IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

PATRICIA BONILLA, Individually and on Behalf of All Others Similarly Situated,

Plaintiffs,

-v-

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

Defendants.

Case No: 2:25-cv-00080

DEMAND FOR JURY TRIAL

CLASS ACTION COMPLAINT FOR MEDICAL MONITORING

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Plaintiff Patricia Bonilla ("Plaintiff"), on behalf of herself and all others similarly situated, by and through counsel, Fegan Scott LLC, brings this Class Action Complaint for medical monitoring against Defendants Pfizer Inc., Pharmacia & Upjohn LLC, Pharmacia LLC, Viatris Inc., Greenstone LLC, and Prasco LLC d/b/a/ Prasco Laboratories, and alleges as follows:

I. INTRODUCTION

1. Pharmaceutical companies have a duty to design, develop, and produce safe and effective medications. Brand manufacturers must adequately inform consumers and healthcare professionals about risks associated with their drugs through adequate warnings, and they must keep abreast of scientific knowledge, discoveries, advances, and research in the field, prioritizing patient safety above all else. Pharmaceutical companies also have a duty to monitor the safety of their products and report to the Food and Drug Administration ("FDA") adverse drug experiences involving their medication from any source, including developing scientific research, and this duty applies to both brand and generic manufacturers alike. And while a generic manufacturer cannot change the label on a generic drug—that is reserved for the brand manufacturer—they have a duty to propose label changes to the FDA when they believe changes are required.

2. Defendants failed to uphold their duties with respect to the contraceptive injection Depo-Provera,[1] which has recently been revealed in the media to cause an increased likelihood of developing brain tumors called intracranial meningiomas. The brand manufacturers failed to keep abreast of the evolving scientific research, failed to conduct their own scientific research in light of the evolving body of scientific evidence, and failed to provide adequate warnings about the risks associated with Depo-Provera. Further, based upon information and belief, the brand and generic manufacturers failed to monitor the safety of Depo-Provera and to report adverse drug experiences

[1] "Depo-Provera" will be used throughout to refer to both the brand name, Depo-Provera, and to medroxyprogesterone acetate or MPA.

to the FDA appearing in scientific studies. Finally, the generic manufacturers failed to propose any label changes to the FDA to warn consumers of the risks associated with their product, based upon information and belief.

3. Defendants instead continued to emphasize the benefits of Depo-Provera while ignoring the evolving science and minimizing or omitting discussions of risks such as the development of intracranial meningiomas, thereby compromising informed decision-making for those individuals receiving Depo-Provera injections.

4. In 1992, Depo-Provera was first approved for contraceptive use. Since then, Depo-Provera has become one of the most widely used forms of hormonal contraception in the United States. In 2020, Depo-Provera was used in more than 2 million prescriptions in the United States.

5. Depo-Provera is the brand name for a contraceptive injection containing 150 mg medroxyprogesterone acetate ("MPA"), which is a synthetic form of the naturally occurring hormone progesterone. The injection is administered every three months into the muscle and prevents pregnancy by stopping ovulation, thickening cervical mucus, and thinning the uterine lining. Unlike other forms of contraception such as the daily "pill," Depo-Provera requires administration only four times a year.

6. However, scientific research first published in the 1980s, before Depo-Provera's approval in 1992 for contraceptive use, found a positive correlation between progesterone and brain tumors called intracranial meningiomas, suggesting that that progesterone plays a role in meningioma growth. Subsequent studies documented a negative correlation between progesterone-inhibiting agents and meningiomas, indicating that anti-progesterone agents inhibited the growth of meningioma cells.

7. Research in the 2010s discovered a connection between synthetic progestin subtypes (specifically, cyproterone acetate, chlormadinone acetate, and nomegestrol acetate) and the development of intracranial meningiomas.

8. In 2023, a study following ten patients treated at the University of Pittsburgh Medical Center found that discontinuation of MPA use—the progestin subtype found in Depo-Provera—had "clear evidence" of meningioma shrinkage, leading the researchers to conclude that there is a "clear progestin meningioma syndrome associated with chronic [ ] MPA use."

9. Then in 2024, a study of French patients subjected to brain surgery for intracranial meningiomas found a 5.5-increased risk for those who used Depo-Provera for more than a year. That finding was bolstered by another study in the United States in 2024, which documented the positive correlation using data from a large database of insurance records. Although the later finding reflected a lower odds ratio of developing intracranial meningiomas, the risk nevertheless equated to 53% increased odds.

10. Intracranial meningiomas are tumors that form on the meninges, which is the protective membrane coating the brain. Although most of these tumors are technically considered non-malignant, their effects can hardly be called benign because they often compress important structures in the brain. Over time, this encroachment causes health issues, such as headaches, changes in vision, seizures, hearing loss, and neurological deficits. Treatment options are often surgical, requiring a craniotomy to remove the skull and resect the tumor. In some cases, treatment options are foreclosed or made riskier by the sensitive location of the tumor unique to progestogen-related meningiomas.

11. Plaintiff, a resident of California, used Depo-Provera consistently for several years. Although she has not been diagnosed with an intracranial meningioma, she is at an increased risk of developing one as a direct and proximate result of using Depo-Provera for a year or more. Accordingly, she brings this lawsuit seeking medical monitoring in the form of diagnostic medical care and the creation of a medical monitoring program to aid in the early detection of meningiomas for herself and a Class who have used Depo-Provera for a year or more.

II. PARTIES

12. At all relevant times, Plaintiff Patricia Bonilla ("Plaintiff") is a citizen of the United States and a resident of California where, beginning in 2012, she received at least 20 Depo-Provera injections. From 2018 to 2023, Plaintiff received MPA injections consistently until she discontinued using it.

13. Plaintiff's medical records indicate that she received both the brand and generic versions of Depo-Provera.

14. Defendant Pfizer Inc. ("Pfizer") is a Delaware corporation with its principal place of business at 235 E. 42nd Street New York, New York 10017.

15. Defendant Pharmacia & Upjohn LLC ("Pharmacia & Upjohn") is a limited liability company organized under Delaware law with its principal place of business at 7171 Portage Road, Kalamazoo, Michigan 49002. It was originally formed in 1995 when the Upjohn Company ("Upjohn") merged with Pharmacia AB to form Pharmacia & Upjohn.

16. Based upon information and belief, from 2002 to 2020, Pfizer owned Pharmacia & Upjohn until Upjohn was spun off in 2020 to create Viatris. The remnant, Pharmacia, was retained by Pfizer.

17. Defendant Pharmacia LLC ("Pharmacia") is a limited liability company organized under Delaware law with its principal place of business at 235 E. 42nd Street New York, New York 10017. Its sole member is Wyeth Holdings LLC, which is a Maine limited liability company with its principal place of business at 66 Hudson Blvd. East, New York, New York 10001. Wyeth's sole member is Anacor Pharmaceuticals LLC. Anacor is a Delaware limited liability company with its principal place of business at 235 E. 42nd Street, New York, New York 10017. Its sole member is Pfizer MAP Holding, Inc., which is organized under Delaware law with an unknown principal place of business.

18. Defendant Viatris Inc. ("Viatris") is a Delaware corporation with its principal place of business at 1000 Mylan Blvd., Canonsburg, Pennsylvania 15317. As stated above, Viatris was formed in 2020 when Upjohn was spun off and combined with Mylan N.V. Based upon information and belief, Pfizer holds 57% of Viatris stock, making it the majority owner.

19. Defendant Greenstone LLC ("Greenstone") is a limited liability company organized under Delaware law with its principal place of business at 100 Route 206 North, Peapack, New Jersey 07977. Greenstone currently has one member, Upjohn US 2 LLC, which is a limited liability company organized under Delaware law with its principal place of business at 1000 Mylan Blvd. Canonsburg, Pennsylvania 15317. Upjohn US 2 LLC has one member, Upjohn US Holdings Inc., which is a Delaware corporation with an unknown principal place of business.

20. Greenstone was founded in 1993, first as a wholly owned subsidiary of Pharmacia & Upjohn and later of Pfizer. At all relevant times, Greenstone was in the business of offering a product portfolio of "authorized generic" medicines, including Depo-Provera. Based upon information and belief, until 2020, Greenstone was wholly owned by Pfizer and staffed with Pfizer personnel in Pfizer facilities. Pfizer also managed Greenstone's business functions, and therefore,

Greenstone was effectively a department within Pfizer until 2020.

21. Defendant Prasco LLC d/b/a Prasco Laboratories ("Prasco") is a limited liability company organized under Ohio law with its principal place of business located at 6125 Commerce Court, Mason, Ohio 45040. Its sole member is Scion Companies LLC, which is an Ohio limited liability company with its principal place of business at 401 N. Michigan Avenue, Suite 400, Chicago, Illinois 60611. The members of Scion Companies LLC are individuals and citizens of Ohio and South Dakota.

22. Pfizer is and has been the current New Drug Application ("NDA") holder for Depo-Provera since 2002 when it acquired the NDA from Pharmacia & Upjohn.

23. When Pfizer acquired the Depo-Provera NDA in 2002, it also acquired the associated responsibilities and liabilities stemming from the manufacturing, sale, and marketing of Depo-Provera.

24. Based on information and belief, in or around 2003, Pfizer's name appeared on the label alongside Pharmacia & Upjohn.

25. Pfizer, Pharmacia & Upjohn, and Pharmacia will be referred to as the "Brand Defendants."

26. Based upon information and belief, Viatris, Greenstone, and Prasco each sell a "generic" version of Depo-Provera that is an "authorized generic." Unlike standard generics, which must contain only the same active ingredients and have the same pharmaceutic effect but can otherwise contain vastly different additives, "authorized generics" are exact replicas of the brand name drug with the identical chemical composition, simply marketed without the brand-name on its label.

27. The FDA has stated that the term "authorized generic" drug is most commonly used to describe an approved brand name drug that is marketed without the brand name on its label. Other than the fact that it does not have the brand name on its label, it is the exact same drug product as the branded product. An "authorized generic" may be marketed by the brand name drug company, or another company with the brand company's permission.[2]

28. Oftentimes, an "authorized generic" distributor may simply take the brand-name pharmaceutical manufactured by the NDA holder and/or another authorized manufacturer and pass it off as its own generic product.

29. In fact, in the case of Depo-Provera, Pfizer's own press release states that "Greenstone Authorized Generics are manufactured to the same standards and at the same facilities as Pfizer brand-name drugs."[3] Based upon information and belief, Pfizer was the actual manufacturer of the authorized generic Depo-Provera that Greenstone distributed and sold.

30. Moreover, based on information and belief, Pfizer is the actual manufacturer of the authorized generic product that Prasco Labs distributes and sells, and Pfizer packages and labels the product with Prasco's name.

31. Viatris, Greenstone, and Prasco will be collectively referred to as the "Generic Defendants."

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[2] U.S. Food & Drug Admin., *FDA List of Authorized Generic Drugs* (Jan. 8, 2025), https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs (last visited Jan. 16, 2025).

[3] Press Release, Pfizer Inc., *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 (last visited Jan. 16, 2025).

III. JURISDICTION AND VENUE

32. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332, as amended by the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2), because (a) there are at least 200 class members; (b) the matter in controversy exceeds $5,000,000 exclusive of interest and costs; and (c) at least one Plaintiff is a citizen of a different state than at least one Defendant.

33. This Court has personal jurisdiction over all Defendants where Defendants engaged and continue to engage in continuous and systematic business within the Commonwealth of Pennsylvania and regularly conduct business, receive substantial revenue, and sell products, including Depo-Provera and its generic equivalent, in Pennsylvania. All Defendants have sufficient minimum contacts with or otherwise intentionally avail themselves to the markets of Pennsylvania through their business operations, real estate, sales, supply chains, and/or services in Pennsylvania.

34. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claim, including the distribution, sale, marketing, and administration of Depo-Provera, occurred in this District; Viatris is headquartered in this District; and Greenstone's member is headquartered in this District.

IV. GENERAL ALLEGATIONS

A. An overview of Depo-Provera.

1. Depo-Provera is a hormonal contraceptive injection containing the progestin subtype MPA, which is artificial progesterone.

35. In the United States, nearly 90% of childbearing-age women use contraceptives to prevent unwanted pregnancy during their lifetimes.[4] Many forms of contraceptives are hormonal,

[4] Laura E. Britton, et al., *An Evidence-Based Update on Contraception*, 120 Am. J. Nursing 22 (2020).

including oral pills, the implant Nexplanon, intrauterine devices, vaginal rings, dermal patches, emergency contraception, and the injection Depo-Provera.[5]

36. Hormonal methods of contraception contain versions of either naturally occurring estrogen and/or progesterone or their synthetic counterparts to prevent the ovaries from releasing egg cells during the menstrual cycle and to prevent sperm cells from reaching egg cells.[6]

37. Progestins or progestogens are synthetic analogs to the naturally produced female hormone progesterone.[7] Progestins are used in certain medications, either alone or in combination with natural hormones, for conditions such as endometriosis, but they are primarily used in contraceptives.[8]

38. Progestins come in several different and distinct formulations or subtypes, and although they are related, they each have different effects.[9] One of these formulations or subtypes is medroxyprogesterone acetate, or MPA as it is known.[10]

39. MPA is a hormonal medication and progestin subtype that is sold under the brand-name Depo-Provera.[11] Although it has been used to treat certain conditions like endometriosis and certain types of cancer, it is most commonly prescribed as a high-dose, long-acting injectable contraceptive.[12]

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[5] *Id.*
[6] *Id.*
[7] Manuel García-Sáenz, et al., *Understanding Progestins: From Basics to Clinical Applicability*, 12 J. Clinical Med. 3388 (2023).
[8] *Id.*
[9] Noémie Roland, et al., *Use of progestogens and the risk of intracranial meningioma: national case-control study*, British Med. J. 384, 385 (2024).
[10] *Id.*
[11] *Id.*
[12] *Id.*

40. Depo-Provera is a 150 mg dose of MPA that is given every three months via intramuscular injection in the arm or buttock, forming a long-lasting "depot" that slowly releases medication over time.[13]

41. Depo-Provera prevents pregnancy by inhibiting the secretion of pituitary gonadotropins, thereby blocking ovulation.[14] As an additional mechanism of pregnancy prevention, Depo-Provera also thickens the cervical mucus, making it more difficult for sperm cells to reach the egg cell.[15]

42. In the United States, nearly a quarter of all sexually active women aged 18-49 have used Depo-Provera for contraception.[16]

43. In 2017, Depo-Provera had annual sales of approximately $211 million in the United States.[17] In 2020, 2 million prescriptions for Depo-Provera or its generic equivalent were written in the United States.[18]

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[13] Cleveland Clinic, *Depo-Provera (Birth Control Shot),* https://my.clevelandclinic.org/health/drugs/4086-depo-provera-birth-control-shot (last visited Jan. 16, 2025). The "depot" mentioned explains why MPA is sometimes referred to as "DMPA."
[14] *Id.*
[15] *Id.*
[16] Russell L. Griffin, *The Association between Medroxyprogesterone Acetate Exposure and Meningioma,* 16 Cancers 3362 (Sept. 30, 2024), https://www.mdpi.com/2072-6694/16/19/3362 (last visited Jan. 16, 2025); *see also* Kimberly Daniels, et al., *Contraceptive Methods Women Have Ever Used: United States 2015-2019*, 195 Nat'l Health Statistics Rep. 1 (2023).
[17] Teva Pharmaceutical Industries Ltd., *Teva Announces Reintroduction of Generic Depo-Provera in the United States* (Sept. 25, 2017), https://www.tevapharm.com/news-and-media/latest-news/teva-announces-reintroduction-of-generic-depo-provera-in-the-united-states/#:~:text=Medroxyprogesterone%20acetate%20injectable%20suspension%2C%20USP%20150%20mg/mL%20had%20annual,data%20as%20of%20July%202017 (last visited Jan. 16, 2025).
[18] Roland, *supra,* note 9, at 9 (citation omitted).

2. Upjohn created Depo-Provera and received FDA approval in 1992 for use as a contraceptive, and Pfizer thereafter acquired the NDA to Depo-Provera.

44. Upjohn introduced Depo-Provera as an injectable intramuscular drug for the treatment of endometrial and renal cancer in 1960.[19]

45. Upjohn then submitted Depo-Provera to the FDA for approval as a contraceptive in 1967, which the FDA rejected.[20] Based upon information and belief, Upjohn then submitted an application to the FDA in 1971, which was approved in 1973 or 1974.[21] However, in 1978, the FDA reportedly reversed its decision after concerns about the drug's potential to cause breast and cervical cancer in a controlled study of dogs and monkeys conducted by Upjohn.[22] Upjohn then submitted another application for approval of Depo-Provera as a contraceptive in 1983, which the FDA rejected.[23]

46. Despite the FDA's rejection of Depo-Provera, starting in the 1960s, Upjohn received approval from regulatory bodies in several countries outside the United States to market Depo-Provera as a contraceptive.[24]

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[19] *See* L.M. Wren, *Depo-Provera: still controversial* (abstract), 9 Int'l Health News 2 (1988), summarized at https://pubmed.ncbi.nlm.nih.gov/12179873/ (last visited Jan. 16, 2025).
[20] *Id.*
[21] Washington Post, *Despite Ban, American Indians Given Depo-Provera* (Aug. 10, 1987), https://www.washingtonpost.com/archive/lifestyle/wellness/1987/08/11/despite-ban-american-indians-given-depo-provera-as-contraceptive/94cbb91d-6497-4b95-abcf-0ddb7ffd5c7b/ (last visited Jan. 16, 2025).
[22] Wren, *supra* note 19.
[23] *Id.*
[24] *Id.*

47. Finally, in October 1992, the FDA approved Upjohn's NDA for Depo-Provera as a contraceptive.[25] However, FDA approval was granted on the condition that Upjohn conduct a post-approval study on the risk of osteoporosis.[26]

48. Regarding this approval in 1992, members of the FDA's advisory committee on fertility and maternal health drugs said that they found the evidence from years of use in other countries to be compelling enough to approve the drug in the United States.[27] Additionally, the FDA pointed to a series of studies conducted by the World Health Organization that suggested that the risk of breast cancer (the FDA's earlier concern) was no greater than the risk posed by oral contraceptives.[28] Still, the FDA acknowledged that Depo-Provera was associated with osteoporosis and low birth weight in accidental pregnancies, warranting more research on those issues in the future.[29]

49. In 2004, the FDA issued a "black box" warning, stating that the prolonged use of MPA may result in significant loss of bone mineral density, which can increase the risk of fractures.[30] The warning also states that the loss increases the longer MPA is used, and that the loss may not be completely reversible after discontinuing MPA.[31]

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[25] William Green, *The FDA, contraceptive marketing approval and products liability litigation: Depo-Provera and the risk of osteoporosis* (abstract), 68 Food & Drug L.J. 115 (2013).
[26] *Id.*
[27] Marlene Cimons, *FDA Panel Backs Contraceptive's Approval: Medicine: An injection of Depo-Provera provides protection for 3 months. Researchers discount past concerns of increased cancer risks.,* L.A. Times, (June 20, 1992, 12:00 AM), https://www.latimes.com/archives/la-xpm-1992-06-20-mn-460-story.html (last visited Jan. 16, 2025).
[28] *Id.*
[29] *Id.*
[30] *Depot Medroxyprogesterone Acetate and Bone Effects*, 602 Am. Coll. Obstetricians & Gynecologists (June 2014), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2014/06/depot-medroxyprogesterone-acetate-and-bone-effects (last visited Jan. 16, 2025).
[31] *Id.*

3. Depo-Provera is often used in at-risk communities and communities of color.

50. Depo-Provera requires administration only four times a year, unlike the pill which must be taken daily. Moreover, it is not invasive like an intrauterine device or arm implant.[32] Moreover, Depo-Provera has a lenient 4-week grace period for users who miss a follow-up injection to receive another, and it is relatively low-cost.[33] Due to these factors, Depo-Provera use is highest among women in at-risk communities in which contraceptive access is limited, such as psychiatric patients, low-income communities, and rural communities.

51. Moreover, according to the Center for Disease Control ("CDC"), significantly higher percentages of Hispanic and Black women have used Depo-Provera at 27.2% and 41.2%, respectively.[34] Meanwhile, only 20.3% of white women and 7.1% of Asian women have used it.[35]

52. The CDC also reports that the use of Depo-Provera is roughly three times as common among women without high school diplomas or GEDs, or 39.9%, compared with those with a bachelor's degree or higher, or 12.7%.[36]

53. Additionally, the CDC reports that women living in rural areas are more likely to have used Depo-Provera, 29.4%, than those who live in urban settings, 23.5%.[37]

[32] *See id.*
[33] *See id.*
[34] Daniels, *supra* note 16, at 3.
[35] *Id.*
[36] *Id.*
[37] *Id.*

54. Before the FDA approved Depo-Provera as a contraceptive in 1992, the United States Indian Health Services Agency prescribed it to many Indigenous-American women despite the FDA reversing its approval as a contraceptive in 1978 after concerns arose about carcinogenic effects.[38]

55. Moreover, when the FDA permitted Upjohn to conduct human clinical trials, it had to terminate the company's major domestic testing program because it was administering Depo-Provera to largely low-income, Black women, and the agency found there was insufficient informed consent procedures, serious issues with the testing protocol, inaccurate screening, and no follow-up.[39]

56. Thus, Depo-Provera has been and is predominantly used by communities of color and at-risk communities.

4. Intracranial meningiomas.

57. Meningiomas are tumors that arise from the protective membrane covering the spinal cord and brain.[40] Meningiomas account for 40% of primary tumors of the central nervous system.[41]

58. Meningiomas are generally benign rather than malignant, meaning they usually do

[38] Associated Press, *Despite Ban American Indians Given Depo-Provera as Contraceptive*, Wash. Post (Aug. 10, 1987), https://www.washingtonpost.com/archive/lifestyle/wellness/1987/08/11/despite-ban-american-indians-given-depo-provera-as-contraceptive/94cbb91d-6497-4b95-abcf-0ddb7ffd5c7b/ (last visited Jan. 16, 2025).

[39] William Green, *The Grady Hospital Study: The Corruption of Contraceptive Research* (abstract), NYU Press Scholarship Online (Jan. 18, 2018), https://academic.oup.com/nyu-press-scholarship-online/book/19021/chapter-abstract/177397745?redirectedFrom=fulltext (last visited Jan. 16, 2025).

[40] Cory D. Adamson, et al., *Meningioma: A Review of Epidemiology, Pathology, Diagnosis, Treatment, and Future Directions*, 9 Biomedicine 319 (2021).

[41] *Id.*

not contain cancerous cells.[42] Still, approximately 10% to 15% of meningiomas are malignant, and such meningiomas are more likely to recur after treatment.[43]

59. Although meningiomas are largely slow growing and generally do not metastasize to other areas of the body, they nevertheless compress the surrounding brain tissue, often requiring a craniotomy to resect the tumor.[44] A craniotomy is a highly invasive surgical procedure where a portion of the skull is removed to reach the brain.[45]

60. When a meningioma begins compressing surrounding tissue, symptoms can include headaches, blurred vision, seizures, memory loss, numbness, and dizziness. In some cases, meningiomas can become life-threatening.[46]

61. Therefore, there is significant clinical value in early detection and diagnosis of intracranial meningiomas.

62. The clinical manifestation and time to diagnosis is dependent on the location and size of the meningioma. In fact, many patients remain asymptomatic for years as the tumor grows and continues encroaching on other brain structures.[47]

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[42] Brigham & Women's Hosp., *Meningioma Brain Tumors,* https://www.brighamandwomens.org/neurosurgery/meningioma#:~:text=Meningiomas%20are%20tumors%20that%20develop,or%20malignant%20meningioma%20(cancerous) (last visited Jan. 16, 2025).
[43] *Id.*
[44] *Id.*
[45] Mayo Clinic, *Craniotomy*, https://www.mayoclinic.org/testsprocedures/craniotomy/about/pac-20568981 (last visited Jan. 16, 2025).
[46] Cleveland Clinic, *Meningioma*, https://my.clevelandclinic.org/health/diseases/17858-meningioma (last visited Jan. 16, 2025).
[47] Brigham & Women's Hosp., *Meningioma Brain Tumors*, https://www.brighamandwomens.org/neurosurgery/meningioma (last visited Jan. 16, 2025).

63. Meningiomas are primarily diagnosed using imaging tests, such as computerized tomography (CT) scans and magnetic resonance imaging (MRIs) with contrast.[48] Although MRIs are the most common imaging used in the diagnosis and monitoring of meningiomas, some meningiomas may display characteristics that cannot be assessed using MRIs.[49] Especially where a malignant meningioma is suspected, other imaging tools can be more reliable, such as a spectroscopy.[50]

64. These imaging tests are not a part of routine medical care and can cost thousands of dollars.[51]

65. In addition to often requiring surgical resection, meningiomas may require long-term medication or radiation therapy, especially where the meningioma is located in a risky location.[52]

66. Even when it is determined that surgical intervention is not yet needed, patients must generally return for regular follow-up imaging for several years to monitor the growth of the meningioma.[53]

67. The compression of other structures and the resulting need for surgical intervention is particularly concerning with progestin-related meningiomas (like those caused by MPA use) because research has shown that they tend to occur more frequently at the base of the skull and in

[48] J. Watts, et al., *Magnetic resonance imaging of meningiomas: a pictorial review*, 5 Insights Imaging 113, 114 (2014).
[49] *Id.*
[50] *Id.*
[51] *See* Arielle Dreher, *Nonprofit, government hospitals charge more than for-profit facilities for brain imaging: study*, Axios (Mar. 22, 2023), https://www.axios.com/2023/03/22/brain-imaging-commercial-costs (last visited Jan. 16, 2025).
[52] Jing Wang, et al., *An Overview of Managements in Meningiomas*, 10 Front. Oncology 1523 (2020).
[53] *See id.*

the spheno-orbital region, which are more sensitive and high-risk areas.[54]

68. In fact, one study found that out of 72 meningioma patients with a history of hormonal contraceptives, 48 of them developed visual impairments, and almost all of their meningiomas were located in the spheno-orbital region.[55]

69. Therefore, even in the absence of malignancy, meningiomas can hardly be considered "benign" or harmless. They cause potentially disabling symptoms and the need for surgical intervention. Moreover, brain surgery carries the risk of surgical complications like extensive brain swelling and morbidity, especially in the locations that progestin-related meningiomas often develop, as noted above.[56]

70. Even where surgical intervention is successful, it often still has adverse consequences. In the short term, seizures are a known complication, requiring the use of anti-epileptic drugs for several years.[57] Other serious conditions are also known to follow meningioma resections, such as hydrocephalus, hematomas, and spontaneous bleeding.[58]

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[54] *See, e.g.*, Roland, *supra* note 9 at 9; Rachel Wrigley, et al., *Skull Base Meningiomas as Part of a Novel Meningioma Syndrome Associated with Chronic Depot Medroxyprogesterone Acetate Use* (abstract), 84 J. Neurol Surg B Skull Base 1 (2023); Rusdy Ghazali Malueka, et al., *Association of Hormonal Contraception with Meningioma Location in Indonesian Patients*, 23 Asian Pac. J. Cancer Prev. 1047 (2022); Caroline Apra, et al., *Female Gender and exogenous progesterone exposition as risk factors for spheno-orbital meningiomas*, 149 J. Neuro-Oncology 95 (2020); Mirella Hage, et al., *Estrogen and Progesterone Therapy and Meningiomas*, 163 Endocrinology 1, 10 (2022) (noting that progesterone-mediated meningiomas are often located frequently at the anterior and middle base of the skull and are more likely to require multiple intensive interventions).

[55] Malueka, *supra* note 54.

[56] *See, e.g.*, J.R. Vignes, et al., *Peritumoral edema and prognosis in intracranial meningioma surgery* (abstract), 15 J. Clin. Neurosci. 764, 765 (2008).

[57] Roland, *supra* note 9.

[58] *See, e.g.*, Pascal O. Zinn, et al., *Predicting postoperative hydrocephalus in 227 patients with skull base meningioma*, 30 Neurosurg. Focus (2011); Rudiger Gerlach, et al., *Post-operative hematoma after surgery for intracranial meningiomas: causes, avoidable risk factors and clinical outcome* (abstract), 26 Neurol. Res. 61 (2004); Roman Bosnjak, *Spontaneous intracranial*

71. Moreover, several studies have also shown the potential for postoperative anxiety, depression, and memory loss.[59, 60]

B. Defendants knew or should have known of the growing body of scientific research that ultimately linked MPA to the development of intracranial meningiomas.

1. The positive correlation between progesterone and intracranial meningiomas has been the subject of scientific research since the 1980s.

72. The association between the naturally occurring female sexual hormone progesterone and meningiomas has been the subject of scientific research emerging in the 1980s, before Depo-Provera's approval in 1992.

73. In 1983, researchers published scientific articles on the presence of progesterone receptors on meningioma cells, especially relative to the lower number of estrogen receptors present.[61] These findings were significant in the medical community because many hypothesized that meningioma cells, like breast cancer cells, would tend to have more estrogen receptors.[62] Instead, these researchers found the opposite phenomenon, indicating that progesterone plays a role in meningioma growth.[63]

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meningioma bleeding: clinicopathological features and outcome (abstract), 103 J. Neurosurg. 473 (2005).

[59] Tak Kyu Oh, et al., *Depression and mortality after craniotomy for brain tumor removal: A Nationwide cohort study in South Korea* (abstract), 295 J. Affect. Disord. 291 (2021).

[60] SWNS, *I felt hung over and thought everyone was speaking a different language: Turns out I had a brain tumor*, N.Y. Post (July 12, 2024, 1:48 PM), https://nypost.com/2024/07/12/lifestyle/nurse-lists-symptoms-of-her-brain-tumor/ (last visited Jan. 16, 2025).

[61] *See, e.g.*, M.A. Blankenstein, et al., *Presence of progesterone receptors and absence of oestrogen receptors in human intercranial meningioma cytosols* (abstract), 19 Eur. J. Cancer Clin. Oncol. 365 (1983).

[62] *Id.*

[63] *Id.*

74. Supporting a connection between progesterone-inhibiting agents and meningiomas was research published in 1989 that indicated the use of mifepristone, an anti-progesterone agent, inhibited the growth of meningioma cells.[64] Numerous studies published in the decades after presented similar findings on the negative correlation between progesterone-inhibiting agents and meningiomas.[65]

75. The predominance of females within meningioma patients became well-established, and the research theorized this was because the growth of meningiomas were hormone dependent.[66]

76. Around the 2010s, studies began to investigate synthetic progestin subtypes. Several studies emerged focusing on the positive correlation between the synthetic progestin subtype cyproterone acetate and the incidents and growth rate of meningiomas.[67] A literature review in 2017 collected articles showing that three progestin subtypes, cyproterone acetate, chlormadinone acetate, and nomegestrol acetate, were shown to increase the risk

[64] M.A. Blankenstein, et al., *Effect of steroids and antisteroids on human meningioma cells in primary culture* (abstract), 34 J. Steroid Biochem. 419 (1989).

[65] *See, e.g.*, Steven M. Grunberg M.D., et al., *Treatment of unresectable meningiomas with the antiprogesterone agent mifepristone*, 74 J. Neurosurg. 861 (1991); Giulia Cossu, et al., *The Role of Mifepristone in Meningiomas Management: A Systematic Review of the Literature,* 2015 BioMed Res. Int. 267831 (2015), https://doi.org/10.1155/2015/267831 (last visited Jan. 16, 2025).

[66] *See, e.g.*, Joseph Wiemels, *Epidemiology and etiology of meningioma*, 99 J. Neurooncol. 307 (2010) (finding that meningiomas are found twice as much in women as in men); Francesco Maiuri, et al., *Meningiomas in Premenopausal Women: Role of the Hormone Related Conditions*, 10 Front. Oncol. 556701 (2020), https://pmc.ncbi.nlm.nih.gov/articles/PMC7759676/ (last visited Jan. 16, 2025).

[67] Miguel Gil, et al., *Risk of meningioma among users of high doses of cyproterone acetate as compared with the general population: evidence from a population-based cohort study,* 72 Br. J. Clin. Pharmacol. 965 (2011); *see also* 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 (2015).

of developing meningiomas.[68]

2. Recent studies documented the significant risk of developing meningiomas by Depo-Provera use.

77. In 2023, researchers published a case series in the *Journal of Neurological Surgery* following patients treated at the University of Pittsburgh Medical Center between 2014 and 2021.[69] The scientists noted that the association between chronic progestin use and meningioma patients has been studied in Europe, but the association had not been examined in the United States, particularly regarding MPA.[70]

78. The study followed 10 out of 25 patients who developed one or more meningiomas after chronic use of the progestin subtype MPA (Depo-Provera). Those ten patients were instructed to stop using MPA, and afterwards, five of the patients had "clear evidence" of meningioma shrinkage, leading the scientists to conclude that there is a "clear progestin meningioma syndrome associated with chronic DMPA use." [71] The other five patients were either lost to follow-up or stopped the MPA within the previous year, thus not allowing for an adequate assessment.[72]

79. Then in March 2024, the *British Medical Journal,* one of the most respected medical journals in the world, published the largest case control study to date on the correlation between the use of progestogens to assess the risk of meningiomas. This was the first study of its size to analyze other progestogen subtypes beyond the three mentioned above (cyproterone acetate,

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[68] *See, e.g.*, Hage, *supra* note 54 (explaining that a review of medical literature establishes a dose-dependent relationship between meningiomas and cyproterone acetate, nomegestrol acetate, and chlormadinone acetate); Roland, *supra* note 9 (noting that existing research on these three medications resulted in their complete discontinuation in the EU).

[69] Abou-Al-Shaar Hussam, et al., *Skull Base Meningiomas as Part of a Novel Meningioma Syndrome Associated with Chronic Depot Medroxyprogesterone Acetate Use* (abstract), 84 J. Neurol. Surg. B Skull Base 1 (2023).

[70] *Id.*

[71] This study referred to MPA as "DMPA," because the injection leaves a "depot" of MPA. *See* Cleveland Clinic, *supra* note 13.

[72] Abou-al-Shaar Hussam, *supra* note 69.

chlormadinone acetate, and nomegestrol acetate), and like the University of Pittsburgh Medical Center study, the study specifically included MPA.[73]

80. The study was undertaken by the French National Agency for Medicines and Health Products Safety, led by Noemie Roland (the "Roland Study").[74] Roland and her team analyzed data of over 108,000 women in the French National Health Data System, focusing specifically on 18,061 women in France who received brain surgery for a meningiomas between 2009 and 2018. Researchers matched each patient with five control subjects to ensure a fair comparison.[75]

81. Using UK cancer registries, the researchers determined that about 4 in every 1,000 30-year-old women would be expected to develop a meningioma by the age of 80. But where MPA was used for more than one year, that figure rose to 20 in every 1,000.[76] Thus, those who used Depo-Provera for over one year faced a 5.5-fold increase in risk of developing a meningioma.[77] The study found that this was an "important new finding" since injectable MPA was a "widely used contraceptive."[78]

82. In addition to MPA, the Roland Study evaluated the effects of other medications containing progesterone and other progestin subtypes. Researchers observed no excess risk of meningiomas with exposure to natural progesterone via other modes of administration, like percutaneous or oral.

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[73] Roland, *supra,* note 9, at 9.
[74] *Id.* at 1.
[75] *Id.*
[76] *See id.*; Ian Sample, *Hormone medication could increase risk of brain tumours, French study finds*, The Guardian (Mar. 27, 2024) https://www.theguardian.com/society/2024/mar/27/hormone-medication-brain-tumours-risk-progestogens-study (last visited Jan. 16, 2025).
[77] Roland, *supra,* note 9, at 1.
[78] *Id.*

83. Moreover, the Roland Study found that the longer a patient was exposed to MPA, the greater their risk of developing meningiomas. The Roland Study considered "prolonged use" to be equal to or over one year.[79]

84. The study also noted that 28.8% of the women used antiepileptic drugs three years after the index date of their intracranial surgery, highlighting the long-term and adverse consequences associated with the surgery.[80]

85. Notably, the Roland Study used women residing in France of all ages who underwent surgery for intracranial meningiomas between January 2009 and December 2018.[81] The use of MPA for contraception is far less common in France than the United States. The authors posited that the results might show an even stronger association if conducted on American women.[82]

86. Another characteristic of the Roland Study is that it likely underestimates the true prevalence of progesterone-related meningiomas because a hospital admission for a craniotomy was the outcome of interest.[83] Thus, the study left out progestin-related meningiomas that were not symptomatic and/or did not require surgery.[84]

87. Six months later, in September 2024, a study was published analyzing over 117,000 meningioma cases in the United States from 2006-2022 (the "Griffin Study").[85] The data was extracted from a large national database of insurance records. The study found that injection

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[79] *Id.*
[80] *Id.* at 8.
[81] *Id.*
[82] *Id.* at 9 (noting that injectable contraceptives are "much less widely used in Europe" with only 3.1 percent of childbearing age women in the U.K. and 0.2 percent of childbearing age women in France using this form of contraception).
[83] *Id.* at 1.
[84] *Id.* at 10.
[85] Griffin, *supra,* note 16 at 1-2.

exposure to MPA was nearly twice as high among meningioma cases than controls. Adjustments to the data found the odds of exposure to MPA via injection was associated with a 1.53-fold increased risk of meningioma development, further increasing with prolonged use.[86]

88. This study theorized that the difference in outcomes as compared to the Roland study could be the result of the smaller sample size in the Roland study, its use of national health system data, and its ability to adjust for area of residence.[87]

89. The Griffin Study noted that while it did not aim to identify a biologic mechanism for the association between MPA and intracranial meningioma, such mechanism existed based on the prior decades of research showing that meningiomas inhibit sex hormone receptors, which receptors play a role in the growth of meningiomas.[88] In sum, "meningioma growth could be stimulated by the presence of MPA, increasing the likelihood of a meningioma diagnosis…."[89]

90. A month after the Griffin Study, in October 2024, researchers published an abstract titled "Progesterone Contraception and Tumor-Related Visual Impairment in Premenopausal Women with Meningioma Referred for Radiation." This paper reported on a retrospective case-control study that examined the role of hormonal contraception in the development of intracranial meningioma causing visual impairment in women under the age of 55. The authors concluded "[p]rogesterone use is a significant risk factor for meningioma-related visual deficits . . . with a disproportionate number on [Depo-]Provera specifically."[90]

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[86] *Id.* at 5.
[87] *Id.* at 7.
[88] *Id.*
[89] *Id.*
[90] M.M. Bailey, et al., *Progesterone Contraception and Tumor-Related Visual Impairment in Premenopausal Women with Meningioma Referred for Radiation* (abstract), 120 Int'l J. of Radiation Oncology, Biology, Physics E217 (2024), https://www.redjournal.org/article/S0360-3016(24)01252-5/fulltext (last visited Jan. 16, 2025).

C. Despite the growing body of research first connecting progesterone and then progestins to intracranial meningiomas, the Brand Defendants failed to investigate the risk, conduct their own studies, or warn of the risk.

1. The Brand Defendants failed to investigate a known risk of Depo-Provera correlating with intracranial meningiomas.

91. Because the assessment of drug safety in pre-approval clinical trials is limited by factors like duration or pre-defined patient populations, the FDA relies on drug manufacturers to engage in post-approval surveillance to identify potential safety concerns that arise in the real-world setting.[91]

92. This ongoing duty of manufacturers to continue pharmacovigilance is an essential obligation that includes staying abreast of research concerning the safety of their products and performing their own research and investigation.[92]

93. In light of the studies beginning in the 1980s which first linked progesterone to intracranial meningiomas, Upjohn and then the Brand Defendants had a duty to keep abreast of this scientific research and should have themselves investigated whether MPA found in Depo-Provera was linked to intracranial meningiomas. Certainly, in the 2010s when progestin subtypes were directly linked to meningioma growth, the Brand Defendants as the NDA holders for Depo-Provera, should have conducted studies to determine whether the progestin subtype MPA was also linked to the development of intracranial meningiomas. The Brand Defendants, as large, sophisticated, well-resourced pharmaceutical corporations, were best positioned to conduct such research.

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[91] Sylvia Lucas, et al., *Pharmacovigilance: reporting requirements throughout a product's lifecycle,* 13 Therapeutic Adv. Drug Safety (2022), https://pubmed.ncbi.nlm.nih.gov/36187302/ (last visited Jan. 16, 2025).

[92] *See id.*

94. Given the development of the body of research, it was foreseeable that a high-dose of MPA used for an extended period of time—a year or more—could cause the growth of intracranial meningiomas.

95. Because the Brand Defendants did not investigate this risk, countless women continued to receive high-dose quarterly injections for years, increasing their meningioma risk the longer they used it.

96. The Brand Defendants are also liable for the conduct of their predecessors, including Upjohn, who failed to adequately test any connection between intracranial meningiomas and Depo-Provera.

2. The Brand Defendants failed to disclose the risk of meningiomas through warnings or otherwise, and the Generic Defendants failed to propose any similar warnings to the FDA.

97. After the publication of the Roland Study, in April 2024, Pfizer reportedly stated, "[w]e 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."[93]

98. Pfizer recognized the need to update warnings and labels despite the decades of medical research, first showing an association between meningiomas and progesterone generally, and then certain progestin subtypes, and then MPA specifically. Yet, to this day, Pfizer has not made any changes to the United States Depo-Provera label to mention meningiomas.

99. According to the FDA, the Brand Defendants have updated the label for Depo-Provera 13 times since 2003, and the latest update was in July 2024.[94] Despite there being at least

[93] *See* Sample, *supra* note 76. (citing Pfizer statement).
[94] *See* U.S. Food & Drug Admin., *Drugs@FDA: FDA-Approved Drugs*, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020246 (last visited Jan. 16, 2025).

14 iterations of the Depo-Provera label, there has never been any mention of the increased risk of developing intracranial meningiomas.

100. Further, Pfizer changed the label in the European Union and the United Kingdom in October 2024. The recently updated Depo-Provera label in the European Union contains the following addition: "Special Warnings and Precautions for Use: Meningiomas: Meningiomas have been reported following long-term administration of progesterones including medroxyprogesterone acetate. Depo-Provera should be discontinued if a meningioma is diagnosed. Caution is advised when recommending Depo-Provera to patients with a history of meningiomas." Additionally, the package leaflet in the European Union states that "before using Depo-Provera, it is important to tell your doctor or healthcare professional if you have, or have ever had in the past, a meningioma…." Despite already including these changes in the European Union and the United Kingdom packaging, Pfizer has failed to do so in the United States.

101. The Brand Defendants could have filed a Changes Being Effected, or CBE, supplement under 21 C.F.R. § 314.70(c) which allows manufacturers to make "moderate changes" to a pharmaceutical product's label without FDA approval.[95] Moderate label changes that can be done via a CBE include changes that "reflect newly acquired information" to "add or strengthen a contraindication, warning, precaution, or adverse reaction."[96] Under this statutory language, an addition about the risk of intracranial meningiomas based on studies that have been developing over several years would have fallen within this provision.

[95] 21 C.F.R. § 314.70(c).
[96] *Id.*

102. And while the Generic Defendants cannot change the label on a drug by CBE or otherwise, they could have proposed label changes to the FDA regarding the risk of intracranial meningiomas from extended MPA use.[97]

3. All Defendants failed to monitor the safety of their products and report the adverse events to the FDA contained in the scientific studies.

103. Under federal law, all manufacturers must monitor the safety of their products and must "develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences" to the FDA. 21 CFR §314.80(b). These adverse experiences must be reported "from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers." *Id.* These obligations apply to brand and generic manufacturers alike.

104. Defendants failed to monitor the safety of their MPA products in the scientific literature and based upon information and belief, did not report any adverse drug experiences that were contained in the growing body of scientific literature regarding the link between MPA and intracranial meningiomas.

D. Plaintiff received Depo-Provera injections for contraception for an extended period of time.

105. Plaintiff received at least 20, 150 mg injections of Depo-Provera or its authorized generic.

106. Although she first received injections beginning in 2012, Plaintiff received regular injections of Depo-Provera from September 2018 through November 2023, when she stopped receiving the medication.

[97] *See PLIVA, Inc. v. Mensing,* 564 U.S. 604, 616 (2011) (articulating the FDA's position but ultimately applying preemption).

107. Her medical records reflect both "Depo-Provera" and "medroxyprogesterone (Depo-Provera)" injections. Based upon information and belief, Plaintiff received both the brand name drug manufactured by the Brand Defendants and/or its authorized generic equivalent manufactured and/or sold by the Generic Defendants.

108. Plaintiff was unaware until seeing significant publicity associated with the Roland Study that receiving Depo-Provera injections for over a year put her at an increased risk of developing intracranial meningiomas.

E. Medical Monitoring for the development of intracranial meningiomas for Plaintiff and the Class is essential.

109. As a proximate result of Defendants actions and omissions, Plaintiff and the Class have been, and are presently, at an increased risk of developing intracranial meningiomas, requiring them to incur, both now and in the future, the cost of medically necessary monitoring, diagnostic testing, clinical examinations, and consultations for the early detection of such tumors arising from their use of Depo-Provera for a year or more.

110. Plaintiff and Class members have suffered a present bodily injury including subcellular injury proximately caused by Defendants' tortious conduct. Plaintiffs have a legally protected interest in not being exposed to developing intracranial meningiomas. Plaintiff and the Class also have a legally protected interest in avoiding the present and ongoing medical need for expensive medical monitoring, diagnostic testing, clinical examinations, and consultations.

111. Receiving Depo-Provera injections, the consequent subcellular or other physiological changes in Plaintiffs and Class members, and the resulting increased risk of developing intracranial meningiomas, have caused Plaintiffs and Class members a present and ongoing economic injury. This economic injury consists of the need to incur the cost of medically necessary monitoring, diagnostic testing, clinical examinations, and consultations for the early

detection of these tumors.

112. Plaintiffs and the Class are reasonably concerned that they will develop intracranial meningiomas as a result of their Depo-Provera use. They should not have to wait until they actually develop intracranial meningiomas; instead, they should benefit from a medical monitoring program that will allow early detection.

113. Plaintiffs and Class members should not have to bear the burden of funding and/or performing such medical monitoring, testing, and/or research, which will likely cost millions of dollars, when Plaintiffs and Class members were not aware that they were being put at risk when they received Depo-Provera injections. This is especially true because meningiomas are primarily diagnosed using imaging tests, such as computerized tomography (CT) scans and magnetic resonance imaging (MRIs) with contrast, which are not a part of routine medical care and can cost thousands of dollars. Defendants should have to bear this expense where Defendants have reaped millions, if not billions of dollars in profits from selling Depo-Provera.

V. TOLLING OF STATUTE OF LIMITATIONS

A. The statute of limitations is tolled by equitable tolling and fraudulent concealment.

114. The running of any statute of limitations has been equitably tolled by Defendants' fraudulent concealment and/or omissions regarding the correlation between Depo-Provera and an increased risk of developing intracranial meningiomas. Through their affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff, the Class, and their physicians the true risks associated with Depo-Provera.

115. As a result of Defendants' actions and/or omissions, Plaintiff and the Class were unaware, and could not have reasonably known or learned through reasonable diligence, that they had been exposed to an increased risk of developing intracranial meningiomas and that those risks

and harms were the direct and proximate result of Defendants' acts and omissions.

116. Plaintiff and the Class do not have the technical, scientific or medical knowledge and information, as Defendants have, sufficient to ascertain the risk that Depo-Provera presented.

117. Any statute of limitations has been tolled by equitable tolling and/or fraudulent concealment.

B. Accrual of the statute of limitations has been delayed by the discovery rule.

118. In addition, accrual of any statute of limitations has also been delayed by the discovery rule. As set out above, Plaintiff and the Class did not have the technical, scientific or medical knowledge and information sufficient to ascertain the risk that Depo-Provera presented, and Plaintiff and the Class members could not have discovered their increased risk of developing intracranial meningioma through reasonable care and diligence.

119. Accrual of any statute of limitations for Plaintiff and the Class's claims has therefore been delayed under the discovery rule, and therefore, these claims are timely.

VI. CLASS ALLEGATIONS

120. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(2) or (b)(3) as representative of the Nationwide Medical Monitoring Class (or, the "Class"), defined as the following:

> **Nationwide Medical Monitoring Class:** All persons who received 50 mg Depo-Provera injections for a year or more while a resident of Arizona, California, Colorado, District of Columbia, Florida, Maryland, Missouri, Nevada, New Jersey, Ohio, Pennsylvania, South Dakota, Utah, Vermont, or West Virginia and who have not been diagnosed with intracranial meningioma(s).

121. Alternatively, and in addition, Plaintiff seeks certification on behalf of subclasses defined as more fully set forth below and collectively referred to as the "State Medical Monitoring Subclasses" or, individually, the "[state] Subclass:"

Arizona Subclass: All persons who received 50 mg Depo-Provera injections for a year or more while a resident of Arizona and who have not been diagnosed with intracranial meningioma(s).

California Subclass: All persons who received 50 mg Depo-Provera injections for a year or more while a resident of California and who have not been diagnosed with intracranial meningioma(s).

Colorado Subclass: All persons who received 50 mg Depo-Provera injections for a year or more while a resident of Colorado and who have not been diagnosed with intracranial meningioma(s).

District of Columbia Subclass: All persons who received 50 mg Depo-Provera injections for a year or more while a resident of the District of Columbia and who have not been diagnosed with intracranial meningioma(s).

Florida Subclass: All persons who received 50 mg Depo-Provera injections for a year or more while a resident of Florida and who have not been diagnosed with intracranial meningioma(s).

Maryland Subclass: All persons who received 50 mg Depo-Provera injections for a year or more while a resident of Maryland and who have not been diagnosed with intracranial meningioma(s).

Missouri Subclass: All persons who received 50 mg Depo-Provera injections for a year or more while a resident of Missouri and who have not been diagnosed with intracranial meningioma(s).

Nevada Subclass: All persons who received 50 mg Depo-Provera injections for a year or more while a resident of Nevada and who have not been diagnosed with intracranial meningioma(s).

New Jersey Subclass: All persons who received 50 mg Depo-Provera injections for a year or more while a resident of New Jersey and who have not been diagnosed with intracranial meningioma(s).

Ohio Subclass: All persons who received 50 mg Depo-Provera injections for a year or more while a resident of Ohio and who have not been diagnosed with intracranial meningioma(s).

Pennsylvania Subclass: All persons who received 50 mg Depo-Provera injections for a year or more while a resident of Pennsylvania and who have not been diagnosed with intracranial meningioma(s).

South Dakota Subclass: All persons who received 50 mg Depo-Provera injections for a year or more while a resident of South Dakota and who have not been diagnosed with intracranial meningioma(s).

Utah Subclass: All persons who received 50 mg Depo-Provera injections for a year or more while a resident of Utah and who have not been diagnosed with intracranial meningioma(s).

Vermont Subclass: All persons who received 50 mg Depo-Provera injections for a year or more while a resident of Vermont and who have not been diagnosed with intracranial meningioma(s).

West Virginia Subclass: All persons who received 50 mg Depo-Provera injections for a year or more while a resident of West Virginia and who have not been diagnosed with intracranial meningioma(s).

122. Excluded from the Class is anyone presently suffering from or diagnosed with intracranial meningiomas; Defendants and any of their affiliates, parents, subsidiaries, employees, officers, and directors; any entity in which Defendants have a controlling interest; all persons who make a timely election to be excluded from the class; governmental entities; and all judges assigned to hear any aspect of this litigation.

123. Plaintiff reserves the right to modify or amend the Class definition following discovery and prior to class certification.

124. ***Numerosity:*** The members of the Class are so numerous that joinder is impracticable. Depo-Provera has been a frequently-prescribed contraceptive for decades, and thus, it is reasonable to infer that the Class includes thousands of members.

125. ***Commonality:*** There are numerous questions of law and fact common to the Class, including, but not limited to:

(a) Whether the Brand Defendants were negligent in failing to keep abreast of scientific knowledge, discoveries, advances, and research regarding the relationship between progesterone and progestins and intracranial meningiomas;

(b) Whether the Brand Defendants should have conducted studies regarding MPA and intracranial meningiomas;

(c) Whether the Brand Defendants failed to warn consumers regarding the risk of developing intracranial meningiomas with Depo-Provera use for a year or more;

(d) Whether both the Brand and Generic Defendants failed to monitor the safety of Depo-Provera;

(e) Whether both the Brand and Generic Defendants failed to report the adverse drug experiences identified in the scientific literature or otherwise, linking Depo-Provera to intracranial meningioma;

(f) Whether the Generic Defendants failed to propose label changes to the FDA to warn of the risk of developing intracranial meningiomas with Depo-Provera use for a year or more;

(g) Whether receiving Depo-Provera injections for a year or more exposed Plaintiff and the Class to an increased risk of developing intracranial meningiomas relative to the public at large;

(h) Whether receiving Depo-Provera injections for a year or more have caused subcellular or other physiological changes to Plaintiff and the Class;

(i) Whether early detection of intracranial meningiomas will provide benefits to Plaintiff and the Class;

(j) Whether Plaintiff and the Class are entitled to medical monitoring relief as a result of their increased risk of developing intracranial meningiomas because they received Depo-Provera injections for a year or more; and

(k) The type and format of medical monitoring relief, declaratory relief and/or injunctive relief that is appropriate.

126. ***Typicality.*** Plaintiff's claims are typical of the claims of the Class in that Plaintiff's claims arose out of the same common course of conduct that gives rise to the claims of the other Class members. Plaintiff, like each Class member, received Depo-Provera injections for a year or more. Plaintiff, like each Class member, faces an increased risk of developing intracranial meningiomas. Plaintiff is advancing the same legal theory on behalf of herself and the Class based on Defendants' common course of misconduct. There are no unique defenses or intervening causes that would make Plaintiff's pursuit of her own interests not also advance the interests of the Class.

127. ***Adequacy.*** Plaintiff will fairly and adequately protect the interests of the Class members. Plaintiff's interests and the interests of all other members of the Class are identical and

do not present conflicts of interest. Plaintiff intends to vigorously prosecute this case and will fairly and adequately protect the Class members' interests. Plaintiff has retained counsel who are competent and experienced in litigating class actions of this kind and who will fairly and adequately represent the interests of the Class. Class counsel have sufficient financial resources to fund the litigation.

128. ***Rule 23(b)(2).*** Defendants have acted on grounds that apply generally to Plaintiff and the Class members so that preliminary and/or final injunctive relief and corresponding declaratory relief is appropriate respecting the Classes as a whole. Plaintiff has received 50 mg Depo-Provera injections for a year or more to necessitate the medical monitoring and other relief sought in this Class Action medical monitoring complaint and can establish such sufficiency through common proof and evidence.

129. ***Rule 23(b)(3), Predominance and Superiority.*** The common questions identified above predominate over any issues affecting only individual Class members. Moreover, a class action is superior to other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. The quintessential purpose of the class action mechanism is to permit litigation against wrongdoers even when damages to an individual plaintiff may not be sufficient to justify individual litigation. Here, the damages suffered by Plaintiff and the Class are relatively small compared to the burden and expense required to individually litigate their claims against Defendants, and thus, individual litigation to redress Defendants' wrongful conduct would be impracticable. Individual litigation by each Class member would also strain the court system, create the potential for inconsistent or contradictory judgments, and increase the delay and expense to all parties and the court system. By contrast, the class action device presents fewer management difficulties and provides the

benefits of a single adjudication, economies of scale, and comprehensive supervision by a single court.

VII. CAUSES OF ACTION

COUNT I
MEDICAL MONITORING

130. Plaintiff incorporates paragraphs 1 through 129, as if set forth in full herein.

131. Plaintiff brings this claim of medical monitoring against Defendants on behalf of herself and the Class, as defined above.

132. The Brand Defendants owed Plaintiff and the Class a duty to keep abreast of scientific knowledge, discoveries, advances, and research in the field, to adequately inform consumers and healthcare professionals about risks associated with their drugs, and to use reasonable care to issue warnings or instructions concerning any such danger.

133. Both Brand and Generic Defendants owed Plaintiff and the Class a duty to monitor the safety of Depo-Provera and report adverse drug experiences, including those identified in the scientific research connecting Depo-Provera to the increased risk of intracranial meningiomas.

134. The Generic Defendants had a duty to request label changes to the FDA when they believe that change is required to effectively warn consumers of risks.

135. The Brand Defendants breached their duties by, *inter alia,* failing to keep abreast of scientific knowledge, discoveries, advances, and research in the field, to adequately inform consumers and healthcare professionals about risks associated with Depo-Provera, and to use reasonable care to issue warnings or instructions concerning the positive correlation with developing intracranial meningiomas.

136. Both Brand and Generic Defendants also breached their duties to Plaintiff and each Class member by failing to monitor the safety of Depo-Provera and, based on information and belief, failing to report adverse drug experience where Depo-Provera use led to intracranial meningiomas.

137. The Generic Defendants also failed to, based upon information and belief, propose label changes to the FDA to warn consumers of the risk of intracranial meningiomas with Depo-Provera use.

138. As a proximate result of Defendants' acts and omissions, Plaintiff and the Class are at an increased risk of developing intracranial meningiomas.

139. Plaintiff and each Class member's exposure to Depo-Provera and the associated and increased risk of developing intracranial meningiomas was solely and proximately caused by Defendants' acts and omissions identified above.

140. Defendants' negligent acts and omissions put Plaintiff and the Class at an increased risk of developing intracranial meningiomas. Intracranial meningiomas present a serious health condition because they often compress important structures in the brain. This encroachment can cause health issues, such as headaches, changes in vision, seizures, hearing loss, and neurological deficits. Treatment options are often surgical, requiring a craniotomy to remove the skull and resect the tumor. In some cases, treatment options are foreclosed or made riskier by the sensitive location of the tumor, which is a particular issue among progesterone-related meningiomas.

141. Medical monitoring, including diagnostic tests, are necessary because Plaintiff and the Class may not develop intracranial meningiomas for many years.

142. Technology, analytical tools, test and/or monitoring procedures exist and are

readily available to detect intracranial meningiomas. These technologies, tools, tests, and/or monitoring procedures are accepted and widely used by the scientific and medical community. The existing scientific methods include, but are not limited to, diagnostic radiological imaging and examinations that will assist in diagnosing meningiomas.

143. The tests and treatments for the detection and treatment of intracranial meningioma must be prescribed by a qualified physician, and are conducted according to the latest, contemporary, and widely accepted scientific principles within the medical community specializing in the diagnosis and treatment of brain tumors, including intracranial meningiomas. The prescribed monitoring regime is different from that normally recommended in the absence of exposure. Further, Plaintiff and the Class require screenings not within the purview of routine medical exams.

144. Plaintiff and the Class seek the creation of a Court-supervised, Defendants-funded medical monitoring program which will facilitate the detection and, if necessary, treatment of Plaintiff and the Class members for intracranial meningiomas. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiff and the Class for medical monitoring as frequently and appropriately as necessary.

145. Accordingly, Defendants should be required to establish a medical monitoring program that includes, among other things: (a) notifying all Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis; (b) providing for necessary testing, evaluations and screening, and other necessary medical consultations; (c) providing for all necessary medical and surgical procedures for diagnosis and treatment; and (d) providing for all necessary attorneys' fees, costs, interest, and such other and further relief as this Court deems just and appropriate.

146. Plaintiff and the Class do not have an adequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical losses due to receiving Depo-Provera injections for more than a year. Without a court-approved medical monitoring program, as described herein, or established by the Court, Plaintiff will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT II
DECLARATORY RELIEF

147. Plaintiff incorporates paragraphs 1 through 146, as if set forth in full herein.

148. Plaintiff brings this claim for declaratory relief against Defendants on behalf of herself and the Class, as defined above.

149. An actual, substantial, and justiciable controversy has arisen and exists between Plaintiff and the Class, on one hand, and Defendants on the other, and their respective rights, obligations, and duties with respect to the increased risk that Plaintiff and Class members will develop intracranial meningiomas as a result of Defendants' acts and/or omissions.

150. As a result, Plaintiff and the Class seeks a declaratory judgment against Defendants that Defendants are responsible for this increased risk, request all equitable and/or injunctive relief, and such other relief as the Court may Order that the Court deems just and appropriate.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of members of the Class, respectfully requests that this Court:

A. Issue an Order certifying this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and 23(b)(2) or 23(b)(3), directing that reasonable notice of this action be given to the Class, appointing Plaintiff as the Class representative, and appointing Plaintiff's counsel as Class Counsel;

B. Enter judgment against Defendants and in favor of Plaintiff and the Class;

C. Order equitable relief in the form of a medical monitoring program to be implemented, funded, and maintained by the Defendants;

D. Declare that Defendants are responsible for the increased risk of developing intracranial meningiomas as a result of Depo-Provera use for a year or more;

E. Award Plaintiff the costs and disbursements of the action, along with reasonable attorneys' fees, costs, and expenses;

F. Award pre-judgment and post-judgment interest where appropriate; and

G. Grant such other and further relief as this Court deems just and appropriate.

IX. DEMAND FOR JURY TRIAL

Plaintiff demands a jury trial on all claims so triable.

Dated: January 17, 2025

Respectfully submitted,

By: */s/ Lynn A. Ellenberger*

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