UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA

DONNA TONEY, Plaintiff, vs. **PFIZER INC.; PHARMACIA & UPJOHN CO. LLC; and PHARMACIA LLC,** Defendants.	**COMPLAINT AND DEMAND FOR JURY TRIAL** Case No. 24-624

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

INTRODUCTION

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

2. Defendants manufacture, promote, and sell Depo-Provera as a prescription drug used for contraception and/or to treat endometriosis, among other indications. Depo-Provera is manufactured as an injection to be administered

intramuscularly every three (3) months in either the upper arm or buttocks.

3. Depo-Provera injured Plaintiff Donna Toney by causing or substantially contributing to the development of an intracranial meningiomas, *i.e.*, brain tumor, which required significant and invasive treatment and has resulted in serious injuries.

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

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

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

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

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

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

10. Plaintiff therefore demands judgment against Defendants and requests, among other things, compensatory damages, statutory damages, punitive damages, attorneys' fees, and costs.

PARTIES

11. At all relevant times hereto, Plaintiff Donna Toney (hereinafter "Plaintiff") was and is a resident and citizen of Cantonment, Escambia County, Florida.

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

13. Pfizer has a registered agent for service of process, CT Corporation System, at 1200 South Pine Island Road, Plantation, Florida 33324.

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

49002.

15. Pharmacia & Upjohn has a registered agent for service of process, CT Corporation System, at 1200 South Pine Island Road, Plantation, Florida 33324.

16. Defendant PHARMACIA LLC (hereinafter "Pharmacia") is a corporation organized under Delaware law and headquartered at 28 Liberty St., New York, New York, 10005.

17. Pharmacia has a registered agent for service of process, CT Corporation System, at CT Corp., at 820 Bear Tavern Road, West Trenton, New Jersey 08628.

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

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

20. All Defendants do business in Florida by, among other things,

distributing, marketing, selling, and/or profiting from Depo-Provera in Florida, as well as throughout the United States.

21. Defendants were obligated to undertake reasonable measures to ensure patients like Plaintiff were not at risk of suffering from meningioma or other related injuries and, further, had an obligation to warn of such dangers relating to Defendants' product, including in the State of Florida.

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

23. Defendants are jointly and severally liable to Plaintiff for the injuries and damages caused by her injections of Depo Provera.

JURISDICTION AND VENUE

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

25. All Defendants regularly conduct business in Florida.

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

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

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

29. For example, in or around 2021, Pfizer built a "global capability hub" in Tampa, Florida, which hosts "logistics and business development departments like finance, human resources[,] and digital operations."[1]

30. Moreover, Defendants Pfizer and Pharmacia & Upjohn are both registered to do business in the State of Florida and can be served at their registered agent for service of process, CT Corporation System, at 1200 South Pine Island Road, Plantation, Florida 33324.

PLAINTIFF DONNA TONEY'S SPECIFIC FACTS

31. In or around 1997, Plaintiff Donna Toney was first administered Depo-Provera for contraception at Brooke Army Medical Center (BAMC) in Sam Houston, Texas. Over time, Plaintiff would continue to receive Depo-Provera shots

[1] *See* https://www.tampabay.com/news/business/2021/02/18/pfizer-to-open-new-business-hub-in-tampas-heights-union/.

from Fort Johnson, formerly Fort Polk, located in Vernon Parish, Louisiana.

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

33. From approximately January 1997 to September 1997, Plaintiff was subjected to brand-name Depo-Provera injections pursuant to her physicians' prescriptions.

34. In 2001, Plaintiff moved to Cantonment, Florida, however, she did not experience any symptoms at that time that would have put her on notice of a growing brain tumor behind her right ear near the base of her skull. Unbeknownst to Plaintiff, from 2001 to 2011, she had a slowly growing brain tumor that would eventually grow to a size sufficient to cause the necessary mass effect and symptoms to cause her to seek medical attention. During this timeframe, Plaintiff resided in, was injured and suffered in, this District.

35. Not until 2011, 13 years after her injections, did Plaintiff developed alarming symptoms, including vertigo and dizziness. Plaintiff, additionally, had experience some onset hearing loss. Plaintiff immediately sought medical attention and underwent an MRI revealing a brain tumor.

36. In or around 2011, Plaintiff underwent brain surgery at Sacred Heart of Pensacola to remove the meningioma by neurosurgeon Dr. Michael L. Goodman.

37. Plaintiff's As a result of the meningioma and related brain surgery to remove the same, Plaintiff suffered injuries, including but not limited to: placement of a mesh at the removal site; scarring; hearing loss; tinnitus; cochlear implant placement; loss of ability to fully speak; speech therapy; mental anguish; depression; isolation; and other injuries therefrom.

38. During the recovery period Plaintiff was out of work for on or around 8-9 weeks after removal surgery. The meningioma, related surgeries and resulting injuries have caused Plaintiff economic damages in addition to her injuries.

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

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

GENERAL ALLEGATIONS

A. Intracranial Meningioma

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

42. Although the tumor formed by an intracranial meningioma is

typically histologically benign (meaning it usually does not metastasize), the growing tumor can nevertheless press against the sensitive surrounding tissues, i.e., the brain, and thereby cause a number of severe and debilitating symptoms ranging from seizures and vision problems to weakness, difficulty speaking, and even death, among others. Moreover, a sizeable number of meningiomas (15-20%) do become metastatic, greatly increasing their danger.

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

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

B. Depo-Provera

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

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

47. According to a recent National Health Statistics Report published in December 2023, nearly a quarter (24.5%) of all sexually experienced women ages 15-49 in the United States between 2015 and 2019 had ever used Depo-Provera.[2]

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

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

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

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

51. Among reproductive age women who used any form of contraception from 2017-2019, the contraceptive injection was most often used by young women, lower-income women, and Black women.[4]

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

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

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

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

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

57. As early as 1969, Upjohn successfully received approval for Depo-

[4] *See* https://www.kff.org/womens-health-policy/fact-sheet/dmpa-contraceptive-injection-use-and-coverage/ (last accessed November 11, 2024).

Provera for contraception in international markets, including France.

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

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

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

61. Pfizer has effectively held the Depo-Provera NDA since acquiring Pharmacia & Upjohn in 2002, and has solely held the NDA since 2020.

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

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

64. Defendants are also liable for the conduct of its predecessors who failed to adequately design, test, and warn of the dangers associated with use of Depo-Provera.

C. The Dangers of Depo-Provera

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

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

67. This finding was surprising and notable within the medical and scientific communities because it had previously been thought that meningioma cells, like breast cancer cells, would show a preference for estrogen receptors.[6] Researchers publishing in the *European Journal of Cancer and Clinical Oncology* instead found the opposite, indicating progesterone was involved in the incidence, mediation, and growth rate of meningiomas.[7] This particular study was published nearly a decade before the FDA approved Depo-Provera for contraception in 1992. In those nine (9) years before Depo-Provera was approved for contraception, and in

[5] *See* Blankenstein, et al., "Presence of progesterone receptors and absence of oestrogen receptors in human intracranial meningioma cytosols," *Eur J Cancer & Clin Oncol*, Vol. 19, No. 3, pp. 365-70 (1983).
[6] *See id.*
[7] *See id.*

the thirty-two (32) years since—more than forty (40) years in all—Defendants have seemingly failed to investigate the effect of their high-dose progesterone Depo-Provera on the development of meningioma.

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

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

70. Relatedly, a number of studies published in the interim have reported on the positive correlation between a progesterone and/or progestin medication and the incidence and growth rate of meningioma.[11]

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[8] *See* Blankenstein, et al., "Effect of steroids and antisteroids on human meningioma cells in primary culture," *J Steroid Biochem*, Vol. 34, No. 1-6, pp. 419-21 (1989).
[9] *See id.*
[10] *See*, *e.g.*, Grunberg, et al., "Treatment of unresectable meningiomas with the antiprogesterone agent mifepristone," *J Neurosurgery*, Vol. 74, No. 6, pp. 861-66 (1991); *see also* Matsuda, et al., "Antitumor effects of antiprogesterones on human meningioma cells in vitro and in vivo," *J Neurosurgery*, Vol. 80, No. 3, pp. 527-34 (1994).
[11] *See*, *e.g.*, Gil, et al., "Risk of meningioma among users of high doses of cyproterone acetate as compared with the general population: evidence from a population-based cohort study," *Br J Clin*

71. In 2015, a retrospective literature review published in the peer-reviewed journal *BioMed Research International* by Cossu, et al. surveyed the relevant literature including many of the studies cited above and concluded that mifepristone, an antiprogesterone agent, had a regressive effect on meningioma, meaning it stopped or reversed its growth.[12] Reviewing the Blankenstein studies as well as many others conducted over a span of more than thirty (30) years, the authors concluded that mifepristone competes with progesterone for its receptors on meningioma cells and, by blocking progesterone from binding, stems or even reverses the growth of meningioma.

72. In light of the aforementioned studies, for several decades the manufacturers and sellers of Depo-Provera, Defendants, had an unassignable duty to investigate the foreseeable potential that a high dose synthetic progesterone delivered in the deep tissue could cause the development or substantially contribute to the growth of meningioma. Defendants were also best positioned to perform such investigations. Had Defendants done so, they would have discovered decades ago that their high dose progestin Depo-Provera was associated with a highly increased

Pharmacol. Vol. 72, No. 6, pp. 965-68 (2011); *see also* Bernat, et al., "Growth stabilization and regression of meningiomas after discontinuation of cyproterone acetate: a case series of 12 patients," *Acta Neurochir* (*Wien*). Vol. 157, No. 10, pp. 1741-46 (2015); *see also* Kalamarides, et al., "Dramatic shrinkage with reduced vascularization of large meningiomas after cessation of progestin treatment," *World Neurosurg.* Vol. 101, pp 814.e7-e10 (2017).

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

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

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

74. In 2022, an article was published in the journal *Endocrinology* entitled "Estrogen and Progesterone Therapy and Meningiomas."[13] This retrospective literature review noted that a "dose-dependent relationship" has been established between at least one progestin and the incidence and growth rate of meningioma. The study authors further noted that progesterone-mediated meningiomas appear to be located most often in the anterior and middle base of the skull and are more likely to be multiple and require more intensive treatment.

75. In 2023, researchers reported on a direct link between Depo-Provera

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

and meningioma. That year a case series was published in the *Journal of Neurological Surgery Part B: Skull Base* titled "Skull Base Meningiomas as Part of a Novel Meningioma Syndrome Associated with Chronic Depot Medroxyprogesterone Acetate Use."[14] The abstract reported on 25 individuals who developed one or more intracranial meningiomas related to chronic use of Depo-Provera. Of the twenty-five (25) patients, ten (10) were instructed to cease Depo-Provera use, after which five (5) of those patients had "clear evidence of tumor shrinkage," leading the authors to conclude "there appears to be a clear progestin meningioma syndrome associated with chronic DMPA use."

76. In 2024, the French National Agency for Medicines and Health Products Safety along with several French neurosurgeons, epidemiologist, clinicians, and researchers published a large case control study in the *British Medical Journal* (*BMJ*), one of the premier scientific journals in the world, to assess the risk of intracranial meningioma with the use of numerous progestogens among women in France, hereinafter referred to as the *Roland* study.[15]

77. By way of history, the *Roland* study noted that concerns over meningiomas associated with high dose progestogen medications resulted in the

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

[15] Roland, et al., "Use of progestogens and the risk of intracranial meningioma: national case-control study," *BMJ*, Vol. 384, published online Mar. 27, 2024 at https://doi.org/10.1136/bmj-2023-078078 (last accessed November 11, 2024).

recent discontinuation of three such medications in France and the EU. Specifically, there were "postponements in the prescription of chlormadinone acetate, nomegestrol acetate, and cyproterone acetate, following the French and European recommendations to reduce the risk of meningioma attributable to these progestogens in 2018 and 2019."[16]

78. The study analyzed 18,061 cases of women undergoing surgery for intracranial meningioma between 2009 and 2018. The study found that "prolonged use of ... medroxyprogesterone acetate [Depo-Provera] ... was found to increase the risk of intracranial meningioma." Specifically, the authors found that prolonged use of Depo-Provera resulted in a 555% increased risk of developing intracranial meningioma. The study authors concluded "[t]he increased risk associated with the use of injectable medroxyprogesterone acetate, a widely used contraceptive," was an important finding. The authors also noted Depo-Provera is "often administered to vulnerable populations," i.e., lower-income women who have no other choice but to take the subsidized option which only requires action every three months to remain effective for its intended use of preventing pregnancy, and, in the case of the subcutaneous variant, treating endometriosis.

79. The 2024 *Roland* study published in *BMJ* studied the effect of several other progestogen-based medications. Three study subjects showed no excess risk

[16] *See id.*

of intracranial meningioma surgery with exposure to oral or intravaginal progesterone or percutaneous progesterone, dydrogesterone or spironolactone, while no conclusions could be drawn for two others due to lack of exposed cases. The other medications, including medroxyprogesterone acetate (Depo-Provera), were found to be associated with an increased risk of intracranial meningioma, with Depo-Provera having by far the second highest increased risk, surpassed only by the product cyproterone acetate, which had already been withdrawn from the market due to its association with meningioma.

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

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

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

D. Defendants' Failure to Test Depo-Provera

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

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

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

85. According to the Drugs@FDA website, the label for Depo-Provera has been updated on at least thirteen (13) occasions since 2003, with the most recent update coming in July 2024.[17] Despite the fact there are at least fourteen (14) iterations of the Depo-Provera label, Defendants' labels have not contained any warning or any information whatsoever on the increased propensity of Depo-Provera to cause severe and debilitating intracranial meningioma like that suffered by Plaintiff.

[17] *See* Drugs@FDA:FDA-Approved Drugs- Depo-Provera, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020246 (last visited November 11, 2024).

86. Despite the aforementioned article in the *BMJ* and all the preceding medical literature cited above demonstrating the biological plausibility of the association between progesterone and meningioma, evidence of Depo-Provera related cases of meningioma and the evidence of other high dose progesterones causing meningiomas, Defendants have still made no change to the U.S. Depo-Provera label related to intracranial meningioma. Furthermore, Defendants have failed to take any steps to otherwise warn the medical community and Depo-Provera users of these significant health risks, despite changing the label as recently as July 2024 to include warnings about pregnancy-related risks, and despite Defendant Pfizer stating to The Guardian when the *BMJ* article was released in April 2024: "We are aware of this potential risk associated with long-term use of progestogens and, in collaboration with regulatory agencies, are in the process of updating product labels and patient information leaflets with appropriate wording."[18]

87. Defendant Pfizer *has* changed the label in the EU and the UK and potentially in other countries. Specifically, Defendants' Depo-Provera label in the EU now contains the following addition under the section titled "**Special warnings and precautions for use**": "Meningioma: Meningiomas have been reported

[18] Ian Sample, *Hormone medication could increase risk of brain tumours, French study finds*, THE GUARDIAN (Mar. 27, 2024), available at https://www.theguardian.com/society/2024/mar/27/hormone-medication-brain-tumours-risk-progestogens-study) (last accessed November 11, 2024).

following long term administration of progestogens, including medroxyprogesterone acetate. Depo-Provera should be discontinued if a meningioma is diagnosed. Caution is advised when recommending Depo-Provera to patients with a history of meningioma."[19]

88. Additionally, Defendants' Package Leaflet in the EU which provides information for the patient states that "before using Depo-Provera[,]... it is important to tell your doctor or healthcare professional if you have, or have ever had in the past ... a meningioma (a usually benign tumor that forms in the layers of tissue that cover your brain and spinal cord)."[20]

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

90. Specifically, Defendants could have filed a "Changes Being Effected" ("CBE") supplement under 21 C.F.R. § 314.70(c) to update Depo-Provera's label

[19] *See also* PHARMACOVIGILANCE RISK ASSESSMENT COMMITTEE (PRAC) MINUTES OF PRAC MEETING ON 2-5 SEPTEMBER 2024 (Oct. 21, 2024) (last visited November 12, 2024) ("Having considered the available evidence in EudraVigilance, the literature, and the cumulative review submitted by the MAHs, PRAC concluded that there is sufficient evidence to establish a causal association between medroxyprogesterone acetate (MPA) and meningioma. Therefore, the product information should be updated to add meningioma as a contraindication and a warning . . . .").

[20] *See also* PFIZER, DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION – MEDROXYPROGESTERONE ACETATE: RISK OF MENINGIOMA AND MEASURES TO MINIMIZE THIS RISK (Oct. 7, 2024), available at https://assets.publishing.service.gov.uk/media/672a36c1fbd69e1861921b9c/Medroxyprogesterone_acetate_-_Risk_of_meningioma_and_measures_to_minimise_this_risk_-_to_publish.pdf (last visited November 12, 2024).

without any prior FDA approval.

91. Examples of "moderate" label changes that can be made via a CBE supplement explicitly include changes "to reflect newly acquired information" in order to "add or strengthen a contraindication, warning, precaution, or adverse reaction." By definition, and by regulation, such changes to add a warning based on newly acquired information—such as that imparted by newly emerging literature like the litany of studies cited above—are considered a "moderate change." 21 C.F.R. § 314.70(c)(6)(iii).

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

93. Defendants could have also instructed physicians to consider its own safer alternative design, a lower dose medroxyprogesterone acetate injected subcutaneously instead of the more invasive and painful intramuscular injection

method. Studies going back at least ten years have shown that the 150 mg dose of Depo-Provera—when administered subcutaneously, instead of intramuscularly—is absorbed by the body at a similarly slower rate as the lower dose 104 mg Depo-SubQ Provera 104 version.[21] Nevertheless, Defendants never produced a 150 mg subcutaneous version.

94. Knowing that the lower dose 104 mg Depo-SubQ Provera 104 was equally effective and was easier to administer since it involved a smaller needle being injected only below the skin and not all the way into the muscle, Defendants could have educated the gynecology community that it had a safer alternative product to Depo-Provera which was more well known to prescribers and patients.

95. In Europe and other counties outside of the United States, this 104 mg subcutaneous dose has a more accessible trade name, "Sayana Press," unlike the unwieldy proprietary developmental name of "Depo-SubQ Provera 104". Sayana Press sold in Europe may be self-administered by patients, obviating the need for quarterly visits to a medical practitioner.

96. When Depo-SubQ Provera 104, under NDA number 21-583, submitted by Defendant Pharmacia & Upjohn, a subsidiary of Defendant Pfizer, was approved by the FDA on February 17, 2004, more than two decades ago, those Defendants

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

submitted a proposed trade name that the FDA did not approve, so instead, the proprietary name Depo-SubQ Provera 104 was deemed to be the brand name.

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

98. The "lowest effective dose" is a well-known concept in the field of pharmaceutics wherein a drug-maker should seek to find the lowest possible dose at which the drug of interest is efficacious for the intended use, as any additional dosage on top of that lowest effective dose is inherently superfluous and can increase the risk of unwanted side effects.

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

continues to date.

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

101. Defendants' Depo-Provera was at all times and is utilized and prescribed in a manner foreseeable to Defendants, as Defendants generated the instructions for use for Plaintiff to receive Depo-Provera injections.

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

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

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

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

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

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

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

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

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

109. Defendants willfully, wantonly, and intentionally conspired, and acted

in concert, to withhold safety-related warnings from the Plaintiff, and the general public concerning the known hazards associated with the use of, and exposure to, Depo-Provera, particularly over extended periods of time.

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

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

112. 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.

113. 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.

114. Further, Defendants actively concealed the true risks associated with the use of Depo-Provera, particularly as they relate to the risk of serious intracranial meningioma, by affirmatively representing in numerous communications, which were disseminated to Plaintiff, her healthcare providers, and which included, without limitation, the Package Insert and the Medication Guide, that there were no warnings required to safely prescribe and take Depo-Provera and no intracranial meningioma-related adverse side effects associated with use of Depo-Provera.

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

116. 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.

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

COUNT I

STRICT LIABILITY – FAILURE TO WARN
(Against All Defendants)

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

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

120. 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.

121. 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.

122. 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.

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

124. Defendants marketed, promoted, distributed and sold an unreasonably dangerous and defective prescription drug, Depo-Provera, to health care providers empowered to prescribe and dispense Depo-Provera, to consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data regarding the risk of meningioma and the risks of unnecessarily excessive progestin exposure which was available and generally accepted within the scientific

community. Through both omission and affirmative misstatements, Defendants misled the medical community about the risk and benefit balance of Depo-Provera, which resulted in injury to Plaintiff.

125. 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.

126. Despite the fact that Defendants knew or should have known based on information generally accepted within the scientific community that Depo-Provera with its higher than needed progestin dosage caused unreasonable and dangerous side effects, they continue to promote and market Depo-Provera without providing adequate clinically relevant information and data or recommending patients be monitored.

127. Defendants knew that a safer alternative design and product existed, including its own Depo-SubQ Provera 104 which contained substantially less progestin but was equally effective in preventing pregnancy but failed to warn the medical community and the patients about the risks of the high dose which could be mitigated by using the lower dose formulation, Depo-SubQ Provera 104.

128. Defendants knew or should have known that consumers, and Plaintiff,

specifically, would foreseeably and needlessly suffer injury as a result of Defendants' failures.

129. 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.

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

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

132. Plaintiff's prescribing physician would not have prescribed and administered Depo-Provera to Plaintiff had they been apprised by Defendants of the

unreasonably high risk of meningioma associated with usage of Depo-Provera.

133. Alternatively, even if Defendants had apprised Plaintiff's prescribing physician of the unreasonably high risk of meningioma associated with usage of Depo-Provera and this physician had still recommended usage of Depo-Provera to Plaintiff, the prescribing physician would have relayed the information concerning the risk of meningioma to Plaintiff, and the alternative treatment of the lower dose subcutaneous Depo-SubQ Provera 104, and Plaintiff as an objectively prudent person would not have chosen to take Depo-Provera, and/or would have opted to take safer and lower dose Depo-SubQ Provera 104, notwithstanding Plaintiff's prescribing physician's continued recommendation.

134. Similarly, if Defendants had warned of the unreasonably high risk of meningioma

associated with the usage of Depo-Provera, and the availability of the safer and equally effective lower dose Depo-SubQ Provera 104 in the Patient Information handout, Plaintiff as an objectively prudent person would not have chosen to take Depo-Provera, and/or would have opted to take the safer, lower, and equally effective dose of Depo-SubQ Provera 104, notwithstanding Plaintiff's prescribing physician's recommendation.

135. Defendants failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Plaintiff and

Plaintiff's prescribing physician of the dangerous risks of Depo-Provera including, among other things, the development of intracranial meningioma.

136. 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.

137. 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.

138. Defendants had an obligation to provide Plaintiff and Plaintiff's prescribing physician 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.

139. 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.

140. 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.

141. 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.

142. 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.

143. As a direct and proximate result of Defendants' conduct, including the inadequate warnings, dilution or lack of information, lack of adequate testing and research, and the defective and dangerous nature of Depo-Provera, Plaintiff suffered

bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

COUNT II

STRICT LIABILITY – DESIGN DEFECT
(Against All Defendants)

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

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

146. 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.

147. Depo-Provera was designed in such a way, using such a high dose of

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

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

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

150. Defendant failed to promote and encourage conversion of the prescribing gynecological community to Depo-SubQ Provera 104, fearing that doing so could instill a concern of safety as to the risks of its high dose progesterone long standing product, Depo-Provera.

151. It has long been a tenet in the medical and toxicological community that the "dose makes the poison." Defendants had a viable safer and lower dose alternative in Depo-SubQ Provera 104 but failed to warn the medical community prescribing and administering Depo-Provera that Depo-SubQ Provera 104 was a safer alternative.

152. Moreover, the 150 mg Depo-Provera itself could have been a viable lower effective dose if it had simply been designed, approved, and sold to be administered subcutaneously, like Depo-SubQ Provera 104 is administered, instead of intramuscularly.

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

154. Studies have shown that 150 mg Depo-Provera administered intramuscularly causes a spike in blood serum levels of DMPA that is more than four (4) times higher than the peak blood serum concentration of DMPA when that same 150 mg Depo-Provera shot is given subcutaneously, and that very high intramuscular peak concentration persists for several days.[22] In fact, 150 mg Depo-Provera administered subcutaneously has a remarkably similar pharmacokinetic profile to Depo-SubQ Provera 104.[23]

155. Thus, there are two lower effective doses of Depo-Provera—both Depo-SubQ Provera 104 *and* the very same 150 mg Depo-Provera simply given subcutaneously instead of intramuscularly.

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[22] *See* Shelton, et al., "Subcutaneous DPMA: a better low dose approach," *Contraception*, Vol. 89, pp. 341-43 (2014).
[23] *See id.* at 342.

156. Defendants wantonly and willfully failed to apprise the public, including the FDA, the medical community, Plaintiff, Planned Parenthood, and Plaintiff's physicians, of the greatly reduced risk of meningioma when injecting 150 mg Depo-Provera subcutaneously compared to the indicated method of intramuscular injection because Defendants did not want to raise any alarms with respect to the safety profile of Depo-Provera and did not want to lose any of its lucrative market share.

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

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

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

160. 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.

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

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

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

164. 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.

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

166. The Depo-Provera supplied to Plaintiff by Defendants was defective in

design or formulation in that, when it left the hands of the manufacturer or supplier, it had not been adequately tested, was in an unreasonably dangerous and defective condition, provided an excessive dose of progestin for its purpose and posed a risk of serious and potentially debilitating intracranial meningioma to Plaintiff and other consumers.

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

168. 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.

169. 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.

170. 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.

171. Defendants knew or should have known through testing, generally accepted scientific knowledge, advances in the field, published research in major peer-reviewed journals, or other means, that Depo-Provera created a risk of serious and potentially debilitating intracranial meningioma and sequelae related thereto.

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

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

174. 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.

175. As a direct and proximate result of Defendants' conduct and defective design, including inadequate testing and research, and the defective and dangerous

nature of Depo-Provera, Plaintiff suffered bodily injuries that resulted in pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money, and other economic losses. The losses are either permanent or continuing, and Plaintiff will suffer losses in the future.

COUNT III

NEGLIGENCE
(Against All Defendants)

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

177. At all times relevant herein, it was the duty of Defendants to use reasonable care in the design, labeling, manufacturing, testing, marketing, distribution and/or sale of Depo-Provera.

178. 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.

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

180. In disregard of its duty, Defendants committed one or more of the

following negligent acts or omissions:

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

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

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Depo-Provera was safe for its intended use;

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

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

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

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

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

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

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

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

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

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

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

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

181. A reasonable manufacturer, designer, distributor, promoter, or seller under the same or similar circumstances would not have engaged in the

aforementioned acts and omissions.

182. As a direct and proximate result of the Defendants' negligent testing, monitoring, and pharmacovigilance of Depo-Provera, Defendants introduced a product that they knew or should have known would cause serious and permanent injuries related to the development of intracranial meningioma, and Plaintiff has been injured tragically and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

183. As a direct and proximate result of one or more of the above-stated negligent acts by Defendants, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of consortium, loss of ability to earn money and other economic losses. The losses are either permanent or continuing, and Plaintiff will suffer losses in the future.

COUNT IV

NEGLIGENT FAILURE TO WARN
(Against All Defendants)

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

185. At all times material herein, Defendants had a duty to exercise reasonable care and had the duty of an expert in all aspects of the warning and post-

sale warning to assure the safety of Depo-Provera when used as intended or in a way that Defendants could reasonably have anticipated, and to assure that the consuming public, including Plaintiff and Plaintiff's physicians, obtained accurate information and adequate instructions for the safe use or non-use of Depo-Provera.

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

187. Defendants had a duty to warn Plaintiff, Plaintiff's physicians, and consumers of Depo-Provera of the known and/or 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.

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

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

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

the severity and potentially irreversible nature of such adverse effects;

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

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

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

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

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

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

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

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

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

k. Failing to provide adequate training or information to medical

care providers for appropriate use of Depo-Provera and patients taking Depo-Provera;

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

m. Failing to warn that there is a safer feasible alternative with a lower effective dose of progestin; and

n. Failing to warn that the 150 mg dosage of progestin injected intramuscularly was an excessive and thus toxic dose capable of causing and or substantially contributing to the development and growth of meningioma tumors.

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

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

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

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

194. The warnings, or lack thereof, that were given by Defendants failed to properly warn prescribing physicians, including Plaintiff's prescribing

physician, of the known and knowable risk of serious and potentially irreversible injuries related to the development of intracranial meningioma, and failed to instruct prescribing physicians to test and monitor for the presence of the injuries and to discontinue use when symptoms of meningioma manifest.

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

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

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

198. As a direct and proximate result of Defendants' negligent failure to warn, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of consortium, loss of ability to earn money and other economic losses. The losses are either permanent or

continuing, and Plaintiff will suffer the losses in the future.

COUNT V

NEGLIGENT DESIGN DEFECT
(Against All Defendants)

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

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

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

202. Each of the following acts and omissions herein alleged was negligently

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

a. Failing to use due care in developing, testing, designing, and manufacturing Depo-Provera so as to avoid the aforementioned risks to individuals when Depo-Provera was being used for contraception and other indications;

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

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

d. Failing to use due care in developing, testing, designing, and manufacturing Depo-Provera with the lowest effective dose as a safer alternative which clearly existed at all relevant times so as to avoid the aforementioned risks to individuals when high dose progestin Depo-Provera was being used for contraception.

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

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

205. As a direct and proximate result of Defendants' negligence, Plaintiff

suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of consortium, loss of ability to earn money and other economic losses. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

COUNT VI

NEGLIGENT MISREPRESENTATION
(Against All Defendants)

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

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

208. The information distributed by the Defendants to the public, the medical community, Plaintiff, and her physicians, 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.

209. Defendants' intent and purpose in making these misrepresentations was

to deceive and defraud the public and the medical community, including Plaintiff and her physicians; to falsely assure them of the quality of Depo-Provera and induce the public and medical community, including Plaintiff and her physicians to request, recommend, purchase, and prescribe Depo-Provera.

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

211. 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.

212. 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.

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

214. Defendants misrepresented and overstated that the Depo-Provera dosage was needed to protect against pregnancy when Defendants knew that a safer

alternative existed with forty-six (46) fewer mg per dose of the powerful progestin being ingested quarterly in women, and when Defendants could have warned and recommended usage of Depo-SubQ Provera 104 instead.

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

216. In reliance upon the false and negligent misrepresentations and omissions made by the Defendants, Plaintiff and Plaintiff's physicians were unable to associate the injuries sustained by Plaintiff with her Depo-Provera use, and therefore unable to provide adequate treatment. Defendants knew or should have known that the Plaintiff, Plaintiff's physicians, and the general medical community did not have the ability to determine the true facts which were intentionally and/or negligently concealed and misrepresented by the Defendants.

217. Plaintiff and her physicians would not have used or prescribed Depo-Provera had the true facts not been concealed by the Defendants.

218. 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.

219. At the time Plaintiff was prescribed and administered Depo-Provera,

Plaintiff and her physicians were unaware of Defendants' negligent misrepresentations and omissions.

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

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

222. Plaintiff and her physicians' reliance on the foregoing misrepresentations and omissions was the direct and proximate cause of Plaintiff's injuries.

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

either permanent or continuing, and Plaintiff will suffer the losses in the future.

COUNT VII

FRAUDULENT MISREPRESENTATION
(Against All Defendants)

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

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

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

227. Defendants knew or should have known of the falsity of such a representation to consumers, physicians, and the public in general since Depo-Provera is far from the only contraceptive approved by the FDA, and it is not the only contraception option. Nevertheless, Defendants' marketing of Depo-Provera falsely represented Depo-Provera to be a safe and effective contraceptive option with no increased risk of intracranial meningioma and sequelae related thereto.

228. The representations were, in fact, false. When Defendants made these

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

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

230. These representations were made by the Defendants with the intent of defrauding and deceiving the medical community, Plaintiff, and the public, and also inducing the medical community, Plaintiff, Plaintiff's physicians, 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.

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

"Warnings" section. To date, the Depo-Provera label still does not include any warnings whatsoever that indicate the dangers of intracranial meningioma and sequela related thereto after using Depo-Provera.

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

233. In representations to Plaintiff and/or to her physicians, Defendants fraudulently stated that Depo-Provera was safe and concealed and intentionally omitted material information from the Depo-Provera product labeling in existence at the time Plaintiff was prescribed Depo-Provera in 2006.

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

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

236. 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.

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

238. At the time these representations were made by Defendants, and at the time Plaintiff and/or her physicians used Depo-Provera, Plaintiff and/or her physicians were unaware of the falsehood of these representations.

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

240. In comporting with the standard of care for prescribing physicians, Plaintiff's prescribing physicians relied on the labeling for Depo-Provera in existence at the date of prescription that included the aforementioned fraudulent statements and omissions.

241. 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.

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

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

244. For the reasons set forth above and addressed below, Defendant Pfizer acted with a conscious disregard of the safety of Plaintiff and all the other women, many who were young and of lower socioeconomic status, who were subjected to high dose injections of 150 mg Depo-Provera with the known and/or knowable risk of meningioma brain tumors which was generally accepted in the scientific community, while Defendant Pfizer had available its very own safer alternative medication, Depo Sub-Q Provera 104.

245. Defendants have engaged in willful, malicious, and intentional conduct and/or acted grossly negligent that it demonstrates a wanton disregard for the safety of others, including Plaintiff, such that the imposition of exemplary damages is warranted here.

COUNT VIII

BREACH OF EXPRESS WARRANTY
(Against All Defendants)

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

247. 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.

248. Defendants expressly warranted to Plaintiff, Plaintiff's physicians, 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.

249. Depo-Provera materially failed to conform to those representations

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

250. 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.

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

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

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

254. Plaintiff's physicians 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.

255. Plaintiff purchased and was injected with 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.

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

COUNT IX

BREACH OF IMPLIED WARRANTY
(Against All Defendants)

257. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth 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 were the sellers of the Depo-Provera and sold Depo-Provera to be taken for contraception or to treat endometriosis, among other indications. Plaintiff was prescribed and purchased Depo-Provera for these intended purposes.

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

261. 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.

262. Defendants breached their implied warranties of the Depo-Provera product because the Depo-Provera sold to Plaintiff was not fit for its ordinary purpose as a contraceptive or to treat endometriosis safely and effectively, among other uses.

263. The Depo-Provera would not pass without objection in the trade; is not of fair average quality; is not fit for its ordinary purposes for which the product is

used; was not adequately contained, packaged and labeled; and fails to conform to the promises or affirmations of fact made on the container or label.

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court:

1. Award Plaintiff compensatory and punitive exemplary damages in an amount to be determined at trial, and also including, but not limited to:

   a. General Damages for severe physical pain, mental suffering, inconvenience, and loss of the enjoyment of life;

   b. Special Damages, including all expenses, incidental past and future expenses, medical expenses, and loss of earnings and earning capacity;

2. Award interest as permitted by law;

3. Award reasonable attorneys' fees and costs, as provided for by law; and

4. Grant such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

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

Dated: December 13, 2024

Respectfully submitted,

/s/ Bryan F. Aylstock
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Douglass A. Kreis, FL Bar #129704
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Attorneys for Plaintiff

JS 44 (Rev. 03/24)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Donna Toney

(b) County of Residence of First Listed Plaintiff Escambia County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC
17 E. Main Street, Suite 200
Pensacola, FL 32502

DEFENDANTS

PFIZER INC.; PHARMACIA & UPJOHN CO. LLC; and PHARMACIA LLC

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

INTELLECTUAL PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding | ☐ 2 Removed from State Court | ☐ 3 Remanded from Appellate Court | ☐ 4 Reinstated or Reopened | ☐ 5 Transferred from Another District *(specify)* | ☐ 6 Multidistrict Litigation - Transfer | ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. § 1332

Brief description of cause:
Pharmaceutical product liability and negligence resulting in personal injury

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
12/13/2024

SIGNATURE OF ATTORNEY OF RECORD
/s/ Bryan F. Aylstock

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. Origin. Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related cases, if any. If there are related cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Northern District of Florida

DONNA TONEY

Plaintiff(s)

v.

PFIZER INC.; PHARMACIA & UPJOHN CO. LLC; and PHARMACIA LLC

Defendant(s)

Civil Action No. 24-624

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* PFIZER INC.
CT Corporation System
1200 South Pine Island Road
Plantation, Florida 33324

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Bryan F. Aylstock
AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC
17 E. Main Street, Suite 200
Pensacola, FL 32502

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 24-624

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Northern District of Florida

DONNA TONEY

Plaintiff(s)

v.

PFIZER INC.; PHARMACIA & UPJOHN CO. LLC; and PHARMACIA LLC

Defendant(s)

Civil Action No. 24-624

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Pharmacia & Upjohn Co. LLC
CT Corporation System
1200 South Pine Island Road
Plantation, Florida 33324

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Bryan F. Aylstock
AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC
17 E. Main Street, Suite 200
Pensacola, FL 32502

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 24-624

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Northern District of Florida

DONNA TONEY

Plaintiff(s)

v.

PFIZER INC.; PHARMACIA & UPJOHN CO. LLC; and PHARMACIA LLC

Defendant(s)

Civil Action No. 24-624

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Pharmacia LLC
CT Corporation System
820 Bear Tavern Road
West Trenton, NJ 08628

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Bryan F. Aylstock
AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC
17 E. Main Street, Suite 200
Pensacola, FL 32502

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 24-624

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: