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Case No. N26C-02-356 DEP

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

TYJHANE MANNING, *Plaintiff*, -vs- PFIZER INC., PHARMACIA LLC, AND PHARMACIA & UPJOHN COMPANY LLC, *Defendants*.	C.A. No. Severed from C.A. No. N25C-08-031 KMV **JURY TRIAL DEMANDED**

PLAINTIFF'S SEVERED COMPLAINT

The above-captioned Plaintiff ("Plaintiff"), by and through her undersigned attorneys, alleges as follows:

COMPLAINT – CIVIL ACTION
PRODUCT LIABILITY

Plaintiff brings this Complaint and Demand for Jury Trial (the "Complaint") against Defendants Pfizer Inc., Pharmacia LLC, and Pharmacia & Upjohn Company LLC because Plaintiff was injured after using medroxyprogesterone acetate, brand name Depo-Provera, that Defendants designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, and/or sold. Plaintiff alleges the following upon personal knowledge as to Plaintiff's own acts and experiences and upon information and belief, including investigation conducted by Plaintiff's attorneys, as to all other matters:

INTRODUCTION

1. This action arises out of Defendants' wrongful conduct in connection with the development, design, testing, manufacture, labeling, packaging, promoting, advertising, marketing, distribution, and selling of Depo-Provera.

2. Plaintiff brings these causes of action against Defendants to recover for injuries that are the direct and proximate result of Plaintiff's exposure to Defendants' unreasonably dangerous injectable contraceptive products.

3. For decades, Defendants have manufactured, marketed, and/or sold Depo-Provera.

4. Up to 25% of women in the United States between the ages of 18–49, who have had intercourse, have used Depo-Provera, making the contraceptive highly lucrative for Defendants. But for decades, and since at least 2000, scientific evidence has shown an association between Depo-Provera and intracranial meningioma, a slow-growing tumor that originates in the meninges, the membranes surrounding the brain and spinal cord.

5. Although Defendants have a duty to design and sell a reasonably safe product, they continued to market and sell Depo-Provera knowing it is inherently dangerous.

6. Defendants also have a duty to adequately warn of risks associated with Depo-Provera, yet they have not fulfilled their obligation to study, investigate, and independently assess the risks, and have not taken appropriate steps to warn Depo-Provera users of these risks.

7. Defendants' failure to warn women and providers of medroxyprogesterone acetate's risks has caused serious and debilitating injuries to Depo-Provera users across the country over the past several decades, including Plaintiff.

PARTIES

PLAINTIFF

8. Plaintiff Tyjhane Manning is a citizen and resident of Brownsville, Tennessee. She was prescribed and administered Depo Provera from approximately 2019 to 2021, and on July 1, 2022, Plaintiff was diagnosed with meningioma.

9. During the time that Plaintiff purchased and used Depo-Provera, she was not aware that Depo-Provera could cause or exacerbate meningioma.

10. As a result of Plaintiff's meningioma and subsequent treatment, she has suffered and continues to suffer significant bodily injury, pain and suffering, mental anguish, disfigurement, loss of earnings and earning capacity, and have and will incur past and future medical expenses.

DEFENDANTS

11. Defendant Pfizer Inc. is a corporation organized under Delaware law with its principal place of business at The Spiral, 66 Hudson Boulevard East, New York, New York 10001. Pfizer is therefore a citizen of Delaware and New York. Pfizer has a registered office for service of process at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

12. Defendant Pharmacia LLC (f/n/a Pharmacia Corporation) ("Pharmacia") is a limited liability company organized under Delaware law with its principal place of business in New York. Pharmacia's sole member is Wyeth Holdings LLC, whose sole member is Anacor Pharmaceuticals, LLC, whose sole member is Pfizer MAP Holding, Inc., which is a Delaware corporation headquartered in New York. Pharmacia is therefore a citizen of Delaware and New York. Pharmacia has a registered office for service of process at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801, and a principal place of business at 66 Hudson Boulevard East, New York, New York 10001-2192.

13. Defendant Pharmacia & Upjohn Company LLC is a limited liability company organized under Delaware law, with a principal place of business in Kalamazoo, Michigan. Pharmacia & Upjohn's members are Pharmacia & Upjohn LLC (whose sole member is Pharmacia) and Anacor Pharmaceuticals, LLC. Pharmacia & Upjohn is therefore a citizen of Delaware and New York. Pharmacia & Upjohn has a registered office for service of process at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801. Pharmacia & Upjohn Company LLC and Pharmacia LLC are wholly owned subsidiaries of Pfizer, Inc. and together with Pfizer, Inc. will be referred to collectively as "Pfizer."

14. Defendant Pfizer holds the New Drug Application ("NDA") for Depo-Provera and has held the NDA in its own name since it acquired Pharmacia LLC, the then-NDA holder, in 2003.

15. Pfizer manufactures and distributes under the NDA both the brand-name Depo-Provera and the authorized generic.

JURISDICTION & VENUE

16. This Court has jurisdiction over the subject matter of this action and the parties.

17. This Court has general personal jurisdiction over Defendants because Defendants are all citizens of Delaware.

18. Defendants have sufficient minimum contacts with and purposefully avail themselves of the markets of Delaware. The Court's exercise of jurisdiction would be consistent with traditional notions of fair play and substantial justice

19. At all times, Defendants were present and doing business in Delaware and should have expected that their acts would have consequences within the State of Delaware.

20. The causes of action alleged in this Complaint arise out of or relate to the Defendants' contacts with Delaware. Substantial activities relating to the design, development, marketing, labeling, warnings, promotion and sales of

medroxyprogesterone acetate products were performed by Defendants in Delaware.

21. Venue in this action properly lies in Delaware because all Defendants are incorporated in or organized under the laws of Delaware and are citizens of Delaware as alleged in this complaint.

FACTUAL ALLEGATIONS

A. Depo-Provera

22. Depo-Provera is used primarily as a contraceptive but may also be used to treat conditions such as abnormal uterine bleeding, endometrial hyperplasia, or pain related to endometriosis.

23. The FDA approved Depo-Provera in 1992 to be used as a contraceptive.

24. Depo-Provera is a 150 mg/mL dose of medroxyprogesterone acetate or depot medroxyprogesterone acetate ("DMPA") that is injected every three (3) months into the deep tissue musculature of either the buttocks or the upper arm.

25. In 2004, the FDA approved a 104 mg/mL dose version of medroxyprogesterone acetate, SubQ Provera 104; in 2005, SubQ Provera 104 was approved for treatment of endometriosis. SubQ Provera is injected just beneath the skin.

26. Medroxyprogesterone is a progestin similar to naturally occurring progesterone. It works by "binding the progesterone receptor in the hypothalamus, female reproductive tract, and pituitary and inhibiting the secretion of gonadotropin-releasing hormone,"[1] which ultimately prevents follicular maturation and ovulation.

27. Medroxyprogesterone also thickens the cervical mucus, which prevents sperm from successfully getting to the egg. Long-terms users of Depo-Provera may experience irregular menstrual periods or may stop bleeding altogether.

28. Depo-Provera is available by prescription only. It is typically administered in the doctor's office, either at the time of prescription or after picking up the prescription from the pharmacy; sometimes, a patient will self-administer the injection at home.

29. Up to 25% of women in the United States between the ages of 18-49, who have had intercourse, have used Depo-Provera.[2]

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[1] Abha Sathe et al., *Medroxyprogesterone*, in StatPearls [Internet] (last update Feb. 29, 2024), https://www.ncbi.nlm.nih.gov/books/NBK559192/ [https://perma.cc/NA2K-ERJF].

[2] *See Key Statistics from the National Survey of Family Growth – C Listing*, Nat'l Ctr. for Health Statistics (last reviewed June 29, 2022), https://www.cdc.gov/nchs/nsfg/key_statistics/c-keystat.htm#contraception [https://perma.cc/AG89-54ZF].

30. Among reproductive age women who used any form of contraception from 2017-2019, Depo-Provera was most often used by young women, lower-income women, and Black women.[3]

31. DMPA was first discovered by Upjohn Company in the 1950s.

32. In 1963, the FDA granted Upjohn Investigative New Drug status for Depo-Provera. Two years later, Upjohn initiated field studies and in 1967 submitted an NDA for approval of Depo-Provera for contraceptive use. The FDA refused to approve the application several times. In 1978, the FDA denied the application because studies showed that Depo-Provera caused breast cancer in dogs, there was an increased chance of birth defects because of fetal exposure, and there was no pressing need for the drug. In 1984, the FDA again determined the application should not be approved.

33. On or about October 29, 1992, the FDA finally approved Depo-Provera for contraceptive use.

34. In 1995, Upjohn merged with Pharmacia AB to become Pharmacia & Upjohn.

35. In 2000, Pharmacia & Upjohn merged with Monsanto and Searle to form Pharmacia.

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[3] *See DMPA Contraceptive Injection: Use and Coverage*, KFF (May 30, 2024), https://www.kff.org/womens-health-policy/fact-sheet/dmpa-contraceptive-injection-use-and-coverage/ [https://perma.cc/AMQ5-9X9K].

36. In or around April 2003, Pfizer purchased Pharmacia and they began operating as a unified company. Pfizer thereby acquired the Depo-Provera NDA and the associated responsibilities and liabilities stemming from the manufacturing, sale, and marketing of Depo-Provera.

37. Pfizer has held the Depo-Provera NDA in its own name since 2002.

38. Pfizer manufactures under the NDA brand-name Depo-Provera and the authorized generic.

39. An authorized generic is 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."[4]

40. An authorized generic is "the same" as the brand-name drug. As such, authorized generics do not operate under an ANDA; instead, they are manufactured under the brand-name NDA,[5] and use the same label as the NDA drug. The FDA requires that the NDA holder notify the FDA if it markets an authorized generic, and the FDA publishes a Listing of Authorized Generic Drugs. "The NDA holder

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[4] *FDA List of Authorized Generic Drugs*, U.S. Food & Drug Admin. (last updated Oct. 10, 2025), https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs [https://perma.cc/XVR6-XZY4].

[5] *Id.* ("An authorized generic drug is the same as the brand-name drug but does not use the brand name on the label. . . . Because an authorized generic drug is marketed under the brand name drug's New Drug Application (NDA), it is not listed in the FDA's [Orange Book]."

may market both the authorized generic and the brand-name product at the same time."[6]

41. Authorized generics are manufactured "to the same standards and at the same facilities as Pfizer brand-name drugs."[7]

42. Pfizer manufacturers, packages, and labels the authorized generic Depo-Provera, and sends the Depo-Provera in final packaged form to the authorized generic distributors, who then distribute the authorized generic to their customers.

43. Pfizer's authorized generic was distributed by Greenstone LLC from September 2004 until November 2020.

44. Until November 2020, Greenstone was a wholly owned subsidiary of Pfizer and shared the same corporate space with Pfizer in Peapack, New Jersey.

45. On information and belief, Greenstone was effectively a department within Pfizer.

46. In November 2020, Pfizer spun off its Upjohn Business, which included Greenstone, to combine with Mylan N.V. and became Viatris Inc. As a result, Greenstone became an indirectly wholly owned subsidiary of Viatris.

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[6] *Id.*

[7] Press Release, Pfizer, Pfizer's Greenstone and Digital Men's Health Clinic Roman Collaborate to Offer Patients Remote Access to the Only FDA-Approved Authorized Generic Version of Viagra® (sildenafil citrate) (Jan. 23, 2020), https://www.pfizer.com/news/press-release/press-release-detail/pfizers-greenstone-and-digital-mens-health-clinic-roman [https://perma.cc/3M8S-2APD].

47. Concerned with some aspects of the Upjohn-Mylan merger, the FTC required Pfizer to divest to Prasco LLC the rights and assets related to medroxyprogesterone acetate injectable solution. "[T]he generic drugs divested to Prasco will continue to be manufactured by Upjohn and Mylan's current suppliers, reducing the risk of any interruption in supply. In some instances, Pfizer—which will remain a separate entity from Viatris—will serve as Prasco's contract manufacturer, allowing Prasco to step into the shoes of Upjohn/Greenstone."[8]

48. Since November 2020, Pfizer's authorized generic is distributed by Prasco.

49. According to Prasco, "an **Authorized Generic*** is the brand prescription product."[9]

50. Pfizer packages and labels the products it manufactures, and both the brand and authorized generic labels can be found on Pfizer's website.[10]

51. The brand and authorized generic labels are identical, and each warn about risks of Depo-Provera use associated with thromboembolic disorders, breast cancer, ectopic pregnancy, anaphylaxis and anaphylactoid reactions, liver function,

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[8] Press Release, F.T.C., FTC Imposes Conditions on Combination of Pfizer Inc.'s Upjohn and Mylan N.V. (Oct. 30, 2020), https://www.ftc.gov/news-events/news/press-releases/2020/10/ftc-imposes-conditions-combination-pfizer-incs-upjohn-mylan-nv [https://perma.cc/8N3Q-ENQH].

[9] PRASCO, What We Do | Authorized Generics, https://prasco.com/authorized-generics/ [https://perma.cc/FW2L-9BK6] (last visited Dec. 9, 2025).

[10] *Depo-Provera Contraceptive Injection*, Pfizer, https://www.pfizer.com/products/product-detail/depo_provera [https://perma.cc/B2J8-M7XN] (last visited Dec. 9, 2025).

and carbohydrate metabolism. The labels also include a boxed warning about the loss of bone mineral density.

52. The U.S. label does not mention any risk related to meningiomas.

B. Intracranial Meningioma

53. Intracranial meningioma are primary brain tumors that originate from the meninges, the protective layers that surround the brain and the spinal cord.

54. Although most meningiomas are benign, they can grow until they are very large, and if left undiscovered, can exert pressure on nearby brain tissue, nerves, or vessels and can be severely disabling and/or life-threatening.

55. Most meningiomas grow very slowly, but some forms are more aggressive requiring more aggressive treatment. Approximately 80% of meningiomas are considered Grade I, which can usually be treated with surgery.[11]

56. Most meningioma patients develop a single meningioma, but some patients may develop several tumors, either growing at the same time or one after the other.

57. Symptoms of meningioma may include changes in vision, hearing loss or ringing in the ears, loss of smell, headaches, seizures, face pain, numbness and/or weakness in the arms and legs, confusion or memory issues, and/or personality changes.

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[11] Sathe, *supra* note 1.

58. Because most meningiomas grow slowly, and often without any negative symptoms, they may be observed without the need for invasive treatment. But once the meningioma begins to show symptoms or grows too large, it needs to be treated.

59. Treatment of intracranial meningioma typically requires invasive and complex brain surgery where the surgeon tries to remove the entire tumor or, if not all, as much as possible.

60. Progestin-related meningiomas tend to occur more frequently at the skull base, which involves a challenging surgery.[12]

61. If the entire meningioma cannot be removed surgically, it may be treated with radiation. Radiation therapy uses a large machine to aim high-powered energy beams at the tumor cells, with the goal to destroy the cells and keep the meningioma from coming back.

62. If surgery or radiation cannot be used, meningioma may be treated with chemotherapy.

63. Treatment of meningioma comes with its own risks. With surgery, there is a risk of infection and bleeding, brain swelling or fluid buildup resulting in brain damage, injury to cranial nerves, or accidental damage to normal brain tissue.

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[12] Noémi Roland et al., *Use of Progestogens and the Risk of Intracranial Meningioma: National Case-Control Study*, 384 BMJ e078078, 4 (Mar. 27, 2024).

Studies have also shown a potential for postoperative anxiety and depression, and a high intake of antidepressants and sedative in the medium term.[13] Another possible complication from surgery is seizures, requiring antiepileptic drugs in the years following surgery; one study found that almost three in ten women were using antiepileptic drugs three years after their surgeries.[14]

64. Radiation and chemotherapy treatment may cause hair loss, fatigue, cognitive changes, or headaches.

65. Meningioma is the only cerebral tumor that presents in women significantly (2:1) more than men; for women of childbearing age, the ratio increases to 3:1.[15]

C. The Connection Between Depo-Provera and Meningioma

66. The association between progesterone and meningioma has been known or knowable for decades, especially for sophisticated pharmaceutical companies like Defendants, who are required to engage in post-market surveillance of their products for safety issues. Defendants had an obligation and a duty to keep

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[13] *Id.* at 8.
[14] *Id*.
[15] Mikaël Agopiantz, et al., *Hormone Receptor Expression in Meningiomas: A Systematic Review*, 15 Cancers (Basel) 980 (Feb. 3, 2023), https://pmc.ncbi.nlm.nih.gov/articles/PMC9913299/ [https://perma.cc/2PHE-LNSE]; *see also* A.E. Hensiek, A.J. Kellerman & J.T. Hill, *Spontaneous Regression of a Solitary Cerebral Metastases in Renal Carcinoma Followed by Meningioma Development Under Medroxyprogesterone Acetate Therapy*, 14 Br. J. of Neurosurg. 354, 354-56 (2000) (noting a 1990 study showing there is a sex predilection for meningiomas in females, which begins after puberty and disappears in the elderly).

current with emerging relevant studies and literature and, where appropriate, perform their own long-term studies and follow-up research.

67. Since at least 1983, the medical and scientific communities have been aware of a connection between hormones and meningioma.

68. Yet, in the more than forty years since these early studies, Defendants have seemingly failed to investigate the effect of their medroxyprogesterone acetate on the development and growth of meningioma.

69. A study published in the *European Journal of Cancer and Clinical Oncology*[16] sought to discover more about the presence of hormone receptors on meningioma cells. Contrary to expectations, the cells did not show a preference for estrogen receptors like breast cancer cells. And instead, the authors made the "remarkable observation" of the "occurrence in meningioma tissue of progesterone receptors in the absence of detectable amounts of oestrogen receptors." The authors suggested it would be useful to study the effect of other progestins and anti-progestins on meningiomas.

70. In 2000, researchers published a case study in the *British Journal of Neurosurgery* in which the authors first noted that the relationship between

[16] M.A. Blankenstein et al., *Presence of Progesterone Receptors and Absence of Oestrogen Receptors in Human Intracranial Meningioma Cytosols*, 19 Eur. J. Cancer & Clin. Oncol. 365, 365-70 (1983).

meningiomas and female hormones has been well documented.[17] The authors discussed several then-recent studies showing that when antiprogesterone therapy is given, the meningiomas get smaller, and they hypothesized the obvious converse: progesterones may result in "enhanced tumour growth." In this specific study, the patient took medroxyprogesterone acetate (100 mg) and then developed "a rather fast growing meningioma." The authors concluded that there is a "likely link" between medroxyprogesterone acetate and meningiomas. Finally, the authors noted that it is important to investigate the issue further, including in women using Depo-Provera as a contraceptive.

71. Another case-study in 2007 found a similar connection. In that case, a patient was treated with medroxyprogesterone acetate (500 mg) and developed a large meningioma, as well as several smaller ones.[18] The doctors stopped her hormonal treatment, removed the large mass, and the smaller meningiomas regressed. The authors noted that "growth of meningioma in a postmenopausal woman under progesterone therapy and regression after withdrawal may confirm the influence of hormonal treatment on the disease."[19] The authors suggest that patients treated with progesterone should be routinely screened with MRI and should stop the hormonal treatment if they develop a meningioma.

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[17] Hensiek, *supra* note 15.
[18] Eugenio Possati et al., *Rapid Growth and Regression of Intracranial Meningiomas in Lymphangioleiomyomatosis: Case Report*, 68 Surg. Neurol. 671, 671-75 (Dec. 2007).
[19] *Id.* at 674.

72. In 2015,[20] researchers looked specifically at women who had been diagnosed with meningiomas and taken cyproterone acetate ("CA"), a progesterone agonist, which had been linked to meningiomas as early as 2008.[21] The authors discovered that patients who took the drug for longer were more likely to have multiple tumors, and that discontinuation of CA led to tumor shrinkage in 11/12 patients and stoppage of tumor growth in the twelfth. In conclusion, the authors warned that: "For patients diagnosed with a meningioma and treated with CA, medication withdrawal followed by observation should be the first line of treatment. Care should be taken with long-term use of high doses of CA, and serial brain MRIs should be considered after several years of CA."[22]

73. In light of those studies, for several decades, Defendants, the manufacturers and sellers of Depo-Provera and its authorized generic and generic analogues, had an unassignable duty to investigate the foreseeable potential that a progesterone such as DMPA could cause the development or substantially contribute to the growth of meningioma. Defendants were also best positioned to perform such investigations. Had Defendants done so, they would have discovered decades ago that their progestin Depo-Provera/DMPA was associated with a highly

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[20] Anne Laure Bernat et al., *Growth Stabilization and Regression of Meningiomas After Discontinuation of Cyproterone Acetate: A Case Series of 12 Patients*, 157 Acta Neurochir (Wien) 1741 (Oct. 2015).
[21] Helene Cebula et al., *Regression of Meningiomas After Discontinuation of Cyproterone Acetate in a Transsexual Patient*, 152 Acta Neurochir (Wien) 1955, 1955-56 (Nov. 2010).
[22] Bernat, *supra* note 20.

increased risk of meningioma and would have spared Plaintiff and countless others the pain and suffering associated with meningioma. Instead, Defendants did nothing, and therefore willfully failed to apprise the medical community, and the patients receiving DMPA of this dangerous risk.

74. More recent studies have only confirmed what would have been expected from the earlier studies.

75. Studies have shown that the risk of developing meningioma is greatly increased with progestogen treatments: multiplied by 7 after 6 months of exposure to cyproterone acetate and by 20 after 5 years of exposure; multiplied by 12 after 5 years of exposure with nomegestrol acetate, and by 7 after 3.5 years of exposure to chlormadinone acetate.[23]

76. In 2022, an article published in *Endocrinology* titled "Estrogen and Progesterone Therapy and Meningiomas"[24] reviewed published literature and noted that a "dose-dependent relationship" has been established between at least one progestin (CA) and the incidence and growth rate of meningioma. The study authors further noted that progesterone-mediated meningiomas appear to be located most often in the anterior and middle base of the skull and are more likely to be multiple and require more intensive treatment.

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[23] Sylvain Portet et al., *New Insights into Expression of Hormonal Receptors by Meningiomas*, 140 World Neurosurgery e87, e87-e96 (Aug. 2020).

[24] Mirella Hage et al., *Estrogen and Progesterone Therapy and Meningiomas*, 163 Endocrinology 1, 1-10 (Feb. 2022).

77. In 2023, researchers reported a direct link between Depo-Provera and meningioma. A study by the University of Pittsburgh Medical Center concluded that "[t]here appears to be a clear progestin meningioma syndrome associated with chronic DMPA use."[25] The authors found that "[p]atients with DMPA-associated meningiomas tend to be younger, middle-aged women with multiple meningiomas, of which one is commonly located at the skull base."[26] The authors had performed a retrospective review of meningioma patients with a history of DMPA use and reported on 25 female patients with one or more meningioma. Of the 25 patients, 10 were told to stop using Depo-Provera; of the ten, five (5) had clear evidence of tumor shrinkage. The authors warned that "Females that fit these criteria should be screened and counseled for progestin use."[27]

78. In 2024, the French National Health Data System (Système National des Données de Santé), along with several French neurosurgeons, epidemiologists, clinicians, and researchers published a large case control study in the *British Medical Journal* (the "*Roland* study"[28]), one of the premier scientific journals in

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[25] Hussam Abou-Al-Shaar et al., *Skull Base Meningiomas as Part of a Novel Meningioma Syndrome Associated with Chronic Depot Medroxyprogesterone Acetate Use*, 84 J. Neurol. Surg. B Skull Base S1, S1-344 (2023), https://www.thieme-connect.com/products/ejournals/html/10.1055/s-0043-1762201 [https://perma.cc/Y4NV-PDBU].
[26] *Id.*
[27] *Id.*
[28] Roland, *supra* note 12, at 2.

the world, to assess the risk of intracranial meningioma with the use of progestogens among women in France.

79. As an introduction, the study notes that several studies have shown a high "excess risk" of meningioma associated with the use of high doses of cyproterone acetate and the "lower, but still substantial" risk for chlormadinone acetate and nomegestrol acetate. *Id.* at 2. The study "aimed to assess the real-life risk of intracranial meningioma associated with the use of progestogens from an extensive list . . . with different routes of administration." *Id.*

80. The study included 108,366 women living in France, 18,061 of whom had surgery for intracranial meningioma between 2009 and 2018, and found an association between prolonged use of medroxyprogesterone acetate (150 mg) and an excess risk of intracranial meningioma requiring surgery. Specifically, the study found that prolonged (defined as a year or more) use of medroxyprogesterone acetate resulted in a 562% increased risk of developing intracranial meningioma.

81. The authors state that their study likely "underestimated the prevalence of meningiomas attributable to the use of progestogens" and note that the link is eminently biologically plausible given how sensitive meningiomas are to hormones. *Id.* at 10. The authors conclude that "[t]he increased risk associated with the use of injectable medroxyprogesterone acetate, a widely used contraceptive" is an important finding. *Id.* at 1. And that further studies are

needed to assess the meningioma risk with the use of medroxyprogesterone acetate.

82. The Roland study also looked at several other progestogen-based medications and found no increased risk of intracranial meningioma after exposure to oral or intravaginal progesterone.

83. Of those medications included in the *Roland* study, medroxyprogesterone acetate had by far the highest risk of meningioma surgeries, making 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 vision problems, hearing loss or tinnitus, loss of smell, face pain, headaches, memory loss, trouble speaking, dizziness, seizures and death.

84. Further, the Roland study found the longer duration of exposure had a greater risk, noting that "the excess risk associated with prolonged use was higher than that measured for short term and prolonged exposure combined." *Id.* at 7.

85. In September 2024, yet another study found an increased risk of meningioma among patients using DMPA. "The current results are consistent with the prior literature, which reports an association between injection exposures to MPA and a stronger association with increasing use of MPA. Women should be

cautioned about the prolonged use of MPA, and future research should examine whether the extended use of MPA is associated with the meningioma grade."[29]

86. Defendants knew or should have known of the potential for medroxyprogesterone acetate to cause or exacerbate intracranial meningiomas but failed to adequately study these adverse effects.

87. Furthermore, despite studies emerging over the course of decades providing evidence of the meningioma-related risks and dangers of progesterone and progestins and Depo-Provera specifically, Defendants have failed to adequately investigate the threat that Depo-Provera poses to patients' well-being or to warn the medical community, providers, and patients of the risk of intracranial meningioma and sequelae related thereto.

D. Despite the Overwhelming Science, Defendants Still Sell Depo-Provera and Have Never Warned of the Dangers Associated with Using Depo-Provera.

88. Despite the overwhelming science showing that Depo-Provera is inherently dangerous, Defendants continue to market and sell Depo-Provera to unsuspecting consumers, even though there are many other safe alternative forms of birth control that do not cause brain tumors.

89. Further, in the United States, the Depo-Provera label has been updated over a dozen times since it was first approved in 1992, with the most recent update

[29] Russell L. Griffin, *The Association Between Medroxyprogesterone Acetate Exposure and Meningioma*, 16 Cancers (Basel) 3362 (Sept. 30, 2024).

in July 2024. Yet none of the labels contain any warning or information on the increased propensity of Depo-Provera to cause intracranial meningioma like that suffered by Plaintiff.

90. Defendants have represented to providers and to consumers, like Plaintiff, that their products are safe and that they take affirmative steps to ensure the safety of their products, and providers and consumers rely on those safety representations.

91. Pfizer, with Depo-Provera, was the first company to advertise female contraceptive on television.

92. Direct-to-consumer advertising has played a large role in Pfizer's sales of Depo-Provera.

93. In these advertisements, Pfizer touted that Depo-Provera "has been used safely for over 30 years by millions of women worldwide."

94. At no time did Pfizer warn that use of Depo-Provera could cause meningioma.

95. Even after the Roland study, the 2022 study by UPMC, all the preceding medical literature cited above showing the biological plausibility of the association between progesterone and meningioma, evidence of Depo-Provera-related cases of meningioma, and the evidence of other progesterones causing meningioma, Defendants have still made no change to the U.S. Depo-Provera

label related to intracranial meningioma. Furthermore, Defendants have failed to take any steps to otherwise warn the medical community and users of these significant health risks, despite changing the label as recently as July 2024 to include warnings about pregnancy-related risks.

96. Following the publication of the *Roland* study, Defendant Pfizer stated, "We are aware of this potential risk associated with long-term use of progestogens and, in collaboration with regulatory agencies, are in the process of updating product labels and patient information leaflets with appropriate wording."[30] Yet Defendant Pfizer has not updated the product label for Depo-Provera in the United States.

97. Defendant Pfizer has changed the label in the EU, the UK, Canada, and others.

98. Specifically, the electronic Medicines Compendium ("eMC"), which hosts the labeling information approved by the UK or European government agencies, shows that Defendant Pfizer added a "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

[30] Ian Sample, *Hormone Medication Could Increase Risk of Brain Tumours, French Study Finds*, Guardian (Mar. 27, 2024), https://www.theguardian.com/society/2024/mar/27/hormone-medication-brain-tumours-risk-progestogens-study [https://perma.cc/UPS5-LPKM].

when recommending Depo-Provera to patients with a history of meningioma."[31] The Pfizer UK label was last updated on May 29, 2024.[32]

99. Defendants' Package Leaflet, linked on the Pfizer UK website,[33] warns that "It is important to tell your doctor or healthcare professional if you have, or have ever had in the past . . . [a] meningioma (a usually benign tumour of the tissue layer surrounding the brain and spinal cord)."[34] The leaflet was last revised in September 2025.[35]

100. The Canadian label for Depo-Provera has listed "meningioma" as a "Post-Market Adverse Drug Reactions" since at least 2018. In September 2024, Defendant Pfizer updated its Product Monograph and Patient Information brochure in Canada.[36] The Monograph now includes: "Meningiomas have been reported following long-term administration of progestins, including medroxyprogesterone acetate (MPA). MPA should be discontinued if a meningioma is diagnosed. Caution is advised when recommending medroxyprogesterone to patients with a

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[31] *Healthcare Professionals (SmPC)*, eMC, https://www.medicines.org.uk/emc/product/6721/smpc [https://perma.cc/LLJ3-49CU] (last updated Sept. 29, 2025).
[32] *Patient Leaflet (PIL)*, eMC, https://www.medicines.org.uk/emc/files/pil.6721.pdf [https://perma.cc/34HG-EU7H] (last updated Sept. 22, 2025).
[33] *Id.*; *see also Depo-Provera (Medroxyprogesterone Acetate)*, Pfizer, https://www.pfizer.co.uk/products/prescription-medicines/depo-provera [https://perma.cc/K2JR-2XNA] (last visited Dec. 9, 2025).
[34] *Id.*
[35] *Id.*
[36] *DEPO-PROVERA (Medrozyprogesterone Acetate Injectable Suspension, USP)*, Pfizer, https://www.pfizer.ca/en/our-products/depo-provera-medroxyprogesterone-acetate-injectable-suspension-usp [https://perma.cc/3TRY-UCKP] (last visited Dec. 9, 2025).

history of meningioma."[37] The Patient Information advises patients to tell their healthcare provider if they "Have a history of meningioma (tumor in tissues that cover the brain and spinal cord)."[38]

101. On September 6, 2024, the Pharmacovigilance Risk Assessment Committee ("PRAC") of the European Medicines Agency recommended that patients with meningioma or meningioma history not take medicines containing medroxyprogesterone acetate, and that patients taking medroxyprogesterone acetate be monitored for symptoms of meningioma. PRAC also noted that "[t]he product information for medicines containing high-dose medroxyprogesterone acetate will be updated to include meningioma as a possible side effect of unknown frequency."[39]

102. On September 30, 2024, PRAC issued the new required warnings for all DMPA-containing injectable or ≥ 100mg oral products with non-oncological

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[37] Pfizer Canada ULC, *Product Monograph Including Patient Medication Information—* *[Pr]DEPO-PROVERA®* 16 (May 17, 1961, rev'd Nov. 19, 2024), https://webfiles.pfizer.com/file/35c7d606-8a12-480f-bba3-988d9e3d771e?referrer=ccb731e5-4f2d-4f4a-b2dc-e5e912145fc6 [https://perma.cc/KG7E-BAGU].

[38] *Id.* at 37.

[39] *Meeting Highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 2-5 September 2024*, European Meds. Agency (Sept. 6, 2024), https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-2-5-september-2024 [https://perma.cc/B3V4-DBVV]. The National Pharmaceutical Regulatory Agency (NPRA) Ministry of Health Malaysia likewise issued a warning about the connection between medroxyprogesterone acetate and meningiomas. Choo Sim Mei, *Progestogens (Cyproterone Acetate, Medroxyprogesterone Acetate, Chlormadinone): Risk of Meningioma*, NPRA (Aug. 26, 2024), https://www.npra.gov.my/index.php/en/component/content/article/454-english/safety-alerts-main/safety-alerts-2024/1527647-progestogens-cyproterone-acetate-medroxyprogesterone-acetate-chlormadinone-risk-of-meningioma.html?Itemid=1391 [https://perma.cc/EUE8-UHYK].

indications: "Cases of meningioma (single and multiple) have been reported in patients treated with medroxyprogesterone acetate for a prolonged time (several years). Patients treated with medroxyprogesterone acetate should be monitored for signs and symptoms of meningioma in accordance with clinical practice. If a patient is diagnosed with meningioma, medroxyprogesterone acetate must be stopped, as a precautionary measure."[40] In the package leaflet, manufacturers are required to include under "do not use," "If you have meningioma or have ever been diagnosed with a meningioma (a usually benign tumour of the tissue layer surrounding the brain and spinal cord)."[41] PRAC also requires the following "warnings and precautions": "Use of medroxyprogesterone acetate has been linked to the development of a usually benign tumour of the tissue surrounding the brain and spinal cord (meningioma). The risk increases especially when you use it for longer duration (several years). If you are diagnosed with meningioma, your doctor will stop your treatment with <product name> (see section 'Do not take…'). If you notice any symptoms such as changes in vision (e.g. seeing double or blurriness), hearing loss or ringing in the ears, loss of smell, headaches that worsen with time, memory loss, seizures, weakness in your arms or legs, you must tell

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[40] *New Product Information Wording – Extracts from PRAC Recommendations on Signals*, European Meds. Agency, 2 (Sept. 30, 2024), https://www.ema.europa.eu/en/documents/prac-recommendation/new-product-information-wording-extracts-prac-recommendations-signals-adopted-2-5-september-2024-prac_en.pdf [https://perma.cc/U5XG-XP94].
[41] *Id.* at 3.

your doctor straightaway."[42] Nothing was or is stopping Defendants from adding similar language to the label and package insert for Depo-Provera in the United States.

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

104. As the NDA holder, Pfizer had to submit, and the FDA approved, the labels for Depo-Provera. At any time, Pfizer could have made changes "in the labeling to reflect newly acquired information" to "add or strengthen a contraindication, warning, precaution, or adverse reaction."[43]

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

106. A manufacturer of an approved drug can use the CBE supplement to immediately make changes "in the labeling to reflect newly acquired information" to "add or strengthen a contraindication, warning, precaution, or adverse reaction."[44] By definition and by regulation, such changes to add a warning based on newly acquired information—such as that discovered through newly emerging

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[42] *Id.*
[43] 21 C.F.R. § 314.70(c)(6)(iii).
[44] *Id.*

literature and studies like those discussed above—are considered "moderate changes."[45]

107. Yet, at no time did Defendants attempt to include a warning on the Depo-Provera label that consumers were at a high risk of developing intracranial meningioma.

108. Based on the public scientific information, Defendants knew or should have known that Depo-Provera could cause consumers to develop intracranial meningiomas.

109. Defendants ignored reports from patients and healthcare providers throughout the United States that indicated that Depo-Provera was inherently dangerous and failed to perform as intended. Defendants also knew or should have known of the effects associated with long-term use of Depo-Provera, which led to the severe and debilitating injuries suffered by Plaintiff and numerous other patients. Rather than conducting adequate testing or otherwise following up to determine the cause of these injuries for which it had notice, or to rule out Depo-Provera's design as the cause of the injuries, Defendants continued to sell and falsely and misleadingly market Depo-Provera as a safe and effective prescription drug for contraception and other indications.

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[45] 21 C.F.R. § 314.70(c).

E. Defendant Pfizer Has at All Relevant Times Been Responsible for the Depo-Provera Label.

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

111. To market a generic version of an FDA-approved drug, a manufacturer must submit an Abbreviated New Drug Application ("ANDA"). The generic manufacturer relies 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.

112. The brand-name manufacturer is responsible for the accuracy and adequacy of the drug label, while generic manufacturers are required to ensure that their labels mirror the brand-name version. As a result, the content on Defendant Pfizer's label controls the content on the labels of generic forms of medroxyprogesterone acetate.

113. Because generic manufacturers must replicate exactly the brand-name label, Defendant Pfizer exerted exclusive control over the contents of the labels used by generic manufacturers of medroxyprogesterone acetate that Plaintiff may

have been prescribed and administered. Consequently, any deficiencies or omissions in Defendant Pfizer's label would be reflected in the generic labels.

114. As the brand-name manufacturer of Depo-Provera, Defendant Pfizer had and continues to have a duty to ensure that the Depo-Provera label, and consequently the generic labels, remain 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.[46]

115. Defendant Pfizer was in the best position to provide warnings regarding Depo-Provera's risks and was also the only entity legally authorized to update the label unilaterally under federal law.

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

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[46] *See* 21 C.F.R. § 201.80(e).

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

118. Despite the ability and obligation to provide timely and adequate warnings, Defendant Pfizer failed to take such action.

119. To the extent that any of the medroxyprogesterone acetate used or consumed by, or administered to, Plaintiff was generic, Defendant Pfizer is additionally liable for any resultant harm to Plaintiff from those generic doses.

F. Plaintiff Used Defendants' Depo-Provera and Developed Intracranial Meningioma

120. Plaintiff used Depo-Provera that was designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold by Defendants.

121. Plaintiff used Defendants' Depo-Provera products from approximately 2019 to 2021.

122. Many (or all) of the injections Plaintiff received were marketed and labeled by Pfizer, either as the brand or authorized generic.

123. Plaintiff was diagnosed with meningioma on July 1, 2022 and suffered injuries from meningioma.

124. Plaintiff will continue to have life-long debilitation from her meningioma.

125. Plaintiff at all times used, and Plaintiff's providers at all times prescribed, Depo-Provera in a manner foreseeable to Defendants, as Defendants generated the instructions for use for Plaintiff to receive Depo-Provera injections.

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

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

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

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

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

131. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with medical providers, the nature of Plaintiff's injuries and damages and their relationship to Depo-Provera was not discovered, and through reasonable care and diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims.

TOLLING / FRAUDULENT CONCEALMENT

132. Plaintiff asserts all applicable statutory and common law rights and theories related to the tolling or extension of any applicable statutes of limitations or repose, including equitable tolling, delayed discovery, discovery rule and/or fraudulent concealment.

133. The discovery rule applies to toll the running of the statutes of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of her injuries, the cause of her injuries, and the tortious nature of the wrongdoing that caused her injuries.

134. The nature of Plaintiff's injuries, damages, or their causal relationship to Defendants' conduct was not discovered, and through reasonable care and due

diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims.

135. The running of the limitations period is also equitably tolled because of Defendants fraudulent concealment. Based on information and belief, Defendants affirmatively withheld and/or misrepresented facts concerning Depo-Provera's safety. As a result of Defendant's misrepresentations and concealment, Plaintiff was unaware and could not have known or have learned through reasonable diligence, of facts related to Defendants' misrepresentations or omissions that Plaintiff had been exposed to the risks alleged herein, or that those risks were the direct and proximate result of the wrongful acts and/or omissions of Defendants.

136. Defendants are estopped from relying on any statutes of limitation or repose by virtue of their fraudulent concealment, through affirmative misrepresentations and omissions to Plaintiff regarding the safety of Depo-Provera. Based on information and belief, Defendants affirmatively withheld and/or misrepresented facts concerning Depo-Provera's safety. As a result of Defendant's misrepresentations and concealment, Plaintiff was unaware and could not have known or have learned through reasonable diligence, of facts related to Defendants' misrepresentations or omissions that Plaintiff had been exposed to the

risks alleged herein, or that those risks were the direct and proximate result of the wrongful acts and/or omissions of Defendants.

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

138. The studies discussed above reveal that discontinuing use of progesterone and progestin, including Depo-Provera, can stop or slow the growth of meningiomas. But Defendants took affirmative steps to keep this information about how to potentially mitigate the damage of a developing meningioma from the medical community and Plaintiff.

139. 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. Defendants failed to disclose a known defect and, instead, affirmatively misrepresented that Depo-Provera was safe for its intended use. Defendants disseminated labeling, marketing, promotion and/or sales information to Plaintiff, her healthcare providers, and the general public regarding the safety of Depo-Provera knowing such information was false, misleading, and/or inadequate

to warn of the safety risks associated with long-term Depo-Provera use. Defendants did so willfully, wantonly, and with the intent to prevent the dissemination of information known to them concerning Depo-Provera's safety.

140. 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 healthcare providers, and which included, without limitation, the package insert and the medication guide—no warnings required to safely prescribe and take Depo-Provera and no intracranial meningioma-related adverse side effects associated with use of Depo-Provera.

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

142. Due to the absence of any instructions for how to identify and/or monitor Depo-Provera patients for potential intracranial meningioma-related complications, Plaintiff was unaware that Depo-Provera could cause serious,

intracranial meningioma-related injuries, as this danger was not known to Plaintiff, Plaintiff's healthcare providers, or the general public.

143. Given Defendants' affirmative actions of concealment by failing to disclose this known but non-public information about the defects, safety, and risks—information over which Defendants had exclusive control—and because Plaintiff could not reasonably have known that Depo-Provera could cause meningioma, Defendants are estopped from relying on any statutes of limitations or repose that might otherwise be applicable to the claims asserted herein.

CONDUCT WARRANTING PUNITIVE DAMAGES

144. For the reasons set forth above and addressed below, Defendants acted with a reckless disregard for human life, oppression, and malice. Defendants were fully aware of Depo-Provera's risks, including that use of Depo-Provera could cause and/or exacerbate intracranial meningiomas, causing severe and life-altering injuries to users and consumers of the drug, including Plaintiff. Nonetheless, Defendants deliberately crafted their label and marketing to mislead consumers and profit from the lucrative sale of the injectable contraceptive to women generally, and especially to those who were young and of lower socioeconomic status. Defendants' conduct was carried out with a willful and conscious disregard for Plaintiff's safety and subjected Plaintiff to cruel and unjust hardship. On information and belief, Plaintiff alleges that Defendant's wrongful conduct was

known, adopted, and approved by Defendants' employees that exercised substantial independent authority and judgment such that the employees' decisions ultimately determine corporate policy. Exemplary damages are warranted to punish and deter Defendants and others from such conduct in the future.

CAUSES OF ACTION

COUNT I: STRICT LIABILITY—FAILURE TO WARN

145. Plaintiff incorporates the preceding paragraphs as if fully stated herein.

146. A manufacturer has a duty to adequately warn of the potential risks or hazards associated with a product where there is unequal knowledge, actual or constructive, of a dangerous condition, and the defendant, possessed of such knowledge, knows or should know that harm might or could occur if no warning is given.

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

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

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

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

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

152. Defendants marketed, promoted, distributed and sold an unreasonably dangerous and defective prescription drug, Depo-Provera, to healthcare providers empowered to prescribe and dispense Depo-Provera to consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data regarding the risk of meningioma and the risks of unnecessarily excessive progestin exposure, which was available and generally accepted within the scientific community. Through both omission and affirmative misstatements, Defendants misled the medical community about the risks and benefits of Depo-Provera, which resulted in injury to Plaintiff.

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

154. Although Defendants knew or should have known based on information generally accepted within the scientific community that Depo-Provera caused unreasonable and dangerous side effects, they continue to promote and market Depo-Provera without providing adequate clinically relevant information and data or recommending patients be monitored.

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

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

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

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

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

160. Alternatively, even if Defendants had apprised Plaintiff's Healthcare Providers of the unreasonably high risk of meningioma associated with Depo-Provera and Plaintiff's Healthcare Providers had still recommended Depo-Provera to Plaintiff, Plaintiff's Healthcare Providers would have relayed the information concerning the risk of meningioma to Plaintiff, and Plaintiff as an objectively prudent person would not have chosen to take Depo-Provera, notwithstanding Plaintiff's Healthcare Providers' continued recommendation.

161. Similarly, if Defendants had warned of the unreasonably high risk of meningioma associated with Depo-Provera in the Patient Information handout, Plaintiff as an objectively prudent persons would not have chosen to take Depo-Provera, notwithstanding Plaintiff's Healthcare Providers' recommendation.

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

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

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

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

166. By failing to adequately test and research harms associated with Depo-Provera, and by failing to provide appropriate warnings and instructions about Depo-Provera use, patients and the medical community, including prescribing doctors, were inadequately informed about the true risk-benefit profile of Depo-Provera and were not sufficiently aware that serious and potentially debilitating intracranial meningioma might be associated with use of Depo-Provera. Nor were the medical community, patients, patients' families, or regulators appropriately informed that serious and potentially debilitating

intracranial meningioma might be a side effect of Depo-Provera and should or could be reported as an adverse event.

167. The Depo-Provera products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate post-marketing surveillance and/or warnings because, even after Defendants knew or should have known of the risks of severe and permanent intracranial meningioma-related injuries from ingesting Depo-Provera, Defendants failed to provide adequate warnings to users or consumers of the products, and continued to improperly advertise, market and/or promote Depo-Provera.

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

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

170. Defendants' failure to warn was a substantial factor in causing Plaintiff's injuries, and but for Defendants' failure to warn, Plaintiff would not have been injured.

171. As a direct and proximate result of Defendants' conduct, including the inadequate warnings, dilution or lack of information, lack of adequate testing and research, and the defective and dangerous nature of Depo-Provera, Plaintiff was injured, suffered severe and permanent pain, suffering, disability, impairment, mental anguish, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. The losses are either permanent or continuing, and Plaintiff will suffer additional losses in the future.

172. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT II: STRICT LIABILITY—DESIGN DEFECT

173. Plaintiff incorporates the preceding paragraphs as if fully stated herein.

174. At all relevant times, Defendants engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Depo-Provera and placed Depo-Provera into the stream of commerce in a defective and unreasonably

dangerous condition. These actions were under the ultimate control and supervision of Defendants.

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

176. Depo-Provera was designed in such a way that it posed an unreasonable risk of intracranial meningioma and by placing and keeping Depo-Provera on the market despite Depo-Provera being in a defective condition.

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

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

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

180. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Depo-Provera, a defective product which

created an unreasonable risk to the health of consumers, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

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

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

183. The Depo-Provera injected into Plaintiff was in a condition not contemplated by Plaintiff in that it was unreasonably dangerous, posing a serious risk of permanent injuries.

184. Depo-Provera is a medication prescribed for contraception and treatment of endometriosis, among other uses. Depo-Provera in fact causes serious and potentially debilitating intracranial meningioma, a brain tumor that can cause severe damage and require invasive surgical removal, harming Plaintiff and other consumers. Plaintiff, ordinary consumers, and prescribers would not expect a

contraceptive drug designed, marketed, and labeled for contraception to cause intracranial meningioma.

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

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

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

188. Studies have shown that oral contraceptives do not have the same increased risk of intracranial meningioma. The design defects render Depo-Provera more dangerous than other drugs and therapies designed for contraception and causes an unreasonable increased risk of injury, including, but not limited, to potentially debilitating intracranial meningioma and sequelae related thereto.

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

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

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

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

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

193. Defendants' defective design was a substantial factor in causing Plaintiff's injuries, and but for Defendants' defective design, Plaintiff would not have been injured.

194. As a direct and proximate result of Defendants' conduct and defective design, including inadequate testing and research and an inadequate label, and the

defective and dangerous nature of Depo-Provera, Plaintiff was injured, suffered severe and permanent pain, suffering, disability, impairment, mental anguish, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. The losses are either permanent or continuing, and Plaintiff will suffer additional losses in the future.

195. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT III: NEGLIGENCE

196. Plaintiff incorporates the preceding paragraphs as if fully stated herein.

197. Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, and/or sold Depo-Provera products that were used by Plaintiff.

198. At all relevant times, Defendants had a duty to design, label, manufacture, test, market, distribute and/or sell their Depo-Provera products with reasonable and due care for the safety and well-being of the consuming public in general, and Plaintiff in particular, who was subject to and used the product.

199. Depo-Provera can cause and exacerbate intracranial meningioma. Defendants knew or should have known about this risk and warned consumers and their physicians about the same.

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

201. Defendants breached their duty of care to Plaintiff and Plaintiff's Healthcare Providers in the testing, monitoring, and pharmacovigilance of Depo-Provera.

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

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

b. Manufacturing, producing, promoting, advertising, formulating, creating, developing, and designing, and distributing Depo-Provera while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of Depo-Provera;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether Depo-Provera was safe for its intended use;

d. Failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendants knew and had reason to know that Depo-Provera was unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users;

e. Failing to warn Plaintiff, Plaintiff's providers, the medical and healthcare community, and consumers of the known and knowable risk of harm, which was unreasonable;

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

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

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

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

j. Failing to use reasonable and prudent care in the design, research, testing, manufacture, and development of Depo-Provera so as to avoid the risk of serious harm associated with the use of Depo-Provera;

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

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

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

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

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

204. Defendants knew or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in the design, manufacture, testing, marketing, labeling, packaging, distribution, and sale of Depo-Provera.

205. Plaintiff's injuries were reasonably foreseeable to Defendants because Defendants knew or should have known that medroxyprogesterone acetate could cause or exacerbate meningioma, and that the warnings disseminated with their Depo-Provera products failed to communicate warnings and instructions that were appropriate and adequate to render these products safe for ordinary, intended and reasonably foreseeable uses.

206. Had Defendants used reasonable care in communicating adequate warnings and/or instructions of the risks of using their Depo-Provera products, Plaintiff would have read and heeded those warnings and/or instructions and could have obtained or used alternative medication. As a result, Plaintiff would not have used Defendants' Depo-Provera and would not have been injured.

207. Each of Defendants' actions listed above was a substantial factor in causing Plaintiff's injuries, and but for these actions, Plaintiff would not have been injured

208. As a direct and proximate result of one or more of the above-stated negligent acts by Defendants, Plaintiff was injured, suffered severe and permanent

pain, suffering, disability, impairment, mental anguish, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. The losses are either permanent or continuing, and Plaintiff will suffer additional losses in the future.

209. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT IV: NEGLIGENT FAILURE TO WARN

210. Plaintiff incorporates the preceding paragraphs as if fully stated herein.

211. At all relevant times, Defendants had a duty to exercise reasonable care and had the duty of an expert in all aspects of the warning and post-sale warning to assure the safety of Depo-Provera when used as intended or in a way that Defendants could reasonably have anticipated, and to assure that the consuming public, including Plaintiff and Plaintiff's physicians, obtained accurate information and adequate instructions for the safe use or non-use of Depo-Provera.

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

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

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

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

a. Failing to accompany their product with proper and adequate warnings, labeling, or instructions concerning the potentially dangerous, defective, unsafe, and deleterious propensity of Depo-Provera and of the risks associated with its use, including the severity and potentially irreversible nature of such adverse effects;

b. Disseminating information to Plaintiff and Plaintiff's Healthcare Providers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff;

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

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

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

f. Failure to adequately warn of the risk of serious and potentially irreversible injuries related to the development or exacerbation of intracranial meningioma;

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

h. Failure to instruct patients, prescribers, and consumers of the need to discontinue Depo-Provera in the event of symptoms potentially related to the development or exacerbation of intracranial meningioma;

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

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

k. Failing to provide adequate training or information to medical care providers for appropriate use of Depo-Provera and patients taking Depo-Provera; and

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

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

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

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

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

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

221. The warnings that were given by Defendants failed to properly warn Plaintiff and Plaintiff's Healthcare Providers of the prevalence of intracranial meningioma and sequelae related thereto.

222. Plaintiff and Plaintiff's Healthcare Providers reasonably relied upon the skill, superior knowledge, and judgment of Defendants. Defendants had a continuing duty to warn Plaintiff and her prescribing providers of the dangers associated with Depo-Provera. Had Plaintiff received adequate warnings regarding the risks of Depo-Provera, Plaintiff would not have used the product.

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

224. Defendants' failure to warn was a substantial factor in causing Plaintiff's injuries, and but for Defendants' failure to warn, Plaintiff would not have been injured.

225. As a direct and proximate result of Defendants' negligent failure to warn, Plaintiff was injured, suffered severe and permanent pain, suffering, disability, impairment, mental anguish, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. The losses are either permanent or continuing, and Plaintiff will suffer additional losses in the future.

226. WHEREFORE, Plaintiff respectfully request this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT V: NEGLIGENT DESIGN

227. Plaintiff incorporates the preceding paragraphs as if fully stated herein.

228. At all relevant times, Defendants had a duty to exercise reasonable care and had the duty of an expert in all aspects of the design, formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, promotion, advertising, sale, and research to assure the safety of Depo-Provera when used as intended or in a way that Defendants could reasonably have anticipated, and to assure that the consuming public, including Plaintiff and Plaintiff's physicians, obtained accurate information and adequate instructions for the safe use or non-use of Depo-Provera.

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

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

a. Failing to use due care in developing, testing, designing, and manufacturing Depo-Provera so as to avoid the aforementioned risks

to individuals when Depo-Provera was being used for contraception and other indications;

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

c. Designing, manufacturing, and placing into the stream of commerce a product that was and is unreasonably dangerous for its reasonably foreseeable use, which Defendants knew or should have known could cause injury to Plaintiff.

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

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

233. Defendants' negligent design was a substantial factor in causing Plaintiff's injuries, and but for Defendants' negligent design, Plaintiff would not have been injured.

234. As a direct and proximate result of Defendants' negligent design, Plaintiff was injured, suffered severe and permanent pain, suffering, disability, impairment, mental anguish, loss of enjoyment of life, loss of care, loss of comfort,

and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. The losses are either permanent or continuing, and Plaintiff will suffer additional losses in the future.

235. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT VI: NEGLIGENT MISREPRESENTATION

236. Plaintiff incorporates the preceding paragraphs as if fully stated herein.

237. At all relevant times, Plaintiff used the products at issue in their intended manner and for their intended purpose.

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

239. The information distributed by Defendants to the public, the medical community, Plaintiff, and Plaintiff's Healthcare Providers, including advertising campaigns, labeling materials, print advertisements, commercial media, was false

and misleading and contained omissions and concealment of truth about the dangers of Depo-Provera.

240. Defendants' misrepresentations were intended to and did in fact induce Plaintiff and Plaintiff's Healthcare Providers to request, recommend, purchase, and prescribe Depo-Provera.

241. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, medical device manufacturers, Plaintiff, Plaintiff's Healthcare Providers and the public, the known risks of Depo-Provera, including its propensity to cause intracranial meningioma and sequelae related thereto.

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

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

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

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

246. In reliance upon the false and negligent misrepresentations and omissions made by the Defendants, Plaintiff and Plaintiff's Healthcare Providers were unable to associate the injuries sustained by Plaintiff with her Depo-Provera use, and therefore unable to provide adequate treatment.

247. Defendants knew or should have known that the Plaintiff, Plaintiff's Healthcare Providers, and the general medical community did not have the ability to determine the true facts that were intentionally and/or negligently concealed and misrepresented by the Defendants.

248. Plaintiff and Plaintiff's Healthcare Providers would not have used or prescribed Depo-Provera had the true facts not been concealed by the Defendants.

249. 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.

250. At the time Plaintiff was prescribed and administered Depo-Provera, Plaintiff and Plaintiff's Healthcare Providers were unaware of Defendants' negligent misrepresentations and omissions.

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

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

253. Plaintiff and Plaintiff's Healthcare Providers' reliance on the foregoing misrepresentations and omissions was the direct and proximate cause of Plaintiff's injuries.

254. Defendants' negligent misrepresentations were a substantial factor in causing Plaintiff's injuries, and but for Defendants' negligent misrepresentations, Plaintiff would not have been injured.

255. As a direct and proximate result of reliance upon Defendants' negligent misrepresentations, Plaintiff was injured, suffered severe and permanent pain, suffering, disability, impairment, mental anguish, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to

past and future medical expenses, lost income, and other damages. The losses are either permanent or continuing, and Plaintiff will suffer additional losses in the future.

256. WHEREFORE, Plaintiff respectfully request this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT VII: BREACH OF EXPRESS WARRANTY

257. Plaintiff incorporates the preceding paragraphs as if fully stated herein.

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

259. Defendants expressly warranted to Plaintiff, Plaintiff's Healthcare Providers, and the general public, by and through Defendants and/or their authorized agents or sales representatives, in publications, labeling, the internet, and other communications intended for physicians, patients, Plaintiff, and the

general public, that Depo-Provera was safe, effective, fit and proper for its intended use.

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

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

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

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

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

265. Plaintiff's Healthcare Providers justifiably relied on Defendants' representations through Defendants' marketing and sales representatives in deciding to prescribe Depo-Provera over other alternative treatments on the market, and Plaintiff justifiably relied on Defendants' representations in deciding to purchase and use the drug.

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

267. Defendants' conduct was a substantial factor in causing Plaintiff's injuries, and but for this conduct, Plaintiff would not have been injured.

268. As a direct and proximate result of Defendants' breach, Plaintiff has been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. Plaintiff may also require additional medical and/or hospital care, attention, and services in the future.

269. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT VIII: BREACH OF IMPLIED WARRANTY

270. Plaintiff incorporates the preceding paragraphs as if fully stated herein.

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

272. Defendants' Depo-Provera was expected to reach and did in fact reach consumers, including Plaintiff and/or Plaintiff's Healthcare Providers, without substantial change in the condition in which it was manufactured and sold by Defendants.

273. Defendants sold Depo-Provera primarily to be taken for contraception, but also to treat conditions such as abnormal uterine bleeding,

endometrial hyperplasia, or pain related to endometriosis. Plaintiff was prescribed and purchased Depo-Provera for these intended purposes.

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

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

276. Defendants breached their implied warranties of the Depo-Provera product because the Depo-Provera sold to Plaintiff was not fit for its ordinary purpose as a contraceptive or to treat abnormal uterine bleeding, endometrial hyperplasia, or pain related to endometriosis safely and effectively.

277. Depo-Provera is not fit for its ordinary purposes for which the product is used; was not adequately contained, packaged and labeled; and fails to conform to the promises or affirmations of fact made on the container or label. Depo-Provera instead causes significant and irreparable damage through the development of debilitating intracranial meningioma.

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

279. Defendants' conduct was a substantial factor in causing Plaintiff's injuries, and but for this conduct, Plaintiff would not have been injured.

280. As a direct and proximate result of Defendants' breach, Plaintiff has been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. Plaintiff may also require additional medical and/or hospital care, attention, and services in the future.

281. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT IX: FRAUDULENT MISREPRESENTATION

282. Plaintiff incorporates the preceding paragraphs as if fully stated herein.

283. At all relevant times, Plaintiff used the products at issue in their intended manner and for their intended purpose.

284. The Defendants falsely and fraudulently represented and continue to represent to the medical and healthcare community, Plaintiff and Plaintiff's Healthcare Providers, and the public in general that Depo-Provera has been appropriately tested and was found to be safe and effective.

285. At all relevant times, Defendants misrepresented to consumers and physicians, including Plaintiff and Plaintiff's Healthcare Providers and the public in general, that Depo-Provera is safe for use as a contraceptive and for other indications.

286. At all relevant times, Defendants' marketing of Depo-Provera falsely represented Depo-Provera to be a safe and effective contraceptive option with no increased risk of intracranial meningioma and sequelae related thereto.

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

288. The representations were, in fact, false.

289. Prior to Plaintiff's use of Depo-Provera, Defendants knew or should have known of adverse event reports and scientific and other studies indicating the

development or exacerbation of intracranial meningioma in individuals who had taken Depo-Provera.

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

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

292. Despite that Defendants knew or should have known of Depo-Provera's propensity to cause serious and potentially debilitating injuries due to the development or exacerbation of intracranial meningioma and sequelae related thereto, the label did not contain any of this information in the "Warnings" section. In fact, the label for Depo-Provera has been updated at least a dozen times over the past 20 years. Yet at no point did Defendants provide any of the foregoing information in the "Warnings" section. To date, the Depo-Provera label still does

not include any warnings that indicate the dangers of intracranial meningioma and sequela related thereto after using Depo-Provera.

293. In representations to Plaintiff and/or to Plaintiff's Healthcare Providers, Defendants fraudulently stated that Depo-Provera was safe and omitted warnings related to intracranial meningioma.

294. In representations to Plaintiff and/or to Plaintiff's Healthcare Providers, Defendants fraudulently stated that Depo-Provera was safe and concealed and intentionally omitted material information from the Depo-Provera product label in existence during all the time Plaintiff was prescribed Depo-Provera.

295. Defendants were under a duty to disclose to Plaintiff and Plaintiff's Healthcare Providers the defective nature of Depo-Provera, including but not limited to, the propensity to cause the development of intracranial meningioma, and consequently, its ability to cause debilitating and permanent injuries.

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

297. Defendants knew or had reason to know of the dangerous side effects of Depo-Provera as a result of information from case studies, clinical trials, literature, and adverse event reports available to the Defendants at the time of the

development and sale of Depo-Provera, as well as at the time of Plaintiff's prescription.

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

299. At the time these representations were made by Defendants, and at the time Plaintiff and/or Plaintiff's Healthcare Providers used Depo-Provera, Plaintiff and/or Plaintiff's Healthcare Providers were unaware of the falsehood of these representations.

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

301. In comporting with the standard of care for prescribing providers, Plaintiff's Healthcare Providers relied on the labeling for Depo-Provera in

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

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

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

304. Defendants' fraudulent misrepresentations were a substantial factor in causing Plaintiff's injuries, and but for Defendants' fraudulent misrepresentations, Plaintiff would not have been injured.

305. As a direct and proximate result of reliance upon Defendants' fraudulent misrepresentations, Plaintiff was injured, suffered severe and permanent pain, suffering, disability, impairment, mental anguish, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. The losses are either permanent or continuing, and Plaintiff will suffer additional losses in the future.

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

307. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT X: GROSS NEGLIGENCE / RECKLESSNESS

308. Plaintiff incorporates the preceding paragraphs as if fully stated herein.

309. Defendants' conduct was aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary (or punitive) damages, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious disregard to the rights, safety, or welfare of others; or included material

representations that were false, with Defendants knowing that they were false or with reckless disregard as to the truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff.

310. Defendants ignored or disregarded the dangerous risks associated with Depo-Provera.

311. Defendants' ignorance of these risks was ongoing through the date Plaintiff used the product.

312. Given Defendants' inherent knowledge and awareness of the risks associated with Depo-Provera, and the product's propensity to cause meningioma, Defendants' failure to ensure that the product was safe and effective constitutes gross negligence, malice, and a reckless disregard for the safety of Plaintiff and others.

313. Plaintiff relied on Defendants to introduce into the marketplace a safe and adequately tested product, and Plaintiff suffered catastrophic injuries because of Defendants' failure to do so.

314. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

315. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitutes gross

negligence that proximately caused Plaintiff's injuries. In that regard, Plaintiff will seek exemplary damages in an amount that would punish Defendants for their conduct, and which would deter other manufacturers and sellers from engaging in such misconduct in the future.

316. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

JURY TRIAL DEMAND

317. Pursuant to Del. Code tit. 10, § 1328(b), Plaintiff hereby demands a trial by jury on all the triable issues within this pleading.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the Court enter judgment in Plaintiff's favor and against Defendants for:

a. actual or compensatory damages in an amount to be determined at trial, and as provided by applicable law;

b. exemplary damages sufficient to punish and deter Defendants and others from future wrongful practices;

c. pre-judgment and post-judgment interest;

d. reasonable attorneys' fees as provided for by law;

e. costs and expenses of these actions;

f. statutory damages, treble damages and other relief as permitted by the laws of the states that will govern these actions; and

g. any other further relief the Court may deem just and proper.

Dated: February 4, 2026

Respectfully submitted,

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