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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

ALICIA WILSON,

Plaintiff,

vs.

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

Defendants.

**COMPLAINT AND DEMAND
FOR JURY TRIAL**

Civil Action No.: 5:24-cv-02524

Plaintiff Alicia Wilson, by and through her undersigned counsel, brings this civil action against Defendants for personal injuries and damages suffered by Plaintiff, and alleges as follows:

I. INTRODUCTION

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

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

14 3. Depo-Provera injured Plaintiff Alicia Wilson (hereinafter “Plaintiff”) by
15 causing or substantially contributing to the development of intracranial meningioma,
16 requiring significant and invasive medical treatment (with severe side effects), and has
17 now significantly increased Plaintiff’s risk of future adverse health consequences which
18 will continue to require routine medical surveillance for the remainder of her life.
19

20 4. Defendants knew or should have known for decades that Depo-Provera,
21 when administered and prescribed as intended, can cause or substantially contribute to
22 the development of meningiomas.
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1 5. Several scientific studies have established that progesterone, its synthetic
2 analogue progestin, and Depo-Provera in particular, cause or substantially contribute to
3 the development of intracranial meningioma, a type of brain tumor.
4

5 6. Defendants’ Product Monographs for Depo-Provera distributed in Canada
6 have listed “meningioma” among its “Post-Market Adverse Drug Reactions” since at
7 least 2015. Depo-Provera labeling in the European Union (EU) and the United Kingdom
8 similarly list meningioma within the “special warnings and precautions for use” section
9 and advise EU patients to speak with their doctors before using Depo-Provera if they
10 have any history of meningioma.
11
12

13 7. To date, however, the U.S. label for Depo-Provera makes no mention of
14 the increased risk to patients of developing intracranial meningioma.
15

16 8. Defendants failed to warn, instruct, advise, educate, or otherwise inform
17 Depo-Provera users and prescribers in the United States about the risk of intracranial
18 meningioma or the need for monitoring for resultant symptoms.
19

20 9. As a proximate result of Defendants’ wrongful actions and inactions,
21 Plaintiff used Depo-Provera and suffered substantial damages, including severe
22 physical and emotional injuries.
23

24 10. Plaintiff therefore demands judgment against Defendants and requests,
25 among other things, compensatory damages, statutory damages, punitive damages, pre-
26 and post-judgment interest, attorneys’ fees, and costs.
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1 **II. PARTIES**

2 **A. PLAINTIFF ALICIA WILSON**

3 11. At all relevant times hereto, Plaintiff Alicia Wilson was and is a resident
4 and citizen of Upland, San Bernardino, California.
5

6 **B. DEFENDANT PFIZER, INC.**

7 12. Defendant PFIZER, INC. (hereinafter “Pfizer”) is a publicly held
8 corporation incorporated under the laws of the State of Delaware with its principal place
9 of business at The Spiral, 66 Hudson Boulevard East, New York, NY 10001.
10

11 13. For purposes of jurisdiction based on diversity under 28 U.S.C. § 1332(a),
12 Pfizer is considered to be a citizen of Delaware and New York.
13

14 14. Pfizer has a registered agent for service of process, CT Corp., at 330 North
15 Brand Boulevard in Glendale, California.

16 **C. DEFENDANT VIATRIS, INC.**

17 15. Defendant VIATRIS, INC. (hereinafter “Viatri”) is a publicly traded
18 corporation organized under the laws of the State of Delaware law with its principal
19 place of business at 1000 Mylan Boulevard, Canonsburg, PA 15317.
20

21 16. For purposes of jurisdiction based on diversity under 28 U.S.C. § 1332(a),
22 therefore, Viatri Inc. is considered to be a citizen of Delaware and Pennsylvania.
23

24 17. Viatri has a registered agent for service of process, CT Corp., at 330
25 North Brand Boulevard in Glendale, California.
26

27 **D. DEFENDANT GREENSTONE, LLC**

1 18. Defendant GREENSTONE, LLC (hereinafter “Greenstone”) is an
2 indirectly wholly owned subsidiary of Defendant Viatris. Greenstone is a company
3 organized under Delaware law with its principal place of business at 2898
4 Manufacturers Road, Office #112, Greensboro, NC 27406.
5

6 19. Defendant GREENSTONE, LLC has one member, Upjohn US 2 LLC,
7 which is a company organized and existing under the law of Delaware. Upjohn US 2
8 LLC has one member, Upjohn US Holdings, Inc., which is a corporation organized and
9 existing under the law of Delaware with its principal place of business in Pennsylvania.
10

11 20. For purposes of jurisdiction based on diversity under 28 U.S.C. § 1332(a),
12 Greenstone LLC is considered to be a citizen of Delaware and Pennsylvania.
13

14 21. Greenstone has a registered agent for service of process, CT Corp., at 5098
15 Washington Street West, Suite 407, Charleston, WV 25313.
16

17 **E. DEFENDANT PHARMACIA & UPJOHN COMPANY, LLC**

18 22. Defendant PHARMACIA & UPJOHN COMPANY, LLC (hereinafter
19 “Pharmacia & Upjohn” or “Upjohn”) is a company organized under the laws of the
20 State of Delaware and headquartered at 7171 Portage Road, Kalamazoo, MI 49002.
21

22 23. Pharmacia & Upjohn has two members: Pharmacia & Upjohn, LLC and
23 Anacor Pharmaceuticals, LLC.
24

25 24. Pharmacia & Upjohn has a registered agent for service of process, CT
26 Corp., at 330 North Brand Boulevard in Glendale, CA
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1 25. Defendant Pharmacia & Upjohn Company LLC is therefore a citizen of
2 Delaware and New York for the purposes of diversity under 28 U.S.C. § 1332(a).

3
4 26. Defendant Pharmacia & Upjohn Company LLC is therefore a citizen of
5 Delaware and New York for the purposes of diversity under 28 U.S.C. § 1332(a).

6 **F. DEFENDANT PHARMACIA, LLC**

7 27. Defendant PHARMACIA, LLC (formerly known as “Pharmacia
8 Corporation”) (hereinafter “Pharmacia”) is a company organized under Delaware law
9 with a principal place of business in New York, New York. Its sole member is Wyeth
10 Holdings, LLC.
11

12 28. Pharmacia’s sole member is Wyeth Holdings. LLC, a Maine limited
13 liability company, with its principal place of business in New York, New York. Wyeth
14 Holdings’ sole member is Anacor Pharmaceuticals, LLC, a Delaware limited liability
15 company with a principal place of business in New York, New York. Its sole member
16 is Pfizer MAP Holding, Inc, a Delaware corporation with a principal place of business
17 in New York, New York.
18

19 29. Defendant Pharmacia has a registered agent for service of process, CT
20 Corp., at 820 Bear Tavern Road, West Trenton, NJ 08628.
21

22 30. For purposes of jurisdiction based on diversity under 28 U.S.C. § 1332(a),
23 Pharmacia is considered to be a citizen of Delaware and New York.
24

25 **G. DEFENDANT PRASCO, LLC d/b/a PRASCO LABORATORIES**

1 31. Defendant PRASCO, LLC, doing business as PRASCO
2 LABORATORIES (hereinafter “Prasco”), is a company organized under the laws of
3 the State of Ohio with its principal place of business at 6125 Commerce Court, Mason,
4 OH 45040.
5

6 32. The sole member of Prasco, LLC is Scion Companies, LLC. The members
7 of Scion Companies, LLC are private citizens of Ohio and South Dakota.
8

9 33. Defendant Prasco is therefore a citizen of Ohio and South Dakota for the
10 purposes of diversity under 28 U.S.C. § 1332(a).
11

12 34. Defendant Pfizer is the current New Drug Application (hereinafter
13 “NDA”) holder for Depo-Provera and has solely held the NDA for Depo-Provera since
14 2020. Upon information and belief, Pfizer has effectively held the NDA since at least
15 2002 when it acquired Pharmacia & Upjohn—who then held the NDA—as a wholly
16 owned subsidiary. No later than 2003 did Pfizer’s name appear on the label alongside
17 Pharmacia & Upjohn.
18

19 35. At all relevant times, Defendant Pharmacia & Upjohn was a wholly owned
20 subsidiary of Defendant Pfizer until Upjohn was spun off in a merger in 2020 to create
21 Defendant Viartis and the remnant, i.e., Defendant Pharmacia, was retained by Pfizer.
22

23 36. Defendant Greenstone, founded in 1993, was a wholly owned subsidiary
24 first of Pharmacia & Upjohn and later of Pfizer that, at pertinent times, was in the
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1 business of offering a product portfolio of “authorized generic” medicines, including
2 Depo-Provera.

3
4 37. Defendant Greenstone is a company that until November 2020 was styled
5 as a wholly owned subsidiary of Pfizer but was in fact exclusively staffed with Pfizer
6 personnel who reported to Pfizer’s HR department, were on Pfizer’s payroll, and shared
7 the same corporate space with Pfizer in Peapack, NJ. Pfizer also managed Greenstone's
8 key business functions including financial and sales analysis, business technology,
9 customer service, legal matters, intellectual property, and supply chain operations.
10 Thus, Greenstone was effectively a department within Pfizer.
11

12
13 38. Intellectual property challenges in the early 2000s to Pfizer’s portfolio of
14 brand name pharmaceuticals including Depo-Provera presented a “watershed moment
15 at Pfizer by setting [Pfizer’s] new Greenstone generic strategy into play.”¹ Pfizer began
16 to utilize Greenstone as part of its patent protection tactics, with the company president
17 at the time stating: “[B]eing able to launch our own Pfizer quality Greenstone generic
18 let’s [*sic*] us continue our market presence in the face of generic competition.”²
19

20
21 39. Pfizer executives stated in 2004 it was not just Greenstone’s precise brand-
22 name chemical formulation of its authorized generics that would remain identical to
23 Pfizer’s, but every facet of Pfizer’s business operations, from manufacture to sale: “By
24
25
26

27 ¹ Pfizer Analyst Meeting Transcript, *Fair Disclosure Wire* (Nov. 30, 2004), at 6.

28 ² *Id.*

1 Pfizer quality I mean not just the medication itself, but our reliable supply chain, our
2 organizational ability to support our medicine both branded and generic.”³

3
4 40. Defendants Greenstone/Pfizer sold a “generic” version of Depo-Provera
5 that was in fact what is known as an “authorized generic.” Unlike standard generics,
6 which must contain only the same active ingredients and have the same pharmaceutical
7 effect but can otherwise contain vastly different additives, “authorized generics” are
8 exact replicas of the brand name drug, with the identical chemical composition, simply
9 marketed without the brand-name on its label. In other words, Greenstone was
10 presenting itself as a distinct generic manufacturing entity when it was in fact Pfizer
11 personnel producing the exact same brand-name Depo-Provera at Pfizer’s own facility.

12
13
14 41. The FDA has stated that the term “authorized generic” drug is most
15 commonly used to describe an approved brand name drug that is marketed without the
16 brand name on its label. Other than the fact that it does not have the brand name on its
17 label, it is the exact same drug product as the branded product. An “authorized generic”
18 may be marketed by the brand name drug company, or another company with the brand
19 company’s permission.⁴

20
21
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23
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25
26 _____
27 ³ *Id.*

28 ⁴ See <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs> (last accessed Nov. 26, 2024).

1 42. Indeed, Pfizer’s website still states that “GREENSTONE Authorized
2 Generics are manufactured to the same standards and at the same facilities as Pfizer
3 brand-name drugs.”⁵
4

5 43. Pfizer was the actual manufacturer of the authorized generic product that
6 Greenstone distributed and sold.
7

8 44. Defendant Viartis was formed by the merger of Upjohn, Greenstone, and
9 another company, Mylan N.V., in November 2020. Viartis is thus merely the latest
10 iteration of Upjohn and Greenstone.
11

12 45. Even after the merger, Defendant Greenstone continued to operate from
13 the same location at Pfizer’s corporate offices in Peapack, NJ.
14

15 46. Additionally, Defendant Pfizer retained 57% ownership of Viartis stock,
16 making Pfizer the majority owner of Viartis, and since Pfizer retained the remnants of
17 Pharmacia, Pfizer effectively remains the majority owner of Defendants Pharmacia &
18 Upjohn and Greenstone.
19

20 47. Defendant Prasco is another “authorized generic” manufacturer of Depo-
21 Provera, meaning Prasco simply takes brand-name Depo-Provera manufactured by
22 Defendants Greenstone and/or Pfizer and passes it off as its own generic product.
23 Defendant Prasco consistently maintains a sizeable percentage of the market share for
24 Depo-Provera sales in the United States.
25
26

27 ⁵ See [https://www.pfizer.com/news/press-release/press-release-detail/pfizers-greenstone-and-digital-](https://www.pfizer.com/news/press-release/press-release-detail/pfizers-greenstone-and-digital-mens-health-clinic-roman)
28 [mens-health-clinic-roman](https://www.pfizer.com/news/press-release/press-release-detail/pfizers-greenstone-and-digital-mens-health-clinic-roman) (last accessed Sept. 26, 2024).

1 48. All Defendants do business in California by, among other things,
2 distributing, marketing, selling, and/or profiting from brand name and/or “authorized
3 generic” Depo-Provera in California, as well as throughout the United States.
4

5 49. At all times material herein, Defendants were, and still are, pharmaceutical
6 companies involved in the manufacturing, research, development, marketing,
7 distribution, sale, and release for use to the general public of pharmaceuticals, including
8 Depo-Provera and its “authorized generics” in California and throughout the United
9 States.
10

11 **III. JURISDICTION AND VENUE**
12

13 50. This Court has diversity jurisdiction over this action pursuant to 28 U.S.C.
14 § 1332, as the amount in controversy exceeds \$75,000.00 and the Parties are citizens of
15 different States.
16

17 51. All Defendants regularly conduct business in California.

18 52. This Court has supplemental jurisdiction over the remaining common law
19 and state claims pursuant to 28 U.S.C. § 1367.
20

21 53. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a
22 substantial part of the events or omissions giving rise to the claim, including the
23 distribution, sale, and administration of Depo-Provera to Plaintiff and Plaintiff’s
24 development, diagnosis, and treatment of meningioma, all occurred in the Central
25 District of California.
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1 54. Defendant Pfizer has extensive connections to the State of California that
2 are highly relevant to the subject matter of the instant action.

3
4 55. For example, Pfizer maintains the Pfizer La Jolla Research Site, a 25-acre
5 “campus” complete with a 500,000-square-foot state-of-the-art facility devoted to the
6 study of oncology, drug safety, and pharmacokinetics.⁶

7
8 56. As of December 2018, Defendant Pfizer’s La Jolla campus is home to more
9 than 900 scientists and clinicians studying, *inter alia*, the effects of drugs on the
10 development of tumors.⁷

11
12 57. According to Pfizer’s website, the “Pfizer La Jolla campus is an important
13 part of California’s life sciences community and partners with academic institutions and
14 other research organizations to advance scientific understanding and deliver new
15 medicines.”⁸

16
17 58. Pfizer’s website states: “In 2011, Pfizer announced that it is partnering
18 with the University of California, San Diego Health Sciences and Sanford-Burnham
19 Medical Research Institute through [Pfizer’s] Centers for Therapeutic Innovation
20 (CTI).” Pfizer’s website explains “CTI is a network of collaborative partnerships with
21 top-tier life science research institutions in California, Massachusetts and New York
22
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26 ⁶ <https://www.pfizer.com/la-jolla-california> (Last accessed Oct. 13, 2024).

27 ⁷ See <https://www.sandiegouniontribune.com/2018/12/11/pfizer-adds-100-to-cancer-research-center-in-la-jolla/> (Dec. 11, 2018) (Last accessed Oct. 13, 2024).

28 ⁸ <https://www.pfizer.com/la-jolla-california> (Last accessed Oct. 13, 2024).

1 that aims to accelerate and transform drug discovery and development. In San Diego,
2 CTI's home base is located on the Pfizer La Jolla campus.”⁹

3
4 59. CTI was launched by Pfizer in 2010 as “an entrepreneurial network of
5 partnerships with leading academic medical centers to transform research and
6 development by accessing leading translational researchers.”¹⁰

7
8 60. The University of California, San Francisco was “the first collaboration in
9 the network.”¹¹

10
11 61. Pfizer's senior vice president of Worldwide BioTherapeutics Research and
12 Development stated at the time of the announcement, “UCSF is a world-class academic
13 medical center with a strong focus on both basic science and clinical research, which is
14 why Pfizer is partnering with them on this initiative. Ultimately, we believe this could
15 create significant benefit for the patient.”¹²

16
17 62. Pfizer has thus deliberately created strong connections not just to the
18 consumers and patients of California but also to the life and health sciences
19 communities and the State educational institutions of California as well.

20
21 63. Moreover, Defendants Pfizer, Viatrix, Prasco and Upjohn & Pharmacia are
22 all registered to do business in the State of California and can be served at their
23

24
25 ⁹ *Id.*

26 ¹⁰ https://www.pfizer.com/news/press-release/press-release-detail/pfizer_launches_global_centers_for_therapeutic_innovation_a_network_of_research_partners_hips_with_university_of_california_san_francisco (Nov. 16, 2010) (Last accessed Oct. 13, 2024).

27 ¹¹ *Id.*

28 ¹² *Id.*

1 registered agent for service of process, CT Corp., at 330 North Brand Boulevard in
2 Glendale, CA.

3
4 64. All Defendants at different periods of time had a contractual and/or sales
5 relationship directly or through intermediaries to sell Depo-Provera to Kaiser
6 Permanente Health System knowing that health care providers at Kaiser Permanente in
7 California would be injecting Depo-Provera into patients.

8
9 65. At various points of time, Defendant Pfizer sponsored continuing
10 education courses, seminars, and meetings to promote the use of Depo-Provera to
11 Plaintiff's health care providers and the Kaiser Permanente Health System in California.

12
13 **IV. PLAINTIFF'S USE OF DEPO-PROVERA & RELATED INJURIES**

14 66. In or around 1998, Plaintiff Alicia Wilson was first administered Depo-
15 Provera for contraception at Kaiser Hospital in Pasadena, California.

16
17 67. Plaintiff's healthcare providers prescribed and administered Depo-Provera
18 injections to her between 1998 and 2019.

19
20 68. In 2019, Plaintiff suffered a stroke and was treated at San Antonio
21 Regional Hospital in Upland, California, during which it was discovered that she was
22 suffering from an intracranial meningioma.

23
24 69. On or about April 9, 2019, at the age of 51, Plaintiff underwent a
25 craniotomy to surgically remove a left frontal meningioma with surrounding reactive
26 vasogenic brain edema (swelling due to damage to the blood brain barrier).

1 70. Following Plaintiff’s craniotomy, pathology confirmed that the tumor
2 suffered was a Grade 1 meningioma tumor.

3
4 71. As a result of her meningioma tumor and related treatment and recovery,
5 Plaintiff has suffered severe adverse health consequences, mental distress, fear of
6 recurrence was no longer able to work, and

7
8 72. As a result of Defendant’s actions and omissions, Plaintiff was made to
9 suffer serious injuries and damages, specifically, the development of a intracranial
10 meningioma requiring invasive brain surgery and additional medical treatment and
11 surveillance for recurrence.

12
13 73. Plaintiff first became aware of the connection between her meningioma
14 diagnosis and use of Depo-Provera in or around September 2024.

15
16 74. As a result of Defendants’ actions and inactions, Plaintiff has suffered
17 serious injuries, including the development of an intracranial meningioma and sequelae
18 related thereto.

19
20 **V. GENERAL ALLEGATIONS**

21 **A. INTRACRANIAL MENINGIOMA**

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

24
25 76. Although the tumor formed by an intracranial meningioma is typically
26 histologically benign (meaning it usually does not metastasize), the growing tumor can
27 nevertheless press against the sensitive surrounding tissues, i.e., the brain, and thereby
28

1 cause a number of severe and debilitating symptoms ranging from seizures and vision
2 problems to weakness, difficulty speaking, and even death, among others. Moreover, a
3 sizeable number of meningiomas (15-20%) do become metastatic, greatly increasing
4 their danger.
5

6 77. Treatment of a symptomatic intracranial meningioma typically requires
7 highly invasive brain surgery that involves the removal of a portion of the skull, i.e., a
8 craniotomy, in order to access the brain and meninges. Radiation therapy and
9 chemotherapy may also be required as the sensitive location of the tumor in the brain
10 can render complete removal highly risky and technically difficult.
11

12 78. Due to the sensitive location of an intracranial meningioma immediately
13 proximate to critical neurovascular structures and the cortical area, surgery can have
14 severe neurological consequences. Many studies have described the potential for
15 postoperative anxiety and depression and an attendant high intake of sedatives and
16 antidepressants in the postoperative period. Surgery for intracranial meningioma can
17 also lead to seizures requiring medication to treat epilepsy. Moreover, meningiomas
18 related to progesterone-based contraceptives tend to manifest at the base of the skull
19 where removal is even more challenging, further increasing the risks of injuries.
20
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22

23 **B. DEPO-PROVERA**

24 79. Depo-Provera (depot medroxyprogesterone acetate, hereinafter “DMPA”)
25 was first approved by the FDA in 1992 to be used as a contraceptive, and later, with the
26
27
28

1 approval of the Depo-SubQ Provera 104 variant in 2004, as a treatment for
2 endometriosis.

3
4 80. Depo-Provera is administered as a contraceptive injection that contains a
5 high dose of progestin, a synthetic progesterone-like hormone that suppresses ovulation.

6
7 81. According to a recent National Health Statistics Report published in
8 December 2023, nearly a quarter (24.5%) of all sexually experienced women in the
9 United States between 2015 and 2019 had ever used Depo-Provera.¹³

10
11 82. According to that same report, those proportions increase even further for
12 Hispanic (27.2%) women and Black (41.2%) women who had ever used Depo-
13 Provera.¹⁴

14
15 83. Depo-Provera is a 150 mg/mL dosage of DMPA that is injected every three
16 (3) months into the deep tissue musculature of either the buttocks or the upper arm, with
17 present labelling recommending alternating the injection site at each injection.

18
19 84. Defendant Pfizer represents Depo-Provera to be one of the most effective
20 contraceptives in existence. In fact, the Depo-Provera label groups injectable
21 contraceptives like Depo-Provera alongside “Sterilization” as the most effective
22 contraceptive methods resulting in the fewest unintended pregnancies.

23
24
25
26
27 ¹³ Daniels, K et al., “Contraceptive Methods Women Have Ever Used: United States, 2015-2019”,
Nat’l Health Statistics Report, No. 195, Dec. 14, 2023.

28 ¹⁴ *Id.*

1 85. Among reproductive age women who used any form of contraception
2 from 2017-2019, the contraceptive injection was most often used by young women,
3 lower-income women, and Black women.¹⁵
4

5 86. Depo-Provera was first developed by Defendant Upjohn (later acquired
6 by Defendant Pfizer) in the 1950s.
7

8 87. Upjohn introduced Depo-Provera as an injectable intramuscular
9 formulation for the treatment of endometrial and renal cancer in 1960.
10

11 88. The NDA for Depo-Provera for use as a contraceptive was originally
12 submitted to the FDA by Upjohn in 1967; however, this application was rejected.
13

14 89. Upjohn again applied to the FDA for approval to market Depo-Provera as
15 a contraceptive in 1978 but was again rebuffed.
16

17 90. Upjohn applied to the FDA for a third time for the approval of Depo-
18 Provera as a contraceptive in 1983, but the FDA once again rejected the application.
19

20 91. As early as 1969, Upjohn successfully received approval for Depo-Provera
21 for contraception in international markets, including France.
22

23 92. Upjohn's NDA for Depo-Provera for use as a contraceptive was
24 eventually approved by the FDA on or about October 29, 1992.
25

26 93. Upjohn merged with Swedish manufacturer Pharmacia AB to form
27 Pharmacia & Upjohn in 1995.
28

¹⁵ See <https://www.kff.org/womens-health-policy/fact-sheet/dmpa-contraceptive-injection-use-and-coverage/> (last accessed Sept. 30, 2024).

1 94. Defendant Pfizer acquired Pharmacia & Upjohn in 2002, thereby
2 acquiring the Depo-Provera NDA as well as the associated responsibilities and
3 liabilities stemming from the manufacturing, sale, and marketing of Depo-Provera.
4

5 95. Pfizer has effectively held the Depo-Provera NDA since acquiring
6 Pharmacia & Upjohn in 2002, and has solely held the NDA since 2020, when Upjohn
7 was spun off to form Defendant Viatrix.
8

9 96. Throughout the time Defendants marketed both variants of Depo-
10 Provera, Defendants failed to provide adequate warnings to patients and the medical
11 community, including Plaintiff's prescribing physician, of the risks associated with
12 using the drug.
13

14 97. Defendants also failed to adequately test Depo-Provera to investigate
15 the potential for intracranial meningioma.
16

17 98. Defendants are also liable for the conduct of its predecessors who failed
18 to adequately design, test, and warn of the dangers associated with use of Depo-Provera.
19

20 **C. THE DANGERS OF DEPO-PROVERA**

21 99. The association between progesterone and meningioma has been known
22 or knowable for decades, particularly for sophisticated pharmaceutical corporations like
23 Defendants engaging in FDA-required post-market surveillance of their products for
24 potential safety issues. That duty includes an obligation to keep current with emerging
25 relevant literature and where appropriate, perform their own long- term studies and
26 follow-up research.
27
28

1 100. Since at least 1983, the medical and scientific communities have been
2 aware of the high number of progesterone receptors on meningioma cells, especially
3 relative to estrogen receptors.¹⁶
4

5 101. This finding was surprising and notable within the medical and scientific
6 communities because it had previously been thought that meningioma cells, like breast
7 cancer cells, would show a preference for estrogen receptors.¹⁷ Researchers publishing
8 in the *European Journal of Cancer and Clinical Oncology* instead found the opposite,
9 indicating progesterone was involved in the incidence, mediation, and growth rate of
10 meningiomas.¹⁸ This particular study was published nearly a decade before the FDA
11 approved Depo-Provera for contraception in 1992. In those nine (9) years before Depo-
12 Provera was approved for contraception, and in the thirty-two (32) years since—more
13 than forty (40) years in all—Defendants have seemingly failed to investigate the effect
14 of their high-dose progesterone Depo-Provera on the development of meningioma.
15
16
17

18 102. Since at least as early as 1989, researchers have also been aware of the
19 relationship between progesterone-inhibiting agents and the growth rate of
20 meningioma.¹⁹ That year, the same authors published a study in the *Journal of Steroid*
21
22
23

24 ¹⁶ See Blankenstein, et al., “Presence of progesterone receptors and absence of oestrogen receptors in
25 human intracranial meningioma cytosols,” *Eur J Cancer & Clin Oncol*, Vol. 19, No. 3, pp. 365-70
(1983).

26 ¹⁷ See *id.*

27 ¹⁸ See *id.*

28 ¹⁹ 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).

1 *Biochemistry* entitled, “Effect of steroids and antisteroids on human meningioma cells
2 in primary culture,” finding that meningioma cell growth was significantly reduced by
3 exposure to mifepristone, an antiprogestone agent.²⁰
4

5 103. Numerous studies published in the decades since have presented similar
6 findings on the negative correlation between progesterone-inhibiting agents and
7 meningioma.²¹
8

9 104. Relatedly, a number of studies published in the interim have reported on
10 the positive correlation between a progesterone and/or progestin medication and the
11 incidence and growth rate of meningioma.²²
12

13 105. In 2015, a retrospective literature review published in the peer-reviewed
14 journal *BioMed Research International* by Cossu, et al. surveyed the relevant literature
15 including many of the studies cited above and concluded that mifepristone, an
16 antiprogestone agent, had a regressive effect on meningioma, meaning it stopped or
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21 ²⁰ *See id.*

22 ²¹ *See, e.g.,* Grunberg, et al., “Treatment of unresectable meningiomas with the antiprogestone agent
23 mifepristone,” *J Neurosurgery*, Vol. 74, No. 6, pp. 861-66 (1991); *see also* Matsuda, et al., “Antitumor
24 effects of antiprogestones on human meningioma cells in vitro and in vivo,” *J Neurosurgery*, Vol.
80, No. 3, pp. 527-34 (1994).

25 ²² *See, e.g.,* Gil, et al., “Risk of meningioma among users of high doses of cyproterone acetate as
26 compared with the general population: evidence from a population-based cohort study,” *Br J Clin
27 Pharmacol.* Vol. 72, No. 6, pp. 965-68 (2011); *see also* Bernat, et al., “Growth stabilization and
28 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).

1 reversed its growth.²³ Reviewing the Blankenstein studies as well as many others
2 conducted over a span of more than thirty (30) years, the authors concluded that
3 mifepristone competes with progesterone for its receptors on meningioma cells and, by
4 blocking progesterone from binding, stems or even reverses the growth of meningioma.
5

6 106. In light of the aforementioned studies, for several decades the
7 manufacturers and sellers of Depo-Provera and its authorized generic and generic
8 analogues, Defendants, had an unassignable duty to investigate the foreseeable potential
9 that a high dose synthetic progesterone delivered in the deep tissue could cause the
10 development or substantially contribute to the growth of meningioma. Defendants were
11 also best positioned to perform such investigations. Had Defendants done so, they
12 would have discovered decades ago that their high dose progestin Depo-Provera was
13 associated with a highly increased risk of meningioma and would have spared Plaintiff
14 and countless others the pain and suffering associated with meningioma. Instead,
15 Defendants did nothing, and therefore willfully failed to apprise the medical
16 community, and the women patients receiving quarterly high dose injections, of this
17 dangerous risk.
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22 107. Indeed, more recently, researchers have found that prolonged use (greater
23 than one year) of progesterone and progestin, and specifically Depo-Provera, is linked
24
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27 ²³ See Cossu et al., “The Role of Mifepristone in Meningiomas Management: A Systematic Review of
28 the Literature” *BioMed Res. Int.* 267831 (2015), <https://doi.org/10.1155/2015/267831>

1 to a greater incidence of developing intracranial meningioma, as would be expected
2 based on all the aforementioned studies and recognition of the relationship between dose
3 and duration of use and the development of adverse events well recognized in the fields
4 of pharmacology, toxicology, and medicine.
5

6 108. In 2022, an article was published in the journal *Endocrinology* entitled
7 “Estrogen and Progesterone Therapy and Meningiomas.”²⁴ This retrospective literature
8 review noted that a “dose-dependent relationship” has been established between at least
9 one progestin and the incidence and growth rate of meningioma. The study authors
10 further noted that progesterone-mediated meningiomas appear to be located most often
11 in the anterior and middle base of the skull and are more likely to be multiple and require
12 more intensive treatment.
13
14
15

16 109. In 2023, researchers reported on a direct link between Depo-Provera and
17 meningioma. That year a case series was published in the *Journal of Neurological*
18 *Surgery Part B: Skull Base* titled “Skull Base Meningiomas as Part of a Novel
19 Meningioma Syndrome Associated with Chronic Depot Medroxyprogesterone Acetate
20 Use.”²⁵ The abstract reported on 25 individuals who developed one or more intracranial
21 meningiomas related to chronic use of Depo-Provera. Of the twenty-five (25) patients,
22
23
24

25 ²⁴ Hage, et al., “Estrogen and progesterone therapy and meningiomas,” *Endocrinology*, Vol. 163, pp.
26 1-10 (2022).

27 ²⁵ Abou-Al-Shaar, et al., “Skull base meningiomas as part of a novel meningioma syndrome associated
28 with chronic depot medroxyprogesterone acetate use,” *J Neurol Surg Part B Skull Base*, Vol. 84:S1-
344 (2023).

1 ten (10) were instructed to cease Depo-Provera use, after which five (5) of those patients
2 had “clear evidence of tumor shrinkage,” leading the authors to conclude “there appears
3 to be a clear progestin meningioma syndrome associated with chronic DMPA use.”
4

5 110. In 2024, the French National Agency for Medicines and Health Products
6 Safety along with several French neurosurgeons, epidemiologist, clinicians, and
7 researchers published a large case control study in the *British Medical Journal (BMJ)*,
8 one of the premier scientific journals in the world, to assess the risk of intracranial
9 meningioma with the use of numerous progestogens among women in France,
10 hereinafter referred to as the *Roland* study.²⁶
11
12

13 111. By way of history, the *Roland* study noted that concerns over meningiomas
14 associated with high dose progestogen medications resulted in the recent discontinuation
15 of three such medications in France and the EU. Specifically, there were “postponements
16 in the prescription of chlormadinone acetate, nomegestrol acetate, and cyproterone
17 acetate, following the French and European recommendations to reduce the risk of
18 meningioma attributable to these progestogens in 2018 and 2019.”²⁷
19
20

21 112. The study analyzed 18,061 cases of women undergoing surgery for
22 intracranial meningioma between 2009 and 2018. The study found that “prolonged use
23 of ... medroxyprogesterone acetate [Depo-Provera] ... was found to increase the risk of
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25

26 ²⁶ Roland, et al., “Use of progestogens and the risk of intracranial meningioma: national case-control
27 study,” *BMJ*, Vol. 384, published online Mar. 27, 2024 at <https://doi.org/10.1136/bmj-2023-078078>
(last accessed Apr. 21, 2024).

28 ²⁷ *See id.*

1 intracranial meningioma.” Specifically, the authors found that prolonged use of Depo-
2 Provera resulted in a 555% increased risk of developing intracranial meningioma. The
3 study authors concluded “[t]he increased risk associated with the use of injectable
4 medroxyprogesterone acetate, a widely used contraceptive,” was an important finding.
5 The authors also noted Depo-Provera is “often administered to vulnerable populations,”
6 i.e., lower-income women who have no other choice but to take the subsidized option
7 which only requires action every three months to remain effective for its intended use
8 of preventing pregnancy, and, in the case of the subcutaneous variant, treating
9 endometriosis.
10
11
12

13 113. The 2024 *Roland* study published in *BMJ* studied the effect of several other
14 progestogen-based medications. Three study subjects showed no excess risk of
15 intracranial meningioma surgery with exposure to oral or intravaginal progesterone or
16 percutaneous progesterone, dydrogesterone or spironolactone, while no conclusions
17 could be drawn for two others due to lack of exposed cases. The other medications,
18 including medroxyprogesterone acetate (Depo-Provera), were found to be associated
19 with an increased risk of intracranial meningioma, with Depo-Provera having by far the
20 second highest increased risk, surpassed only by the product cyproterone acetate, which
21 had already been withdrawn from the market due to its association with meningioma.
22
23
24

25 114. Depo-Provera had by far the highest risk of meningioma surgeries
26 amongst progesterone contraceptive products studied, rendering Depo-Provera more
27
28

1 dangerous than other drugs and treatment options designed to prevent pregnancy due to
2 the unreasonably increased risk of injury associated with intracranial meningioma,
3 including but not limited to seizures, vision problems, and even death.
4

5 115. Further, the *Roland* study found the longer duration of exposure had a
6 greater risk noting the results show that three quarters of the women in the case group
7 who had been exposed for more than a year had been exposed for more than three years.
8

9 116. The *Roland* study noted that among cases of meningioma observed in the
10 study, 28.8% (5,202/18,061) of the women used antiepileptic drugs three years after the
11 index date of intracranial surgery.
12

13 117. More recently, in September 2024, an article entitled “The Association
14 between Medroxyprogesterone Acetate Exposure and Meningioma” was published in
15 *Cancers*. This large case-control study analyzed over 117,000 meningioma cases and
16 more than one million matched controls and found that “injection exposure” of
17 medroxyprogesterone acetate, i.e. Depo-Provera usage, was associated with a 53%
18 increase in the development of meningioma. The association was specific to cerebral
19 meningiomas and became even stronger with prolonged use.²⁸
20
21

22 118. In October 2024, researchers at the University of Cincinnati published an
23 abstract in the *International Journal of Radiation Oncology Biology Physics* titled
24 “Progesterone Contraception and Tumor-Related Visual Impairment in Premenopausal
25
26

27 ²⁸ Griffin, “The association between medroxyprogesterone acetate exposure and meningioma,”
28 *Cancers*, Vol. 16, No. 3362 (2024).

1 Women with Meningioma Referred for Radiation.” This paper reported on a
2 retrospective case-control study that examined, *inter alia*, the role of hormonal
3 contraception in the development of intracranial meningioma causing visual
4 impairment in women under the age of 55. The authors concluded “progesterone use is
5 a significant risk factor for meningioma-related visual deficits ..., with a
6 disproportionate number on [Depo-] Provera specifically.”²⁹
7
8

9 **D. THE DEFENDANTS’ FAILURE TO TEST DEPO-PROVERA**

10 119. Defendants knew or should have known of the potential impact of the drug
11 to cause the development of intracranial meningioma but failed to adequately study
12 these adverse effects.
13

14 120. Furthermore, despite the fact that studies have emerged over the course of
15 decades providing evidence of the meningioma-related risks and dangers of progesterone
16 and progestins and Depo-Provera specifically, Defendants have failed to adequately
17 investigate the threat that Depo-Provera poses to patients' well-being or warn the medical
18 community and patients of the risk of intracranial meningioma and sequelae related
19 thereto.
20
21

22 **E. THE DEFENDANTS’ CONTINUING FAILURE TO DISCLOSE DEPO-
23 PROVERA’S HEALTH RISKS**
24
25
26

27 ²⁹ Bailey, et al., “Progesterone contraception and tumor-related visual impairment in premenopausal
28 women with meningioma referred for radiation,” *Int’l J of Radiation Oncology Biology Physics*, Vol.
120, No. 2 Supp., pp. E217 (2024).

1 121. According to the Drugs@FDA website, the label for Depo-Provera has
2 been updated on at least thirteen (13) occasions since 2003, with the most recent update
3 coming in July 2024.³⁰ Despite the fact there are at least fourteen (14) iterations of the
4 Depo-Provera label, Defendants’ labels have not contained any warning or any
5 information whatsoever on the increased propensity of Depo-Provera to cause severe
6 and debilitating intracranial meningioma like that suffered by Plaintiff.
7

8
9 122. Despite the aforementioned article in the *BMJ* and all the preceding medical
10 literature cited above demonstrating the biological plausibility of the association
11 between progesterone and meningioma, evidence of Depo-Provera related cases of
12 meningioma and the evidence of other high dose progestones causing meningiomas,
13 Defendants have still made no change to the U.S. Depo-Provera label related to
14 intracranial meningioma. Furthermore, Defendants have failed to take any steps to
15 otherwise warn the medical community and Depo-Provera users of these significant
16 health risks, despite changing the label as recently as July 2024 to include warnings
17 about pregnancy-related risks, and despite Defendant Pfizer stating to The Guardian
18 when the *BMJ* article was released in April 2024: “We are aware of this potential risk
19 associated with long-term use of progestogens and, in collaboration with regulatory
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³⁰ See Drugs@FDA:FDA-Approved Drugs- Depo-Provera,
<https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020246> (last visited Apr. 29, 2024).

1 agencies, are in the process of updating product labels and patient information leaflets
2 with appropriate wording.”³¹

3
4 123. Defendant Pfizer *has* changed the label in the EU and the UK and
5 potentially in other countries. Specifically, Defendants’ Depo-Provera label in the EU
6 now contains the following addition under the section titled “**Special warnings and**
7 **precautions for use**”: “Meningioma: Meningiomas have been reported following long
8 term administration of progestogens, including medroxyprogesterone acetate. Depo-
9 Provera should be discontinued if a meningioma is diagnosed. Caution is advised when
10 recommending Depo-Provera to patients with a history of meningioma.”

11
12
13 124. Additionally, Defendants’ Package Leaflet in the EU which provides
14 information for the patient states that “before using Depo-Provera[,]... it is important to
15 tell your doctor or healthcare professional if you have, or have ever had in the past ... a
16 meningioma (a usually benign tumor that forms in the layers of tissue that cover your
17 brain and spinal cord).”

18
19
20 125. Nothing was or is stopping Defendants from adding similar language to the
21 label and package insert for Depo-Provera in the United States. Defendants could have
22 at any time made “moderate changes” to the label.

23
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26 ³¹ “Hormone medication could increase risk of brain tumours, French study finds,” The Guardian,
27 published online Mar. 27, 2024 (available at
28 <https://www.theguardian.com/society/2024/mar/27/hormone-medication-brain-tumours-risk-progestogens-study>) (last accessed Sept. 12, 2024).

1 126. Specifically, Defendants could have filed a “Changes Being Effectuated”
2 (“CBE”) supplement under Section 314.70(c) of the FDCA to make “moderate changes”
3 to Depo-Provera’s label without any prior FDA approval.
4

5 127. Examples of moderate label changes that can be made via a CBE
6 supplement explicitly include changes “to reflect newly acquired information” in order
7 to “add or strengthen a contraindication, warning, precaution, or adverse reaction.” By
8 definition and by regulation such changes to add a warning based on newly acquired
9 information—such as that imparted by newly emerging literature like the litany of
10 studies cited above—are considered a “moderate change.” § 340.70(c)(6)(iii).
11
12

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

25 129. Defendants could have also instructed physicians to consider its own safer
26 alternative design, a lower dose medroxyprogesterone acetate injected subcutaneously
27
28

1 instead of the more invasive and painful intramuscular injection method. Studies going
2 back at least ten years have shown that the 150 mg dose of Depo-Provera—when
3 administered subcutaneously, instead of intramuscularly—is absorbed by the body at a
4 similarly slower rate as the lower dose 104 mg Depo-SubQ Provera 104 version and
5 never exceeds more than a small fraction of the dangerously high serum levels seen in
6 the first several days with intramuscular administration of 150 mg Depo-Provera.³²
7
8 Nevertheless, Defendants never produced a 150 mg subcutaneous version.
9

10 130. Another study published in *Contraception: X* in 2022 concluded that not
11 only was the lower dose Depo-SubQ Provera 104 just as effective as 150 mg Depo-
12 Provera when administered properly, but it could also be administered every 16 weeks
13 instead of every 12 weeks due to the more gradual uptake of the subcutaneous
14 administration route. That same study found that 150 mg Depo-Provera if injected
15 subcutaneously could remain at efficacious levels in the blood for even longer, up to six
16 (6) months.³³
17
18

19 131. As with subcutaneously administered Depo-SubQ Provera 104, the study
20 authors noted “subcutaneous administration of 150 mg Depo-Provera every 6 months
21 would be a highly effective repurposing ... with a similar reduction in cumulative
22 exposure.” The authors concluded: “The use of an unnecessarily high exposure to limit
23
24

25
26 ³² See Shelton, et al., “Subcutaneous DPMA: a better low dose approach,” *Contraception*, Vol. 89, pp.
27 341-43 (2014).

28 ³³ See Taylor, et al., “Ovulation suppression following subcutaneous administration of depot
medroxyprogesterone acetate,” *Contraception: X*, Vol. 4 (2022).

1 the residual chance of treatment failure would be a disservice to the vast majority of
2 women if a lower exposure can reduce side effects, costs, or otherwise make the product
3 more acceptable.”³⁴
4

5 132. Despite knowing the subcutaneous administration of 150 mg Depo-Provera
6 would have resulted in less risk of dangerous side effects like meningioma while
7 providing the same contraceptive efficacy for twice as long (and therefore would have
8 required only half as many doses of Defendants’ product per year), Defendants failed to
9 produce a 150 mg subcutaneous version.
10

11 133. Knowing that the lower dose 104 mg Depo-SubQ Provera 104 was equally
12 effective and easier to administer since it involved a smaller needle being injected only
13 below the skin and not all the way into the muscle, Defendants could have educated the
14 gynecology community that it already had a safer alternative product to 150 mg Depo-
15 Provera, which was more well known to prescribers and patients.
16
17

18 134. In Europe and other countries outside of the United States, this 104 mg
19 subcutaneous dose has a more accessible trade name, “Sayana Press”, unlike the
20 unwieldy proprietary developmental name of “Depo-SubQ Provera 104”. Sayana Press
21 as sold in Europe may be self-administered by patients, obviating the need for quarterly
22 visits to a medical practitioner.
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28 ³⁴ *Id.*

1 135. When Depo-SubQ Provera 104, under NDA number 21-583, submitted by
2 Defendant Pharmacia & Upjohn, a subsidiary of Defendant Pfizer, was approved by the
3 FDA on February 17, 2004, more than two decades ago, those Defendants submitted a
4 proposed trade name that the FDA did not approve, so instead, the proprietary name
5 Depo-SubQ Provera 104 was deemed to be the brand name.
6

7
8 136. Inexplicably, and presumably for commercially beneficial or contractual
9 reasons, Defendant Pfizer made a conscious decision to not seek an alternative
10 commercially more accessible brand name, and to not endeavor to more vigorously
11 advocate for the sale of Depo-SubQ Provera 104 to patients seeking contraception,
12 despite knowing it had a lower safer and effective dosage which would somewhat
13 mitigate the potential for adverse reactions engendered by a high dose progestin,
14 including the risk of developing or worsening meningioma tumors.
15
16

17 137. The “lowest effective dose” is a well-known concept in the field of
18 pharmaceuticals wherein a drug-maker should seek to find the lowest possible dose at
19 which the drug of interest is efficacious for the intended use, as any additional dosage
20 on top of that lowest effective dose is inherently superfluous and can only increase the
21 risk of unwanted and potentially dangerous side effects while providing no additional
22 efficacy.
23
24

25 138. Either change—adding a warning about the risk of meningioma based on
26 “newly acquired information,” or, advising physicians to consider a switch to
27
28

1 subcutaneous Depo-SubQ Provera 104—either on its own, or taken together, would
2 have constituted a “moderate change” justifying a simple CBE supplement that
3
4 Defendants could have effectuated immediately and simply notified the FDA thereafter.
5 Yet, Defendants have failed to do so, and that failure continues to date.

6 139. Defendants ignored reports from patients and health care providers
7
8 throughout the United States which indicated that Depo-Provera failed to perform as
9 intended. Defendants also knew or should have known of the effects associated with
10 long term use of Depo-Provera, which led to the severe and debilitating injuries
11 suffered by Plaintiff and numerous other patients. Rather than conducting adequate
12 testing to determine the cause of these injuries for which it had notice or rule out
13 Depo-Provera’s design as the cause of the injuries, Defendants continued to falsely
14 and misleadingly market Depo-Provera as a safe and effective prescription drug for
15 contraception and other indications.
16
17

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

22 141. Plaintiff and Plaintiff’s physicians foreseeably used Depo-Provera, and
23 did not misuse or alter Depo-Provera in an unforeseeable manner.
24
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1 142. Through its affirmative misrepresentations and omissions, Defendants
2 actively concealed from Plaintiff and Plaintiff's physicians the true and significant
3 risks associated with Depo-Provera use.
4

5 143. As a result of Defendants' actions, Plaintiff and Plaintiff's physicians
6 were unaware, and could not have reasonably known or have learned through
7 reasonable diligence, that Plaintiff would be exposed to the risks identified in this
8 Complaint and that those risks were the direct and proximate result of Defendants'
9 conduct.
10

11 144. As a direct result of being prescribed and consuming Depo-Provera,
12 Plaintiff has been permanently and severely injured, having suffered serious
13 consequences.
14

15 145. As a direct and proximate result of her Depo-Provera use, Plaintiff has
16 suffered severe mental and physical pain and suffering and have sustained permanent
17 injuries and emotional distress, along with economic loss including past and future
18 medical expenses.
19

20 146. Despite diligent investigation by Plaintiff into the cause of these injuries,
21 including consultations with medical providers, the nature of Plaintiff' injuries and
22 damages and their relationship to Depo-Provera was not discovered, and through
23 reasonable care and diligence could not have been discovered, until a date within the
24 applicable statute of limitations for filing Plaintiff' claims.
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1 **F. LIABILITY OF PFIZER, GREENSTONE, VIATRIS, AND PRASCO**
2 **FOR THE “AUTHORIZED GENERICS”**

3 147. Defendants Greenstone, Viatris and Prasco were at different times from
4 2004 until the present the authorized generic “manufacturer” and distributor operating
5 under the same NDA of Depo-Provera, with the express permission of Pfizer, to make,
6 label, distribute, sell, and market Depo-Provera without the brand name on its label,
7 even though it is the exact same drug product as the branded Depo-Provera
8 manufactured in some or all instances by Pfizer.
9

10
11 148. Accordingly, the authorized generic distributors Greenstone, Viatris, and
12 Prasco operated as if they were the brand name holder under the same NDA and could
13 have changed the brand name label to warn of the risks of meningioma and the use of
14 high dose progestins.
15

16 149. Further, the “authorized generics” distributors Greenstone, Viatris, and
17 Prasco could have requested that Pfizer, with whom they were under contract to sell the
18 “authorized generic”, to change the brand name label to warn of the risks of meningioma
19 and the use of high dose progestins.
20

21 150. Pfizer had a duty to change the label knowing that its “authorized generic”
22 distributors Greenstone, Viatris, and Prasco with whom they were in contract and
23 receiving revenue from the sale of the “authorized generic” DMPA, were selling the
24 “authorized generic” without warning of meningioma risk.
25
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1 151. Pfizer knew that its authorized generic manufacturers/distributors held a
2 large market share of its manufactured Depo-Provera under a different name.

3
4 152. Pfizer was at some or all of the pertinent times the actual manufacturer of
5 the DMPA, identical to Depo-Provera other than its name, which was sold by
6 Defendants Greenstone, Viatrix. And Prasco who were at different times the “authorized
7 generic” distributor, with the express permission of Pfizer, to distribute, sell, and market
8 Depo-Provera without the brand name on its label.
9

10 **G. INNOVATOR LIABILITY UNDER CALIFORNIA LAW**

11 153. In October of 2002, Defendant Pfizer's patent for Depo-Provera expired.
12 Following this, the FDA approved various generic versions of Depo-Provera for sale in
13 the United States. Despite the availability of generics, Pfizer has continued to
14 manufacture, market, and distribute the brand-name Depo-Provera across the United
15 States, including in California.
16
17

18 154. A manufacturer wishing to market a generic version of an FDA-approved
19 drug can submit an Abbreviated New Drug Application (ANDA). This allows the
20 generic manufacturer to rely on the NDA filed by the brand-name manufacturer by
21 demonstrating that the generic version contains the same active ingredients and is
22 biologically equivalent to the brand-name drug.³⁵
23
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28 ³⁵ See 21 U.S.C. § 355(j)(2)(A)(ii), (iv).

1 155. As part of the NDA, the brand-name manufacturer must propose the exact
2 text of the label, subject to FDA approval.³⁶ For generics, the ANDA process mandates
3 that the safety and efficacy labeling must be identical to that of the brand-name drug.³⁷
4

5 156. While the brand-name manufacturer bears responsibility for the accuracy
6 and adequacy of the drug label, generic manufacturers are only required to ensure that
7 their labels mirror the brand-name version.³⁸ The California Supreme Court has
8 reasoned that because a brand-name manufacturer is responsible for the content of a
9 drug's warning label, it “knows to a legal certainty ... that any deficiencies in the label
10 for its drug will be perpetrated in the label for its generic bioequivalent.”³⁹ As a result,
11 the content of the generic labels for Depo-Provera bioequivalents is entirely dictated by
12 the brand-name manufacturer Defendant Pfizer’s label. Thus, California law liability
13 for failure to warn can extend to Defendant Pfizer, even when the consumer is
14 prescribed only the generic version.
15
16
17

18 157. Because generic manufacturers must replicate the brand-name label
19 exactly, Defendant Pfizer exerted exclusive control over the contents of the labels used
20 by generic versions of Depo-Provera that Plaintiff may have been prescribed and
21 administered. Consequently, any deficiencies or omissions in Defendant Pfizer’s label
22 would have been reflected in the generic labels.
23
24

25
26 ³⁶ See 21 U.S.C. § 355; see also 21 C.F.R. § 314.105(b).

27 ³⁷ See 21 U.S.C.A. § 355(j); see also *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612-13 (2011).

28 ³⁸ See generally 21 U.S.C. § 355; see also 21 C.F.R. § 314.105(b).

³⁹ *T.H. v. Novartis Pharm. Corp.*, 4 Cal. 5th 145, at 166 (2017).

1 158. As the brand-name manufacturer of Depo-Provera, Defendant Pfizer had
2 and continues to have a duty to ensure that the labeling for Depo-Provera remains
3 accurate and adequate “as soon as there is reasonable evidence of an association of a
4 serious hazard with a drug,” regardless of whether a causal relationship has been
5 established.⁴⁰ Defendant Pfizer was not only in the best position to provide warnings
6 regarding Depo-Provera's risks but was also the only entity legally authorized to update
7 the label unilaterally under federal law.
8

9
10 159. Defendant Pfizer knew or should have known that any failure to adequately
11 warn of Depo-Provera’s risks would be replicated in the labels of its generic
12 bioequivalents, directly affecting the information available to physicians and patients
13 regarding both the brand-name and generic drugs. Accordingly, it is foreseeable that the
14 warnings included or omitted on the brand-name drug label would influence dispensing
15 of the generic drug and the decision-making of unsuspecting doctors and patients, like
16 Plaintiff and Plaintiff’s physicians, as to whether to take a generic equivalent of Depo-
17 Provera and/or brand-named Depo-Provera for contraception.
18
19
20

21 160. As the brand-name manufacturer of Depo-Provera, Defendant Pfizer could
22 have, at any time, unilaterally updated the Depo-Provera label without waiting for FDA
23 preapproval in order to “add or strengthen a contraindication, warning, precaution, or
24 adverse reaction” under the CBE regulation.⁴¹ As the brand name manufacturer of
25
26

27 ⁴⁰ See 21 C.F.R. § 201.80(e).

28 ⁴¹ See 21 C.F.R. § 314.70(c)(6)(iii)(A).

1 Depo-Provera, Defendant Pfizer had a duty to give information about Depo-Provera to
2 the medical community and public at large.

3
4 161. Despite having the ability and obligation to provide timely and adequate
5 warnings, Defendant Pfizer failed to take such action, contributing to the harm suffered
6 by Plaintiff.

7
8 162. Thus, to the extent that any doses of Depo-Provera administered to
9 Plaintiff were generic, Defendant Pfizer is additionally liable for any resultant harm to
10 Plaintiff from those generic doses under California's well-established doctrine of
11 innovator liability.
12

13 **H. EQUITABLE TOLLING OF STATUTE OF LIMITATIONS**

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

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

25 165. Defendants willfully, wantonly, and intentionally conspired, and acted in
26 concert, to withhold instructions from the Plaintiff, her family members, and the general
27
28

1 public concerning how to identify, mitigate, and/or treat known hazards associated with
2 the use of, and exposure to, Depo-Provera, particularly over extended periods of time.
3

4 166. The aforementioned studies reveal that discontinuing use of high dose
5 progesterone and progestin, including Depo-Provera, can retard the growth of
6 meningiomas, but failed to warn the medical community and the Plaintiff of this method
7 to mitigate the damage of a developing meningioma.
8

9 167. Defendants willfully, wantonly, and intentionally conspired, and acted in
10 concert, to ignore relevant safety concerns and to deliberately not study the long-term
11 safety and efficacy of Depo-Provera, particularly in chronic long-term users of Depo-
12 Provera.
13

14 168. Defendants failed to disclose a known defect and, instead, affirmatively
15 misrepresented that Depo-Provera was safe for its intended use. Defendants
16 disseminated labeling, marketing, promotion and/or sales information to Plaintiff,
17 Plaintiff's healthcare providers, and the general public regarding the safety of Depo-
18 Provera knowing such information was false, misleading, and/or inadequate to warn of
19 the safety risks associated with long-term Depo-Provera use. Defendants did so
20 willfully, wantonly, and with the intent to prevent the dissemination of information
21 known to them concerning Depo-Provera's safety.
22
23
24

25 169. Further, Defendants actively concealed the true risks associated with the
26 use of Depo-Provera, particularly as they relate to the risk of serious intracranial
27
28

1 meningioma, by affirmatively representing in numerous communications, which were
2 disseminated to Plaintiff, Plaintiff's healthcare providers, and which included, without
3 limitation, the Package Insert and the Medication Guide, that there were no warnings
4 required to safely prescribe and take Depo-Provera and no intracranial meningioma-
5 related adverse side effects associated with use of Depo-Provera.
6

7
8 170. Due to the absence of any warning by the Defendants as to the significant
9 health and safety risks posed by Depo-Provera, Plaintiff was unaware that Depo-
10 Provera could cause the development of a serious and debilitating intracranial
11 meningioma, as this danger was not known to Plaintiff, Plaintiff's healthcare providers,
12 or the general public.
13

14
15 171. Due to the absence of any instructions for how to identify and/or monitor
16 Depo-Provera patients for potential intracranial meningioma-related complications,
17 Plaintiff was unaware that Depo-Provera could cause serious, intracranial meningioma-
18 related injuries, as this danger was not known to Plaintiff, Plaintiff's healthcare
19 providers, or the general public.
20

21
22 172. Given Defendants' conduct and deliberate actions designed to deceive
23 Plaintiff, Plaintiff's healthcare providers, and the general public, with respect to the
24 safety and efficacy of Depo-Provera, Defendants are estopped from relying on any
25 statute of limitations defenses.
26

27 **I. CONDUCT WARRANTING PUNITIVE DAMAGES**
28

1 173. For the reasons set forth above and addressed below, Defendant Pfizer
2 acted with a conscious disregard of the safety of Plaintiff and all the other women, many
3 who were young and of lower socioeconomic status, who were subjected to high dose
4 injections of 150 mg Depo-Provera with the known and/or knowable risk of
5 meningioma brain tumors which was generally accepted in the scientific community,
6 while Defendant Pfizer had available its very own safer alternative medication, Depo-
7 SubQ Provera 104. Exemplary damages are warranted to punish and deter Defendant
8 Pfizer and others from such conduct in the future.
9
10

11
12 **VI. CAUSES OF ACTION**

13 **FIRST CAUSE OF ACTION**

14 **STRICT LIABILITY – FAILURE TO WARN**

15
16 174. Plaintiff incorporates by reference each and every preceding paragraph as
17 though fully set forth herein.

18
19 175. At all times material herein, Defendants engaged in the business of
20 researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting,
21 handling, storing, distributing, and/or promoting Depo-Provera and placed Depo-Provera
22 into the stream of commerce in a defective and unreasonably dangerous condition. These
23 actions were under the ultimate control and supervision of Defendants.
24

25 176. Defendants, as manufacturers, distributors, and marketers of
26 pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and
27
28

1 further, Defendants knew or should have known based on information that was available
2 and generally accepted in the scientific community that warnings and other clinically
3 relevant information and data which they distributed regarding the risks associated with
4 the use of Depo-Provera were inadequate.
5

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

10 178. Defendants had and continue to have a duty to provide adequate warnings
11 and instructions for Depo-Provera, to use reasonable care to design a product that is not
12 unreasonably dangerous to users, and to adequately understand, test, and monitor their
13 product.
14

15 179. Defendants had and continue to have a duty to provide consumers,
16 including Plaintiff and Plaintiff's physicians, with warnings and other clinically relevant
17 information and data generally accepted within the scientific community regarding the
18 risks and dangers associated with Depo-Provera, as it became or could have become
19 available to Defendants.
20

21 180. Defendants marketed, promoted, distributed and sold an unreasonably
22 dangerous and defective prescription drug, Depo-Provera, to health care providers
23 empowered to prescribe and dispense Depo-Provera, to consumers, including Plaintiff,
24 without adequate warnings and other clinically relevant information and data regarding
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1 the risk of meningioma and the risks of unnecessarily excessive progestin exposure
2 which was available and generally accepted within the scientific community. Through
3 both omission and affirmative misstatements, Defendants misled the medical
4 community about the risk and benefit balance of Depo-Provera, which resulted in injury
5 to Plaintiff.
6

7
8 181. Defendants knew or should have known through testing, scientific
9 knowledge, advances in the field, published research in major peer-reviewed journals,
10 or otherwise, that Depo-Provera created a risk of developing serious and debilitating
11 intracranial meningioma. At all relevant times this information was readily available
12 and generally accepted within the scientific community.
13

14
15 182. Despite the fact that Defendants knew or should have known based on
16 information generally accepted within the scientific community that Depo-Provera with
17 its higher than needed progestin dosage caused unreasonable and dangerous side effects,
18 they continue to promote and market Depo-Provera without providing adequate
19 clinically relevant information and data or recommending patients be monitored.
20

21
22 183. Defendants knew that a safer alternative design and product existed,
23 including its own Depo-SubQ Provera 104 which contained substantially less progestin
24 but was equally effective in preventing pregnancy, but failed to warn the medical
25 community and the patients about the risks of the high dose which could be somewhat
26 mitigated by using the lower dose formulation, Depo-SubQ Provera 104.
27
28

1 184. Defendants knew or should have known that consumers, and Plaintiff,
2 specifically, would foreseeably and needlessly suffer injury as a result of Defendants’
3 failures.
4

5 185. The Depo-Provera supplied to Plaintiff by Defendants was defective,
6 unreasonably dangerous, and had inadequate warnings or instructions at the time it was
7 sold, and Defendants also acquired additional knowledge and information confirming
8 the defective and unreasonably dangerous nature of Depo-Provera. Despite this
9 knowledge and information, Defendants failed and neglected to issue adequate
10 warnings that Depo-Provera causes serious and potentially debilitating intracranial
11 meningioma and/or instructions concerning the need for monitoring and potential
12 discontinuation of use of Depo-Provera.
13
14

15 186. Defendants’ failure to provide adequate warnings or instructions rendered
16 Depo-Provera unreasonably dangerous in that it failed to perform as safely as an
17 ordinary patient, prescriber, and/or other consumer would expect when used as intended
18 and/or in a manner reasonably foreseeable by the Defendants, and in that the risk of
19 danger outweighs the benefits.
20
21

22 187. Defendants failed to provide timely and adequate warnings to physicians,
23 pharmacies, and consumers, including Plaintiff and Plaintiff’s intermediary physicians.
24

25 188. Plaintiff’s various prescribing physicians, nurse practitioners, physician
26 assistants, and nurses (hereinafter collectively referred to as “Plaintiff’s Prescribing and
27
28

1 Administering Health Care Providers”) would not have prescribed and administered
2 Depo-Provera to Plaintiff had they been apprised by Defendants of the unreasonably
3 high risk of meningioma associated with usage of Depo-Provera.
4

5 189. Alternatively, even if Defendants had apprised Plaintiff’s Prescribing and
6 Administering Health Care Providers of the unreasonably high risk of meningioma
7 associated with usage of Depo-Provera and these Prescribing and Administering Health
8 Care Providers had still recommended usage of Depo-Provera to Plaintiff, the
9 Prescribing and Administering Health Care Providers would have relayed the
10 information concerning the risk of meningioma to Plaintiff, and the alternative
11 treatment of the lower dose subcutaneous Depo-SubQ Provera 104, and Plaintiff as an
12 objectively prudent person would not have chosen to take Depo-Provera, and/or would
13 have opted to take safer and lower dose Depo-SubQ Provera 104, notwithstanding
14 Plaintiff’s Prescribing Physician and Administering Health Care Providers’ continued
15 recommendation.
16
17
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19

20 190. Similarly, if Defendants had warned of the unreasonably high risk of
21 meningioma
22 associated with the usage of Depo-Provera, and the availability of the safer and equally
23 effective lower dose Depo-SubQ Provera 104 in the Patient Information handout,
24 Plaintiff as an objectively prudent person would not have chosen to take Depo-Provera,
25 and/or would have opted to take the safer, lower, and equally effective dose of Depo-
26
27
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1 SubQ Provera 104, notwithstanding Plaintiff's Prescribing and Administering Health
2 Care Providers' recommendation.

3
4 191. Defendants failed to include adequate warnings and/or provide adequate
5 clinically relevant information and data that would alert Plaintiff and Plaintiff's
6 Prescribing and Administering Health Care Providers of the dangerous risks of Depo-
7 Provera including, among other things, the development of intracranial meningioma.

8
9 192. Defendants failed to provide adequate post-marketing warnings and
10 instructions after Defendants knew or should have known of the significant risks of,
11 among other things, intracranial meningioma.

12
13 193. Defendants continued to aggressively promote and sell Depo-Provera,
14 even after they knew or should have known of the unreasonable risks of intracranial
15 meningioma caused by the drug.

16
17 194. Defendants had an obligation to provide Plaintiff and Plaintiff's
18 Prescribing and Administering Health Care Providers with adequate clinically relevant
19 information and data and warnings regarding the adverse health risks associated with
20 exposure to Depo-Provera, and/or that there existed safer and more or equally effective
21 alternative drug products.

22
23
24 195. By failing to adequately test and research harms associated with Depo-
25 Provera, and by failing to provide appropriate warnings and instructions about Depo-
26 Provera use, patients and the medical community, including prescribing doctors, were
27

1 inadequately informed about the true risk-benefit profile of Depo-Provera and were not
2 sufficiently aware that serious and potentially debilitating intracranial meningioma
3 might be associated with use of Depo-Provera. Nor were the medical community,
4 patients, patients' families, or regulators appropriately informed that serious and
5 potentially debilitating intracranial meningioma might be a side effect of Depo-Provera
6 and should or could be reported as an adverse event.
7
8

9 196. The Depo-Provera products designed, researched, manufactured, tested,
10 advertised, promoted, marketed, sold and distributed by Defendants were defective due
11 to inadequate post-marketing surveillance and/or warnings because, even after
12 Defendants knew or should have known of the risks of severe and permanent
13 intracranial meningioma-related injuries from ingesting Depo-Provera, Defendants
14 failed to provide adequate warnings to users or consumers of the products, and
15 continued to improperly advertise, market and/or promote Depo-Provera.
16
17

18 197. Depo-Provera is defective and unreasonably dangerous to Plaintiff and
19 other consumers regardless of whether Defendants had exercised all possible care in its
20 preparation and sale.
21

22 198. The foreseeable risk of serious and potentially debilitating intracranial
23 meningioma caused by Depo-Provera could have been reduced or avoided by Plaintiff,
24 prescribers, and/or other consumers had Defendants provided reasonable instructions or
25 warnings of these foreseeable risks of harm.
26
27
28

1 199. As a direct and proximate result of Defendants' conduct, including the
2 inadequate warnings, dilution or lack of information, lack of adequate testing and
3 research, and the defective and dangerous nature of Depo-Provera, Plaintiff suffered
4 bodily injuries and resulting pain and suffering, disability, mental anguish, loss of
5 capacity for the enjoyment of life, expense of medical and nursing care and treatment,
6 loss of earnings, loss of ability to earn money and other economic losses, and
7 aggravation of previously existing conditions. The losses are either permanent or
8 continuing, and Plaintiff will suffer the losses in the future.
9
10

11
12 **SECOND CAUSE OF ACTION**

13 **STRICT LIABILITY – DESIGN DEFECT**

14 200. Plaintiff incorporates by reference each and every preceding paragraph as
15 though fully set forth herein.
16

17 201. At all times material herein, Defendants engaged in the business of
18 researching, testing, developing, manufacturing, labeling, marketing, selling,
19 inspecting, handling, storing, distributing, and/or promoting Depo-Provera and placed
20 Depo-Provera into the stream of commerce in a defective and unreasonably dangerous
21 condition. These actions were under the ultimate control and supervision of Defendants.
22
23

24 202. Defendants, as manufacturers, designers, distributors, and marketers of
25 pharmaceutical drugs, had a duty to design a product free from a defective condition
26 that was unreasonably dangerous to Plaintiff.
27
28

1 203. Depo-Provera was designed in such a way, using such a high dose of
2 progesterone not necessary for effective contraception, that it posed an unreasonable
3 risk of intracranial meningioma and by placing and keeping Depo-Provera on the
4 market despite Depo-Provera being in a defective condition.
5

6 204. Depo-SubQ Provera 104 is a lower dosage version of Depo-Provera that
7 contains 104 mg / 0.65mL and is injected subcutaneously every three (3) months.
8 According to the label, Depo-SubQ Provera 104 can be used for both contraception and
9 treatment of endometriosis.
10

11 205. Depo-SubQ Provera 104 never attained meaningful market share, and
12 Defendant failed to promote the product to the medical community as a safer and
13 equally effective method of contraception for women choosing to receive quarterly
14 injections.
15
16

17 206. Defendant failed to promote and encourage conversion of the prescribing
18 gynecological community to Depo-SubQ Provera 104, fearing that doing so could instill
19 a concern of safety as to the risks of its high dose progesterone long standing product,
20 Depo-Provera.
21

22 207. It has long been a tenet in the medical and toxicological community that
23 the “dose makes the poison.” Defendants had a viable safer and lower dose alternative
24 in Depo-SubQ Provera 104 but failed to warn the medical community prescribing and
25 administering Depo-Provera that Depo-SubQ Provera 104 was a safer alternative.
26
27
28

1 208. Moreover, the 150 mg Depo-Provera itself could have been a viable lower
2 effective dose if it had simply been designed, approved, and sold to be administered
3 subcutaneously, like Depo-SubQ Provera 104 is administered, instead of
4 intramuscularly.
5

6 209. Injections given intramuscularly are well-known to be absorbed by the
7 body and taken up in the blood serum at much faster rates than injections given
8 subcutaneously because of the much higher vascularization of deep muscle tissue
9 compared to the dermis.
10

11 210. Studies have shown that 150 mg Depo-Provera administered
12 intramuscularly causes a spike in blood serum levels of DMPA that is more than four
13 (4) times higher than the peak blood serum concentration of DMPA when that same 150
14 mg Depo-Provera shot is given subcutaneously, and that very high intramuscular peak
15 concentration persists for several days.⁴² In fact, 150 mg Depo-Provera administered
16 subcutaneously has a remarkably similar pharmacokinetic profile to Depo-SubQ
17 Provera 104.⁴³
18
19

20
21 211. Thus, there are two lower effective doses of Depo-Provera—both Depo-
22 SubQ Provera 104, *and* the very same 150 mg Depo-Provera simply given
23 subcutaneously instead of intramuscularly.
24

25
26
27 ⁴² See Shelton, et al., “Subcutaneous DPMA: a better low dose approach,” *Contraception*, Vol. 89, pp.
341-43 (2014).

28 ⁴³ See *id.* at 342.

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

9
10 213. Defendants knew or should have known that the Depo-Provera they
11 developed, manufactured, labeled, marketed, sold, and/or promoted was defectively
12 designed in that it posed a serious risk of severe and permanent intracranial-meningioma-
13 related injuries when injected intramuscularly.
14

15
16 214. Defendants have a continuing duty to design a product that is not
17 unreasonably dangerous to users and to adequately understand, test, and monitor their
18 product.
19

20 215. Defendants sold, marketed and distributed a product that is unreasonably
21 dangerous for its normal, intended, and foreseeable use.
22

23 216. Defendants designed, researched, manufactured, tested, advertised,
24 promoted, marketed, sold and distributed Depo-Provera, a defective product which
25 created an unreasonable risk to the health of consumers, and Defendants are therefore
26 strictly liable for the injuries sustained by Plaintiff.
27
28

1 217. The Depo-Provera supplied to Plaintiff by Defendants was defective in
2 design or formulation in that, when it left the hands of the manufacturer or supplier, it
3 was in an unreasonably dangerous and a defective condition because it failed to perform
4 as safely as an ordinary consumer would expect when used as intended or in a manner
5 reasonably foreseeable to Defendants, posing a risk of serious and potentially
6 debilitating intracranial meningioma to Plaintiff and other consumers.
7
8

9 218. The Depo-Provera ingested by Plaintiff was expected to, and did, reach
10 Plaintiff without substantial change in the condition in which it is sold.
11

12 219. The Depo-Provera ingested by Plaintiff was in a condition not
13 contemplated by the Plaintiff in that it was unreasonably dangerous, posing a serious
14 risk of permanent vision and retinal injuries.
15

16 220. Depo-Provera is a medication prescribed for contraception and treatment
17 of endometriosis, among other uses. Depo-Provera in fact causes serious and potentially
18 debilitating intracranial meningioma, a brain tumor that can cause severe damage and
19 require invasive surgical removal, harming Plaintiff and other consumers.
20

21 221. Plaintiff, ordinary consumers, and prescribers would not expect a
22 contraceptive drug designed, marketed, and labeled for contraception to cause
23 intracranial meningioma.
24

25 222. The Depo-Provera supplied to Plaintiff by Defendants was defective in
26 design or formulation in that, when it left the hands of the manufacturer or supplier, it
27
28

1 had not been adequately tested, was in an unreasonably dangerous and defective
2 condition, provided an excessive dose of progestin for its purpose and posed a risk of
3 serious and potentially debilitating intracranial meningioma to Plaintiff and other
4 consumers.
5

6 223. The Depo-Provera supplied to Plaintiff by Defendants was defective in
7 design or formulation in that its effectiveness as a contraceptive did not outweigh the
8 risks of serious and potentially debilitating intracranial meningioma posed by the drug.
9 In light of the utility of the drug and the risk involved in its use, the design of the Depo-
10 Provera drug makes the product unreasonably dangerous.
11

12 224. Depo-Provera's design is more dangerous than a reasonably prudent
13 consumer would expect when used in its intended or reasonably foreseeable manner. It
14 was more dangerous than Plaintiff expected.
15

16 225. The intended or actual utility of Depo-Provera is not of such benefits to
17 justify the risk of intracranial meningioma which may cause severe and permanent
18 injuries, thereby rendering the product unreasonably dangerous.
19

20 226. The design defects render Depo-Provera more dangerous than other drugs
21 and therapies designed for contraception and causes an unreasonable increased risk of
22 injury, including, but not limited, to potentially debilitating intracranial meningioma
23 and sequelae related thereto.
24
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1 227. Defendants knew or should have known through testing, generally accepted
2 scientific knowledge, advances in the field, published research in major peer-reviewed
3 journals, or other means, that Depo-Provera created a risk of serious and potentially
4 debilitating intracranial meningioma and sequelae related thereto.
5

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

15 229. Defendants knew or should have known that consumers, Plaintiff
16 specifically, would foreseeably and needlessly suffer injury as a result of Depo-Provera's
17 defective design.
18

19 230. Depo-Provera is defective and unreasonably dangerous to Plaintiff and
20 other consumers even if Defendants had exercised all possible care in the preparation
21 and sale of Depo-Provera.
22

23 231. As a direct and proximate result of Defendants' conduct and defective
24 design, including inadequate testing and research, and the defective and dangerous
25 nature of Depo-Provera, Plaintiff suffered bodily injuries that resulted in pain and
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1 suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense
2 of medical and nursing care and treatment, loss of earnings, loss of ability to earn
3 money, and other economic losses. The losses are either permanent or continuing, and
4 Plaintiff will suffer losses in the future.
5

6
7 **THIRD CAUSE OF ACTION**

8 **NEGLIGENCE**

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

12 233. At all times relevant herein, it was the duty of Defendants to use
13 reasonable care in the design, labeling, manufacturing, testing, marketing, distribution
14 and/or sale of Depo-Provera.
15

16 234. Defendants failed to exercise ordinary care in the labeling, design,
17 manufacturing, testing, marketing, distribution and/or sale of Depo-Provera in that
18 Defendants knew or should have known that Depo-Provera created a high risk of
19 unreasonable harm to Plaintiff and other users.
20

21 235. Defendants breached its duty of care to the Plaintiff and her physicians, in
22 the testing, monitoring, and pharmacovigilance of Depo-Provera.
23

24 236. In disregard of its duty, Defendants committed one or more of the
25 following negligent acts or omissions:
26
27
28

- 1 a. Manufacturing, producing, promoting, formulating, creating,
2 developing, designing, selling, and distributing Depo-Provera
3 without thorough and adequate pre- and post-market testing of
4 the product;
5
6 b. Manufacturing, producing, promoting, advertising, formulating,
7 creating, developing, and designing, and distributing Depo-
8 Provera while negligently and intentionally concealing and
9 failing to disclose clinical data which demonstrated the risk of
10 serious harm associated with the use of Depo-Provera;
11
12 c. Failing to undertake sufficient studies and conduct necessary
13 tests to determine whether or not Depo-Provera was safe for its
14 intended use;
15
16 d. Failing to disclose and warn of the product defect to the
17 regulatory agencies, the medical community, and consumers that
18 Defendants knew and had reason to know that Depo-Provera was
19 indeed unreasonably unsafe and unfit for use by reason of the
20 product's defect and risk of harm to its users;
21
22 e. Failing to warn Plaintiff, the medical and healthcare community,
23 and consumers of the known and knowable product's risk of
24 harm which was unreasonable and that there were safer and
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effective alternative products available to Plaintiff and other consumers;

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

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

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

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

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

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

4
5 l. Failing to ensure the product was accompanied by proper and
6 accurate warnings about monitoring for potential symptoms
7 related to intracranial meningioma associated with the use of
8 Depo-Provera;

9
10 m. Failing to ensure the product was accompanied by proper and
11 accurate warnings about known and knowable adverse side
12 effects associated with the use of Depo-Provera and that use of
13 Depo-Provera created a high risk of severe injuries; and

14
15 n. Failing to conduct adequate testing, including pre-clinical and
16 clinical testing, and post-marketing surveillance to determine the
17 safety of Depo-Provera.

18
19 o. Failing to sell a product with the lowest effective dose knowing
20 that there were safer lower effective dose formulations.

21
22 237. A reasonable manufacturer, designer, distributor, promoter, or seller under
23 the same or similar circumstances would not have engaged in the aforementioned acts
24 and omissions.
25
26
27
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1 238. As a direct and proximate result of the Defendants' negligent testing,
2 monitoring, and pharmacovigilance of Depo-Provera, Defendants introduced a product
3 that they knew or should have known would cause serious and permanent injuries
4 related to the development of intracranial meningioma, and Plaintiff has been injured
5 tragically and sustained severe and permanent pain, suffering, disability, and
6 impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.
7

8
9 239. As a direct and proximate result of one or more of the above-stated
10 negligent acts by Defendants, Plaintiff suffered bodily injuries and resulting pain and
11 suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense
12 of medical and nursing care and treatment, loss of earnings, loss of ability to earn money
13 and other economic losses. The losses are either permanent or continuing, and Plaintiff
14 will suffer losses in the future.
15
16

17 **FOURTH CAUSE OF ACTION**

18 **NEGLIGENT FAILURE TO WARN**

19
20 240. Plaintiff incorporates by reference each and every preceding paragraph as
21 though fully set forth herein.
22

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

3
4 242. Defendants' duty of care was that a reasonably careful designer,
5 manufacturer, seller, importer, distributor and/or supplier would use under like
6 circumstances.

7
8 243. Defendants had a duty to warn Plaintiff, Plaintiff's physicians, and
9 consumers of Depo-Provera's known and knowable dangers and serious side effects,
10 including serious and potentially debilitating intracranial meningioma, as it was
11 reasonably foreseeable to Defendants that Depo-Provera could cause such injuries.

12
13 244. At all times material herein, Defendants failed to exercise reasonable care
14 and knew, or in the exercise of reasonable care should have known, that Depo-Provera
15 had inadequate instructions and/or warnings.

16
17 245. Each of the following acts and omissions herein alleged was negligently
18 and carelessly performed by Defendants, resulting in a breach of the duties set forth
19 above. These acts and omissions include, but are not restricted to:

- 20
21 p. Failing to accompany their product with proper and adequate
22 warnings, labeling, or instructions concerning the potentially
23 dangerous, defective, unsafe, and deleterious propensity of
24 Depo-Provera and of the risks associated with its use, including
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- the severity and potentially irreversible nature of such adverse effects;
- q. Disseminating information to Plaintiff and Plaintiff's physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff;
 - r. Failing to provide warnings or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks;
 - s. 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;
 - t. Failure to adequately warn of the risks that Depo-Provera could cause the development of intracranial meningioma and sequelae related thereto;
 - u. Failure to adequately warn of the risk of serious and potentially irreversible injuries related to the development of intracranial meningioma, a brain tumor;
 - v. Failure to instruct patients, prescribers, and consumers of the need for al monitoring when taking Depo-Provera for symptoms

1 potentially related to the development of intracranial
2 meningioma;

3
4 w. Failure to instruct patients, prescribers, and consumers of the
5 need to discontinue Depo-Provera in the event of symptoms
6 potentially related to the development of intracranial
7 meningioma;

8
9 x. Failing to provide instructions on ways to safely use Depo-
10 Provera to avoid injury, if any;

11
12 y. Failing to explain the mechanism, mode, and types of adverse
13 events associated with Depo-Provera;

14
15 z. Failing to provide adequate training or information to medical
16 care providers for appropriate use of Depo-Provera and patients
17 taking Depo-Provera; and

18
19 aa. Representing to physicians, including but not limited to
20 Plaintiff's prescribing physicians, that this drug was safe and
21 effective for use.

22
23 bb. Failing to warn that there is a safer feasible alternative with a
24 lower effective dose of progestin.

25
26 cc. Failing to warn that the 150 mg dosage of progestin injected
27 intramuscularly was an excessive and thus toxic dose capable of
28

1 causing and or substantially contributing to the development and
2 growth of meningioma tumors.

3
4 246. Defendants knew or should have known of the risk and danger of serious
5 bodily harm from the use of Depo-Provera but failed to provide an adequate warning to
6 patients and prescribing physicians for the product, including Plaintiff and Plaintiff's
7 prescribing physicians, despite knowing the product could cause serious injury.
8

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

10 248. Plaintiff could not have known about the dangers and hazards presented
11 by Depo-Provera.
12

13 249. The warnings given by Defendants were not accurate, clear, or complete
14 and/or were ambiguous.
15

16 250. The warnings, or lack thereof, that were given by Defendants failed to
17 properly warn prescribing physicians, including Plaintiff's prescribing physician, of the
18 known and knowable risk of serious and potentially irreversible injuries related to the
19 development of intracranial meningioma, and failed to instruct prescribing physicians
20 to test and monitor for the presence of the injuries and to discontinue use when
21 symptoms of meningioma manifest.
22

23
24 251. The warnings that were given by the Defendants failed to properly warn
25 Plaintiff and prescribing physicians of the prevalence of intracranial meningioma and
26 sequelae related thereto.
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1 252. Plaintiff and Plaintiff's prescribing physicians reasonably relied upon the
 2 skill, superior knowledge, and judgment of Defendants. Defendants had a continuing
 3 duty to warn Plaintiff and prescribing physicians of the dangers associated with Depo-
 4 Provera. Had Plaintiff received adequate warnings regarding the risks of Depo-Provera,
 5 Plaintiff would not have used the product.
 6

7
 8 253. Defendants' failure to exercise reasonable care in the dosing information,
 9 marketing, testing, and warnings of Depo-Provera was a proximate cause of Plaintiff's
 10 injuries and damages.
 11

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

20 **FIFTH CAUSE OF ACTION**
 21 **NEGLIGENT DESIGN DEFECT**
 22

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

25 256. At all times material herein, Defendants had a duty to exercise reasonable
 26 care and had the duty of an expert in all aspects of the design, formulation, manufacture,
 27
 28

1 compounding, testing, inspection, packaging, labeling, distribution, marketing,
2 promotion, advertising, sale, testing, and research to assure the safety of Depo-Provera
3 when used as intended or in a way that Defendants could reasonably have anticipated,
4 and to assure that the consuming public, including Plaintiff and Plaintiff's physicians,
5 obtained accurate information and adequate instructions for the safe use or non-use of
6 Depo-Provera.
7
8

9 257. At all times material herein, Defendants failed to exercise reasonable care
10 and the duty of an expert and knew, or in the exercise of reasonable care should have
11 known, that Depo-Provera was not properly manufactured, designed, compounded,
12 tested, inspected, packaged, distributed, marketed, advertised, formulated, promoted,
13 examined, maintained, sold, prepared, or a combination of these acts.
14
15

16 258. Each of the following acts and omissions herein alleged was negligently
17 and carelessly performed by Defendants, resulting in a breach of the duties set forth
18 above. These acts and omissions include, but are not restricted to negligently and
19 carelessly:
20

21 a. Failing to use due care in developing, testing, designing, and
22 manufacturing Depo-Provera so as to avoid the aforementioned risks to individuals
23 when Depo-Provera was being used for contraception and other indications;
24

25 b. Failing to conduct adequate pre-clinical and clinical testing and
26 post-marketing surveillance to determine the safety of Depo-Provera; and
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28

1 c. Designing, manufacturing, and placing into the stream of
2 commerce a product which was unreasonably dangerous for its reasonably
3 foreseeable use, which Defendants knew or should have known could cause injury to
4 Plaintiff.
5

6 d. Failing to use due care in developing, testing, designing, and
7 manufacturing Depo-Provera with the lowest effective dose as a safer alternative
8 which clearly existed at all relevant times so as to avoid the aforementioned risks to
9 individuals when high dose progestin Depo-Provera was being used for
10 contraception.
11
12

13 259. Defendants' negligence and Depo-Provera's failures arise under
14 circumstances precluding any other reasonable inference other than a defect in Depo-
15 Provera.
16

17 260. Defendants' failure to exercise reasonable care in the design, dosing
18 information, marketing, warnings, and/or manufacturing of Depo-Provera was a
19 proximate cause of Plaintiff's injuries and damages.
20

21 261. As a direct and proximate result of Defendants' negligence, Plaintiff
22 suffered bodily injuries and resulting pain and suffering, disability, mental anguish,
23 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.
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1 The losses are either permanent or continuing, and Plaintiff will suffer the losses in
2 the future.

3
4 **SIXTH CAUSE OF ACTION**

5 **NEGLIGENT MISREPRESENTATION**

6
7 262. Plaintiff incorporates by reference each and every preceding paragraph as
8 though fully set forth herein.

9
10 263. At all relevant times, Defendants negligently provided Plaintiff, her
11 healthcare providers, and the general medical community with false or incorrect
12 information or omitted or failed to disclose material information concerning Depo-
13 Provera, including, but not limited to, misrepresentations regarding the safety and
14 known risks of Depo-Provera.

15
16 264. The information distributed by the Defendants to the public, the medical
17 community, Plaintiff, and her Prescribing and Administering Health Care Providers,
18 including advertising campaigns, labeling materials, print advertisements, commercial
19 media, was false and misleading and contained omissions and concealment of truth
20 about the dangers of Depo-Provera.

21
22
23 265. Defendants' intent and purpose in making these misrepresentations was to
24 deceive and defraud the public and the medical community, including Plaintiff and
25 Plaintiff's Prescribing and Administering Health Care Providers; to falsely assure them
26 of the quality of Depo-Provera and induce the public and medical community, including
27
28

1 Plaintiff and her Prescribing and Administering Health Care Providers to request,
2 recommend, purchase, and prescribe Depo-Provera.
3

4 266. The Defendants had a duty to accurately and truthfully represent to the
5 medical and healthcare community, medical device manufacturers, Plaintiff, her
6 Prescribing and Administering Health Care Providers and the public, the known risks
7 of Depo-Provera, including its propensity to cause intracranial meningioma and
8 sequelae related thereto.
9

10
11 267. Defendants made continued omissions in the Depo-Provera labeling,
12 including promoting it as safe and effective while failing to warn of its propensity to
13 cause intracranial meningioma and sequelae related thereto.
14

15 268. Defendants made additional misrepresentations beyond the product
16 labeling by representing Depo-Provera as safe and effective for contraception and other
17 indications with only minimal risks.
18

19 269. Defendants misrepresented and overstated the benefits of Depo-Provera to
20 Plaintiff, Plaintiff's Prescribing and Administering Health Care Providers, and the
21 medical community without properly advising of the known risks associated with
22 intracranial meningioma and sequelae related thereto.
23

24 270. Defendants misrepresented and overstated that the Depo-Provera dosage
25 was needed to protect against pregnancy when Defendants knew that a safer alternative
26 existed with forty-six (46) fewer mg per dose of the powerful progestin being ingested
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28

1 quarterly in women, and when Defendants could have warned and recommended usage
2 of Depo-SubQ Provera 104 instead.

3
4 271. In reliance upon the false and negligent misrepresentations and omissions
5 made by the Defendants, Plaintiff and Plaintiff's Prescribing and Administering Health
6 Care Providers were induced to, and did use Depo-Provera, thereby causing Plaintiff to
7 endure severe and permanent injuries.
8

9 272. In reliance upon the false and negligent misrepresentations and omissions
10 made by the Defendants, Plaintiff and Plaintiff's Prescribing and Administering Health
11 Care Providers were unable to associate the injuries sustained by Plaintiff with her
12 Depo-Provera use, and therefore unable to provide adequate treatment. Defendants
13 knew or should have known that the Plaintiff, Plaintiff's Prescribing and Administering
14 Health Care Providers, and the general medical community did not have the ability to
15 determine the true facts which were intentionally and/or negligently concealed and
16 misrepresented by the Defendants.
17
18

19
20 273. Plaintiff and her Prescribing and Administering Health Care Providers
21 would not have used or prescribed Depo-Provera had the true facts not been concealed
22 by the Defendants.
23

24 274. Defendants had sole access to many of the material facts concerning the
25 defective nature of Depo-Provera and its propensity to cause serious and dangerous side
26 effects.
27
28

1 275. At the time Plaintiff was prescribed and administered Depo-Provera,
2 Plaintiff and her Prescribing and Administering Health Care Providers were unaware of
3 Defendants' negligent misrepresentations and omissions.
4

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

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

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

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

3
4 **SEVENTH CAUSE OF ACTION**

5 **FRAUDULENT MISREPRESENTATION**

6
7 280. Plaintiff incorporates by reference each and every preceding paragraph as
8 though fully set forth herein.

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

13
14
15 282. At all times material herein, Defendants misrepresented to consumers and
16 physicians, including Plaintiff and Plaintiff's physicians and the public in general, that
17 Depo-Provera is safe for use as a contraceptive and for other indications.

18
19 283. Defendants knew or should have known of the falsity of such a
20 representation to consumers, physicians, and the public in general since Depo-Provera
21 is far from the only contraceptive approved by the FDA, and it is not the only
22 contraception option. Nevertheless, Defendants' marketing of Depo-Provera falsely
23 represented Depo-Provera to be a safe and effective contraceptive option with no
24 increased risk of intracranial meningioma and sequelae related thereto.
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1 284. The representations were, in fact, false. When the Defendants made these
2 representations, it knew and/or had reason to know that those representations were false,
3 and Defendants willfully, wantonly, and recklessly disregarded the inaccuracies in their
4 representations and the dangers and health risks to users of Depo-Provera.
5

6
7 285. Prior to Plaintiff’s use of Depo-Provera, Defendants knew or should have
8 known of adverse event reports indicating the development of intracranial meningioma
9 in individuals who had taken Depo-Provera.
10

11 286. These representations were made by the Defendants with the intent of
12 defrauding and deceiving the medical community, Plaintiff , and the public, and also
13 inducing the medical community, Plaintiff, Plaintiff’s Prescribing and Administering
14 Health Care Providers, and/or the public, to recommend, prescribe, dispense, and
15 purchase Depo-Provera for use as a contraceptive and other treatment indications while
16 concealing the drug’s known propensity to cause serious and debilitating intracranial
17 meningioma and sequelae related thereto.
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19

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21 287. Despite the fact that the Defendants knew or should have known of Depo-
22 Provera’s propensity to cause serious and potentially debilitating injuries due to the
23 development of intracranial meningioma and sequelae related thereto, the label did not
24 contain any of this information in the “Warnings” section. In fact, the label for Depo-
25 Provera has been updated at least a dozen times over the past 20 years, yet at no point
26 did Defendants provide any of the foregoing information in the “Warnings” section. To
27
28

1 date, the Depo-Provera label still does not include any warnings whatsoever that
2 indicate the dangers of intracranial meningioma and sequela related thereto after using
3 Depo-Provera.
4

5 288. In representations to Plaintiff and/or to her healthcare providers, including
6 Plaintiff's prescribing physician, the Defendants fraudulently stated that Depo-Provera
7 was safe and omitted warnings related to intracranial meningioma.
8

9
10 289. In representations to Plaintiff and/or to her Prescribing and Administering
11 Health Care Providers, Defendants fraudulently stated that Depo-Provera was safe and
12 concealed and intentionally omitted material information from the Depo-Provera
13 product labeling in existence at the time Plaintiff was prescribed Depo-Provera in 2005.
14

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

20
21 291. The Defendants had a duty when disseminating information to the public
22 to disseminate truthful information; and a parallel duty not to deceive the public,
23 Plaintiff, and/or her physicians.
24

25 292. The Defendants knew or had reason to know of the dangerous side effects
26 of Depo-Provera as a result of information from case studies, clinical trials, literature,
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1 and adverse event reports available to the Defendants at the time of the development
2 and sale of Depo-Provera, as well as at the time of Plaintiff 's prescription.
3

4 293. Defendants' concealment and omissions of material facts concerning the
5 safety of the Depo-Provera were made purposefully, willfully, wantonly, and/or
6 recklessly to mislead Plaintiff , Plaintiff's physicians, surgeons and healthcare providers
7 and to induce them to purchase, prescribe, and/or use the drug.
8

9
10 294. At the time these representations were made by Defendants, and at the time
11 Plaintiff and/or her Prescribing and Administering Health Care Providers used Depo-
12 Provera, Plaintiff and/or her Prescribing and Administering Health Care Providers were
13 unaware of the falsehood of these representations.
14

15 295. In reliance upon these false representations, Plaintiff was induced to, and
16 did use Depo-Provera, thereby causing severe, debilitating, and potentially permanent
17 personal injuries and damages to Plaintiff. The Defendants knew or had reason to know
18 that the Plaintiff had no way to determine the truth behind the Defendants' concealment
19 and omissions, and that these included material omissions of facts surrounding the use
20 of Depo-Provera as described in detail herein.
21
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23
24 296. In comporting with the standard of care for prescribing physicians,
25 Plaintiff's prescribing physicians relied on the labeling for Depo-Provera in existence
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1 at the date of prescription that included the aforementioned fraudulent statements and
2 omissions.

3
4 297. These representations made by Defendants were false when made and/or
5 were made with the pretense of actual knowledge when such knowledge did not actually
6 exist, and were made recklessly and without regard to the true facts.
7

8 298. Plaintiff did not discover the true facts about the dangers and serious health
9 and/or safety risks, nor did Plaintiff discover the false representations and omissions of
10 the Defendants, nor could Plaintiff with reasonable diligence have discovered the true
11 facts about the Defendants' misrepresentations at the time when Depo-Provera was
12 prescribed to her.
13
14

15 299. As a direct and proximate result of reliance upon Defendants' fraudulent
16 misrepresentations, Plaintiff suffered bodily injuries and resulting pain and suffering,
17 disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical
18 and nursing care and treatment, loss of earnings, loss of ability to earn money and other
19 economic losses. The losses are either permanent or continuing, and Plaintiff will suffer
20 the losses in the future.
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22

23 300. Defendants have engaged in willful, malicious conduct and/or conduct so
24 careless that it demonstrates a wanton disregard for the safety of others, including
25 Plaintiff, such that the imposition of punitive damages is warranted here.
26
27

28 **EIGHTH CAUSE OF ACTION**

BREACH OF EXPRESS WARRANTY

1
2 301. Plaintiff incorporates by reference each and every preceding paragraph as
3
4 though fully set forth herein.

5 302. At all relevant times herein, Defendants engaged in the business of
6 researching, testing, developing, manufacturing, labeling, marketing, selling,
7 inspecting, handling, storing, distributing, and/or promoting Depo-Provera, and placed
8 it into the stream of commerce in a defective and unreasonably dangerous condition.
9 These actions were under the ultimate control and supervision of Defendants.
10

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

18 304. Depo-Provera materially failed to conform to those representations made
19 by Defendants, in package inserts and otherwise, concerning the properties and effects
20 of Depo-Provera, which Plaintiff purchased and consumed via intramuscular injection
21 in direct or indirect reliance upon these express representations. Such failures by
22 Defendants constituted a material breach of express warranties made, directly or
23 indirectly, to Plaintiff concerning Depo-Provera as sold to Plaintiff.
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1 305. Defendants expressly warranted that Depo-Provera was safe and well-
2 tolerated. However, Defendants did not have adequate proof upon which to base such
3 representations, and, in fact, knew or should have known that Depo-Provera was
4 dangerous to the well-being of Plaintiff and others.
5

6 306. Depo-Provera does not conform to those express representations because
7 it is defective, is not safe, and has serious adverse side effects.
8

9 307. Plaintiff and Plaintiff's physicians justifiably relied on Defendants'
10 representations regarding the safety of Depo-Provera, and Defendants' representations
11 became part of the basis of the bargain.
12

13 308. Plaintiff and Plaintiff's Prescribing and Administering Health Care
14 Providers justifiably relied on Defendants' representations that Depo-Provera was safe
15 and well-tolerated in their decision to ultimately prescribe, purchase and use the drug.
16

17 309. Plaintiff's Prescribing and Administering Health Care Providers justifiably
18 relied on Defendants' representations through Defendants' marketing and sales
19 representatives in deciding to prescribe Depo-Provera over other alternative treatments
20 on the market, and Plaintiff justifiably relied on Defendants' representations in deciding
21 to purchase and use the drug.
22

23 310. Plaintiff purchased and ingested Depo-Provera without knowing that the
24 drug is not safe and well-tolerated, but that Depo-Provera instead causes significant and
25 irreparable damage through the development of debilitating intracranial meningioma.
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1 311. As a direct and proximate result of Defendants' breaches of warranty,
2 Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental
3 anguish, loss of capacity for the enjoyment of life, past and future medical care and
4 treatment, loss of earnings, loss of ability to earn money and other economic losses, and
5 other damages. The losses are either permanent or continuing, and Plaintiff will suffer
6 the losses in the future.
7

9 **NINTH CAUSE OF ACTION**

10 **BREACH OF IMPLIED WARRANTY**

11 312. Plaintiff incorporates by reference each and every preceding paragraph as
12 though fully set forth herein.
13

14 313. At all relevant times herein, Defendants engaged in the business of
15 researching, testing, developing, manufacturing, labeling, marketing, selling,
16 inspecting, handling, storing, distributing, and/or promoting Depo-Provera, and placed
17 it into the stream of commerce in a defective and unreasonably dangerous condition.
18 These actions were under the ultimate control and supervision of Defendants.
19

20 314. Defendants were the sellers of the Depo-Provera and sold Depo-Provera to
21 be taken for contraception or to treat endometriosis, among other indications. Plaintiff
22 was prescribed and purchased Depo-Provera for these intended purposes.
23

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

2 316. Defendants impliedly warranted their Depo-Provera product, which they
3 manufactured and/or distributed and sold, and which Plaintiff purchased and ingested,
4 to be of merchantable quality and fit for the common, ordinary, and intended uses for
5 which the product was sold.
6

7 317. Defendants breached their implied warranties of the Depo-Provera product
8 because the Depo-Provera sold to Plaintiff was not fit for its ordinary purpose as a
9 contraceptive or to treat endometriosis safely and effectively, among other uses.
10

11 318. The Depo-Provera would not pass without objection in the trade; is not of
12 fair average quality; is not fit for its ordinary purposes for which the product is used;
13 was not adequately contained, packaged and labeled; and fails to conform to the
14 promises or affirmations of fact made on the container or label.
15

16 319. Defendants' breach of their implied warranties resulted in the
17 intramuscular administration of the unreasonably dangerous and defective product into
18 Plaintiff, which placed Plaintiff's health and safety at risk and resulted in the damages
19 alleged herein.
20

21 320. As a direct and proximate result of reliance upon Defendants' breaches of
22 warranty, Plaintiff suffered bodily injuries and resulting pain and suffering, disability,
23 mental anguish, loss of capacity for the enjoyment of life, past and future medical care
24 and treatment, loss of earnings, loss of ability to earn money and other economic losses,
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1 and other damages. The losses are either permanent or continuing, and Plaintiff will
2 suffer the losses in the future.
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1 **VII. PRAYER FOR RELIEF**

2 **WHEREFORE**, Plaintiff Alicia Wilson demands judgment against all
3 Defendants to the full extent of the law, and respectfully requests that the Court:
4

- 5 1. Enter judgment for Plaintiff and against each Defendant;
- 6 2. Award Plaintiff compensatory and punitive exemplary damages in an
7 amount to be determined at trial, and also including, but not limited to:
 - 8 a. General and Special damages, including damages to compensate
9 Plaintiff for her past and future physical and emotional injuries
10 sustained as a result of the use of Depo-Provera, including but not
11 limited, to physical pain and suffering, mental anguish, inconvenience,
12 loss of enjoyment of life, emotional distress, economic losses and
13 expenses for past and future hospitalizations and medical treatments,
14 and other economic harm that includes but is not limited to lost earnings
15 and loss of earning capacity;
 - 16 b. Exemplary and/or punitive damages in an amount in excess of the
17 jurisdictional limits;
 - 18 c. Attorneys' fees; Experts' fees; and Costs of litigation as determined in
19 this Court's discretion;
 - 20 d. Costs and services for medical monitoring or surveillance programs as
21 permitted by law;
 - 22 e. Pre-judgment and post-judgment interest at the lawful rate; and,
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f. Any other relief as this Court may deem equitable and just, or that may be lawfully available.

VIII. DEMAND FOR JURY TRIAL

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

Dated: November 26, 2024.

Respectfully Submitted,

By: /s/ Christopher G. Paulos
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