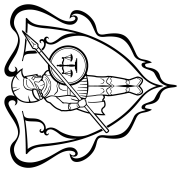


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EGLET ADAMS
EGLET HAM HENRIOD

ROBERT T. EGLET, ESQ.
Nevada Bar No. 3402
ARTEMUS W. HAM, ESQ.
Nevada Bar No. 7001
JOEL D. HENRIOD, ESQ.
Nevada Bar No. 8492
EGLET ADAMS EGLET HAM HENRIOD
400 South 7th Street, 4th Floor
Las Vegas, Nevada 89101
Tel.: 702-450-5400
eservice@egletlaw.com

-and-

STEVE DIMOPOULOS, ESQ.
Nevada Bar No. 12729
JARED B. KAHN, ESQ.
Nevada Bar No. 12603
SCOTT R. COOK, ESQ.
Nevada Bar No. 5265
DIMOPOULOS LAW FIRM
6830 S. Rainbow Blvd., Suite 200
Las Vegas, NV 89118
Tel: (702) 800-6000
jk@stevedimopoulos.com
sc@stevedimopoulos.com
Attorneys for Plaintiffs

**UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA**

TINA STEPHENS-SMITH, an individual; and,
HAROLD ALBERT SMITH III, an individual,

Plaintiffs,

vs.

PFIZER INC.; VIATRIS INC.;
GREENSTONE LLC; PRASCO, LLC d/b/a
PRASCO LABS.; PHARMACIA &
UPJOHN CO. LLC; and PHARMACIA
LLC, Doe Individuals I-XX, inclusive; and ROE
Entities I-XX,

Defendants.

CASE NO.:
DEPT NO.:

COMPLAINT
DEMAND FOR JURY TRIAL

1 Plaintiffs TINA STEPHENS-SMITH and HAROLD ALBERT SMITH III (collectively
2 “Plaintiffs”) by and through their counsel, ROBERT T. EGLET, ESQ., ARTEMUS W. HAM,
3 ESQ., and JOEL D. HENRIOD, ESQ., of EGLET ADAMS EGLET HAM HENRIOD and STEVE
4 DIMOPOULOS, ESQ., JARED B. KAHN, ESQ., and SCOTT R. COOK of DIMOPOULOS
5 LAW FIRM, and for their Complaint against the Defendants, and each of them alleges as follows:

6 **INTRODUCTION**

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

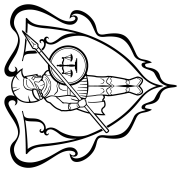
13 2. Defendants manufacture, promote, and sell Depo-Provera as a prescription drug
14 used for contraception or to treat endometriosis, among other indications. Depo-Provera is
15 manufactured as an injection to be administered intramuscularly every three (3) months in either
16 the upper arm or buttocks.

17 3. Defendant Prasco produces and sells MedroxyPROGESTERone Acetate, a generic
18 derivative of Depo-Provera, that was prescribed for, and used by, Plaintiff Tina Stephens-Smith
19 (hereinafter “Plaintiff”).

20 4. Depo-Provera and/or its generic equivalent, injured Plaintiff by causing or
21 substantially contributing to the development of an intracranial meningioma, a type of brain
22 tumor, which has caused serious injuries.

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

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



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

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

9 9. The Canadian label for Depo-Provera has listed “meningioma” among its “Post-
10 Market Adverse Drug Reactions” since at least 2018.

11 10. Despite distributing the product to physicians, patients and consumers for decades,
12 Defendants failed to warn, advise, discuss, instruct, educate or otherwise provide users about the
13 risks of development of intracranial or spinal meningioma or the need for monitoring secondary
14 to the development of symptoms related to the same.

15 11. Plaintiff used Depo-Provera, and/or its genetic derivative, as recommended and
16 prescribed and, as a result of the Defendants wrongful actions, was injured and suffered damages
17 from its use.

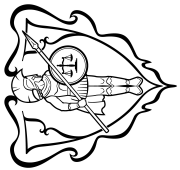
18 12. As a proximate result of Defendants’ wrongful actions and inactions, Plaintiff was
19 injured and suffered damages from Plaintiff’s use of Depo-Provera.

20 13. Plaintiff therefore demands judgment against Defendants and requests, among
21 other things, compensatory damages, statutory damages, punitive damages, attorneys’ fees, and
22 costs.

23 **PARTIES**

24 14. At all times relevant herein, Plaintiff Tina Stephens-Smith is and was a resident
25 of Clark County, Nevada.

26 15. At all times relevant herein, Plaintiff Harold Albert Smith III, is and was a
27 resident of Clark County, State of Nevada.



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

4 17. Pfizer has a registered agent for service of process, CT Corp., at 701 S. Carson
5 Street, Suite 200, Carson City, NV 89701.

6 18. Defendant VIATRIS INC. (hereinafter “Viatris”) is a corporation organized
7 under Delaware law with its principal place of business at 1000 Mylan Boulevard, Canonsburg,
8 PA 15317.

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

12 20. Greenstone has a registered agent for service of process, CT Corp., at 701 S.
13 Carson Street, Suite 200, Carson City, NV 89701.

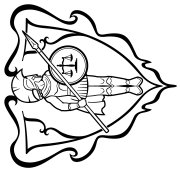
14 21. Defendant PRASCO, LLC d/b/a PRASCO LABS. (hereinafter “Prasco”) is a
15 corporation organized under Ohio law with its principal place of business at 6125 Commerce
16 Court, Mason, OH 45040.

17 22. Defendant PHARMACIA & UPJOHN CO. LLC (hereinafter “Pharmacia &
18 Upjohn” or “Upjohn”) is or was a corporation organized under Michigan law and headquartered
19 at 7171 Portage Road, Kalamazoo, MI 49002.

20 23. Pharmacia & Upjohn has a registered agent for service of process, CT Corp., at
21 701 S. Carson Street, Suite 200, Carson City, NV 89701.

22 24. Defendant PHARMACIA LLC (hereinafter “Pharmacia”) is a limited liability
23 company organized under Delaware law and headquartered at Pfizer Peapack Campus, 100
24 Route 206 North, Peapack, NJ 07977.

25 25. The true names and capacities, whether individual, corporate, association or
26 otherwise of Defendants DOES I through XX and ROE CORPORATIONS I through XX,
27 inclusive, are unknown to Plaintiff, who therefore sue said Defendants by such fictitious names.
28 Plaintiff is informed and believes, and thereupon alleges, that each of the Defendants designated



1 herein as DOES and/or ROES are responsible in some manner for the events and happenings
2 herein referred to, and in some manner caused the injuries and damages proximately thereby to
3 Plaintiff, as alleged herein; that Plaintiff will ask for leave of this Court to amend this Complaint
4 to insert the true names and capacities of said Defendants, DOES I through XX and/or ROE
5 CORPORATIONS I through XX, inclusive, when the same have been ascertained by Plaintiff,
6 together with the appropriate charging allegations, and to join such Defendants in this action.

7 26. Defendant Pfizer is the current New Drug Application (hereinafter “NDA”)
8 holder for Depo-Provera and has solely held the NDA for Depo-Provera since 2020. Upon
9 information and belief, Pfizer has effectively held the NDA since at least 2002 when it acquired
10 Pharmacia & Upjohn— who then held the NDA—as a wholly owned subsidiary. No later than
11 2003 did Pfizer’s name appear on the label alongside Pharmacia & Upjohn.

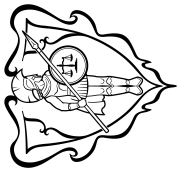
12 27. At all relevant times, Defendant Pharmacia & Upjohn was a wholly owned
13 subsidiary of Defendant Pfizer until Upjohn was spun off in a merger in 2020 to create Defendant
14 Viartis and the remnant, i.e., Defendant Pharmacia, was retained by Pfizer.

15 28. Defendant Greenstone, founded in 1993, was a wholly owned subsidiary of
16 Pfizer, that at pertinent times was in the business of offering a product portfolio of “authorized
17 generic” medicines, including Depo-Provera.

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

25 30. Defendants Greenstone/Pfizer sold a “generic” version of Depo-Provera that was
26 in fact what is known as an “authorized generic.” Unlike standard generics, which must contain
27 only the same active ingredients and have the same pharmaceutical effect but can otherwise
28 contain vastly different additives, “authorized generics” are exact replicas of the brand name

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1 drug, with the identical chemical composition, simply marketed without the brand-name on its
2 label. In other words, Greenstone was presenting itself as a distinct generic manufacturing entity
3 when it was in fact Pfizer personnel producing the exact same brand-name Depo-Provera at
4 Pfizer's own facility.

5 31. The FDA has stated that the term "authorized generic" drug is most commonly
6 used to describe an approved brand name drug that is marketed without the brand name on its
7 label. Other than the fact that it does not have the brand name on its label, it is the exact same
8 drug product as the branded product. An "authorized generic" may be marketed by the brand
9 name drug company, or another company with the brand company's permission.¹

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

13 33. Pfizer was the actual manufacturer of the authorized generic product that
14 Greenstone distributed and sold.

15 34. Defendant Viatrix was formed by the merger of Upjohn, Greenstone, and another
16 company, Mylan N.V., in November 2020. Viatrix is thus merely the latest iteration of Upjohn
17 and Greenstone.

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

20 36. Additionally, Defendant Pfizer retained 57% ownership of Viatrix stock, making
21 Pfizer the majority owner of Viatrix, and since Pfizer retained the remnants of Pharmacia, Pfizer
22 effectively remains the majority owner of Defendants Pharmacia & Upjohn and Greenstone.

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

26
27 ¹ See <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-genericdrugs>
(last accessed Nov. 10, 2024)

28 ² See <https://www.pfizer.com/news/press-release/press-release-detail/pfizers-greenstone-and-digital-mens-health-clinic-roman>(last accessed Nov. 10, 2024).

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

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

6 40. All Defendants do business in Nevada by, among other things, distributing,
7 marketing, selling, and/or profiting from brand name and/or “authorized generic” Depo-Provera
8 in Nevada, as well as throughout the United States.

9 41. At all times material herein, Defendants were, and still are, pharmaceutical
10 companies involved in the manufacturing, research, development, marketing, distribution, sale,
11 and release for use to the general public of pharmaceuticals, including Depo-Provera and its
12 “authorized generic” version, in Nevada, and throughout the United States.

13 **JURISDICTION AND VENUE**

14 42. All Defendants regularly conduct business in Nevada.

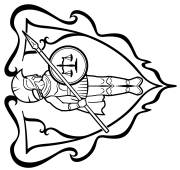
15 43. This Court has diversity jurisdiction over this action pursuant to 28 U.S.C. § 1332,
16 as the amount in controversy exceeds \$75,000.00 and the Parties are citizens of different States.

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

19 45. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial
20 part of the events or omissions giving rise to the claim, including the distribution, sale, and
21 administration of Depo-Provera to Plaintiff and Plaintiff’s development, diagnosis, and
22 treatment of meningioma, all occurred in Nevada.

23 46. Defendant Pfizer has extensive connections to the State of Nevada that are highly
24 relevant to the subject matter of this instant action.

25 47. For example, during material times herein, Pfizer previously maintained a
26 manufacture, supply and distribution facility in Reno, Nevada, and, maintained an administration
27 and business office in Las Vegas, Nevada.
28



1 48. Pfizer has thus deliberately created strong connections not just to the consumers
2 and patients of Nevada but also to the life and health sciences communities of Nevada as well.

3 49. Moreover, Defendants Pfizer and Upjohn & Pharmacia are registered to do
4 business in the State of Nevada and can be served at their registered agent for service of process,
5 CT Corp., at 701 S. Carson St., Ste 200, Carson City, NV, 89701

6 50. All Defendants at different periods of time had a contractual and/or sales
7 relationship directly or through intermediaries to sell Depo-Provera to health care providers in
8 Nevada would be injecting Depo-Provera into patients, including with Plaintiff's medical
9 providers.

10 **PLAINTIFF TINA STEPHENS-SMITH'S SPECIFIC FACTS**

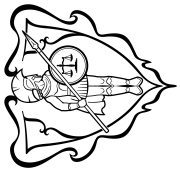
11 51. In or around 2002, after giving birth to her son, Plaintiff Tina Stephens-Smith
12 was first administered Depo-Provera from her OBGYN in Las Vegas, Nevada.

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

16 53. After approximately seven (7) years of regularly receiving Depo-Provera shot in
17 three-month intervals pursuant to her physicians' prescriptions that amounted to approximately
18 twenty-eight (28) shots, Plaintiff desired to try for additional children and stopped taking Depo-
19 Provera. During the approximate two years after stopping Depo-Provera between 2008-2010,
20 Plaintiff suffered multiple miscarriages and thereafter decided not to pursue trying for additional
21 children.

22 54. In or around 2011, Plaintiff again began regularly receiving Depo-Provera shots
23 pursuant to her physicians' prescriptions in the three-month intervals continuously for
24 approximately thirteen (13) years, which amounted to an additional approximate fifty-two (52)
25 shots.

26 55. Plaintiff was administered approximately eighty (80) shots of Depo-Provera
27 pursuant to her physicians' prescriptions and her reliance upon the Depo-Provera shot to be
28 appropriate and safe.



1 56. At least one of these injections was Greenstone/Pfizer's "authorized generic"
2 Depo- Provera, which is identical to the brand-name version, sold and distributed by Prasco.

3 57. Over time, the Plaintiff experienced concerning symptoms such as headaches,
4 blurred vision, eye pain, eye swelling and trouble communicating, resulting in Shoib Myint,
5 M.D. referred her for an MRI of the Orbit, Face, Neck with and without contrast.

6 58. On July 5, 2025, Steven Braff, M.D., FACR of SimonMed reported his MRI
7 findings as follows:

8 a. Large and homogeneously enhancing mass centered at the greater wing of
9 the sphenoid bone and encroaching upon the latera rectus muscle and anterior temporal lobe with
10 crowding of the right orbital apex.

11 b. Second meningioma originates from the left anterior temporal fossa floor.

12 c. Enhancing dural tail related to the larger right-sided lesion extends
13 posteriorly along the inner table of the skull. Abnormal temporal bone signal intensity and
14 enhancement external to the outer table of the calvarium suggestive of transtemporal bone
15 involvement.

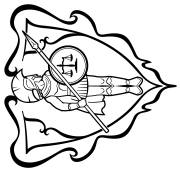
16 59. On July 12, 2023, at the age of 49, while seeking a treatment plan for her eye pain
17 and blurred vision, Plaintiff also underwent a CT scan which revealed three densely calcified
18 meningiomas.

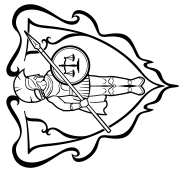
19 60. On September 25, 2023, Plaintiff saw Dr. Wong Kim at UCLA Medical Center
20 who scheduled a craniotomy to remove the brain tumor behind Plaintiff's right eye.

21 61. On December 5, 2023, Dr. Kim performed the surgery to remove the tumor
22 behind Plaintiff's right eye.

23 62. On February 16, 2024, Dr. Tania Kaprealian, oncologist, and Dr. Noriko
24 Salamon, neuroradiologist, prescribed radiation treatment in an attempt to shrink the large tumor
25 on the base of Plaintiff's skull.

26 63. Beginning May 20, 2024, until July 2, 2024, Plaintiff underwent thirty (30)
27 radiation treatments.





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69. Plaintiff was unaware until very recently in October 2024, after discovering a post on social media, which followed 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

72. Treatment of symptomatic intracranial meningioma typically requires highly invasive brain surgery that involves the removal of a portion of the skull, i.e., a craniotomy, in

1 order to access the brain and meninges. Radiation therapy and chemotherapy may also be
 2 required as the sensitive location of the tumor in the brain can render complete removal highly
 3 risky and technically difficult.

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

12 **B. Depo-Provera**

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

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

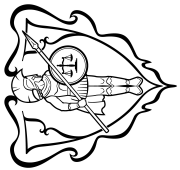
18 76. According to a recent National Health Statistics Report published in December
 19 2023, nearly a quarter (24.5%) of all sexually experienced women in the United States between
 20 2015 and 2019 had ever used Depo-Provera.³

21 77. According to that same report, those proportions increase even further for
 22 Hispanic (27.2%) women and Black (41.2%) women who had ever used Depo-Provera.⁴

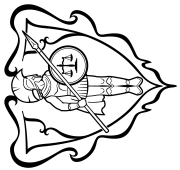
23 78. Depo-Provera is a 150 mg/mL dosage of DMPA that is injected every three (3)
 24 months into the deep tissue musculature of either the buttocks or the upper arm, with present
 25 labelling recommending alternating the injection site at each injection.

26
 27
 28 ³ Daniels, K et al., “Contraceptive Methods Women Have Ever Used: United States, 2015-2019”, *Nat’l Health Statistics Report*, No. 195, Dec. 14, 2023.

⁴ *Id.*



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79. 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.

80. 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.⁵

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

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

83. 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.

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

85. 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.

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

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

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

89. 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.

⁵ See <https://www.kff.org/womens-health-policy/fact-sheet/dmpa-contraceptive-injection-use-andcoverage/> (last accessed Nov. 10, 2024).

90. Pfizer has effectively held the Depo-Provera NDA since acquiring Pharmacia & Upjohn in 2002, and has solely held the NDA since 2020, when Upjohn was spun off to form Defendant Viatrix.

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

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

93. 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

94. 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.

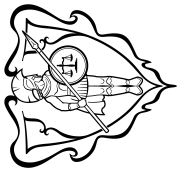
95. Since at least 1983, the medical and scientific communities have been aware of the high number of progesterone receptors on meningioma cells, especially relative to estrogen receptors.⁶

96. 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.⁷ 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.⁸ This particular study was published nearly a decade before the FDA approved Depo-Provera for contraception in

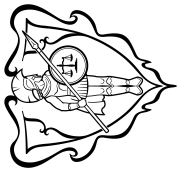
⁶ See Blankenstein, et al., "Presence of progesterone receptors and absence of oestrogen receptors in human intracranial meningioma cytosols," *Eur J Cancer & Clin Oncol*, Vol. 19, No. 3, pp. 365-70 (1983).

⁷ *Id.*

⁸ *Id.*



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1992. In those nine (9) years before Depo-Provera was approved for contraception, and in the thirty-two (32) years since— more than forty (40) years in all—Defendants have seemingly failed to investigate the effect of their high-dose progesterone Depo-Provera on the development of meningioma.

97. 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.⁹ That year, the same authors published a study in the *Journal of Steroid Biochemistry* entitled, “Effect of steroids and antisteroids on human meningioma cells in primary culture,” finding that meningioma cell growth was significantly reduced by exposure to mifepristone, an antiprogesterone agent.¹⁰

98. Numerous studies published in the decades since have presented similar findings on the negative correlation between progesterone-inhibiting agents and meningioma.¹¹

99. 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.¹²

100. In 2015, a retrospective literature review published in the peer-reviewed journal *BioMed Research International* by Cossu, et al., surveyed the relevant literature including many of the studies cited above and concluded that mifepristone, an antiprogesterone agent, had a regressive effect on meningioma, meaning it stopped or reversed its growth.¹³ Reviewing the

⁹ 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).

¹⁰ *Id.*

¹¹ 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).

¹² See, e.g., Gil, et al., “Risk of meningioma among users of high doses of cyproterone acetate as compared with the general population: evidence from a population-based cohort study,” *Br J Clin 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).

¹³ See Cossu et al., “The Role of Mifepristone in Meningiomas Management: A Systematic Review of the Literature” *BioMed Res. Int.* 267831 (2015), <https://doi.org/10.1155/2015/267831>

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.

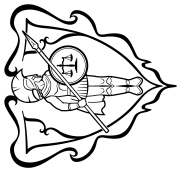
101. In light of the aforementioned studies, for several decades the manufacturers and sellers of Depo-Provera and its authorized generic and generic analogues, Defendants, had an unassignable duty to investigate the foreseeable potential that a high dose synthetic progesterone delivered in the deep tissue could cause the development or substantially contribute to the growth of meningioma. Defendants were also best positioned to perform such investigations. Had Defendants done so, they would have discovered decades ago that their high dose progestin Depo-Provera was associated with a highly increased risk of meningioma and would have spared Plaintiff and countless others the pain and suffering associated with meningioma. Instead, Defendants did nothing, and therefore willfully failed to apprise the medical community, and the women patients receiving quarterly high dose injections, of this dangerous risk.

102. 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.

103. In 2022, an article was published in the journal *Endocrinology* entitled “Estrogen and Progesterone Therapy and Meningiomas.”¹⁴ This retrospective literature review noted that “dosedependent 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.

¹⁴ Hage, et al., “Estrogen and progesterone therapy and meningiomas,” *Endocrinology*, Vol. 163, pp. 1-10 (2022).

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104. In 2023, researchers reported on a direct link between Depo-Provera and meningioma. That year a case series was published in the Journal of Neurological Surgery Part B: Skull Base titled “Skull Base Meningiomas as Part of a Novel Meningioma Syndrome Associated with Chronic Depot Medroxyprogesterone Acetate Use.”¹⁵ 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 conclude¹⁶ “there appears to be a clear progestin meningioma syndrome associated with chronic DMPA use.”

105. 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.

106. By way of history, the Roland study noted that concerns over meningiomas associated with high dose progestogen medications resulted in the recent discontinuation of three such medications in France and the EU. Specifically, there were “postponements in the prescription of chlormadinone acetate, nomegestrol acetate, and cyproterone acetate, following the French and European recommendations to reduce the risk of meningioma attributable to these progestogens in 2018 and 2019.”¹⁷

107. 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

¹⁵ 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).

¹⁶ 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>.

¹⁷ *Id.*

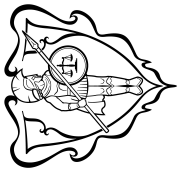
1 555% increased risk of developing intracranial meningioma. The study authors concluded “[t]he
2 increased risk associated with the use of injectable medroxyprogesterone acetate, a widely used
3 contraceptive,” was an important finding. The authors also noted Depo-Provera is “often
4 administered to vulnerable populations,” i.e., lower-income women who have no other choice
5 but to take the subsidized option which only requires action every three months to remain
6 effective for its intended use of preventing pregnancy, and, in the case of the subcutaneous
7 variant, treating endometriosis.

8 108. The 2024 Roland study published in BMJ studied the effect of several other
9 progestogen-based medications. Three study subjects showed no excess risk of intracranial
10 meningioma surgery with exposure to oral or intravaginal progesterone or percutaneous
11 progesterone, dydrogesterone or spironolactone, while no conclusions could be drawn for two
12 others due to lack of exposed cases. The other medications, including medroxyprogesterone
13 acetate (Depo-Provera), were found to be associated with an increased risk of intracranial
14 meningioma, with Depo-Provera having by far the second highest increased risk, surpassed only
15 by the product cyproterone acetate, which had already been withdrawn from the market due to
16 its association with meningioma.

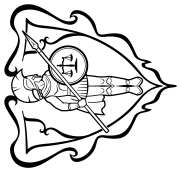
17 109. Depo-Provera had by far the highest risk of meningioma surgeries amongst
18 progesterone contraceptive products studied, rendering Depo-Provera more dangerous than other
19 drugs and treatment options designed to prevent pregnancy due to the unreasonably increased
20 risk of injury associated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

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

25 111. The Roland study noted that among cases of meningioma observed in the study,
26 28.8% (5,202/18,061) of the women used antiepileptic drugs three years after the index date of
27 intracranial surgery.
28



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112. More recently, in September 2024, an article entitled “The Association between Medroxyprogesterone Acetate Exposure and Meningioma” was published in *Cancers*. This large case control study analyzed over 117,000 meningioma cases and more than one million matched controls and found that “injection exposure” of medroxyprogesterone acetate, i.e. Depo-Provera usage, was associated with a 53% increase in the development of meningioma. The association was specific to cerebral meningiomas and became even stronger with prolonged use.¹⁸

113. In October 2024, researchers at the University of Cincinnati published an abstract in the *International Journal of Radiation Oncology Biology Physics* titled “Progesterone Contraception and Tumor-Related Visual Impairment in Premenopausal Women with Meningioma Referred for Radiation.” This paper reported on a retrospective case-control study that examined, inter alia, the role of hormonal contraception in the development of intracranial meningioma causing visual impairment in women under the age of 55. The authors concluded “progesterone use is a significant risk factor for meningioma-related visual deficits ..., with a disproportionate number on [Depo-] Provera specifically.”¹⁹

D. Defendants’ Failure to Test Depo-Provera

114. 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.

115. 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.

¹⁸ Griffin, “The association between medroxyprogesterone acetate exposure and meningioma,” *Cancers*, Vol. 16, No. 3362 (2024).

¹⁹ Bailey, et al., “Progesterone contraception and tumor-related visual impairment in premenopausal women with meningioma referred for radiation,” *Int’l J of Radiation Oncology Biology Physics*, Vol. 120, No. 2 Supp., pp. E217 (2024).

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

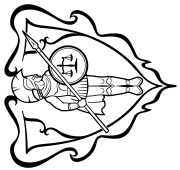
116. According to the Drugs@FDA website, the label for Depo-Provera has been updated on at least thirteen (13) occasions since 2003, with the most recent update coming in July 2024.²⁰ Despite the fact there are at least fourteen (14) iterations of the Depo-Provera label, Defendants' labels have not contained 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.

117. 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 progestones 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."²¹

118. Defendant Pfizer has *changed the label in the EU and the UK* and potentially in other countries. Specifically, Defendants' Depo-Provera label in the EU now contains the following addition under the section titled **"Special warnings and precautions for use"**: "Meningioma: Meningiomas have been reported following long-term administration of progestogens, including medroxyprogesterone acetate. Depo-Provera should be discontinued if

²⁰ See Drugs@FDA:FDA-Approved Drugs- Depo-Provera, <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=0202>

²¹ "Hormone medication could increase risk of brain tumours, French study finds," The Guardian, published online Mar. 27, 2024 (available at <https://www.theguardian.com/society/2024/mar/27/hormone-medication-brain-tumours-riskprogestogens-study>) (last accessed Nov. 10, 2024).



1 a meningioma is diagnosed. Caution is advised when recommending Depo-Provera to patients
2 with a history of meningioma.”

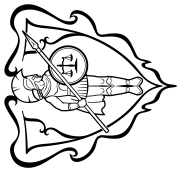
3 119. Additionally, Defendants’ Package Leaflet in the EU which provides information
4 for the patient states that “before using Depo-Provera[,]... it is important to tell your doctor or
5 healthcare professional if you have, or have ever had in the past ... a meningioma (a usually
6 benign tumor that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

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

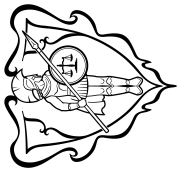
10 121. Specifically, Defendants could have filed a “Changes Being Effectuated” (“CBE”)
11 supplement under Section 314.70(c) of the FDCA to make “moderate changes” to Depo-
12 Provera’s label without any prior FDA approval.

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

19 123. Recently, the Third Circuit reaffirmed that plain text interpretation of the CBE
20 supplement process in a precedential decision holding that the defendant in that case, Merck,
21 could not rely on a preemption defense based on an allegedly irreconcilable conflict between
22 federal (FDCA) and state (civil tort) law so long as the warning could have been effected via a
23 CBE change. See generally *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, Case No.
24 22-3412, D.I. 82 at 73 on the docket (J. Jordan) (3d Cir. Sept. 20, 2024) (noting “the availability
25 of a label change via a CBE supplement is problematic for Merck, as will very often be the case
26 for pharmaceutical companies raising an impossibility defense”).



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124. 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 and never exceeds more than a small fraction of the dangerously high serum levels seen in the first several days with intramuscular administration of 150 mg Depo-Provera.²² Nevertheless, Defendants never produced a 150 mg subcutaneous version.

125. Another study published in *Contraception: X* in 2022 concluded that not only was the lower dose Depo-SubQ Provera 104 just as effective as 150 mg Depo-Provera when administered properly, but it could also be administered every 16 weeks instead of every 12 weeks due to the more gradual uptake of the subcutaneous administration route. That same study found that 150 mg Depo- Provera if injected subcutaneously could remain at efficacious levels in the blood for even longer, up to six (6) months.²³

126. As with subcutaneously administered Depo-SubQ Provera 104, the study authors noted “subcutaneous administration of 150 mg Depo-Provera every 6 months would be a highly effective repurposing ... with a similar reduction in cumulative exposure.” The authors concluded: “The use of an unnecessarily high exposure to limit the residual chance of treatment failure would be a disservice to the vast majority of women if a lower exposure can reduce side effects, costs, or otherwise make the product more acceptable.”²⁴

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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 Taylor, et al., “Ovulation suppression following subcutaneous administration of depot medroxyprogesterone acetate,” *Contraception: X*, Vol. 4 (2022).

²⁴ *Id.*

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

6 128. Knowing that the lower dose 104 mg Depo-SubQ Provera 104 was equally
7 effective and was easier to administer since it involved a smaller needle being injected only
8 below the skin and not all the way into the muscle, Defendants could have educated the
9 gynecology community that it already had a safer alternative product to 150 mg Depo-Provera,
10 which was more well known to prescribers and patients.

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

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

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

1 132. The “lowest effective dose” is a well-known concept in the field of pharmaceuticals
2 wherein a drug-maker should seek to find the lowest possible dose at which the drug of interest
3 is efficacious for the intended use, as any additional dosage on top of that lowest effective dose
4 is inherently superfluous and can only increase the risk of unwanted and potentially dangerous
5 side effects while providing no additional efficacy.

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

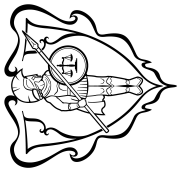
12 134. Defendants ignored reports from patients and health care providers throughout
13 the United States which indicated that Depo-Provera failed to perform as intended. Defendants
14 also knew or should have known of the effects associated with long term use of Depo-Provera,
15 which led to the severe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

20 135. Defendants’ Depo-Provera was at all times utilized and prescribed in a manner
21 foreseeable to Defendants, as Defendants generated the instructions for use for Plaintiff to
22 receive Depo-Provera injections.

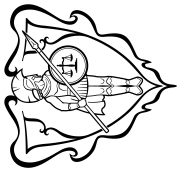
23 136. Plaintiff and Plaintiff’s physicians foreseeably used Depo-Provera, and did not
24 misuse or alter Depo-Provera in an unforeseeable manner.

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

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138. 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.

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

140. 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.

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

LIABILITY OF PFIZER, GREENSTONE, VIATRIS, AND PRASCO FOR THE
“AUTHORIZED GENERICS”

142. Defendants Greenstone, Viatris, and Prasco were at different times from 2004 until the present the authorized generic “manufacturer” and distributor operating under the same NDA of Depo-Provera, with the express permission of Pfizer, to make, label, distribute, sell, and market Depo-Provera without the brand name on its label, even though it is the exact same drug product as the branded Depo-Provera manufactured in some or all instances by Pfizer.

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

144. Further, the “authorized generics” distributors Greenstone, Viatris, and Prasco could have requested that Pfizer, with whom they were under contract to sell the “authorized generic”, to change the brand name label to warn of the risks of meningioma and the use of high dose progestins.

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

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

7 147. Pfizer was at some or all of the pertinent times the actual manufacturer of the
 8 DMPA, identical to Depo-Provera other than its name, which was sold by Defendants
 9 Greenstone, Viatris, and Prasco who were at different times the “authorized generic” distributor,
 10 with the express permission of Pfizer, to distribute, sell, and market Depo-Provera without the
 11 brand name on its label.

12 **INNOVATOR LIABILITY**²⁵

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

17 149. A manufacturer wishing to market a generic version of an FDA-approved drug
 18 can submit an Abbreviated New Drug Application (ANDA). This allows the generic
 19 manufacturer to rely on the NDA filed by the brand-name manufacturer by demonstrating that
 20 the generic version contains the same active ingredients and is biologically equivalent to the
 21 brand-name drug.²⁶

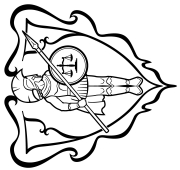
22 150. As part of the NDA, the brand-name manufacturer must propose the exact text of
 23 the label, subject to FDA approval.²⁷ For generics, the ANDA process mandates that the safety
 24 and efficacy labeling must be identical to that of the brand-name drug.²⁸

25 _____
 26 ²⁵ Plaintiff recognizes that some federal authority seems to indicate that Nevada does not recognize this theory of
 27 liability; however, the Nevada Supreme Court has not yet addressed this issue. Plaintiff therefore asserts this
 allegation in good faith.

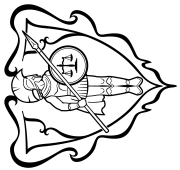
28 ²⁶ See 21 U.S.C. § 355(j)(2)(A)(ii), (iv).

²⁷ See 21 U.S.C. § 355; see also 21 C.F.R. § 314.105(b).

²⁸ See 21 U.S.C.A. § 355(j); see also *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612-13 (2011).



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151. While the brand-name manufacturer bears responsibility for the accuracy and adequacy of the drug label, generic manufacturers are only required to ensure that their labels mirror the brand name version.²⁹ The California Supreme Court has reasoned that because a brand-name manufacturer is responsible for the content of a drug's warning label, it “knows to a legal certainty ... that any deficiencies in the label for its drug will be perpetrated in the label for its generic bioequivalent.”³⁰ As a result, the content of the generic labels for Depo-Provera bioequivalents is entirely dictated by the brand-name manufacturer Defendant Pfizer’s label. Thus, liability for failure to warn can extend to Defendant Pfizer, even when the consumer is prescribed only the generic version.

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

153. As the brand-name manufacturer of Depo-Provera, Defendant Pfizer had and continues to have a duty to ensure that the labeling for Depo-Provera remains accurate and adequate “as soon as there is reasonable evidence of an association of a serious hazard with a drug,” regardless of whether a causal relationship has been established.³¹ Defendant Pfizer was not only in the best position to provide warnings regarding Depo-Provera's risks to Plaintiff’s physician but was also the only entity legally authorized to update the label unilaterally under federal law.

154. Defendant Pfizer knew or should have known that any failure to adequately warn of Depo-Provera’s risks would be replicated in the labels of its generic bioequivalents, directly affecting the information available to physicians and patients regarding both the brand-name and generic drugs. Accordingly, it is foreseeable that the warnings included or omitted on the brand-

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

³⁰ See *T.H. v. Novartis Pharm. Corp.*, 4 Cal. 5th 145, at 166 (2017); see also *Leon v. URL Pharma, Inc.*, 692 F.Supp.3d 973 (Cal.Cent.Dist. 2023)

³¹ See 21 C.F.R. § 201.80(e).

1 name drug label would influence dispensing of the generic drug and the decision-making of
 2 unsuspecting doctors and patients, like Plaintiff and Plaintiff's physicians, as to whether to take
 3 a generic equivalent of Depo-Provera and/or brand-named Depo-Provera for contraception.

4 155. As the brand-name manufacturer of Depo-Provera, Defendant Pfizer could have,
 5 at any time, unilaterally updated the Depo-Provera label without waiting for FDA preapproval
 6 in order to "add or strengthen a contraindication, warning, precaution, or adverse reaction" under
 7 the CBE regulation.³² As the brand name manufacturer of Depo-Provera, Defendant Pfizer had
 8 a duty to give information about Depo-Provera to the medical community and public at large.

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

12 157. Thus, to the extent that any of the approximately eighty (80) doses of Depo-
 13 Provera administered to Plaintiff were generic, Defendant Pfizer is additionally liable for any
 14 resultant harm to Plaintiff from those generic doses under the well-established doctrine of
 15 innovator liability.

16 **EQUITABLE TOLLING OF STATUTE OF LIMITATIONS**

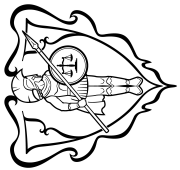
17 158. Defendants willfully, wantonly, and intentionally conspired, and acted in concert,
 18 to withhold information from Plaintiff, Plaintiff's healthcare providers, and the general public
 19 concerning the known hazards associated with the use of, and exposure to, Depo-Provera,
 20 particularly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

21 159. Defendants willfully, wantonly, and intentionally conspired, and acted in concert,
 22 to withhold safety-related warnings from the Plaintiff, and the general public concerning the
 23 known hazards associated with the use of, and exposure to, Depo-Provera, particularly over
 24 extended periods of time.

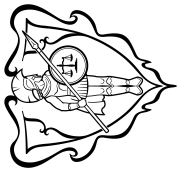
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³² See 21 C.F.R. § 314.70(c)(6)(iii)(A).



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160. 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.

161. 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.

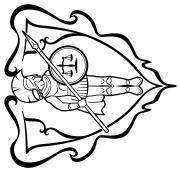
162. Defendants willfully, wantonly, and intentionally conspired, and acted in concert, to ignore relevant safety concerns and to deliberately not study the long-term safety and efficacy of Depo-Provera, particularly in chronic long-term users of Depo-Provera.

163. 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.

164. 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.

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165. 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.

166. 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.

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

CONDUCT WARRANTING PUNITIVE DAMAGES

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

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

STRICT LIABILITY – FAILURE TO WARN

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

170. 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

1 commerce in a defective and unreasonably dangerous condition. These actions were under the
2 ultimate control and supervision of Defendants.

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

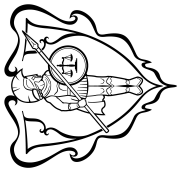
8 172. Plaintiff and Plaintiff's treating physicians did not have the same knowledge as
9 Defendants and no adequate warning or other clinically relevant information or data was
10 communicated to Plaintiff or to Plaintiff's treating physicians.

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

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

18 175. Defendants marketed, promoted, distributed and sold an unreasonably dangerous
19 and defective prescription drug, Depo-Provera, to health care providers empowered to prescribe
20 and dispense Depo-Provera, to consumers, including Plaintiff, without adequate warnings and
21 other clinically relevant information and data regarding the risk of meningioma and the risks of
22 unnecessarily excessive progestin exposure which was available and generally accepted within
23 the scientific community. Through both omission and affirmative misstatements, Defendants
24 misled the medical community about the risk and benefit balance of Depo-Provera, which
25 resulted in injury to Plaintiff.

26 ///



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

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

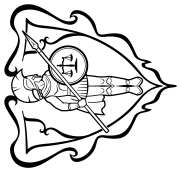
11 178. Defendants knew that a safer alternative design and product existed, including its
12 own Depo-SubQ Provera 104 which contained substantially less progestin but was equally
13 effective in preventing pregnancy, but failed to warn the medical community and the patients
14 about the risks of the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

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

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

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

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

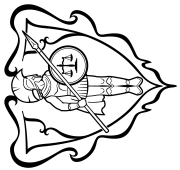
183. Plaintiff's various prescribing physicians, nurse practitioners, physician assistants, and nurses (hereinafter collectively referred to as "Plaintiff's Prescribing and Administering Health Care Providers") would not have prescribed and administered Depo-Provera to Plaintiff had they been apprised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

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

185. Similarly, if Defendants had warned of the unreasonably high risk of meningioma associated with the usage of Depo-Provera, and the availability of the safer and equally effective lower dose Depo-SubQ Provera 104 in the Patient Information handout, Plaintiff as an objectively prudent person would not have chosen to take Depo-Provera, and/or would have opted to take the safer, lower, and equally effective dose of Depo-SubQ Provera 104, notwithstanding Plaintiff's Prescribing and Administering Health Care Providers' recommendation.

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

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187. 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.

188. 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.

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

190. 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.

191. 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.

192. 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.

193. 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.

194. 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.

SECOND CLAIM FOR RELIEF

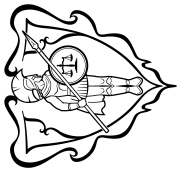
STRICT LIABILITY – DESIGN DEFECT

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

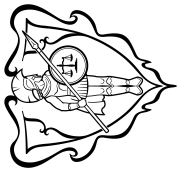
196. At all times material herein, Defendants engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Depo-Provera and placed Depo-Provera into the stream of commerce in a defective and unreasonably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

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

198. 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.



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199. 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.

200. 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.

201. 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.

202. 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.

203. 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.

204. 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.

205. 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.³³ In fact, 150 mg Depo-Provera administered subcutaneously has a remarkably similar pharmacokinetic profile to Depo-SubQ Provera 104.³⁴

³³ See Shelton, et al., “Subcutaneous DPMA: a better low dose approach,” *Contraception*, Vol. 89, pp. 341-43 (2014).

³⁴ *Id.*

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

4 207. Defendants wantonly and willfully failed to apprise the public, including the
5 FDA, the medical community, Plaintiff, Planned Parenthood, and Plaintiff’s physicians, of the
6 greatly reduced risk of meningioma when injecting 150 mg Depo-Provera subcutaneously
7 compared to the indicated method of intramuscular injection because Defendants did not want
8 to raise any alarms with respect to the safety profile of Depo-Provera and did not want to lose
9 any of its lucrative market share held in part through its contracts with “authorized generic”
10 partners and subsidiaries.

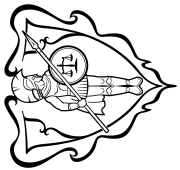
11 208. Defendants knew or should have known that the Depo-Provera they developed,
12 manufactured, labeled, marketed, sold, and/or promoted was defectively designed in that it posed
13 a serious risk of severe and permanent intracranial-meningioma-related injuries when injected
14 intramuscularly.

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

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

19 211. Defendants designed, researched, manufactured, tested, advertised, promoted,
20 marketed, sold and distributed Depo-Provera, a defective product which created an unreasonable
21 risk to the health of consumers, and Defendants are therefore strictly liable for the injuries
22 sustained by Plaintiff.

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



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

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

6 215. Depo-Provera is a medication prescribed for contraception and treatment of
7 endometriosis, among other uses. Depo-Provera in fact causes serious and potentially
8 debilitating intracranial meningioma, a brain tumor that can cause severe damage and require
9 invasive surgical removal, harming Plaintiff and other consumers.

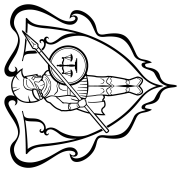
10 216. Plaintiff, ordinary consumers, and prescribers would not expect a contraceptive
11 drug designed, marketed, and labeled for contraception to cause intracranial meningioma.

12 217. The Depo-Provera supplied to Plaintiff by Defendants was defective in design or
13 formulation in that, when it left the hands of the manufacturer or supplier, it had not been
14 adequately tested, was in an unreasonably dangerous and defective condition, provided an
15 excessive dose of progestin for its purpose and posed a risk of serious and potentially debilitating
16 intracranial meningioma to Plaintiff and other consumers.

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

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

25 220. The intended or actual utility of Depo-Provera is not of such benefits to justify
26 the risk of intracranial meningioma which may cause severe and permanent injuries, thereby
27 rendering the product unreasonably dangerous.
28



1 221. The design defects render Depo-Provera more dangerous than other drugs and
2 therapies designed for contraception and causes an unreasonable increased risk of injury,
3 including, but not limited, to potentially debilitating intracranial meningioma and sequelae
4 related thereto.

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

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

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

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

20 226. As a direct and proximate result of Defendants' conduct and defective design,
21 including inadequate testing and research, and the defective and dangerous nature of Depo-
22 Provera, Plaintiff suffered bodily injuries that resulted in pain and suffering, disability, mental
23 anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and
24 treatment, loss of earnings, loss of ability to earn money, and other economic losses. The losses
25 are either permanent or continuing, and Plaintiff will suffer losses in the future.

26 ///

THIRD CLAIM FOR RELIEF

NEGLIGENCE

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

228. 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.

229. 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.

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

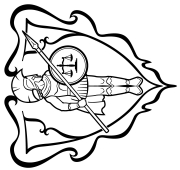
231. In disregard of its duty, Defendants committed one or more of the following negligent acts or omissions:

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;



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

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

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

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

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

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

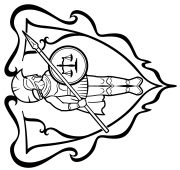
16 k. Failing to design and manufacture Depo-Provera so as to ensure the drug
17 was at least as safe and effective as other similar products;

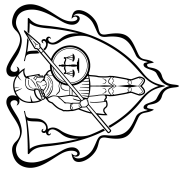
18 l. Failing to ensure the product was accompanied by proper and accurate
19 warnings about monitoring for potential symptoms related to intracranial meningioma associated
20 with the use of Depo-Provera;

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

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

26 o. Failing to sell a product with the lowest effective dose knowing that there
27 were safer, lower effective dose formulations.
28





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234. 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.

NEGLIGENT FAILURE TO WARN

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

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

239. 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.

240. 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;

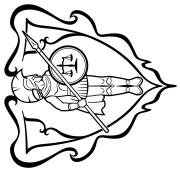
b. Disseminating information to Plaintiff and Plaintiff's physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff;

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;



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

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

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

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

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

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

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

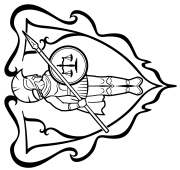
17 n. Failing to warn that the 150 mg dosage of progestin injected
18 intramuscularly was an excessive and thus toxic dose capable of causing and or substantially
19 contributing to the development and growth of meningioma tumors.

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

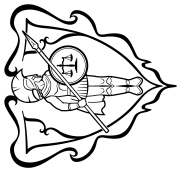
24 242. Plaintiff was prescribed and used Depo-Provera for its intended purpose. Plaintiff
25 could not have known about the dangers and hazards presented by Depo-Provera.

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

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1 244. The warnings, or lack thereof, that were given by Defendants failed to properly
2 warn prescribing physicians, including Plaintiff's prescribing physician, of the known and
3 knowable risk of serious and potentially irreversible injuries related to the development of
4 intracranial meningioma, and failed to instruct prescribing physicians to test and monitor for the
5 presence of the injuries and to discontinue use when symptoms of meningioma manifest.

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

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

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

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

22 **FIFTH CLAIM FOR RELIEF**

23 **NEGLIGENT DESIGN DEFECT**

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

26 250. At all times material herein, Defendants had a duty to exercise reasonable care
27 and had the duty of an expert in all aspects of the design, formulation, manufacture,
28 compounding, testing, inspection, packaging, labeling, distribution, marketing, promotion,

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

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

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

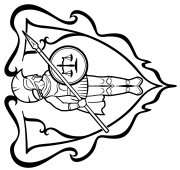
13 a. Failing to use due care in developing, testing, designing, and
14 manufacturing Depo-Provera so as to avoid the aforementioned risks to individuals when Depo-
15 Provera was being used for contraception and other indications;

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

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

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

25 253. Defendants' negligence and Depo-Provera's failures arise under circumstances
26 precluding any other reasonable inference other than a defect in Depo-Provera.
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259. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff and Plaintiff's Prescribing and Administering Health Care Providers; to falsely assure them of the quality of Depo-Provera and induce the public and medical community, including Plaintiff and her Prescribing and Administering Health Care Providers to request, recommend, purchase, and prescribe Depo-Provera.

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

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

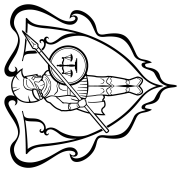
8 262. Defendants made additional misrepresentations beyond the product labeling by
9 representing Depo-Provera as safe and effective for contraception and other indications with
10 only minimal risks.

11 263. Defendants misrepresented and overstated the benefits of Depo-Provera to
12 Plaintiff, Plaintiff's Prescribing and Administering Health Care Providers, and the medical
13 community without properly advising of the known risks associated with intracranial
14 meningioma and sequelae related thereto.

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

20 265. In reliance upon the false and negligent misrepresentations and omissions made
21 by the Defendants, Plaintiff and Plaintiff's Prescribing and Administering Health Care Providers
22 were induced to, and did use Depo-Provera, thereby causing Plaintiff to endure severe and
23 permanent injuries.

24 266. In reliance upon the false and negligent misrepresentations and omissions made
25 by the Defendants, Plaintiff and Plaintiff's Prescribing and Administering Health Care Providers
26 were unable to associate the injuries sustained by Plaintiff with her Depo-Provera use, and
27 therefore unable to provide adequate treatment. Defendants knew or should have known that the
28 Plaintiff, Plaintiff's Prescribing and Administering Health Care Providers, and the general



1 medical community did not have the ability to determine the true facts which were intentionally
2 and/or negligently concealed and misrepresented by the Defendants.

3 267. Plaintiff and her Prescribing and Administering Health Care Providers would not
4 have used or prescribed Depo-Provera had the true facts not been concealed by the Defendants.

5 268. Defendants had sole access to many of the material facts concerning the defective
6 nature of Depo-Provera and its propensity to cause serious and dangerous side effects.

7 269. At the time Plaintiff was prescribed and administered Depo-Provera, Plaintiff and
8 her Prescribing and Administering Health Care Providers were unaware of Defendants'
9 negligent misrepresentations and omissions.

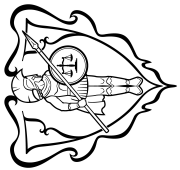
10 270. The Defendants failed to exercise ordinary care in making representations
11 concerning Depo-Provera while they were involved in their manufacture, design, sale, testing,
12 quality assurance, quality control, promotion, marketing, labeling, and distribution in interstate
13 commerce, because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

15 271. Plaintiff and Plaintiff's Prescribing and Administering Health Care Providers
16 reasonably relied upon the misrepresentations and omissions made by the Defendants, where the
17 concealed and misrepresented facts were critical to understanding the true dangers inherent in
18 the use of Depo-Provera.

19 272. Plaintiff and Plaintiff's Prescribing and Administering Health Care Providers'
20 reliance on the foregoing misrepresentations and omissions was the direct and proximate cause
21 of Plaintiff's injuries.

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

27 274. The losses are either permanent or continuing, and Plaintiff will suffer the losses
28 in the future.



SEVENTH CLAIM FOR RELIEF
FRAUDULENT MISREPRESENTATION

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

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

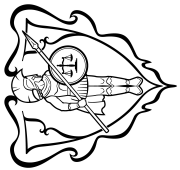
277. At all times material herein, Defendants misrepresented to consumers and physicians, including Plaintiff and Plaintiff's physicians and the public in general, that Depo-Provera is safe for use as a contraceptive and for other indications.

278. 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.

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

280. 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.

281. These representations were made by the Defendants with the intent of defrauding and deceiving the medical community, Plaintiff, and the public, and also inducing the medical community, Plaintiff, Plaintiff's Prescribing and Administering Health Care Providers, and/or the public, to recommend, prescribe, dispense, and purchase Depo-Provera for use as a



1 contraceptive and other treatment indications while concealing the drug's known propensity to
2 cause serious and debilitating intracranial meningioma and sequelae related thereto.

3 282. Despite the fact that the Defendants knew or should have known of Depo-
4 Provera's propensity to cause serious and potentially debilitating injuries due to the development
5 of intracranial meningioma and sequelae related thereto, the label did not contain any of this
6 information in the "Warnings" section. In fact, the label for Depo-Provera has been updated at
7 least a dozen times over the past 20 years, yet at no point did Defendants provide any of the
8 foregoing information in the "Warnings" section. To date, the Depo-Provera label still does not
9 include any warnings whatsoever that indicate the dangers of intracranial meningioma and
10 sequela related thereto after using Depo-Provera.

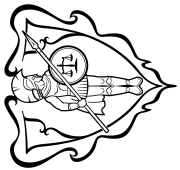
11 283. In representations to Plaintiff and/or to her healthcare providers, including
12 Plaintiff's prescribing physician, the Defendants fraudulently stated that Depo-Provera was safe
13 and omitted warnings related to intracranial meningioma.

14 284. In representations to Plaintiff and/or to her Prescribing and Administering Health
15 Care Providers, Defendants fraudulently stated that Depo-Provera was safe and concealed and
16 intentionally omitted material information from the Depo-Provera product labeling in existence
17 at the time Plaintiff was prescribed Depo-Provera between 2002-2024.

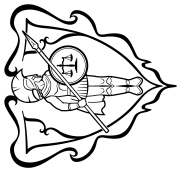
18 285. Defendants were under a duty to disclose to Plaintiff and her physicians the
19 defective nature of Depo-Provera, including but not limited to, the propensity to cause the
20 development of intracranial meningioma, and consequently, its ability to cause debilitating and
21 permanent injuries.

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

25 287. The Defendants knew or had reason to know of the dangerous side effects of
26 Depo-Provera as a result of information from case studies, clinical trials, literature, and adverse
27 event reports available to the Defendants at the time of the development and sale of Depo-
28 Provera, as well as at the time of Plaintiff's prescription.



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288. 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.

289. At the time these representations were made by Defendants, and at the time Plaintiff and/or her Prescribing and Administering Health Care Providers used Depo-Provera, Plaintiff and/or her Prescribing and Administering Health Care Providers were unaware of the falsehood of these representations.

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

291. 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.

292. 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.

293. 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.

294. 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

1 and treatment, loss of earnings, loss of consortium, loss of ability to earn money and other
2 economic losses.

3 295. The losses are either permanent or continuing, and Plaintiff will suffer the losses
4 in the future.

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

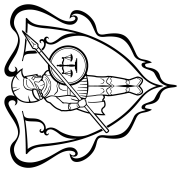
8 **EIGHTH CLAIM FOR RELIEF**
9 **BREACH OF EXPRESS WARRANTY**

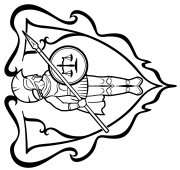
10 297. Plaintiff incorporates by reference each and every preceding paragraph as though
11 fully set forth herein.

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

17 299. Defendants expressly warranted to Plaintiff, Plaintiff's Prescribing and
18 Administering Health Care Providers, and the general public, by and through Defendants and/or
19 their authorized agents or sales representatives, in publications, labeling, the internet, and other
20 communications intended for physicians, patients, Plaintiff, and the general public, that Depo-
21 Provera was safe, effective, fit and proper for its intended use.

22 300. Depo-Provera materially failed to conform to those representations made by
23 Defendants, in package inserts and otherwise, concerning the properties and effects of Depo-
24 Provera, which Plaintiff purchased and consumed via intramuscular injection in direct or indirect
25 reliance upon these express representations. Such failures by Defendants constituted a material
26 breach of express warranties made, directly or indirectly, to Plaintiff concerning Depo-Provera
27 as sold to Plaintiff.
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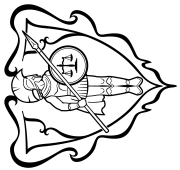
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307. As a direct and proximate result of Defendants' breaches of warranty, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, past and future medical care and 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.

BREACH OF IMPLIED WARRANTY

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

6 310. Defendants were the sellers of the Depo-Provera and sold Depo-Provera to be
7 taken for contraception or to treat endometriosis, among other indications. Plaintiff was
8 prescribed and purchased Depo-Provera for these intended purposes.

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

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

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

19 314. The Depo-Provera would not pass without objection in the trade; is not of fair
20 average quality; is not fit for its ordinary purposes for which the product is used; was not
21 adequately contained, packaged and labeled; and fails to conform to the promises or affirmations
22 of fact made on the container or label.

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

26 316. As a direct and proximate result of reliance upon Defendants' breaches of
27 warranty, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental
28 anguish, loss of capacity for the enjoyment of life, past and future medical care and treatment,

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

4 **TENTH CLAIM FOR RELIEF**

5 **LOSS OF CONSORTIUM**

6 317. At all relevant times, Harold Albert Smith III, was the lawful spouse of Plaintiff.

7 318. As a proximate result of Defendants' actions and omissions as set forth above,
8 Harold Albert Smith III has been deprived of the services, society, and companionship of his
9 spouse, his comfort and happiness has been impaired, and this deprivation and impairment will
10 necessarily continue in the future.

11 **PRAYER FOR RELIEF**

12 WHEREFORE, Plaintiff respectfully requests that the Court:

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

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

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

19 2. Award interest as permitted by law;

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

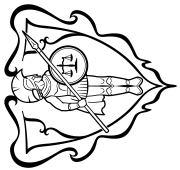
21 4. Grant such other and further relief as the Court deems just and proper.

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DEMAND FOR JURY TRIAL

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

Dated this 14th day of November, 2024.

EGLET ADAMS EGLET HAM HENRIOD

/s/ Robert T. Eglet

ROBERT T. EGLET, ESQ.

Nevada Bar No. 3402

ARTEMUS W. HAM, ESQ.

Nevada Bar No. 7001

JOEL D. HENRIOD, ESQ.

Nevada Bar No. 8492

400 South 7th Street, 4th Floor

Las Vegas, Nevada 89101

Tel.: 702-450-5400

eservice@egletlaw.com

-and-

STEVE DIMOPOULOS, ESQ.

Nevada Bar No. 12729

JARED B. KAHN, ESQ.

Nevada Bar No. 12603

SCOTT R. COOK, ESQ.

Nevada Bar No. 5265

DIMOPOULOS LAW FIRM

6830 S. Rainbow Blvd., Suite 200

Las Vegas, NV 89118

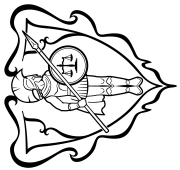
Tel: (702) 800-6000

jk@stevedimopoulos.com

sc@stevedimopoulos.com

Attorneys for Plaintiffs

DIMOPOULOS
LAW FIRM



EGLET ADAMS
EGLET HAM HENRIOD