progesterone and progestin-based medications and meningiomas;

d. whether Defendants' acts and omissions, described herein, constituted breaches of those duties;

e. whether exposure to Depo-Provera materially increases a user's risk of developing intracranial meningioma;

f. whether and when Defendants knew, or should have known, that Depo-Provera materially increased a user's risks of developing meningioma;

g. whether intracranial meningioma is a serious disease warranting early monitoring;

h. whether early detection of intracranial meningioma has benefits;

i. whether Defendants could have promoted, marketed, distributed, and sold lower dosage subcutaneous DMPA products that subjected patients to lower risks of meningioma; and

j. whether a Medical Monitoring program, established by the Court and paid for by Defendants, is an appropriate remedy in light of the clinical benefits of early detection and treatment of meningiomas.

170. **Typicality**: Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff, like Class Members, has been exposed to Depo-Provera to an extent that is shown to increase a patient's risk of intracranial meningioma.

171. **Adequacy of Representation**: Plaintiff is an adequate Class representative because her interests do not conflict with the interests of the other Class Members whom she seeks to represent. Plaintiff has retained competent counsel who are experienced in complex class action litigation, and Plaintiff intends to prosecute this action vigorously. Class Members' interests will be fairly and adequately protected by Plaintiff and her counsel.

172. **Rule 23(b)(2).** The Class is certifiable under Rule 23(b)(2) because Defendants have acted on grounds that apply generally to Class Members such that preliminary and/or final injunctive relief and corresponding declaratory relief is appropriate respecting the Class as a whole. Plaintiff and the Class have been exposed to Depo-Provera at levels sufficient to necessitate medical monitoring and other relief sought in this Complaint, and can establish such sufficiency through common proof and evidence.

173. **Rule 23(b)(3) Predominance**. Common questions of law and fact predominate over any questions affecting only individual Class Members. Similar or identical violations, business practices, and injuries are involved. Individual questions, if any, pale by comparison, in both quality and quantity, to the numerous common questions that dominate this action. For example, Defendants' liability, whether there is an increased risk of meningioma posed to exposed patients, what early detection testing exists for meningiomas, and whether those meningiomas are a serious disease warranting early detection, are all common questions to Plaintiff and each member of the Class that predominate over any individual issues.

174. **Rule 23(b)(3) Superiority**: A class action is superior to any other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. The value of the medical monitoring that Plaintiff demands is relatively small compared to the burden and expense that would be required to individually litigate her claims against Defendants, making it impracticable for Class Members to individually seek redress of Defendants' wrongful conduct. Even if Class Members could afford individual litigation, the court system could not. Individual litigation creates a potential for inconsistent or contradictory

judgments and increases the delay and expense to all parties and the court system. By contrast, the class action device presents far fewer management difficulties and provides the benefits of a single adjudication, economies of scale, and comprehensive supervision by a single court.

175. **Ascertainability**: Members of the Class are ascertainable. Class Membership is defined using precise, objective, and presently ascertainable criteria.

VI. CAUSES OF ACTION

FIRST CLAIM FOR RELIEF

STRICT LIABILITY – PRODUCT DEFECT

176. Plaintiff repeats and re-alleges the factual allegations above as if fully alleged herein.

177. 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.

178. Plaintiff, Class Members, ordinary consumers, and health care providers would not expect a contraceptive drug designed, marketed, and labeled for contraception to cause intracranial meningioma.

179. At all relevant times, Defendants were engaged in the business of researching, developing, testing, manufacturing, labeling, marketing, distributing, and selling Depo-Provera to consumers as an injectable contraceptive. Defendants had a duty to produce pharmaceutical drugs free from defective conditions that are unreasonably dangerous to patients, including Plaintiff and Class Members, who use the drugs as indicated.

180. At the time the Depo-Provera left Defendants' possession, it was dangerous beyond the extent to which Plaintiff, Class Members, or any ordinary consumer could reasonably expect.

181. Defendants expected Depo-Provera to reach consumers, including Plaintiff and Class Members, without substantial change from the condition in which it was

manufactured, distributed, and sold. Depo-Provera reached Plaintiff and Class Members without substantial change from the condition in which it was manufactured, distributed, and sold.

182. 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.

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

184. Depo-Provera was unreasonably dangerous in its design and manufacture, because it used a higher dose of progestogen than was necessary for effective contraception, when Defendants knew that it was possible to produce lower dosage subcutaneous products with similar contraceptive effectiveness but lower risks of intracranial meningioma.

185. Defendants wantonly and willfully failed to apprise the public, including the FDA, the medical community, Plaintiff, Class Members, and their physicians, of the greatly reduced risk of meningioma when injecting 150 mg Depo-Provera subcutaneously compared to the indicated method of intramuscular injection.

186. 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 harm to which Plaintiff and Class Members have been exposed.

187. As a direct and proximate result of Defendants' conduct, Plaintiff and Class Members have been exposed to Depo-Provera in sufficient quantity as to increase their risk of developing intracranial meningioma, a serious medical condition that causes physical injury, disability, pain and suffering, mental anguish, loss of earnings, loss of consortium, loss of capacity for the enjoyment of life, and a heightened risk of future related injury.

188. Plaintiff's and Class Members' risks for suffering severe, painful, and permanently debilitating symptoms will be greatly reduced if intracranial meningioma is detected, diagnosed, and treated as early as medically possible.

SECOND CLAIM FOR RELIEF

STRICT LIABILITY – FAILURE TO WARN

189. Plaintiff repeats and re-alleges the factual allegations above as if fully alleged herein.

190. At all relevant times, Defendants were engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Depo-Provera.

191. Defendants 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.

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

193. Defendants knew or should have known, based on published research, clinical testing, and other scientific knowledge that was available and accessible to them as experts, that Depo-Provera subjected patients to an unreasonable risk of developing intracranial meningioma.

194. Defendants knew or should have known that the information they provided to patients and health care providers about risks associated with Depo-Provera were inadequate and misrepresented or omitted information and data that was material to patients and physicians.

195. The information Defendants provided to the medical community, including to Plaintiff's and Class Members' physicians, was inadequate to inform health care providers of the balance of risks and benefits associated with prescribing Depo-Provera for its intended use.

196. Plaintiff, Class Members, and their physicians did not have the same knowledge or expertise as Defendants, and received inadequate or no warning of the risk of intracranial meningioma associated with Depo-Provera use.

197. Even if Depo-Provera were non-defective and not unreasonably dangerous when used for some purposes, Defendants' failure to warn healthcare providers and

consumers about the risks of long-term use of Depo-Provera as an injectable contraceptive rendered the Product unreasonably dangerous to Plaintiff due to inadequate labeling.

198. As a direct and proximate result of Defendants' failure to warn, Plaintiff and Class Members have been exposed to Depo-Provera in sufficient quantity as to increase their risk of developing intracranial meningioma, a serious medical condition that causes physical injury, disability, pain and suffering, mental anguish, loss of earnings, loss of consortium, loss of capacity for the enjoyment of life, and a heightened risk of future related injury.

199. Plaintiff's and Class Members' risks for suffering severe, painful, and permanently debilitating symptoms will be greatly reduced if intracranial meningioma is detected, diagnosed, and treated as early as medically possible.

THIRD CLAIM FOR RELIEF

NEGLIGENCE

200. Plaintiff repeats and re-alleges the factual allegations above as if fully alleged herein.

201. At all relevant times, Defendants had a duty to exercise reasonable care in designing, labeling, manufacturing, testing, marketing, distributing, and selling Depo-Provera.

202. Defendants breached their duty by marketing, distributing, and/or selling Depo-Provera when they knew or should have known that Depo-Provera created an unreasonable risk of harm to Plaintiff, Class Members, and other individuals who used Depo-Provera as indicated or as Defendants could reasonably foresee.

203. Defendants' negligent acts and omissions include:

a. designing, developing, formulating, manufacturing, promoting, distributing, and selling Depo-Provera without adequate pre- and post-market testing of the product;

b. designing, developing, formulating, manufacturing, promoting, distributing, and selling Depo-Provera without investigating the foreseeable risk that Depo-Provera use was associated with intracranial meningioma;

c. designing, developing, formulating, manufacturing, promoting, distributing, and selling Depo-Provera without disclosing the existence of medical research that demonstrated the link between progestin-based medication and meningioma;

d. continuing to manufacture and sell Depo-Provera while Defendant knew, or should have known, that Depo-Provera was unreasonably unsafe to users;

e. representing that Depo-Provera was safe for its intended use when in fact Defendants knew or should have known the product was not safe for its intended purpose;

f. 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;

g. failing to design and manufacture Depo-Provera so as to ensure the drug was at least as safe and effective as other similar products;

h. failing to provide the medical community and the general public, including Plaintiff, Class Members, and their physicians, accurate warnings about the risks of Depo-Provera or accurate instructions for safer use of the product; and

i. failing to sell a DMPA product with the lowest effective dose.

204. A reasonable manufacturer of pharmaceutical products, under similar conditions, would not have engaged in these acts and omissions.

205. As a direct and proximate result of Defendants' negligence, Plaintiff and Class Members have been exposed to Depo-Provera in sufficient quantity as to increase their risk of developing intracranial meningioma, a serious medical condition that causes physical injury, disability, pain and suffering, mental anguish, loss of earnings, loss of consortium, loss of capacity for the enjoyment of life, and a heightened risk of future related injury.

206. Plaintiff's and Class Members' risks for suffering severe, painful, and permanently debilitating symptoms will be greatly reduced if intracranial meningioma is detected, diagnosed, and treated as early as medically possible.

FOURTH CLAIM FOR RELIEF

NEGLIGENT FAILURE TO WARN

207. Plaintiff repeats and re-alleges the factual allegations above as if fully alleged herein.

208. At all relevant times, Defendants knew or had reason to know that Depo-Provera was likely to be dangerous for users because of its association with intracranial meningioma.

209. Defendants had no reason to believe that consumers, including Plaintiff and Class Members, would realize the dangers that Depo-Provera posed to their health.

210. Defendants had a continuing duty to exercise reasonable care to inform health care providers and consumers, including Plaintiff, Class Members, and their physicians, of the dangerous condition of Depo-Provera and of the facts likely to make Depo-Provera dangerous.

211. Defendants breached their duty by failing to exercise reasonable care to warn. Acts or omissions that constitute this breach of duty include, but are not limited to:

a. disseminating information to Plaintiff, Class Members, and their physicians that was materially inaccurate and/or misleading;

b. failing to provide warnings or other information that accurately communicated to physicians the risks of prescribing Depo-Provera to Plaintiff and Class Members;

c. failing to provide instructions on ways to safely prescribe or use Depo-Provera to avoid injury;

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

e. failing to inform Plaintiff, Class Members, and their physicians that there is a safer feasible alternative for contraception that is not associated with the same dangerous side effects; and

f. failing to adequately warn of the risks that Depo-Provera could cause the development of intracranial meningioma, and of the potentially severe, debilitating, and irreversible injuries related to intracranial meningioma;

212. Defendants knew or should have known of the risk and danger to patients associated with the indicated or reasonably foreseeable use of Depo-Provera.

213. Plaintiff and Class Members were prescribed and used Depo-Provera for its intended purpose.

214. The warnings and information that Defendants gave were inaccurate, unclear, or incomplete, and failed to notify the medical community and general public, including Plaintiff, Class Members, and their physicians, of the risks associated with Depo-Provera.

215. Plaintiff, Class Members, and their physicians were unaware of true risks associated with use of Depo-Provera, and reasonably relied upon the expertise and superior knowledge of Defendants.

216. Had Plaintiff and Class Members received adequate warnings regarding the risks of Depo-Provera, they would not have used Depo-Provera.

217. As a direct and proximate result of Defendants' failure to warn, Plaintiff and Class Members have been exposed to Depo-Provera in sufficient quantity as to increase their risk of developing intracranial meningioma, a serious medical condition that causes physical injury, disability, pain and suffering, mental anguish, loss of earnings, loss of consortium, loss of capacity for the enjoyment of life, and a heightened risk of future related injury.

218. Plaintiff's and Class Members' risks for suffering severe, painful, and permanently debilitating symptoms will be greatly reduced if intracranial meningioma is detected, diagnosed, and treated as early as medically possible.

FIFTH CLAIM FOR RELIEF

NEGLIGENT DESIGN DEFECT

219. Plaintiff repeats and re-alleges the factual allegations above as if fully alleged herein.

220. Defendants had a duty to exercise reasonable care and the duty required of an expert at all stages of researching, developing, designing, formulating, producing, testing, inspecting, packaging, labeling, marketing, promoting, distributing, and selling Depo-Provera. Defendants' duties included the duty to assure the safety of the product when it was used as intended or in a way reasonably foreseeable to Defendants and the duty to provide the medical community and the general public, including Plaintiff, Class Members, and their physicians, with accurate information and instructions for use of Depo-Provera.

221. Defendants failed to exercise reasonable care and failed to perform the duty required of an expert, by the following acts and omissions:

a. failure to conduct adequate pre-clinical and clinical testing or post-marketing surveillance to determine the safety of Depo-Provera;

b. failure to use due care in researching, developing, designing, formulating, testing, and producing Depo-Provera, to avoid subjecting patients to increased risks of intracranial meningioma;

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 subject Plaintiff and Class Members to unreasonable risk of harm; and

d. failing to use due care in researching, developing, designing, formulating, testing, and producing a safer alternative with a lower effective dose.

222. Defendants' negligence and the unreasonable risk posed to patients who use Depo-Provera's as indicated arise under circumstances precluding any other reasonable inference other than a defect in Depo-Provera.

223. As a direct and proximate result of Defendants' negligence in designing Depo-Provera, Plaintiff and Class Members have been exposed to Depo-Provera in sufficient quantity as to increase their risk of developing intracranial meningioma, a serious medical condition that causes physical injury, disability, pain and suffering, mental anguish, loss of earnings, loss of consortium, loss of capacity for the enjoyment of life, and a heightened risk of future related injury.

224. Plaintiff's and Class Members' risks for suffering severe, painful, and permanently debilitating symptoms will be greatly reduced if intracranial meningioma is detected, diagnosed, and treated as early as medically possible.

SIXTH CLAIM FOR RELIEF

NEGLIGENT MISREPRESENTATION

225. Plaintiff repeats and re-alleges the factual allegations above as if fully alleged herein.

226. At all relevant times, Defendants negligently provided Plaintiff, Class Members, their physicians, the medical community, and the general public 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.

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

228. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, and to the general public, including to Plaintiff, Class Members, and their physicians, the known risks of Depo-Provera, including its propensity to cause intracranial meningioma and sequelae related thereto.

229. 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, by negligently misrepresenting Depo-Provera's significant risk of unreasonable and dangerous side effects.

230. The safety and suitability of Depo-Provera, including its associations with intracranial meningioma, are material to consumers, patients, and health care providers, including to Plaintiff, Class Members, and their physicians.

231. At the time Plaintiff and Class Members were prescribed and administered Depo-Provera, Plaintiff, Class Members, and their physicians were unaware of Defendants' negligent misrepresentations and omissions.

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

233. Plaintiff, Class Members, and their physicians would not have used or prescribed Depo-Provera had the true facts not been concealed by the Defendants.

234. 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.

235. As a direct and proximate result of Defendants' negligent misrepresentation, Plaintiff and Class Members have been exposed to Depo-Provera in sufficient quantity as to increase their risk of developing intracranial meningioma, a serious medical condition that causes physical injury, disability, pain and suffering, mental anguish, loss of earnings, loss of consortium, loss of capacity for the enjoyment of life, and a heightened risk of future related injury.

236. Plaintiff's and Class Members' risks for suffering severe, painful, and permanently debilitating symptoms will be greatly reduced if intracranial meningioma is detected, diagnosed, and treated as early as medically possible.

SEVENTH CLAIM FOR RELIEF

FRAUDULENT MISREPRESENTATION

237. Plaintiff repeats and re-alleges the factual allegations above as if fully alleged herein.

238. At the time they manufactured, promoted, sold, and distributed Depo-Provera, Defendants knew or should have known, from clinical trials and case studies, about the potentially dangerous side effects of Depo-Provera.

239. Defendants falsely misrepresented to consumers, patients, and health care providers, including to Plaintiff, Class Members, and their physicians, that Depo-Provera was tested and found to be a safe and suitable option for contraception.

240. Defendants knew or believed that Depo-Provera had not been thoroughly tested and found to be safe and suitable for use as an injectable contraceptive.

241. Defendants knew that they did not have a sufficient factual basis to represent that Depo-Provera was thoroughly tested and found to be safe and suitable for use as an injectable contraceptive.

242. Defendants knew that they did not have confidence in the accuracy of their representations that Depo-Provera was thoroughly tested and found to be safe and suitable for use as an injectable contraceptive.

243. Defendants had a duty to disclose to consumers, patients, and health care providers, including to Plaintiff, Class Members, and their physicians, the defective nature of Depo-Provera, including, but not limited to, the biological mechanisms linking DMPA to meningioma, patients' increased risk of intracranial meningioma caused by exposure to DMPA, and the DMPA's consequent ability to cause severe and/or debilitating physical injury.

244. The safety and suitability of Depo-Provera, including its associations with intracranial meningioma, are material to consumers, patients, and health care providers, including to Plaintiff, Class Members, and their physicians.

245. Defendants made misrepresentations and omissions relating to the safety of Depo-Provera with the intent that consumers including Plaintiff and Class Members, would rely upon such misrepresentations and omissions when deciding whether to use Depo-Provera.

246. 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.

247. When they made these misrepresentations and omissions, Defendants knew that consumers, including Plaintiff and Class Members, had no way to determine the truth of Defendants' representations or discover the material facts concealed and omitted therefrom.

248. Plaintiff, Class Members, and their physicians were unaware of the falsehood of Defendants' misrepresentations and of the material facts omitted therefrom, and relied on Defendants' representations when using Depo-Provera.

249. If Plaintiff, Class Members, and their physicians had known about Depo-Provera's association with increased incidences of intracranial meningioma, they would not have used or prescribed Depo-Provera.

250. As a direct and proximate result of Defendants' fraudulent misrepresentation, Plaintiff and Class Members have been exposed to Depo-Provera in sufficient quantity as to increase their risk of developing intracranial meningioma, a serious medical condition that causes physical injury, disability, pain and suffering, mental anguish, loss of earnings, loss of consortium, loss of capacity for the enjoyment of life, and a heightened risk of future related injury.

251. Plaintiff's and Class Members' risks for suffering severe, painful, and permanently debilitating symptoms will be greatly reduced if intracranial meningioma is detected, diagnosed, and treated as early as medically possible.

EIGHTH CLAIM FOR RELIEF

BREACH OF EXPRESS WARRANTY

252. Plaintiff repeats and re-alleges the factual allegations above as if fully alleged herein.

253. At all relevant times, Defendants were engaged in the business of developing, manufacturing, labeling, marketing, selling, distributing, and promoting Depo-Provera.

254. Defendants place Depo-Provera into the stream of commerce with the intent that Depo-Provera be prescribed by health care providers and used by consumers as an injectable contraceptive.

255. Defendants or their authorized agents and representatives expressly warranted to Plaintiff, Class Members, and their physicians that Depo-Provera was safe for its intended use as an injectable contraceptive. Defendants made these representations or caused these representations to be made through product labels, advertising campaigns, and communications by sales agents.

256. Plaintiff, Class Members, and their physicians reasonably relied on Defendants' affirmations of fact, promises, and descriptions of Depo-Provera. These affirmations of fact, promises, and descriptions were a basis of the bargain that Plaintiff and Class Members made with Defendants.

257. Depo-Provera failed to conform to Defendants' affirmations of fact, promises, and descriptions because it is defective and unsafe, and causes intracranial meningioma. Defendants' sale and distribution of Depo-Provera therefore breached an express warranty.

258. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff and Class Members have been exposed to Depo-Provera in sufficient quantity as to increase their risk of developing intracranial meningioma, a serious medical condition that causes physical injury, disability, pain and suffering, mental anguish, loss of earnings, loss of consortium, loss of capacity for the enjoyment of life, and a heightened risk of future related injury.

259. Plaintiff's and Class Members' risks for suffering severe, painful, and permanently debilitating symptoms will be greatly reduced if intracranial meningioma is detected, diagnosed, and treated as early as medically possible.

NINTH CLAIM FOR RELIEF

BREACH OF IMPLIED WARRANTY

260. Plaintiff repeats and re-alleges the factual allegations above as if fully alleged herein.

261. Defendants regularly develop, manufacture, distribute, and sell Depo-Provera and other similar pharmaceutical products. Defendants are merchants of Depo-Provera within the meaning of the California Uniform Commercial Code, Article 2.

262. Defendants knew that consumers, including Plaintiff and Class Members, use Depo-Provera for the particular purpose of an injectable contraceptive, and rely on Defendants' skill and judgment to provide suitable goods.

263. Defendants impliedly warranted that Depo-Provera was merchantable, fit for ordinary use as a contraceptive, and conformed to promises and affirmations of fact made on the product label or container.

264. In deciding to purchase and use Depo-Provera, Plaintiff and Class Members relied on Defendants' judgment that it was merchantable and fit for its ordinary purpose.

265. In deciding to purchase and use Depo-Provera, Plaintiff and Class Members relied on Defendants' judgment that it was merchantable and fit for the particular purpose as an injectable contraceptive.

266. Contrary to Defendants' implied warranty, Depo-Provera was unfit for ordinary use and for Plaintiff's and Class Members' particular use as an injectable contraceptive.

267. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff and Class Members have been exposed to Depo-Provera in sufficient quantity as to increase their risk of developing intracranial meningioma, a serious medical condition that causes physical injury, disability, pain and suffering, mental anguish, loss of earnings,

loss of consortium, loss of capacity for the enjoyment of life, and a heightened risk of future related injury.

268. Plaintiff's and Class Members' risks for suffering severe, painful, and permanently debilitating symptoms will be greatly reduced if intracranial meningioma is detected, diagnosed, and treated as early as medically possible.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of herself and all other similarly situated persons, prays for relief as follows:

A. An Order certifying the Class, as defined herein, and appointing Plaintiff and her Counsel to represent the Class;

B. Compensatory damages for the cost of diagnostic testing for the early detection of intracranial meningioma and the costs of administration of those tests;

C. In the alternative, for an order establishing a Court-supervised medical monitoring program/fund to gather and forward to treating physicians of Plaintiff and the Class Members information relating to the prevention, detection, and treatment of conditions related to the exposure to Depo-Provera;

D. Attorneys' fees, costs, and litigation expenses, to the extent permitted by law;

E. Pre-judgment and post-judgment interest to Plaintiff and Class Members; and

F. Other relief as the Court shall deem just and proper, all according to proof.

VIII. DEMAND FOR TRIAL BY JURY

Plaintiff and Class Members demand a jury trial on all claims so triable.

Dated: January 23, 2025

LYNCH CARPENTER, LLP

By: */s/ (Eddie) Jae K. Kim*

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