

1 Melinda Davis Nokes, Bar No. 167787
 2 Ellen Relkin (*pro hac vice application pending*)
 3 Brendan A. McDonough (*pro hac vice application pending*)
 4 mnokes@weitzlux.com
 5 erelkin@weitzlux.com
 6 bmcdonough@weitzlux.com
 7 **WEITZ & LUXENBERG, P.C.**
 8 1880 Century Park East, Suite 700
 9 Los Angeles, CA 90067
 10 Telephone: (310) 247-0921
 11 Facsimile: (310) 786-9927

12 *Attorneys for Plaintiff Kristina Schmidt*

13 **UNITED STATES DISTRICT COURT**
14 **NORTHERN DISTRICT OF CALIFORNIA**

15 **KRISTINA SCHMIDT,**

16 Plaintiff,

17 vs.

18 **PFIZER INC., VIATRIS INC.,**
19 **GREENSTONE LLC, PRASCO LABS.,**
20 **and PHARMACIA & UPJOHN,**

21 Defendants.

Case No.: 3:24-cv-6875

22 **COMPLAINT AND DEMAND**
23 **FOR JURY TRIAL**

24 Plaintiff KRISTINA SCHMIDT, by and through Plaintiff’s undersigned counsel,
25 brings this civil action against Defendants for personal injuries and damages suffered by Plaintiff, and
26 alleges upon information and belief as follows:

27 **INTRODUCTION**

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

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

5 3. Depo-Provera injured Plaintiff KRISTINA SCHMIDT (hereinafter “Plaintiff”) by
6 causing or substantially contributing to the development of an intracranial meningioma, a brain tumor,
7 which required significant and invasive treatment and has resulted in serious injuries.

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

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

14 6. Nevertheless, Defendants failed to warn, instruct, advise, educate, or otherwise
15 inform Depo-Provera users and prescribers about the risk of intracranial meningioma or the need for
16 monitoring for resultant symptoms. To date, the U.S. label for Depo-Provera still makes no mention
17 of the increased risk to patients of developing intracranial meningiomas despite the fact that the
18 European Union (EU) and the United Kingdom labels now list meningioma under the “special
19 warnings and precautions for use” section and advise EU patients to speak with their doctors before
20 using Depo-Provera if they have any history of meningioma.

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

23 8. Plaintiff therefore demands judgment against Defendants and requests, among other
24 things, compensatory damages, statutory damages, punitive damages, attorneys’ fees, and costs.
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PARTIES

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2 9. At all relevant times hereto, Plaintiff KRISTINA SCHMIDT (hereinafter “Plaintiff”)
3 was a resident and citizen of Pleasanton, California.

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

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

10 12. Defendant GREENSTONE, LLC (hereinafter “Greenstone”) is a limited liability
11 corporation organized under Michigan law with its principal place of business at its headquarters at
12 Pfizer Peapack Campus, 100 Route 206 North, Peapack, NJ 07977.

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

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

18 15. Defendant Pfizer is the current New Drug Application (hereinafter “NDA”) holder
19 for Depo-Provera and has solely held the NDA for Depo-Provera since 2020. Upon information and
20 belief, Pfizer has effectively held the NDA since at least 2002 when it acquired Pharmacia & Upjohn—
21 who then held the NDA—as a wholly owned subsidiary. No later than 2003 did Pfizer’s name appear
22 on the label alongside Pharmacia & Upjohn.
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25 16. At all relevant times, Defendant Pharmacia & Upjohn was a wholly owned
26 subsidiary of Defendant Pfizer until Upjohn was spun off in a merger in 2020 to create Defendant
27 Viatris and the remnants of Pharmacia were retained by Pfizer.
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1 17. Defendant Greenstone, founded in 1993, was a wholly owned subsidiary of Pfizer,
2 that at pertinent times was in the business of offering a product portfolio of “authorized generic”
3 medicines, covering a broad range of therapeutic areas including Depo-Provera.

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

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

17 20. The FDA has stated that the term “authorized generic” drug is most commonly used
18 to describe an approved brand name drug that is marketed without the brand name on its label. Other
19 than the fact that it does not have the brand name on its label, it is the exact same drug product as the
20 branded product. An “authorized generic” may be marketed by the brand name drug company, or
21 another company with the brand company’s permission.¹
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27 ¹ See [https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-](https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs)
28 [drugs](https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs) (last accessed Sept. 30, 2024).

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

3 22. Defendant Viatris was formed by the merger of Upjohn, Greenstone, and another
4 company, Mylan N.V., in November 2020. Viatris is thus merely the latest iteration of Upjohn and
5 Greenstone.

6 23. Even after the merger, Defendant Greenstone has continued to operate from the same
7 location at Pfizer’s corporate offices in Peapack, NJ.

8 24. Additionally, Defendant Pfizer retained 57% ownership of Viatris stock, making
9 Pfizer the majority owner of Viatris, and since Pfizer retained the remnants of Pharmacia, Pfizer
10 effectively remains the majority owner of Defendants Pharmacia & Upjohn and Greenstone.
11

12 25. Defendant Prasco is another “authorized generic” manufacturer of Depo-Provera,
13 meaning Prasco simply takes brand-name Depo-Provera manufactured by Defendants Greenstone
14 and/or Pfizer and passes it off as its own generic product. Defendant Prasco consistently maintains a
15 sizeable percentage of the market share for Depo-Provera sales in the US.
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17 26. All Defendants do business in California by, among other things, distributing,
18 marketing, selling and/or profiting from brand name and/or “authorized generic” Depo-Provera in
19 California, as well as throughout the United States.

20 27. At all times material herein, Defendants were, and still are, pharmaceutical companies
21 involved in the manufacturing, research, development, marketing, distribution, sale, and release for
22 use to the general public of pharmaceuticals, including Depo-Provera and its “authorized generic”
23 version, in California, and throughout the United States.
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25 **JURISDICTION AND VENUE**
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27 ² 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 38. In October 2022, Plaintiff underwent brain surgery, a right craniotomy, to remove
2 the meningioma at Redwood City Medical Center in Redwood City, California. The delicate and
3 highly invasive surgery lasted nearly three hours and involved total resection of the meningioma,
4 including removal of adjacent dural tissue. Although meningiomas can sometimes be treated with
5 radiation, the “surgical option was felt to be favored for prevention of future problems” in Plaintiff’s
6 case “given her young age as well as involvement of the Sylvian fissure[.]”

7 39. The location of Plaintiff’s meningioma in the “Sylvian fissure” is in the sphenoid-
8 orbital region of the brain which is the exact location that progesterone-mediated meningiomas have
9 been found to develop most often.³

10 40. The brain surgeon described the procedure to access Plaintiff’s meningioma: “The
11 scalp was ... opened with a 10 blade [scalpel] followed by Bovie electrocautery down to the skull. A
12 myocutaneous flap was then reflected interiorly. Next, we placed bur holes, one anterior and one
13 posterior, and converted this into a craniotomy flap using standard craniotome.” A craniotome is a
14 power tool resembling a drill used to “peel back” the cranium and access underlying soft tissue. The
15 meningioma was then exposed and resected.

16 41. After exposing and resecting the meningioma, “abnormal” tissue around the margins
17 of the adjacent dural layer was noted and a significant amount of dural tissue was removed via
18 electrocautery. Subsequently, a piece of “bovine pericardium” (tissue from the heart of a cow) was
19 placed on the affected area. The surgeon then “replaced” Plaintiff’s “bone flap,” “reapproximated” the
20 muscle, and “reapproximated the scalp” with skin staples and two types of sutures.
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26 ³ See Malueka, et al., “Association of Hormonal Contraception with Meningioma Location in
27 Indonesian Patients,” *Asian Pac J Cancer Prev*, Vol. 23, No. 3, pp. 1047-51 (2022) (finding a
28 “significant association between hormonal contraceptive use and meningioma location in the sphenoidal region”).

1 42. Finally, Plaintiff's skull was repaired, which required a 4-square-inch cranial
2 collagen matrix (bone graft) reinforced with a 4.3-inch titanium plate and more than a dozen titanium
3 self-drilling screws.

4 43. Pathology results from the craniotomy later showed the meningioma was between a
5 grade 1 and grade 2 tumor.

6 44. As a result of the surgery and associated recovery, Plaintiff was forced to miss more
7 than a month of work.

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

11 46. Plaintiff was unaware until very recently, following publicity associated with a large
12 case control study in France published in March 2024, that Depo-Provera had any connection to her
13 meningioma.
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15 **GENERAL ALLEGATIONS**

16 **A. Intracranial Meningioma**

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

19 48. Although the tumor formed by an intracranial meningioma is typically histologically
20 benign (meaning it usually does not metastasize), the growing tumor can nevertheless press against
21 the sensitive surrounding tissues, i.e., the brain, and thereby cause a number of severe and debilitating
22 symptoms ranging from seizures and vision problems to weakness, difficulty speaking, and even
23 death, among others. Moreover, a sizeable number of meningiomas (15-20%) do become metastatic,
24 greatly increasing their danger.
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1 49. Treatment of a symptomatic intracranial meningioma typically requires highly
2 invasive brain surgery that involves the removal of a portion of the skull, i.e., a craniotomy, in order
3 to access the brain and meninges. Radiation therapy and chemotherapy may also be required as the
4 sensitive location of the tumor in the brain can render complete removal highly risky and technically
5 difficult.

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

14 **B. Depo-Provera**

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

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

20 53. Depo-Provera is a 150 mg/mL dosage of DMPA that is injected every three (3)
21 months into the deep tissue musculature of either the buttocks or the upper arm, with present labelling
22 recommending alternating the injection site at each injection.
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24 54. Defendant Pfizer represents Depo-Provera to be one of the most effective
25 contraceptives in existence. In fact, the Depo-Provera label groups injectable contraceptives like
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1 Depo-Provera alongside “Sterilization” as the most effective contraceptive methods resulting in the
2 fewest unintended pregnancies.

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

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

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

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

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

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

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

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

20 63. Upjohn merged with Swedish manufacturer Pharmacia AB to form Pharmacia &
21 Upjohn in 1995.

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27 ⁴ See <https://www.kff.org/womens-health-policy/fact-sheet/dmpa-contraceptive-injection-use-and-coverage/> (last accessed Sept. 30, 2024).
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1 64. Defendant Pfizer acquired Pharmacia & Upjohn in 2002, thereby acquiring the Depo-
2 Provera NDA as well as the associated responsibilities and liabilities stemming from the
3 manufacturing, sale, and marketing of Depo-Provera.

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

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

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

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

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15 **C. The Dangers of Depo-Provera**

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

21 70. Since at least 1983, the medical and scientific communities have been aware of the
22 high number of progesterone receptors on meningioma cells, especially relative to estrogen receptors.⁵
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27 ⁵ See Blankenstein, et al., "Presence of progesterone receptors and absence of oestrogen receptors in
28 human intracranial meningioma cytosols," *Eur J Cancer & Clin Oncol*, Vol. 19, No. 3, pp. 365-70
(1983).

1 71. This finding was surprising and notable within the medical and scientific
2 communities because it had previously been thought that meningioma cells, like breast cancer cells,
3 would show a preference for estrogen receptors.⁶ Researchers publishing in the *European Journal of*
4 *Cancer and Clinical Oncology* instead found the opposite, indicating progesterone was involved in
5 the incidence, mediation, and growth rate of meningiomas.⁷ This particular study was published nearly
6 a decade before the FDA approved Depo-Provera for contraception in 1992. In those nine (9) years
7 before Depo-Provera was approved for contraception, and in the thirty-two (32) years since—more
8 than forty (40) years in all—Defendants have seemingly failed to investigate the effect of their high-
9 dose progesterone Depo-Provera on the development of meningioma.
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11 72. Since at least as early as 1989, researchers have also been aware of the relationship
12 between progesterone-inhibiting agents and the growth rate of meningioma.⁸ That year, the same
13 authors published a study in the *Journal of Steroid Biochemistry* entitled, “Effect of steroids and
14 antisteroids on human meningioma cells in primary culture,” finding that meningioma cell growth was
15 significantly reduced by exposure to mifepristone, an antiprogestosterone agent.⁹
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17 73. Numerous studies published in the decades since have presented similar findings on
18 the negative correlation between progesterone-inhibiting agents and meningioma.¹⁰
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23 ⁶ *See id.*

24 ⁷ *See id.*

25 ⁸ *See* Blankenstein, et al., “Effect of steroids and antisteroids on human meningioma cells in primary
26 culture,” *J Steroid Biochem*, Vol. 34, No. 1-6, pp. 419-21 (1989).

27 ⁹ *See id.*

28 ¹⁰ *See, e.g.*, Grunberg, et al., “Treatment of unresectable meningiomas with the antiprogestosterone agent
mifepristone,” *J Neurosurgery*, Vol. 74, No. 6, pp. 861-66 (1991); *see also* Matsuda, et al., “Antitumor
effects of antiprogestosterones on human meningioma cells in vitro and in vivo,” *J Neurosurgery*, Vol.
80, No. 3, pp. 527-34 (1994).

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

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

12 76. In light of the aforementioned studies, for several decades the manufacturers and
13 sellers of Depo-Provera and its authorized generic and generic analogues, Defendants, had an
14 unassignable duty to investigate the foreseeable potential that a high dose synthetic progesterone
15 delivered in the deep tissue could cause the development or substantially contribute to the growth of
16 meningioma. Defendants were also best positioned to perform such investigations. Had Defendants
17 done so, they would have discovered decades ago that their high dose progestin Depo-Provera was
18 associated with a highly increased risk of meningioma and would have spared Plaintiff and countless
19 others the pain and suffering associated with meningioma. Instead, Defendants did nothing, and
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23 ¹¹ See, e.g., Gil, et al., “Risk of meningioma among users of high doses of cyproterone acetate as
24 compared with the general population: evidence from a population-based cohort study,” *Br J Clin
25 Pharmacol.* Vol. 72, No. 6, pp. 965-68 (2011); see also Bernat, et al., “Growth stabilization and
26 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).

27 ¹² 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 therefore willfully failed to apprise the medical community, and the women patients receiving
2 quarterly high dose injections, of this dangerous risk.

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

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

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16 79. 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 Surgery Part B:*
18 *Skull Base* titled “Skull Base Meningiomas as Part of a Novel Meningioma Syndrome Associated with
19 Chronic Depot Medroxyprogesterone Acetate Use.”¹⁴ The abstract reported on 25 individuals who
20 developed one or more intracranial meningiomas related to chronic use of Depo-Provera. Of the
21 twenty-five (25) patients, ten (10) were instructed to cease Depo-Provera use, after which five (5) of
22 those patients had “clear evidence of tumor shrinkage,” leading the authors to conclude “there appears
23 to be a clear progestin meningioma syndrome associated with chronic DMPA use.”
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26 ¹³ Hage, et al., “Estrogen and progesterone therapy and meningiomas,” *Endocrinology*, Vol. 163, pp.
1-10 (2022).

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

6 81. By way of history, the *Roland* study noted that concerns over meningiomas associated
7 with high dose progestogen medications resulted in the recent discontinuation of three such medications
8 in France and the EU. Specifically, there were “postponements in the prescription of chlormadinone
9 acetate, nomegestrol acetate, and cyproterone acetate, following the French and European
10 recommendations to reduce the risk of meningioma attributable to these progestogens in 2018 and
11 2019.”¹⁶

12 82. The study analyzed 18,061 cases of women undergoing surgery for intracranial
13 meningioma between 2009 and 2018. The study found that “prolonged use of ... medroxyprogesterone
14 acetate [Depo-Provera] ... was found to increase the risk of intracranial meningioma.” Specifically,
15 the authors found that prolonged use of Depo-Provera resulted in a 555% increased risk of developing
16 intracranial meningioma. The study authors concluded “[t]he increased risk associated with the use of
17 injectable medroxyprogesterone acetate, a widely used contraceptive,” was an important finding. The
18 authors also noted Depo-Provera is “often administered to vulnerable populations,” i.e., lower-income
19 women who have no other choice but to take the subsidized option which only requires action every
20 three months to remain effective for its intended use of preventing pregnancy, and, in the case of the
21 subcutaneous variant, treating endometriosis.
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26 ¹⁵ 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 ¹⁶ *See id.*

1 83. The 2024 *Roland* study published in *BMJ* studied the effect of several other
2 progestogen-based medications. Three study subjects showed no excess risk of intracranial
3 meningioma surgery with exposure to oral or intravaginal progesterone or percutaneous progesterone,
4 dydrogesterone or spironolactone, while no conclusions could be drawn for two others due to lack of
5 exposed cases. The other medications, including medroxyprogesterone acetate (Depo-Provera), were
6 found to be associated with an increased risk of intracranial meningioma, with Depo-Provera having
7 by far the second highest increased risk, surpassed only by the product cyproterone acetate, which had
8 already been withdrawn from the market due to its association with meningioma.
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10 84. Depo-Provera had by far the highest risk of meningioma surgeries amongst
11 progesterone contraceptive products studied, rendering Depo-Provera more dangerous than other
12 drugs and treatment options designed to prevent pregnancy due to the unreasonably increased risk of
13 injury associated with intracranial meningioma, including but not limited to seizures, vision problems,
14 and even death.
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16 85. Further, the *Roland* study found the longer duration of exposure had a greater risk
17 noting the results show that three quarters of the women in the case group who had been exposed for
18 more than a year had been exposed for more than three years.
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20 86. The *Roland* study noted that among cases of meningioma observed in the study,
21 28.8% (5,202/18,061) of the women used antiepileptic drugs three years after the index date of
22 intracranial surgery.
23

D. Defendants' Failure to Test Depo-Provera

24 87. Defendants knew or should have known of the potential impact of the drug to cause the
25 development of intracranial meningioma but failed to adequately study these adverse effects.
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27 88. Furthermore, despite the fact that studies have emerged over the course of decades
28 providing evidence of the meningioma-related risks and dangers of progesterone and progestins and

1 Depo-Provera specifically, Defendants have failed to adequately investigate the threat that Depo-Provera
 2 poses to patients' well-being or warn the medical community and patients of the risk of intracranial
 3 meningioma and sequelae related thereto.

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

5 89. According to the Drugs@FDA website, the label for Depo-Provera has been updated
 6 on at least thirteen (13) occasions since 2003, with the most recent update coming in July 2024.¹⁷
 7 Despite the fact there are at least fourteen (14) iterations of the Depo-Provera label, Defendants' labels
 8 have not contained any warning or any information whatsoever on the increased propensity of Depo-
 9 Provera to cause severe and debilitating intracranial meningioma like that suffered by Plaintiff.

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

21
 22
 23
 24 ¹⁷ See Drugs@FDA:FDA-Approved Drugs- Depo-Provera,
 25 [https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=0202](https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020246)
 26 [46](https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020246) (last visited Apr. 29, 2024).

27 ¹⁸ "Hormone medication could increase risk of brain tumours, French study finds," The Guardian,
 28 published online Mar. 27, 2024 (available at <https://www.theguardian.com/society/2024/mar/27/hormone-medication-brain-tumours-risk-progestogens-study>) (last accessed Sept. 12, 2024).

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

7
8 92. Additionally, Defendants’ Package Leaflet in the EU which provides information for
9 the patient states that “before using Depo-Provera[,]... it is important to tell your doctor or healthcare
10 professional if you have, or have ever had in the past ... a meningioma (a usually benign tumor that
11 forms in the layers of tissue that cover your brain and spinal cord).”

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

15 94. Specifically, Defendants could have filed a “Changes Being Effected” (“CBE”)
16 supplement under Section 314.70(c) of the FDCA to make “moderate changes” to Depo-Provera’s
17 label without any prior FDA approval.

18 95. Examples of moderate label changes that can be made via a CBE supplement explicitly
19 include changes “to reflect newly acquired information” in order to “add or strengthen a
20 contraindication, warning, precaution, or adverse reaction.” By definition and by regulation such
21 changes to add a warning based on newly acquired information—such as that imparted by newly
22 emerging literature like the litany of studies cited above—are considered a “moderate change.” §
23 340.70(c)(6)(iii).

24 96. Recently, the Third Circuit reaffirmed that plain text interpretation of the CBE
25 supplement process in a precedential decision holding that the defendant in that case, Merck, could not
26
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28

1 rely on a preemption defense based on an allegedly irreconcilable conflict between federal (FDCA)
2 and state (civil tort) law so long as the warning could have been effected via a CBE change. *See*
3 *generally In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, Case No. 22-3412, D.I. 82 at 73 on
4 the docket (J. Jordan) (3d Cir. Sept. 20, 2024) (noting “the availability of a label change via a CBE
5 supplement is problematic for Merck, as will very often be the case for pharmaceutical companies
6 raising an impossibility defense”).

7
8 97. Defendants could have also instructed physicians to consider its own safer alternative
9 design, a lower dose medroxyprogesterone acetate injected subcutaneously instead of the more
10 invasive and painful intramuscular injection method. Studies going back at least ten years have shown
11 that the 150 mg dose of Depo-Provera—when administered subcutaneously, instead of
12 intramuscularly—is absorbed by the body at a similarly slower rate as the lower dose 104 mg Depo-
13 SubQ Provera 104 version.¹⁹ Nevertheless, Defendant never produced a 150 mg subcutaneous version.

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

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

24
25 100. When Depo-SubQ Provera 104, under NDA number 21-583, submitted by Defendant
26 Pharmacia & Upjohn, a subsidiary of Defendant Pfizer, was approved by the FDA on February 17,

27
28 ¹⁹ *See* Shelton, et al., “Subcutaneous DPMA: a better low dose approach,” *Contraception*, Vol. 89, pp.
341-43 (2014).

1 2004, more than two decades ago, those Defendants submitted a proposed trade name that the FDA did
2 not approve, so instead, the proprietary name Depo-SubQ Provera 104 was deemed to be the brand
3 name.

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

11 102. The “lowest effective dose” is a well-known concept in the field of pharmaceuticals
12 wherein a drug-maker should seek to find the lowest possible dose at which the drug of interest is
13 efficacious for the intended use, as any additional dosage on top of that lowest effective dose is
14 inherently superfluous and can increase the risk of unwanted side effects.
15

16 103. Either change—adding a warning about the risk of meningioma based on “newly
17 acquired information” or advising physicians to consider a switch to subcutaneous Depo-SubQ Provera
18 104—either on its own or taken together, would have constituted a “moderate change” or changes
19 justifying a simple CBE supplement that Defendants could have effectuated immediately, and then
20 simply notified the FDA thereafter. Yet, Defendants have failed to do so, and that failure continues to
21 date.
22

23 104. Defendants ignored reports from patients and health care providers throughout the
24 United States which indicated that Depo-Provera failed to perform as intended. Defendants also
25 knew or should have known of the effects associated with long term use of Depo-Provera, which led
26 to the severe and debilitating injuries suffered by Plaintiff and numerous other patients. Rather
27 than conducting adequate testing to determine the cause of these injuries for which it had notice or
28

1 rule out Depo-Provera's design as the cause of the injuries, Defendants continued to falsely and
2 misleadingly market Depo-Provera as a safe and effective prescription drug for contraception and
3 other indications.

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

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

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

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

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

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

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

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

5 112. Defendants Greenstone, Viatris and Prasco were at different times from 2004 until the
6 present the authorized generic “manufacturer” and distributor operating under the same NDA of Depo-
7 Provera, with the express permission of Pfizer, to make, label, distribute, sell, and market Depo-
8 Provera without the brand name on its label, even though it is the exact same drug product as the
9 branded Depo-Provera manufactured in some or all instances by Pfizer.
10

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

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

18 115. Pfizer had a duty to change the label knowing that its “authorized generic” distributors
19 Greenstone, Viatris, and Prasco, with whom they were in contract and receiving revenue from the sale
20 of the “authorized generic” DMPA were selling the “authorized generic” without warning of
21 meningioma risk.

22 116. Pfizer knew that its authorized generic manufacturers held a large market share of its
23 manufactured Depo-Provera under a different name.
24

25 117. Pfizer was at some or all of the pertinent times the actual manufacturer of the DMPA,
26 identical to Depo-Provera other than its name, which was sold by Defendants Greenstone, Viatris, and
27
28

1 Prasco who were at different times the “authorized generic” distributor, with the express permission
2 of Pfizer, to distribute, sell, and market Depo-Provera without the brand name on its label.

3 INNOVATOR LIABILITY UNDER CALIFORNIA LAW

4
5 118. In October of 2002, Defendant Pfizer's patent for Depo-Provera expired. Following
6 this, the FDA approved various generic versions of Depo-Provera for sale in the United States. Despite
7 the availability of generics, Pfizer has continued to manufacture, market, and distribute the brand-
8 name Depo-Provera across the United States, including in California.

9
10 119. A manufacturer wishing to market a generic version of an FDA-approved drug can
11 submit an Abbreviated New Drug Application (ANDA). This allows the generic manufacturer to rely
12 on the NDA filed by the brand-name manufacturer by demonstrating that the generic version contains
13 the same active ingredients and is biologically equivalent to the brand-name drug.²⁰

14
15 120. As part of the NDA, the brand-name manufacturer must propose the exact text of the
16 label, subject to FDA approval.²¹ For generics, the ANDA process mandates that the safety and
17 efficacy labeling must be identical to that of the brand-name drug.²²

18
19 121. While the brand-name manufacturer bears responsibility for the accuracy and adequacy
20 of the drug label, generic manufacturers are only required to ensure that their labels mirror the brand-
21 name version.²³ The California Supreme Court has reasoned that because a brand-name manufacturer
22 is responsible for the content of a drug's warning label, it “knows to a legal certainty ... that any
23 deficiencies in the label for its drug will be perpetrated in the label for its generic bioequivalent.”²⁴ As
24 a result, the content of the generic labels for Depo-Provera bioequivalents is entirely dictated by the

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26 ²⁰ See 21 U.S.C. § 355(j)(2)(A)(ii), (iv).

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

²² See 21 U.S.C.A. § 355(j); see also *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612-13 (2011).

²³ See generally 21 U.S.C. § 355; see also 21 C.F.R. § 314.105(b).

²⁴ *T.H. v. Novartis Pharm. Corp.*, 4 Cal. 5th 145, at 166 (2017).

1 brand-name manufacturer Defendant Pfizer’s label. Thus, California law liability for failure to warn
2 can extend to Defendant Pfizer, even when the consumer is prescribed only the generic version.

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

7
8 123. As the brand-name manufacturer of Depo-Provera, Defendant Pfizer had and continues
9 to have a duty to ensure that the labeling for Depo-Provera remains accurate and adequate “as soon as
10 there is reasonable evidence of an association of a serious hazard with a drug,” regardless of whether
11 a causal relationship has been established.²⁵ Defendant Pfizer was not only in the best position to
12 provide warnings regarding Depo-Provera's risks but was also the only entity legally authorized to
13 update the label unilaterally under federal law.

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

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

26
27
28 ²⁵ See 21 C.F.R. § 201.80(e).

1 regulation.²⁶ As the brand name manufacturer of Depo-Provera, Defendant Pfizer had a duty to give
2 information about Depo-Provera to the medical community and public at large.

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

5 127. Thus, to the extent that any of the approximately sixty-four (64) doses of Depo-Provera
6 administered to Plaintiff were generic, Defendant Pfizer is additionally liable for any resultant harm
7 to Plaintiff from those generic doses under California's well-established doctrine of innovator liability.
8

9 **EQUITABLE TOLLING OF STATUTE OF LIMITATIONS**

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

15 129. Defendants willfully, wantonly, and intentionally conspired, and acted in concert, to
16 withhold safety-related warnings from the Plaintiff, and the general public concerning the known
17 hazards associated with the use of, and exposure to, Depo-Provera, particularly over extended periods
18 of time.
19

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

24 131. The aforementioned studies reveal that discontinuing use of high dose progesterone
25 and progestin, including Depo-Provera, can retard the growth of meningiomas, but failed to warn the
26

27 _____
28 ²⁶ See 21 C.F.R. § 314.70(c)(6)(iii)(A).

1 medical community and the Plaintiff of this method to mitigate the damage of a developing
2 meningioma.

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

6 133. Defendants failed to disclose a known defect and, instead, affirmatively misrepresented
7 that Depo-Provera was safe for its intended use. Defendants disseminated labeling, marketing,
8 promotion and/or sales information to Plaintiff, her healthcare providers, and the general public
9 regarding the safety of Depo-Provera knowing such information was false, misleading, and/or
10 inadequate to warn of the safety risks associated with long-term Depo-Provera use. Defendants did so
11 willfully, wantonly, and with the intent to prevent the dissemination of information known to them
12 concerning Depo-Provera's safety.

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

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

23 136. Due to the absence of any instructions for how to identify and/or monitor Depo-Provera
24 patients for potential intracranial meningioma-related complications, Plaintiff was unaware that Depo-
25

1 Provera could cause serious, intracranial meningioma-related injuries, as this danger was not known
2 to Plaintiff, Plaintiff's healthcare providers, or the general public.

3 137. Given Defendants' conduct and deliberate actions designed to deceive Plaintiff,
4 Plaintiff's healthcare providers, and the general public, with respect to the safety and efficacy of Depo-
5 Provera, Defendants are estopped from relying on any statute of limitations defenses.
6

7 **CONDUCT WARRANTING PUNITIVE DAMAGES**
8

9 138. For the reasons set forth above and addressed below, Defendant Pfizer acted with a
10 conscious disregard of the safety of Plaintiff and all the other women, many who were young and of
11 lower socioeconomic status, who were subjected to high dose injections of 150 mg Depo-Provera with
12 the known and/or knowable risk of meningioma brain tumors which was generally accepted in the
13 scientific community, while Defendant Pfizer had available its very own safer alternative medication,
14 Depo Sub-Q Provera 104. Exemplary damages are warranted to punish and deter Defendant Pfizer
15 and others from such conduct in the future.
16

17 **COUNT I**
18

19 **STRICT LIABILITY – FAILURE TO WARN**

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

22 140. At all times material herein, Defendants engaged in the business of researching, testing,
23 developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing,
24 and/or promoting Depo-Provera and placed Depo-Provera into the stream of commerce in a defective
25 and unreasonably dangerous condition. These actions were under the ultimate control and supervision
26 of Defendants.
27
28

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

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

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

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

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

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

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

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

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

18 150. The Depo-Provera supplied to Plaintiff by Defendants was defective, unreasonably
19 dangerous, and had inadequate warnings or instructions at the time it was sold, and Defendants also
20 acquired additional knowledge and information confirming the defective and unreasonably dangerous
21 nature of Depo-Provera. Despite this knowledge and information, Defendants failed and neglected to
22 issue adequate warnings that Depo-Provera causes serious and potentially debilitating intracranial
23 meningioma and/or instructions concerning the need for monitoring and potential discontinuation of
24 use of Depo-Provera.
25

26 151. Defendants' failure to provide adequate warnings or instructions rendered Depo-
27 Provera unreasonably dangerous in that it failed to perform as safely as an ordinary patient, prescriber,
28

1 and/or other consumer would expect when used as intended and/or in a manner reasonably foreseeable
2 by the Defendants, and in that the risk of danger outweighs the benefits.

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

5 153. Plaintiff's various prescribing physicians, nurse practitioners, physician assistants, and
6 nurses (hereinafter collectively referred to as "Plaintiff's Prescribing and Administering Health Care
7 Providers") would not have prescribed and administered Depo-Provera to Plaintiff had they been
8 apprised by Defendants of the unreasonably high risk of meningioma associated with usage of Depo-
9 Provera.
10

11 154. Alternatively, even if Defendants had apprised Plaintiff's Prescribing and
12 Administering Health Care Providers of the unreasonably high risk of meningioma associated with
13 usage of Depo-Provera and these Prescribing and Administering Health Care Providers had still
14 recommended usage of Depo-Provera to Plaintiff, the Prescribing and Administering Health Care
15 Providers would have relayed the information concerning the risk of meningioma to Plaintiff, and the
16 alternative treatment of the lower dose subcutaneous Depo-SubQ Provera 104, and Plaintiff as an
17 objectively prudent person would not have chosen to take Depo-Provera, and/or would have opted to
18 take safer and lower dose Depo-SubQ Provera 104, notwithstanding Plaintiff's Prescribing Physician
19 and Administering Health Care Providers' continued recommendation.
20

21 155. Similarly, if Defendants had warned of the unreasonably high risk of meningioma
22 associated with the usage of Depo-Provera, and the availability of the safer and equally effective lower
23 dose Depo-SubQ Provera 104 in the Patient Information handout, Plaintiff as an objectively prudent
24 person would not have chosen to take Depo-Provera, and/or would have opted to take the safer, lower,
25 and equally effective dose of Depo-SubQ Provera 104, notwithstanding Plaintiff's Prescribing and
26 Administering Health Care Providers' recommendation.
27
28

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

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

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

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

14 160. By failing to adequately test and research harms associated with Depo-Provera, and by
15 failing to provide appropriate warnings and instructions about Depo-Provera use, patients and the
16 medical community, including prescribing doctors, were inadequately informed about the true risk-
17 benefit profile of Depo-Provera and were not sufficiently aware that serious and potentially
18 debilitating intracranial meningioma might be associated with use of Depo-Provera. Nor were the
19 medical community, patients, patients' families, or regulators appropriately informed that serious and
20 potentially debilitating intracranial meningioma might be a side effect of Depo-Provera and should or
21 could be reported as an adverse event.

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

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

6 163. The foreseeable risk of serious and potentially debilitating intracranial meningioma
7 caused by Depo-Provera could have been reduced or avoided by Plaintiff, prescribers, and/or other
8 consumers had Defendants provided reasonable instructions or warnings of these foreseeable risks of
9 harm.
10

11 164. As a direct and proximate result of Defendants' conduct, including the inadequate
12 warnings, dilution or lack of information, lack of adequate testing and research, and the defective and
13 dangerous nature of Depo-Provera, Plaintiff suffered bodily injuries and resulting pain and suffering,
14 disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing
15 care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and
16 aggravation of previously existing conditions. The losses are either permanent or continuing, and
17 Plaintiff will suffer the losses in the future.
18

19 **COUNT II**

20 **STRICT LIABILITY – DESIGN DEFECT**

21 165. Plaintiff incorporates by reference each and every preceding paragraph as though fully
22 set forth herein.
23

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

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

6 168. Depo-Provera was designed in such a way, using such a high dose of progesterone not
7 necessary for effective contraception, that it posed an unreasonable risk of intracranial meningioma
8 and by placing and keeping Depo-Provera on the market despite Depo-Provera being in a defective
9 condition.
10

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

14 170. Depo-SubQ Provera 104 never attained meaningful market share, and Defendant failed
15 to promote the product to the medical community as a safer and equally effective method of
16 contraception for women choosing to receive quarterly injections.
17

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

21 172. It has long been a tenet in the medical and toxicological community that the “dose
22 makes the poison.” Defendants had a viable safer and lower dose alternative in Depo-SubQ Provera
23 104 but failed to warn the medical community prescribing and administering Depo-Provera that Depo-
24 SubQ Provera 104 was a safer alternative.
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1 173. Moreover, the 150 mg Depo-Provera itself could have been a viable lower effective
2 dose if it had simply been designed, approved, and sold to be administered subcutaneously, like Depo-
3 SubQ Provera 104 is administered, instead of intramuscularly.

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

7 175. Studies have shown that 150 mg Depo-Provera administered intramuscularly causes a
8 spike in blood serum levels of DMPA that is more than four (4) times higher than the peak blood
9 serum concentration of DMPA when that same 150 mg Depo-Provera shot is given subcutaneously,
10 and that very high intramuscular peak concentration persists for several days.²⁷ In fact, 150 mg Depo-
11 Provera administered subcutaneously has a remarkably similar pharmacokinetic profile to Depo-SubQ
12 Provera 104.²⁸

13 176. Thus, there are two lower effective doses of Depo-Provera—both Depo-SubQ Provera
14 104, *and* the very same 150 mg Depo-Provera simply given subcutaneously instead of intramuscularly.

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

21 178. Defendants knew or should have known that the Depo-Provera they developed,
22 manufactured, labeled, marketed, sold, and/or promoted was defectively designed in that it posed a
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27 ²⁷ See Shelton, et al., “Subcutaneous DPMA: a better low dose approach,” *Contraception*, Vol. 89, pp.
341-43 (2014).

28 ²⁸ See *id.* at 342.

1 serious risk of severe and permanent intracranial-meningioma-related injuries when injected
2 intramuscularly.

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

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

7 181. Defendants designed, researched, manufactured, tested, advertised, promoted,
8 marketed, sold and distributed Depo-Provera, a defective product which created an unreasonable risk
9 to the health of consumers, and Defendants are therefore strictly liable for the injuries sustained by
10 Plaintiff.
11

12 182. The Depo-Provera supplied to Plaintiff by Defendants was defective in design or
13 formulation in that, when it left the hands of the manufacturer or supplier, it was in an unreasonably
14 dangerous and a defective condition because it failed to perform as safely as an ordinary consumer
15 would expect when used as intended or in a manner reasonably foreseeable to Defendants, posing a
16 risk of serious and potentially debilitating intracranial meningioma to Plaintiff and other consumers.
17

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

20 184. The Depo-Provera ingested by Plaintiff was in a condition not contemplated by the
21 Plaintiff in that it was unreasonably dangerous, posing a serious risk of permanent vision and retinal
22 injuries.
23

24 185. Depo-Provera is a medication prescribed for contraception and treatment of
25 endometriosis, among other uses. Depo-Provera in fact causes serious and potentially debilitating
26 intracranial meningioma, a brain tumor that can cause severe damage and require invasive surgical
27 removal, harming Plaintiff and other consumers.
28

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

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

8 188. The Depo-Provera supplied to Plaintiff by Defendants was defective in design or
9 formulation in that its effectiveness as a contraceptive did not outweigh the risks of serious and
10 potentially debilitating intracranial meningioma posed by the drug. In light of the utility of the drug
11 and the risk involved in its use, the design of the Depo-Provera drug makes the product unreasonably
12 dangerous.
13

14 189. Depo-Provera's design is more dangerous than a reasonably prudent consumer would
15 expect when used in its intended or reasonably foreseeable manner. It was more dangerous than
16 Plaintiff expected.
17

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

21 191. The design defects render Depo-Provera more dangerous than other drugs and therapies
22 designed for contraception and causes an unreasonable increased risk of injury, including, but not
23 limited, to potentially debilitating intracranial meningioma and sequelae related thereto.
24

25 192. Defendants knew or should have known through testing, generally accepted scientific
26 knowledge, advances in the field, published research in major peer-reviewed journals, or other means,
27
28

1 that Depo-Provera created a risk of serious and potentially debilitating intracranial meningioma and
2 sequelae related thereto.

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

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

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

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

22
23 **COUNT III**

24 **NEGLIGENCE**

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

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

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

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

7
8 201. In disregard of its duty, Defendants committed one or more of the following negligent
9 acts or omissions:

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

13
14 b. Manufacturing, producing, promoting, advertising, formulating, creating,
15 developing, and designing, and distributing Depo-Provera while negligently and intentionally
16 concealing and failing to disclose clinical data which demonstrated the risk of serious harm
17 associated with the use of Depo-Provera;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 203. As a direct and proximate result of the Defendants' negligent testing, monitoring, and
5 pharmacovigilance of Depo-Provera, Defendants introduced a product that they knew or should have
6 known would cause serious and permanent injuries related to the development of intracranial
7 meningioma, and Plaintiff has been injured tragically and sustained severe and permanent pain,
8 suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic
9 damages.
10

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

17 **COUNT IV**

18 **NEGLIGENT FAILURE TO WARN**

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

22 206. At all times material herein, Defendants had a duty to exercise reasonable care and had
23 the duty of an expert in all aspects of the warning and post-sale warning to assure the safety of Depo-
24 Provera when used as intended or in a way that Defendants could reasonably have anticipated, and to
25 assure that the consuming public, including Plaintiff and Plaintiff's physicians, obtained accurate
26 information and adequate instructions for the safe use or non-use of Depo-Provera.
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1 207. Defendants' duty of care was that a reasonably careful designer, manufacturer, seller,
2 importer, distributor and/or supplier would use under like circumstances.

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

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

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

13
14 a. Failing to accompany their product with proper and adequate warnings,
15 labeling, or instructions concerning the potentially dangerous, defective, unsafe, and deleterious
16 propensity of Depo-Provera and of the risks associated with its use, including the severity and
17 potentially irreversible nature of such adverse effects;

18
19 b. Disseminating information to Plaintiff and Plaintiff 's physicians that was
20 negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients
21 such as Plaintiff;

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

24 d. Failing to adequately test and/or warn about the use of Depo-Provera,
25 including, without limitations, the possible adverse side effects and health risks caused by the use
26 of Depo-Provera;
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28

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

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

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

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

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

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

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

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

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

21 n. Failing to warn that the 150 mg dosage of progestin injected intramuscularly
22 was an excessive and thus toxic dose capable of causing and or substantially contributing to the
23 development and growth of meningioma tumors.
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1 211. Defendants knew or should have known of the risk and danger of serious bodily
2 harm from the use of Depo-Provera but failed to provide an adequate warning to patients and
3 prescribing physicians for the product, including Plaintiff and Plaintiff's prescribing physicians,
4 despite knowing the product could cause serious injury.

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

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

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

10 215. The warnings, or lack thereof, that were given by Defendants failed to properly
11 warn prescribing physicians, including Plaintiff's prescribing physician, of the known and
12 knowable risk of serious and potentially irreversible injuries related to the development of
13 intracranial meningioma, and failed to instruct prescribing physicians to test and monitor for the
14 presence of the injuries and to discontinue use when symptoms of meningioma manifest.

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

18 217. Plaintiff and Plaintiff's prescribing physicians reasonably relied upon the skill,
19 superior knowledge, and judgment of Defendants. Defendants had a continuing duty to warn
20 Plaintiff and prescribing physicians of the dangers associated with Depo-Provera. Had Plaintiff
21 received adequate warnings regarding the risks of Depo-Provera, Plaintiff would not have used the
22 product.
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1 223. Each of the following acts and omissions herein alleged was negligently and carelessly
2 performed by Defendants, resulting in a breach of the duties set forth above. These acts and omissions
3 include, but are not restricted to negligently and carelessly:

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

7
8 b. Failing to conduct adequate pre-clinical and clinical testing and post-
9 marketing surveillance to determine the safety of Depo-Provera; and

10
11 c. Designing, manufacturing, and placing into the stream of commerce a
12 product which was unreasonably dangerous for its reasonably foreseeable use, which Defendants
13 knew or should have known could cause injury to Plaintiff.

14
15 d. Failing to use due care in developing, testing, designing, and manufacturing
16 Depo-Provera with the lowest effective dose as a safer alternative which clearly existed at all
17 relevant times so as to avoid the aforementioned risks to individuals when high dose progestin
18 Depo-Provera was being used for contraception.

19
20 224. Defendants' negligence and Depo-Provera's failures arise under circumstances
21 precluding any other reasonable inference other than a defect in Depo-Provera.

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

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

3
4 **COUNT VI**

5 **NEGLIGENT MISREPRESENTATION**

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

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

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

17 230. Defendants' intent and purpose in making these misrepresentations was to deceive and
18 defraud the public and the medical community, including Plaintiff and Plaintiff's Prescribing and
19 Administering Health Care Providers; to falsely assure them of the quality of Depo-Provera and induce
20 the public and medical community, including Plaintiff and her Prescribing and Administering Health
21 Care Providers to request, recommend, purchase, and prescribe Depo-Provera.
22

23 231. The Defendants had a duty to accurately and truthfully represent to the medical and
24 healthcare community, medical device manufacturers, Plaintiff, her Prescribing and Administering
25 Health Care Providers and the public, the known risks of Depo-Provera, including its propensity to
26 cause intracranial meningioma and sequelae related thereto.
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1 232. Defendants made continued omissions in the Depo-Provera labeling, including
2 promoting it as safe and effective while failing to warn of its propensity to cause intracranial
3 meningioma and sequelae related thereto.

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

7 234. Defendants misrepresented and overstated the benefits of Depo-Provera to Plaintiff,
8 Plaintiff's Prescribing and Administering Health Care Providers, and the medical community without
9 properly advising of the known risks associated with intracranial meningioma and sequelae related
10 thereto.

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

15 236. In reliance upon the false and negligent misrepresentations and omissions made by the
16 Defendants, Plaintiff and Plaintiff's Prescribing and Administering Health Care Providers were
17 induced to, and did use Depo-Provera, thereby causing Plaintiff to endure severe and permanent
18 injuries.

19 237. In reliance upon the false and negligent misrepresentations and omissions made by the
20 Defendants, Plaintiff and Plaintiff's Prescribing and Administering Health Care Providers were unable
21 to associate the injuries sustained by Plaintiff with her Depo-Provera use, and therefore unable to
22 provide adequate treatment. Defendants knew or should have known that the Plaintiff, Plaintiff's
23 Prescribing and Administering Health Care Providers, and the general medical community did not
24

1 have the ability to determine the true facts which were intentionally and/or negligently concealed and
2 misrepresented by the Defendants.

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

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

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

10 241. The Defendants failed to exercise ordinary care in making representations concerning
11 Depo-Provera while they were involved in their manufacture, design, sale, testing, quality assurance,
12 quality control, promotion, marketing, labeling, and distribution in interstate commerce, because the
13 Defendants negligently misrepresented Depo-Provera's significant risk of unreasonable and
14 dangerous adverse side effects.
15

16 242. Plaintiff and Plaintiff's Prescribing and Administering Health Care Providers
17 reasonably relied upon the misrepresentations and omissions made by the Defendants, where the
18 concealed and misrepresented facts were critical to understanding the true dangers inherent in the use
19 of Depo-Provera.
20

21 243. Plaintiff and Plaintiff's Prescribing and Administering Health Care Providers' reliance
22 on the foregoing misrepresentations and omissions was the direct and proximate cause of Plaintiff's
23 injuries.
24

25 244. As a direct and proximate result of reliance upon Defendants' negligent
26 misrepresentations, Plaintiff suffered bodily injuries and resulting pain and suffering, disability,
27 mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and
28

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

3
4 **COUNT VII**

5 **FRAUDULENT MISREPRESENTATION**

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

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

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

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

20 249. The representations were, in fact, false. When the Defendants made these
21 representations, it knew and/or had reason to know that those representations were false, and
22 Defendants willfully, wantonly, and recklessly disregarded the inaccuracies in their representations
23 and the dangers and health risks to users of Depo-Provera.
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1 250. Prior to Plaintiff's use of Depo-Provera, Defendants knew or should have known of
2 adverse event reports indicating the development of intracranial meningioma in individuals who had
3 taken Depo-Provera.

4 251. These representations were made by the Defendants with the intent of defrauding and
5 deceiving the medical community, Plaintiff, and the public, and also inducing the medical community,
6 Plaintiff, Plaintiff's Prescribing and Administering Health Care Providers, and/or the public, to
7 recommend, prescribe, dispense, and purchase Depo-Provera for use as a contraceptive and other
8 treatment indications while concealing the drug's known propensity to cause serious and debilitating
9 intracranial meningioma and sequelae related thereto.
10

11 252. Despite the fact that the Defendants knew or should have known of Depo-Provera's
12 propensity to cause serious and potentially debilitating injuries due to the development of intracranial
13 meningioma and sequelae related thereto, the label did not contain any of this information in the
14 "Warnings" section. In fact, the label for Depo-Provera has been updated at least a dozen times over
15 the past 20 years, yet at no point did Defendants provide any of the foregoing information in the
16 "Warnings" section. To date, the Depo-Provera label still does not include any warnings whatsoever
17 that indicate the dangers of intracranial meningioma and sequela related thereto after using Depo-
18 Provera.
19
20

21 253. In representations to Plaintiff and/or to her healthcare providers, including Plaintiff's
22 prescribing physician, the Defendants fraudulently stated that Depo-Provera was safe and omitted
23 warnings related to intracranial meningioma.
24

25 254. In representations to Plaintiff and/or to her Prescribing and Administering Health Care
26 Providers, Defendants fraudulently stated that Depo-Provera was safe and concealed and intentionally
27
28

1 omitted material information from the Depo-Provera product labeling in existence at the time Plaintiff
2 was prescribed Depo-Provera in 2005.

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

6
7 256. The Defendants had a duty when disseminating information to the public to disseminate
8 truthful information; and a parallel duty not to deceive the public, Plaintiff, and/or her physicians.

9
10 257. The Defendants knew or had reason to know of the dangerous side effects of Depo-
11 Provera as a result of information from case studies, clinical trials, literature, and adverse event reports
12 available to the Defendants at the time of the development and sale of Depo-Provera, as well as at the
13 time of Plaintiff's prescription.

14
15 258. Defendants' concealment and omissions of material facts concerning the safety of the
16 Depo-Provera were made purposefully, willfully, wantonly, and/or recklessly to mislead Plaintiff ,
17 Plaintiff's physicians, surgeons and healthcare providers and to induce them to purchase, prescribe,
18 and/or use the drug.

19
20 259. At the time these representations were made by Defendants, and at the time Plaintiff
21 and/or her Prescribing and Administering Health Care Providers used Depo-Provera, Plaintiff and/or
22 her Prescribing and Administering Health Care Providers were unaware of the falsehood of these
23 representations.

24
25 260. In reliance upon these false representations, Plaintiff was induced to, and did use Depo-
26 Provera, thereby causing severe, debilitating, and potentially permanent personal injuries and damages
27 to Plaintiff. The Defendants knew or had reason to know that the Plaintiff had no way to determine
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1 the truth behind the Defendants' concealment and omissions, and that these included material
2 omissions of facts surrounding the use of Depo-Provera as described in detail herein.

3 261. In comporting with the standard of care for prescribing physicians, Plaintiff's
4 prescribing physicians relied on the labeling for Depo-Provera in existence at the date of prescription
5 that included the aforementioned fraudulent statements and omissions.
6

7 262. These representations made by Defendants were false when made and/or were made
8 with the pretense of actual knowledge when such knowledge did not actually exist, and were made
9 recklessly and without regard to the true facts.
10

11 263. Plaintiff did not discover the true facts about the dangers and serious health and/or
12 safety risks, nor did Plaintiff discover the false representations and omissions of the Defendants, nor
13 could Plaintiff with reasonable diligence have discovered the true facts about the Defendants'
14 misrepresentations at the time when Depo-Provera was prescribed to her.
15

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

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

25 **COUNT VIII**

26 **BREACH OF EXPRESS WARRANTY**

27 266. Plaintiff incorporates by reference each and every preceding paragraph as though fully
28

1 set forth herein.

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

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

13 269. Depo-Provera materially failed to conform to those representations made by
14 Defendants, in package inserts and otherwise, concerning the properties and effects of Depo-Provera,
15 which Plaintiff purchased and consumed via intramuscular injection in direct or indirect reliance upon
16 these express representations. Such failures by Defendants constituted a material breach of express
17 warranties made, directly or indirectly, to Plaintiff concerning Depo-Provera as sold to Plaintiff.
18

19 270. Defendants expressly warranted that Depo-Provera was safe and well-tolerated. However,
20 Defendants did not have adequate proof upon which to base such representations, and, in fact, knew or
21 should have known that Depo-Provera was dangerous to the well-being of Plaintiff and others.
22

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

25 272. Plaintiff and Plaintiff's physicians justifiably relied on Defendants' representations
26 regarding the safety of Depo-Provera, and Defendants' representations became part of the basis of the
27 bargain.
28

1 279. Defendants were the sellers of the Depo-Provera and sold Depo-Provera to be taken for
2 contraception or to treat endometriosis, among other indications. Plaintiff was prescribed and
3 purchased Depo-Provera for these intended purposes.

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

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

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

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

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

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

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WHEREFORE, Plaintiff respectfully requests that the Court:

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

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

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

2. Award interest as permitted by law;

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

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

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