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County of Alameda

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By: Damaree Franklin,
Deputy Clerk

1 Karen Barth Menzies (CA SBN 180234)

kbm@kbmlaw.com

2 **KBM Law**

6701 Center Drive West, 1400

3 Los Angeles, California 90045

4 Telephone: (310) 363-0030

Facsimile: (310) 861-0168

5 David P. Matthews (*pro hac vice application forthcoming*)

6 Mark E. Chavez (*pro hac vice application forthcoming*)

dmatthews@thematthewslawfirm.com

7 mchavez@thematthewslawfirm.com

8 **MATTHEWS & ASSOCIATES**

2905 Sackett Street

Houston, TX 77098

9 713-522-5250 Telephone

713-535-7135 Facsimile

10 Brittnie C. Panetta (CA SBN: 333549)

11 bpanetta@thematthewslawfirm.com

12 **MATTHEWS & ASSOCIATES**

1124 S. Main Street, Suite B

Salinas, California 93901

13 Tel: (831)263-6150

14 Fax: (713) 535-7135

15 *Counsel for Plaintiff, Madison Le*

16 **SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF ALAMEDA**

17 MADISON LE,

18 Plaintiff,

19 vs.

20 PFIZER, INC.; PHARMACIA & UPJOHN
21 CO. LLC; PHARMACIA LLC;
22 GREENSTONE LLC; PRASCO LLC d/b/a
23 PRASCO LABS; VIATRIS INC.; KAISER
PERMANENTE INTERNATIONAL;
24 KAISER FOUNDATION HEALTH PLAN
INC.; THE PERMANENTE MEDICAL
25 GROUP, INC., and DOES 1 through 50,
inclusive,

26 Defendants.

Case No.: **24CV099872**

COMPLAINT FOR DAMAGES FOR:

1. **STRICT LIABILITY – FAILURE TO WARN**
2. **STRICT LIABILITY – DESIGN DEFECT**
3. **NEGLIGENCE – FAILURE TO WARN**
4. **NEGLIGENCE – DESIGN**
5. **GENERAL NEGLIGENCE**
6. **NEGLIGENT MISREPRESENTATION**
7. **FRAUD – INTENTIONAL MISREPRESENTATION**
8. **VIOLATION OF CONSUMER PROTECTION LAWS**
9. **BREACH OF EXPRESS WARRANTY**
10. **BREACH OF IMPLIED WARRANTY**

DEMAND FOR JURY TRIAL

1 Plaintiff, Madison Le, by and through undersigned counsel, brings this Complaint against
2 Defendants for personal injuries and damages suffered by Plaintiff and alleges upon information and
3 belief as follows:

4 **INTRODUCTION**

5 1. This action arises from Plaintiff's use of depot medroxyprogesterone acetate
6 ("DMPA") a synthetic hormone-based contraceptive developed and marketed by Defendant Pfizer
7 Inc. ("Pfizer") and sold under the brand name Depo-Provera. Plaintiff was prescribed and used Depo-
8 Provera for contraceptive purposes and developed meningioma, a hormone-sensitive brain tumor, due
9 to her Depo-Provera use.

10 2. Despite long-standing scientific data linking progesterone, and its synthetic analogue
11 progestin, to increased risks of meningiomas, a type of brain tumor, Pfizer and the other Defendants
12 failed to adequately design, test, market, formulate, manufacture, advertise, promote and warn about
13 the dangers of Depo-Provera, a contraceptive containing progestin. Instead, Defendants continued to
14 market the drug as a safe, long-term contraceptive option despite the increased risk of it causing
15 hormone-sensitive meningiomas.

16 3. Even today, after studies have come out indicating that women who used Depo-
17 Provera for more than one year have a staggering 5.6 times greater likelihood of developing
18 meningiomas than those who did not use the drug, the U.S. label for Depo-Provera still fails to warn,
19 instruct, or inform users and prescribers about the risk of meningioma or of the need to monitor for
20 meningioma related symptoms.

21 4. As a result, Plaintiff is one of many previously healthy women who received Depo-
22 Provera injections without having been informed of the drug's serious risks. Exposing Plaintiff to
23 the dangers of Depo-Provera was unnecessary when other, less-dangerous birth control options were
24 available and would have been selected if the true dangers of DMPA had been revealed. As a
25 proximate result of Defendants' wrongful actions and inactions, Plaintiff was injured and suffered
26 damages which she seeks to recover through this action.

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1 **JURISDICTION AND VENUE**

2 5. This Court has jurisdiction over this action pursuant to California Constitution Article
3 VI, Section 10, which grants the Superior Court "original jurisdiction in all causes except those given
4 by statute to other trial courts." The Statutes under which this action is brought do not specify any
5 other basis for jurisdiction. Further, diversity jurisdiction pursuant to 28 U.S.C. § 1332 does not exist
6 based upon the citizenship of Plaintiff and Defendants.

7 6. This Court has personal jurisdiction over each Defendant insofar as some Defendants
8 are residents of California and each Defendant is authorized and licensed to conduct business in the
9 State of California, maintains and carries on systematic and continuous contacts in the State of
10 California, regularly transacts business within the State of California, and regularly avails itself of the
11 benefits of the State of California. All parties have sufficient minimum contacts with the forum state,
12 California, such that, "maintenance of the suit does not offend traditional notions of fair play and
13 substantial justice." *International Shoe Co. v. Washington*, 326 U.S. 310 (1945).

14 7. Additionally, Defendants caused tortious injury by acts and omissions in this judicial
15 jurisdiction and caused tortious injury in this jurisdiction by acts and omissions outside this
16 jurisdiction while regularly doing and soliciting business, engaging in a persistent course of conduct,
17 deriving substantial revenue from goods used or consumed and services rendered in this jurisdiction.

18 8. Venue is proper in this Court pursuant to California Code of Civil Procedure Section
19 395(a) in that the headquarters and principal place of business of Defendants Kaiser Permanente
20 International, Kaiser Foundation Health Plan, Inc., and The Permanente Medical Group are in
21 Alameda County.

22 9. Plaintiff seeks relief that is within the jurisdictional limits of the Court. Federal courts
23 lack jurisdiction over this suit. There is incomplete diversity of citizenship as Plaintiff and Defendant
24 Kaiser are both California citizens. Additionally, Defendant Kaiser is a local forum defendant.
25 Further, Plaintiff's claims raise no federal questions, and Plaintiff seeks no relief under a federal law,
26 statute, regulation, treaty, or constitution. Thus, removal would be improper. To the extent any
27 Defendant seeks to improperly remove this case, Plaintiff requests an award of all costs, expenses,
28 and fees available.

1 **PARTIES**

2 10. Plaintiff Madison Le is a resident of San Jose, California. Plaintiff was prescribed and
3 used Depo-Provera, following her physician’s advice, and subsequently developed a meningioma due
4 to the drug’s synthetic hormone content.

5 **Manufacturer Defendants**

6 11. Defendant **Pfizer Inc.** (“Pfizer”) is a Delaware corporation with its principal place of
7 business at The Spiral, 66 Hudson Boulevard East, New York, NY 100001.

8 12. Pfizer is engaged in the business of designing, manufacturing, marketing, and
9 distributing pharmaceuticals, including Depo-Provera. Pfizer and its subsidiaries are engaged in the
10 research and development, manufacture, and sale of a broad range of products in the healthcare field.
11 Pfizer and its subsidiaries conduct business in virtually all countries of the world.

12 13. Defendant Pfizer is the current New Drug Application holder for Depo Provera and
13 has been the sole holder of the NDA for Depo-Provera since 2020. Upon information and belief,
14 Pfizer has effectively held the NDA since 2002 when it acquired Pharmacia & Upjohn (who then held
15 the NDA) as a wholly owned subsidiary. By 2003, Pfizer’s name appeared on the Depo-Provera label
16 alongside Pharmacia & Upjohn.

17 14. Pfizer may be served with process by serving its registered agent at CT Corporation
18 System t 330 N. Brand Blvd, Suite 700, Glendale, CA 91203.

19 15. Defendant **Pharmacia & Upjohn Co. LLC** (“Upjohn”) is or was a corporation
20 existing under Michigan law and headquartered at 7171 Portage Road, Kalamazoo, MI, 49002.

21 16. At all relevant times, Pharmacia & Upjohn was a wholly owned subsidiary of Pfizer
22 until Upjohn was spun off in a merger in 2020 to create Defendant Viatrix and the remnants of
23 Pharmacia were retained by Pfizer.

24 17. Upjohn may be served with process by serving its registered agent CT Corporation
25 System at 330 N. Brand Blvd, Suite 700, Glendale, CA 91203.

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1 18. Defendant **Pharmacia LLC** (“Pharmacia”) is a corporation organized under Delaware
2 law and headquartered at Pfizer Peapack Campus, 100 Route 206 North, Peapack, NJ 07977. Upon
3 information and belief, Pharmacia is the successor entity to and was formerly known as Pharmacia
4 Corporation.

5 19. Pharmacia may be served with process by serving its registered agent CT Corporation
6 System at 820 Bear Tavern Road, West Trenton, NJ 08682.

7 20. Defendant **Viatrix Inc.** (“Viatrix”) is a corporation organized under Delaware law with
8 its principal place of business at 1000 Mylan Boulevard, Canonsburg, PA 15317.

9 21. Viatrix was formed by the merger of Upjohn, Greenstone and another company, Mylan
10 N.V., in November 2020. Viatrix is the latest iteration of Upjohn and Greenstone.

11 22. Viatrix may be served with process by serving its registered agent at CT Corporation
12 System at 330 N. Brand Blvd, Suite 700, Glendale, CA 91203.

13 23. Defendant **Greenstone, LLC** (“Greenstone”) is a limited liability corporation
14 organized under Michigan law with its principal place of business at its headquarters at Pfizer Peapack
15 Campus, 100 Route 206 North, Peapack, NJ 07977.

16 24. Greenstone was founded in 1993. Until November 2020, Greenstone was styled as a
17 wholly owned subsidiary of Pfizer, though it was staffed and managed by Pfizer and effectively
18 operated as a department within Pfizer. Greenstone offered a portfolio of “authorized generic”
19 medicines including a generic version of Depo-Provera.

20 25. Greenstone may be served with process by serving its registered agent at CT
21 Corporation System at 330 N. Brand Blvd, Suite 700, Glendale, CA 91203.

22 26. Defendant **Prasco LLC d/b/a Prasco Labs** (“Prasco”) is a corporation organized
23 under Ohio law with its principal place of business at 6125 Commerce Court, Mason, OH 45040.

24 27. Prasco was formed by the merger of Upjohn, Greenstone and Mylan N.V. in
25 November 2020. Pfizer is the majority owner of Viatrix.

26 28. Prasco may be served with process by serving its registered agent at CT Corporation
27 System at 330 N. Brand Blvd, Suite 700, Glendale, CA 91203.

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1 35. Defendant **The Permanente Medical Group, Inc.** is a California corporation and has
2 its principal place of business in Oakland, California. The Permanente Medical Group, Inc. is the
3 largest medical group in the United States, providing and arranging professional medical services for
4 over 4.5 million patients in Northern California. At all times relevant, The Permanente Medical
5 Group, Inc. conducted business in California.

6 36. The Permanente Medical Group, Inc., may be served with process by serving its
7 registered agent CT Corporation System at 330 N. Brand Blvd, Suite 700, Glendale, CA 91203.

8 37. At all relevant times, Kaiser Defendants were, and still are, engaged in the business,
9 either directly or indirectly, through third parties or related entities, of prescribing and administering
10 Depo-Provera and its generic equivalents to patients. All Kaiser Defendants were, and still are,
11 engaged in the business of owning, operating and maintaining hospitals, clinics, dispensaries and
12 pharmacies. Kaiser Defendants employ health care professions to provide health care services to the
13 public. Kaiser Defendants do business in California by, among other things, prescribing, distributing,
14 marketing, selling, administering and or profiting from the provision of Depo-Provera and its generic
15 equivalents to patients such as Plaintiff.

16 **Doe Defendants**

17 38. Plaintiff does not currently know the true names or capacities of Defendants sued as
18 DOES 1 through 50 and therefore sues them under fictitious names. Plaintiff alleges, on information
19 and belief, that each DOE Defendant contributed to the injuries and damages sustained by Plaintiff
20 as described herein. Plaintiff will amend this Complaint to include their true names and capacities
21 once they are discovered.

22 39. Plaintiff is informed and believes that at all relevant times, each Defendant, including
23 each DOE Defendant, acted as the agent, servant, employee, or joint venturer of the other Defendants
24 and DOE Defendants and was acting within the course and scope of such agency, service,
25 employment, or joint venture.

1 40. Plaintiff is further informed and believes that Defendants, including DOE Defendants,
2 are or were related entities, such as predecessors, successors, assigns, subsidiaries, affiliates, partners,
3 co-venturers, merged entities, alter egos, or agents. Plaintiff alleges that these entities engaged in
4 researching, manufacturing, designing, marketing, distributing, and selling Depo-Provera, and that
5 they are liable for the tortious conduct of their predecessors and related entities.

6 41. Plaintiff alleges that Defendants and DOE Defendants conducted substantial business
7 in California, including in Alameda County, and were authorized to do so at all relevant times.

8 42. Defendants and DOE Defendants were engaged in the research, development,
9 manufacture, distribution, marketing, and sale of Depo-Provera in interstate commerce and within
10 California, including Alameda County. Plaintiff is informed and believes that these Defendants
11 derived substantial revenue from these activities and reasonably expected their acts to have
12 consequences in California, including Alameda County.

13 **FACTS**

14 43. Plaintiff hereby incorporates every paragraph set forth in this Complaint as if fully
15 copied and set forth at length herein.

16 **About Depo-Provera as a Contraceptive**

17 44. Medroxyprogesterone acetate is a synthetic version of the female hormone
18 progesterone. It is sold under the brand name Depo-Provera.

19 45. Depo-Provera is a depot formulation of medroxyprogesterone acetate that is injected
20 into the muscle tissue of the upper arm or buttocks every three months and is designed to release the
21 active ingredient slowly into the bloodstream over three months. It contains a high dose of the
22 synthetic progesterone-like hormone (150 mg/mL) that suppresses ovulation and thickens cervical
23 mucus to prevent sperm from successfully reaching the egg.

24 46. Depo-Provera was labeled for use as a long-acting injectable contraceptive, with each
25 injection providing three months of birth control. Defendants promoted the drug as a convenient
26 option for women, despite evidence of its long-term risks.

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1 **FDA Approval of Depo Provera for Contraceptive Use**

2 47. Depo-Provera was originally developed by the Upjohn Company in the 1950s. Depo-
3 Provera received FDA approval as a treatment for habitual or threatened miscarriage and
4 endometriosis in 1960. It would later be approved for the additional purpose of treating advanced
5 endometrial cancer.

6 48. Depo-Provera's potential as a contraceptive was discovered during its development
7 for other uses. In the 1960's, Upjohn began testing Depo-Provera as a long-acting contraceptive in
8 studies set up in the United States and other developing countries. These studies raised ethical
9 questions, including questions about the makeup of the study populations and questions about whether
10 participants fully understood the potential adverse effects.

11 49. In 1967, Upjohn felt sufficient data had been accumulated to support submission of a
12 supplemental NDA seeking approval of Depo-Provera as a contraceptive. Upjohn simultaneously
13 began submitting its data to health authorities in other countries as well.

14 50. In 1978, the FDA issued a formal rejection of Depo-Provera as a contraceptive, citing
15 concerns that the drug might cause cancer.¹ More specifically, the FDA rejected Depo-Provera for
16 contraceptive use due to concerns about breast cancer risk and tumor development based on animal
17 studies. These studies indicated a strong link between long-term Depo-Provera use and the
18 development of breast tumors in beagles and endometrial cancer in monkeys. The FDA's Center for
19 Drugs and Biologics said of the drug: "Never has a drug whose target population is entirely healthy
20 people been shown to be so pervasively carcinogenic in animals as has Depo Provera."²

21 51. Meanwhile, Upjohn continued to market and sell Depo-Provera abroad. By 1977,
22 Depo-Provera contraception was available in ninety (90) countries.

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27 ¹ Washington Post, Despite Ban, American Indians Given Depo-Provera as Contraceptive, Aug. 10, 1987
28 (available at <https://www.washingtonpost.com/archive/lifestyle/wellness/1987/08/11/despite-ban-american-indians-given-depo-provera-as-contraceptive/94cbb91d-6497-4b95-abc9-0ddb7ffd5c7b/>)

² *Id.*

1 52. After lobbying efforts and the submission of additional safety data, Depo-Provera was
2 finally approved by the FDA for use as a contraceptive on October 29, 1992, under NDA 020246.
3 Despite the earlier rejection and animal study results, Depo-Provera was marketed as a safe and
4 effective long-term contraceptive option for women, particularly those unable to adhere to daily oral
5 contraceptives.

6 53. In 1995, Upjohn merged with Pharmacia AB to form Pharmacia & Upjohn. Depo-
7 Provera's development and marketing efforts continued under the new entity.

8 54. In 2002, Pfizer acquired Pharmacia & Upjohn. Pfizer thereby acquiring the Depo-
9 Provera NDA. Pfizer has effectively held the Depo-Provera NDA from 2002 and has solely held the
10 NDA since 2020 when Upjohn was spun off to form Viatris.

11 55. When Pfizer acquired Pharmacia & Upjohn, it inherited the regulatory submissions
12 and adverse event data linked to Depo-Provera but failed to meaningfully address the growing body
13 of evidence that the drug increased the risk of hormone-sensitive tumors, including meningiomas.
14 Pfizer is liable both for its conduct in failing to properly design, test and warn with regard to Depo
15 Provera and for the conduct of its predecessors who also failed to adequately design, test and warn of
16 the dangers associated with use of Depo-Provera.

The Dangers of Depo-Provera

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18 56. Extensive research and medical information establish the association between Depo-
19 Provera exposure and the development of meningiomas.³
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27 ³ Roland, N. et al, Use of Progestogens and the risk of intracranial meningioma: National case control study.
28 BJM 2024, 384, e078078. Erratum in BMJ 2024, 384, q776. <https://doi.org/101136/bmj-2030-078078>; PMID:
38537944; PMCID: PMC10966896.

1 57. Meningioma is a medical condition in which a tumor forms in the membranous layers
2 surrounding the brain and spinal court. Treatment of meningiomas typically require invasive brain
3 surgery involving removal of a portion of the skull to access the brain and meninges. Radiation
4 therapy and chemotherapy may also be required depending upon the location of the tumor in the brain.
5 In 1995, Upjohn merged with Pharmacia AB to form Pharmacia & Upjohn. Depo-Provera’s
6 development and marketing efforts continued under the new entity.

7 58. The association between progesterone and meningioma has been known or been
8 knowable for decades.

9 59. In 1983, a study of cytosols from human intracranial meningiomas determined that
10 they contained progesterone receptors in the absence of estrogen receptors.⁴ A follow-up study by the
11 same author in 1987, used an alternative testing method, a monoclonal antibody-based enzyme
12 immunoassay, to confirm that progestin binder detected in meningiomas was a true progestin
13 receptor.⁵ By 1990, the presence of receptors for progesterone in a large portion of human
14 meningioma tissue was described as “well established.”⁶

15 60. Since at least 1989, a number of researchers have observed a relationship between
16 progesterone-inhibiting agents and the growth rate of meningiomas. In particular, meningioma
17 growth was found to be significantly reduced by exposure to anti-progesterone agents.⁷

20 ⁴ Blankenstein, M.A, et al., “Presence of progesterone receptors and absence of oestrogen receptors in human
21 intracranial meningioma cytosols,” *Eur J Cancer & Clin Oncol*, Vol 19, no. 3, pp. 365-70 (1983).

22 ⁵ Blankenstein, M.A. et al, *Assay of oestrogen and progestin receptors in human meningioma cytosols using
23 immunological methods*, *Clinica Chimica Acta* 165 (1987) 189-195.

24 ⁶ Koper JW, Foekens JA, Braakman R, Lamberts SW. Effects of progesterone on the response to epidermal
25 growth factor and other growth factors in cultured human meningioma cells. *Cancer Res.* 1990 May
1;50(9):2604-7. PMID: 2183929.

26 ⁷ E.g. Blankenstein MA, van der Meulen-Dijk C, Thijssen JH. Effect of steroids and antisteroids on human
27 meningioma cells in primary culture. *J Steroid Biochem.* 1989;34(1-6):419-21. doi: 10.1016/0022-
4731(89)90119-2. PMID: 2626036; Grunberg, et al., “Treatment of unresectable meningiomas with the
28 antiprogestosterone agent mifepristone” *J Neurosurgery*, Vol. 74, No. 6, pp. 861-66 (1991); 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 61. By 1990, researchers also recognized that the occurrence of increased rates of growth
2 of meningiomas during pregnancy supported the view that high progesterone levels were related to
3 growth of meningiomas.⁸

4 62. Broad and consistent recognition that blocking progesterone from binding to
5 meningioma cells prevents or reverses the growth of meningiomas should have alerted a sophisticated
6 drug manufacturer, like Pfizer, that high levels of progestins would foster meningioma growth.⁹

7 63. These studies, issued in the 1980's, provided consistent findings that progesterone was
8 involved in the occurrence and growth rate of meningiomas and study authors in the 1980s were
9 calling for further study of how progestins influence the growth of meningiomas.¹⁰ Yet, Pfizer
10 seemingly failed to undertake any investigation into the effects of its the high-dose progestin Depo-
11 Provera on the development of meningiomas before obtaining FDA approval to market Depo-Provera
12 as a contraceptive in 1992.

13 64. Pfizer did little better investigating and acting upon the scientific evidence associating
14 Depo-Provera with meningiomas after DepoProvera received FDA approval. Indeed, in the years
15 following FDA approval, concerns about the potential link between synthetic progestins, including
16 Depo-Provera, and hormone-sensitive tumors continue to surface.

17 65. Pfizer did little better investigating and acting upon the scientific evidence associating
18 Depo-Provera with meningiomas after DepoProvera received FDA approval. Indeed, in the years
19 following FDA approval, concerns about the potential link between synthetic progestins, including
20 Depo-Provera, and hormone-sensitive tumors continue to surface.

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24 ⁸ Koper JW, Foekens JA, Braakman R, Lamberts SW. Effects of progesterone on the response to epidermal
25 growth factor and other growth factors in cultured human meningioma cells. Cancer Res. 1990 May
1;50(9):2604-7. PMID: 2183929.

26 ⁹ Cossu, et al, "The Role of Mifepristone in Meningiomas Management: A Systematic Review of the
27 Literature" BioMed Res. Intl, Vol. 2015, Article ID 267831 <http://dx.doi.org/10.1155/2015/267831>.

28 ¹⁰ Blankenstein, M.A. et al, Assay of oestrogen and progestin receptors in human meningioma cytosols using
immunological methods, Clinica Chimica Acta 165 (1987) 189-195.

1 66. A 2011 Spanish study showed that women who used cyproterone acetate had a
2 significantly higher risk of developing meningiomas. The study identified a dose-response
3 relationship, meaning that the higher the dose a woman used, the higher her risk of developing these
4 tumors.¹¹

5 67. A 2015, retrospective literature review found that an antiprogesterone agent,
6 mifepristone, stopped or reversed meningioma growth.¹²

7 68. More recent studies of progestogens have drilled down on their meningioma causing
8 effects. For instance, in 2022 a French study of 25,000+ people who underwent intercranial
9 meningioma surgery between 2009 and 2018 found a dose-dependent association between
10 progestogen use and intracranial meningiomas.¹³

11 69. In 2024, the French National Agency for Medicines and Health Products Safety along
12 with several French neurosurgeons, epidemiologists, clinicians and researchers published a case
13 control study of over 18,000 women in one of the premier scientific journals in the world, the British
14 Medical Journal. The study, referred to as the Roland Study, examined the association between a
15 wide array of progestogens and the risk of developing a meningioma.¹⁴

21 ¹¹ Gil, M; Oliva B; Timoner J; Macia, MA; Bryant V; de Abajo FJ. Risk of meningioma among users of high
22 doses of cyproterone acetate as compared with the general population: evidence from a population-based
23 cohort study. *Br J Clin Pharmacol.* 2011 Dec; 72(6): 965-969.

24 ¹² Li Y, Rankin C, Grungerg S, et al. Double-Blind Phase III Randomized Trial of the Antiprogesterin Agent
25 Mifepristone in the Treatment of Unresectable Meningioma: SWOG S9005. *J Clin Oncol* 2015 33:4093-4009

26 ¹³ Hoisnard, L.; Laanani, M.; Passeri, T.; Duranteau, L.; Coste, J.; Zureik, M.; Froelich, S.; Weill, A. Risk of
27 intracranial meningioma with three potent progestogens: A population-based case-control study. *Eur. J.*
28 *Neurol.* 2022, 29, 2801–2809. <https://doi.org/10.1111/ene.15423>. PMID: 35621369; PMCID: PMC9543130.

29 ¹⁴ Roland, N. et al, Use of Progestogens and the risk of intracranial meningioma: National case control study.
30 *BJM* 2024, 384, e078078. Erratum in *BMJ* 2024, 384, q776. <https://doi.org/101136/bmj-2030-078078>; PMID:
31 38537944; PMCID: PMC10966896.

1 70. The Roland Study introduced its subject by first discussing the history of concerns
2 over meningiomas associated with high dose progestogen medications. It noted that three such
3 medications, chlormadinone acetate, no megestrol acetate, and cyproterone acetate, had been
4 discontinued in France and the EU pursuant to French and European recommendations to reduce the
5 risk of meningioma attributable to those progestogens in 2018 and 2019.¹⁵

6 71. The Roland Study found that women who used Depo-Provera for more than one year
7 were 5.6 times more likely to develop meningiomas than those who did not use the drug.¹⁶ Women
8 with a longer duration of exposure were shown to have a greater risk.¹⁷ The study further confirmed
9 that prolonged exposure to medroxyprogesterone acetate stimulated progesterone receptors in the
10 brain’s meninges, accelerating tumor growth.

11 72. The most recent study on medroxyprogesterone acetate and meningiomas, the Griffin
12 Study, published on September 30, 2024, found an increased risk of cerebral meningioma among
13 patents using medroxyprogesterone, and particularly among patients who used the drug for two years
14 or more.¹⁸ “The current results are consistent with the prior literature, which reports an association
15 between injection exposures to MPA and a stronger association with use of MPA. Women should be
16 cautioned about the prolonged use of MPA...”

17 **Defendants’ Failures to Test Depo-Provera**

18 73. Defendants owed a duty not to subject Plaintiff to an unreasonable risk of injury due
19 to Depo-Provera. This includes a duty to conduct adequate and well-controlled testing before
20 marketing and during post-marketing surveillance.

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25 ¹⁵ *Id.*

26 ¹⁶ *Id.*

27 ¹⁷ *Id.*

28 ¹⁸ Griffin, R. “The Association between Medroxyprogesterone Acetate Exposure and Meningioma, Dept of
Epidemiology, School of Public Heath, The University of Alabama at Birmingham

1 74. In light of the aforementioned studies and existing medical knowledge, Defendants
2 knew or should have known of the potential for Depo Provera to cause meningioma. Defendants had
3 a duty to investigate the foreseeable potential that a high dose synthetic progesterone like Depo-
4 Provera would cause or substantially contribute to the growth of meningioma. As large and
5 sophisticated pharmaceutical manufacturers, Defendants were best positioned to perform such
6 investigations. Had Defendants properly performed their duties to test, the causal relationship
7 between Depo-Provera and meningioma development would have been uncovered decades ago and
8 Plaintiff (like countless other women) would have been spared the pain and suffering resulting from
9 development of meningioma.

10 75. Instead, Defendants chose to forego adequate and appropriate testing that would have
11 addressed health and safety concerns regarding meningioma to maximize profits by continuing to
12 market and sell Depo-Provera without even a meningioma warning.

13 **Defendants' Failures to Warn About the Risk of Meningiomas**

14 76. Based on the medical literature, adverse event reports, epidemiological studies, what
15 was known about progestones and meningiomas, and other evidence linking Depo-Provera to
16 meningiomas, Defendants knew or should have known that Depo-Provera was not safe for the
17 intended and ordinary purpose for which it is sold and that it was likely to cause and does cause
18 serious and debilitating meningiomas.

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1 77. Despite this knowledge, Defendants failed to act to warn consumers and healthcare
2 providers regarding the increased risk of meningioma. Defendants negligently, willfully, wantonly,
3 and/or recklessly failed to warn about the true risks, dangers, defects, and disadvantages of Depo-
4 Provera. Defendants suppressed the true risks of Depo Provera including information about harmful
5 chemicals in Depo-Provera and the increased risk of meningioma attendant to the drug's use.
6 Defendants have underreported and misreported adverse-event information about the propensity of
7 Depo-Provera to cause serious injury, complications, and death. They have misrepresented the
8 efficacy and safety of Depo-Provera, downplayed the risks, and overstated the benefits through
9 various means and media, actively and intentionally misleading the FDA¹⁹ and the public at large.

10 78. Defendants ignored and downplayed the significance of adverse event data, studies,
11 and medical literature supporting an increased meningioma risk with Depo Provera use, thereby
12 misleading consumers into believe that Depo-Provera was safe for extended us.

13 79. Pfizer also opted not to update the product's label to reflect the meningioma risk.
14 Pfizer's failure to address these concerns reflects a willful disregard for consumer safety.

15 80. The U.S. label for Depo-Provera has been updated at least a dozen times since 2003,
16 yet Defendants have not added any warning or information regarding the increased risk of
17 meningioma associated with Depo-Provera use.

18 81. Indeed, even in the face of the Roland study's finding that women who used Depo-
19 Provera for more than one year were 5.6 times more likely to develop meningiomas than those who
20 did not use the drug, Defendants still have made no change to the US label.

21 82. Defendants have also failed to take any other steps to warn the medical community or
22 consumers that Depo-Provera's increases the risk of meningioma.

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27 ¹⁹ Plaintiffs do not claim fraud on the FDA. Rather, their allegations focus on the Defendants' negligence,
28 defective product design, and failure to provide necessary warnings regarding dangers they either knew or
ought to have been aware of. These dangers should have come to light through a thorough review, adequate
testing, and diligent post-marketing surveillance.

1 83. This is so despite the fact that Pfizer has changed the label in the EU and UK (and
2 potentially in other countries). Under a section titled “Special warnings and precautions for use,” the
3 Depo-Provera label in the EU now states:

4 Meningioma-Meningiomas have been reported following long-term
5 administration of progestogens, including medroxyprogesterone
6 acetate. Depo-Provera should be discontinued if a meningioma is
7 diagnosed. Caution is advised when recommending Depo-Provera to
8 patients with a history of meningioma.

9 84. The Depo-Provera Package Leaflet used in the EU similarly states “before using Depo-
10 Provera [,]... it is important to tell your doctor or healthcare professional if you have, or have ever
11 had in the past...a meningioma (a usually benign tumor that forms in the layers of tissue that cover
12 your brain and spinal cord).”

13 85. Defendant could have added similar language to the US label and package insert for
14 Depo-Provera. Pursuant to Section 314.70 of the FDCA, Pfizer could have filed a “Changes Being
15 Effected” (“CBE”) supplement to make “moderate changes” to the Depo-Provera label without any
16 prior FDA approval. Moderate changes permitted to be made by a CBE supplement include changes
17 reflecting newly acquired information intended to add or strengthen contraindication, warning,
18 precaution, or adverse reaction.

19 86. To this day, Defendants have wrongfully withheld and continue to withhold
20 information from the public on the true risks of Depo-Provera by issuing watered-down statements
21 by public relations firms designed to marginalize safety issues and provide cover for the malfeasance
22 and negligence of the defendants.

23 **Kaiser’s Role in the Selection and Use of Depo-Provera**

24 87. Kaiser provides integrated health services to approximately 8.6 million members,
25 more than three-quarters of which are in California.

26 88. Kaiser is involved in multiple stages of health service provision including marketing
27 and selling medical insurance to members, owning and operating hospitals and clinics, owning and
28 operating dispensaries and pharmacies, and employing physicians, nurses, pharmacists and health
care providers.

1 89. Prescription drugs are a significant cost expenditure to Kaiser, and it maintains control
2 over the prescription of medication to its members. Kaiser aims, and succeeds, in influencing and
3 controlling which drugs its doctors prescribe for members. In California, Kaiser affiliated physicians
4 prescribe drugs from Kaiser’s formulary to Kaiser members 95-98% of the time.

5 90. Kaiser has a Regional Formulary and Therapeutics Committee (“RFTC”) that is tasked
6 with “independently and objectively” evaluating the scientific literature to identify the drugs best
7 suited to treating medical conditions.²⁰

8 91. Kaiser has a Pharmacy and Therapeutics (“P&T”) Committee for each region in which
9 it operates. The Kaiser P&T Committee for each region maintains a drug formulary setting forth the
10 medications that are pre-approved for Kaiser physicians to prescribe.

11 92. Decisions of the P&T Committees are informed by Kaiser’s centralized Drug
12 Information Service (“DIS”) which disseminates drug related information to the P&T Committees.
13 Kaiser has given the DIS a mandate to analyze every medication, evaluate peer-reviewed literature,
14 unpublished data and price information and then forward its recommendations and supporting data to
15 the regional P&T Committees.

16 93. Kaiser’s online advertising and other materials represent that the P&T Committees
17 screen drugs for safety and efficacy before placing them on Kaiser’s drug formulary. For instance,
18 Kaiser represents online that:

- 19 a. Kaiser’s P&T Committee “meets regularly to review and chose the safest, most
20 effective medications for our members.”²¹
- 21 b. Kaiser’s P&T Committee “thoroughly reviews medical literature and selects drugs
22 for the formulary based on factors that include safety and effectiveness.”²²

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24 ²⁰<https://espanol.kaiserpermanente.org/content/dam/kporg/final/documents/forms/drug-formulary-process-nw-en.pdf> (last visited on October 23, 2024).

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26 ²¹<https://healthy.kaiserpermanente.org/health-wellness/drug-formulary/how-itworks#:~:text=The%20Pharmacy%20and%20Therapeutics%20Committee,effective%20medications%20for%20our%20members> (last visited on October 23, 2024).

27
28 ²² <https://healthy.kaiserpermanente.org/northern-california/community-providers/pharmacy> (last visited on October 23, 2024).

- c. Kaiser’s P&T Committee “independently and objectively evaluates the scientific literature to identify the drugs best suited to treat specific medical conditions.”²³
- d. “[S]afety is our foremost concern,”²⁴
- e. “Locally and nationally, Kaiser Permanente independently evaluates the safety of drugs based on clinical trials and other relevant information. In some cases, we do not add FDA-approved drugs to our formulary because of concerns left unanswered.”²⁵
- f. “New drugs, even though approved by the FDA, will not be added to the formulary until their safety is established,”²⁶
- g. Providers have “current, detailed information compiled by the RFTC”.²⁷
- h. “Expert clinical pharmacists support physicians in drug selection, patient monitoring, and patient support.”²⁸

94. Despite Kaiser’s much touted process of independent drug review, Depo-Provera was placed on the Kaiser drug formulary despite its known or knowable risks, including the risk of meningioma.

²³ <https://espanol.kaiserpermanente.org/content/dam/kporg/final/documents/forms/drug-formulary-process-nw-en.pdf> (last visited on October 23, 2024).

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

1 95. Kaiser also failed to provide patients with adequate and accurate safety information
2 about Depo Provera. The Kaiser Permanente web page lists side effects of Depo Provera as “changes
3 in your period,” “mood changes” “less interest in sex,” “weight gain” and possible “bone loss.”²⁹ A
4 patient brochure copyrighted by The Permanente Medical Group lists changes in period regularity,
5 weight gain, tender breasts, headaches, and bone-thinning as possible side effects. Kaiser’s online
6 “Drug encyclopedia” also omitted any discussion of the risk of meningioma.³⁰ Upon information and
7 belief, at no relevant time did Kaiser, provide information that would have been adequate to warn
8 Plaintiff about the increased risk of meningioma.

9 96. Plaintiff does not assert a claim of “professional negligence” against the Kaiser
10 Defendants. Plaintiff’s claims against the Kaiser Defendants arise from the Kaiser’s false promises
11 of enhanced drug safety due to its independent drug evaluations as described herein, which
12 misrepresentations induced Plaintiff to use Depo-Provera. Plaintiff also alleges intentional and
13 fraudulent acts and omissions by the Kaiser Defendants that are outside the scope of professional
14 negligence.

15 **Plaintiff’s Use of Depo-Provera and Resulting Injuries**

16 97. Plaintiff was first administered Depo-Provera for contraceptive purposes around 1996
17 when Plaintiff was 20 years of age. Plaintiff continued to receive regular injections of Depo-Provera
18 from approximately 1996 to 2005 in accordance with her physicians' prescriptions. At all times that
19 Plaintiff was using Depo-Provera, Plaintiff used the drug in an intended or reasonably foreseeable
20 manner as prescribed by her physicians.

21 98. Medroxyprogesterone acetate was administered to Plaintiff at Kaiser Permanente
22 Santa Clara Medical Center in Santa Clara, California.

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26 ²⁹<https://healthy.kaiserpermanente.org/health-wellness/health-encyclopedia/he.Shot-for-Birth-Control-Care-Instructions.ug6424> (last visited on October 23, 2024)

27
28 ³⁰<https://healthy.kaiserpermanente.org/health-wellness/drug-encyclopedia/drug.depo-provera-150-mg-ml-intramuscular-suspension.226806> (last visited on October 23, 2024)

1 99. Plaintiff received approximately 40 injections of Depo-Provera. Plaintiff used brand
2 name Depo Provera. Plaintiff also received some injections of generic medroxyprogesterone acetate
3 - including injections of "authorized generic" versions of the brand name drug Depo-Provera which
4 were identical to brand name Depo-Provera.

5 100. Plaintiff began experiencing symptoms including, but not limited to, headaches,
6 migraines, weakness in the arms and legs, tingling, and memory loss.

7 101. After numerous medical visits and testing procedures, Plaintiff was diagnosed with an
8 intracranial meningioma in 2010, with a recurrence in 2021.

9 102. In December 2010, Plaintiff underwent brain surgery to remove the meningioma at
10 Kaiser Permanente Redwood City Medical Center in California. At the time of surgery, a "golf ball"
11 sized meningioma was removed. She has undergone serial surveillance MRIs since the date of
12 surgery. She has been diagnosed with a recurrence of this primary meningioma in 2021.

13 103. Due to the brain surgery and associated recovery, Plaintiff was forced to miss
14 approximately twelve (12) weeks of work.

15 104. Plaintiff was unaware that her Depo-Provera use had any connection to her
16 meningioma until the large case control study in France, which was published in March 2024,
17 attracted publicity and became broadly known.

18 105. Had Plaintiff known Depo-Provera's unreasonably dangerous characteristics,
19 including that it caused hormone-sensitive tumors such as meningiomas, Plaintiff would never have
20 consented to use the Depo-Provera. Plaintiff would instead have used other safer alternative forms
21 of birth control that were in existence and available on the market.

22 **INNOVATOR LIABILITY**

23 106. California law recognizes that a manufacturer of a brand name drug has a duty to
24 provide accurate and adequate safety information for the brand-name product and "knows to a legal
25 certainty" that such information will be mirrored in the labeling of generic bioequivalents. Because
26 the generic label is entirely dictated by the brand-name manufacturer, California law provides that
27 liability for failures to warn can extend to the brand name manufacturer even when the consumer is
28 prescribed only the generic version of the product.

1 107. Pfizer’s patent for Depo-Provera expired in 2002. Thereafter, generic versions of
2 Depo-Provera entered the market in the United States, even as Pfizer has continued to manufacture,
3 market and distribute brand-name Depo Provera.

4 108. The warnings and precautions on generic medroxyprogesterone acetate are required
5 by law to precisely match the warnings used for branded Depo-Provera. Pfizer is aware that
6 healthcare providers, including physicians and pharmacists, rely upon the warnings and label
7 information for Depo-Provera when prescribing and filling prescriptions with generic
8 medroxyprogesterone acetate.

9 109. A generic drug manufacturer can only change their generic drug's warning label after
10 a brand manufacturer has done so. Thus, it was foreseeable that users of generic medroxyprogesterone
11 acetate would be injured due to the inadequate warnings and instructions, and negligent
12 misrepresentations contained on the Depo-Provera labeling created and controlled by Pfizer. As the
13 innovators of Depo-Provera and the Depo-Provera labeling, Pfizer is liable to Plaintiffs for injuries
14 caused by generic medroxyprogesterone acetate-containing drugs required by federal law to have the
15 same label as Depo-Provera.

16 110. The misrepresentations on the Warnings and Precautions section of the labels for
17 generic medroxyprogesterone acetate were copied from the labels of branded Depo-Provera. That
18 copying was foreseeable, as is required by law. For that reason, Pfizer knew that consumers of generic
19 medroxyprogesterone acetate would be harmed by the misrepresentations they placed on their own
20 branded Depo-Provera.

21 111. As the NDA holder for brand-name Depo-Provera, Pfizer could have at any time, used
22 the CBE regulation to unilaterally update the Depo-Provera label to “add or strengthen a
23 contraindication, warning, precaution or adverse reaction. Pfizer did not have to await FDA pre-
24 approval to take action under the CBE process.

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1 112. Despite having the ability to provide timely and adequate warnings for brand-name
2 Depo Provera, Pfizer failed to take such action. Such failure to provide adequate warnings for brand-
3 name Depo-Provera foreseeably caused the warnings on generic medroxyprogesterone acetate
4 products (which were required to match the brand name warnings) to also be inadequate. Thus, to
5 the extent that any dose of Depo-Provera administered to Plaintiff was generic, Pfizer is liable for any
6 resultant harm to plaintiff from the generic doses under California's innovator liability doctrine.

7 **LIABILITY FOR AUTHORIZED GENERICS**

8 113. At various points from 2004 to the present, Defendants Greenstone, Viartis and Prasco
9 were manufacturers of "authorized generic" versions of Depo-Provera. They operated under the same
10 NDA of Depo-Provera and had the express permission of Pfizer to make, label, distribute, market and
11 sell Depo-Provera without the brand name on its label. The authorized generic version of Depo-
12 Provera manufactured by Greenstone, Viartis and Prasco were the exact same drug as branded Depo-
13 Provera. In some or all instances the authorized generic product was manufactured by Pfizer.

14 114. Because the authorized generic distributors operated as if they were the brand name
15 holder under the same NDA, the authorized generic distributors could have changed the brand name
16 label to warn of the risk of meningioma and the dangers of high dose progestins.

17 115. The authorized generic distributors also could have requested Pfizer, with whom they
18 were in a close business relationship, to change the brand name label to add warnings regarding the
19 risk of meningioma and the dangers of high dose progestins.

20 116. Pfizer had a duty to change the label knowing that its authorized generic distributors,
21 Defendants Greenstone, Viartis and Prasco, were selling the generic product without a warning about
22 the meningioma risk.

23 **EXEMPLARY/PUNITIVE DAMAGES ALLEGATIONS**

24 117. Defendants' conduct as alleged herein was done with conscious and reckless disregard
25 for the safety of Plaintiff and other women who were subject to Depo-Provera without being given
26 warnings about the known and/or knowable risk of meningioma which was generally accepted in the
27 scientific community.

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1 118. Defendants were fully aware of the safety risks of medroxyprogesterone acetate,
2 particularly the drug's propensity to cause meningiomas. Nonetheless, Defendants deliberately
3 crafted their label, marketing, and promotion to omit any warning or information regarding the risk
4 of meningioma.

5 119. This was not done by accident or through some justifiable negligence. Rather,
6 Defendants knew that they could turn a profit by convincing consumers that Depo Provera was
7 harmless to humans, and that full disclosure of the true risks of Depo Provera would limit the amount
8 of money Defendants would make selling medroxyprogesterone acetate. Defendants' object was
9 accomplished not only through their misleading label, but through a comprehensive scheme of
10 selective misleading research and testing, false advertising, and deceptive omissions as more fully
11 alleged throughout this Complaint. Plaintiff was denied the right to make an informed decision about
12 whether to purchase and use medroxyprogesterone acetate, knowing the full risks attendant to that
13 use. Such conduct was done with malice, oppression and conscious disregard of Plaintiff's rights.

14 120. Accordingly, Plaintiff requests punitive damages against Defendants for the harm
15 caused to Plaintiff.

16 **EQUITABLE TOLLING, DISCOVERY RULE, FRAUDULENT**
17 **CONCEALMENT ESTOPPEL**

18 121. Plaintiff asserts all applicable statutory and common law rights and theories related to
19 the tolling or extension of any applicable statute of limitations, including estoppel, equitable tolling,
20 delayed discovery, discovery rule and/or fraudulent concealment.
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1 122. Plaintiff has suffered an injury that has a latency period and does not arise until years
2 after exposure. At the time that Plaintiff used Depo-Provera, Plaintiff had no way of knowing about
3 the risk of meningioma associated with the use of Depo-Provera. Defendants did have knowledge
4 and means of obtaining knowledge regarding the risk of meningiomas associated with Depo-Provera
5 but chose instead to conceal the truth that its lucrative product was linked to meningioma. Defendants
6 had the ability to, and did, spend enormous amounts of money in furtherance of the purposes of
7 marketing and promoting a profitable product, notwithstanding the known or knowable risks
8 associated with the product. Plaintiff and medical professionals could not have afforded to and could
9 not have possibly conducted studies to determine the nature, extent and identity of Depo-Provera's
10 health risks, and so, were forced to rely on Defendants' representations. As a result of Defendants'
11 actions, Plaintiff could not have reasonably known or learned through reasonable diligence that
12 Plaintiff had been exposed to the risk of meningioma and that the meningioma she developed was the
13 direct and proximate result of Defendants' acts and omissions.

14 123. The expiration of any applicable statute of limitations has been equitably tolled by
15 reason of Defendants' misrepresentation concealment and fraudulent conduct. Through affirmative
16 misrepresentations and omissions, Defendants willfully, wantonly, actively, and intentionally
17 concealed from Plaintiff, Plaintiff's physicians, the medical community, and the community at large
18 the true risks associated with use of Depo Provera. Due to Defendants' acts and omissions, Plaintiff's
19 physicians were unaware of the increased risk of meningioma associated with the use of Depo-
20 Provera. Plaintiff's physicians did not warn Plaintiff of the true risks of receiving Depo-Provera
21 injections including the increased risk of meningioma. During the limitations period, Plaintiff could
22 not reasonably have known or learned through reasonable diligence that Plaintiff had been exposed
23 to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts
24 and omissions.

1 124. The discovery rule applies to toll the running of the statute of limitations until Plaintiff
2 knew, or through the exercise of reasonable care and diligence should have known, of facts that
3 Plaintiff had been injured, the cause of the injury, and the tortious nature of the wrongdoing that
4 caused the injury. Within the time period of any applicable statute of limitations, Plaintiff could not
5 have discovered through the exercise of reasonable diligence that Depo-Provera use caused
6 meningioma. Plaintiff did not discover and did not know of facts that would cause a reasonable
7 person to suspect that meningioma was associated with use of Depo-Provera. Nor would a reasonable
8 and diligent investigation by Plaintiff have disclosed that Depo-Provera would cause meningioma.

9 125. Defendants are estopped from relying on any statute of limitations because of their
10 concealment of the truth regarding the safety of Depo-Provera. Defendants had a duty to disclose the
11 true character, quality, and nature of Depo-Provera because this was non-public information over
12 which Defendants continue to have control. Defendants knew that this information was not available
13 to Plaintiff, Plaintiff's medical providers, and/or health facilities, yet Defendants failed to disclose the
14 information to the public, including to the Plaintiff.

15 126. Within the time period of any applicable statute of limitations, Plaintiff could not have
16 discovered through the exercise of reasonable diligence that exposure to Depo-Provera is injurious to
17 human health. Plaintiff's physicians did not warn Plaintiff that the true risks of Depo-Provera
18 included the increased risk of meningioma. Plaintiff did not discover and did not know of facts that
19 would cause a reasonable person to suspect the risk associated with the use of Depo-Provera. Nor
20 would a reasonable and diligent investigation by Plaintiff have disclosed that Depo-Provera would
21 cause Plaintiff's illnesses.

22 127. Plaintiff brings this action within the prescribed time limit following Plaintiff's
23 injuries and Plaintiff's knowledge of the wrongful cause. Prior to such time, Plaintiff did not know
24 and had no reason to know of her injuries and/or the wrongful cause of those injuries.

25 128. Plaintiff was unaware that her Depo-Provera use had any connection to her
26 meningioma until the large case control study in France, which was published in March 2024,
27 attracted publicity and became broadly known.

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1 **CAUSES OF ACTION**
2 **COUNT I: STRICT LIABILITY – FAILURE TO WARN**
3 **(Asserted against Manufacturer Defendants)**

4 129. Plaintiff realleges and incorporates by reference every paragraph of this Complaint as
5 though fully set forth herein.

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

11 131. Defendants designed, manufactured, tested, marketed, labeled, packaged, handled,
12 distributed, stored, sold, and/or otherwise released Depo-Provera into the stream of commerce, and
13 in the course of same, directly marketed the products to consumers and end users, including Plaintiff,
14 and therefore had a duty to warn of the risks associated with the use of Depo-Provera.

15 132. A manufacturer has a duty to adequately warn of the potential risks or hazards
16 associated with a product where there is unequal knowledge, actual or constructive of a dangerous
17 condition, and the defendant, possessed of such knowledge, knows or should know that harm might
18 or could occur if no warning is given.

19 133. Depo-Provera is defective and unreasonably dangerous to consumers, including
20 Plaintiff, because it does not contain adequate warnings or instructions concerning its dangerous
21 characteristics, including its increased risk of developing meningioma. These warnings were under
22 the ultimate control and supervision of Defendants.

23 134. At all relevant times, Defendants had a duty to properly design, manufacture, test,
24 market, label, package, handle, distribute, store, sell, provide proper warnings, and/or take such steps
25 as necessary to ensure their Depo-Provera did not cause users and consumers to suffer from
26 unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiff of dangers
27 associated with Depo-Provera. Defendants, as a manufacturer or seller of pharmaceutical medication,
28 are held to the knowledge of an expert in the field.

1 135. At the time of manufacture, Defendants could have provided warnings or instructions
2 regarding the full and complete risks of Depo-Provera, including the risk of meningioma, because
3 they knew or should have known of the unreasonable risks of harm associated with the use of and/or
4 exposure to such products.

5 136. At all relevant times, Defendants failed and deliberately refused to investigate, study,
6 test, or promote the safety or to minimize the dangers to users and consumers of their products and to
7 those who would foreseeably use or be harmed by Defendants' Depo-Provera.

8 137. Even though Defendants knew or should have known that Depo-Provera posed a grave
9 risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with
10 use and exposure to Depo-Provera. The dangerous propensities of Depo-Provera and the carcinogenic
11 characteristics of NDMA, as described above, were known to Defendants, or scientifically knowable
12 to Defendants through appropriate research and testing by known methods, at the time they
13 distributed, supplied or sold the product, and were not known to end users and consumers, such as
14 Plaintiff.

15 138. Defendants knew or should have known that Depo-Provera created significant risks of
16 serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn or
17 instruct consumers, i.e., the reasonably foreseeable users, and physicians of the risks of exposure to
18 Depo-Provera. Defendants failed to warn and have wrongfully concealed information concerning the
19 dangerous increase in meningiomas associated with Depo-Provera, and further, have made false
20 and/or misleading statements concerning the safety of Depo-Provera.

21 139. The risk of developing meningiomas is a significant danger associated with Depo-
22 Provera, and this risk was known, or should have been known, to Pfizer based on the scientific
23 literature and available data. Despite this knowledge, Pfizer failed to provide adequate warnings or
24 instructions regarding the risk of meningiomas in its product labeling, advertising, or marketing
25 materials.

26 140. At all relevant times, Defendants' Depo-Provera were expected to and did reach
27 Plaintiff without a substantial change in their anticipated or expected design as manufactured, tested,
28 marketed, labeled, packaged, handled, distributed, stored, and/or sold by Defendants.

1 141. At all relevant times, Plaintiff used Depo-Provera for its intended or reasonably
2 foreseeable purposes, without knowledge of their dangerous characteristics.

3 142. Plaintiff was exposed to Defendants' Depo-Provera without knowledge of its
4 dangerous characteristics. Plaintiff could not have reasonably discovered the defects and risks
5 associated with Depo-Provera prior to or at the time Plaintiff was injected with the drug. Plaintiff
6 and her physicians relied upon the skill, superior knowledge, and judgment of Defendants to know
7 about and disclose serious health risks associated with using Defendants' products.

8 143. Defendants knew or should have known that the minimal warnings disseminated with
9 Depo-Provera were inadequate, failed to communicate adequate information on the dangers of
10 meningioma and failed to communicate warnings and instructions that were appropriate and adequate
11 to render the products safe for their ordinary, intended and reasonably foreseeable uses.

12 144. The information that Defendants did provide failed to contain relevant warnings and
13 precautions that would have enabled consumers such as Plaintiff to avoid using the drug. Instead,
14 Defendants disseminated information that was inaccurate, false, and misleading, and which failed to
15 communicate accurately or adequately the comparative severity, duration, and extent of the risk of
16 meningioma associated with use of Depo Provera.

17 145. Defendants continued to aggressively promote the efficacy of Depo-Provera, even
18 after they knew or should have known of the unreasonable risks from use or exposure; and concealed,
19 downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information
20 or research about the risks and dangers of Depo Provera, including meningioma.

21 146. This alleged failure to warn is not limited to the information contained on Depo-
22 Provera' labeling. Defendants were able, in accord with federal law, to comply with relevant state
23 law by disclosing the known risks associated with Depo-Provera through other non-labeling
24 mediums, e.g., promotion, advertisements, public service announcements, and/or public information
25 sources. But Defendants did not disclose these known risks through any medium.

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1 147. Had Defendants provided adequate warnings and instructions and properly disclosed
2 and disseminated the risks associated with their Depo-Provera, Plaintiff could have avoided the risk
3 of developing injuries and could have obtained or used safer alternative medication. Defendants did
4 not advise that there existed other, safer but equally effective, alternative contraceptive options.
5 Defendant did not provide adequate safety information to allow Plaintiff and her health care providers
6 to make an accurate assessment of which contraceptive product is best for Plaintiff.

7 148. Defendants' conduct, as described above, was reckless. Defendants risked the lives of
8 consumers and users of their products, including Plaintiff, with knowledge of the safety problems
9 associated with Depo-Provera, and suppressed this knowledge from the general public. Defendants
10 made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants'
11 reckless conduct warrants an award of punitive damages.

12 149. Defendants' lack of adequate warnings and instructions accompanying their Depo-
13 Provera were a substantial factor in causing Plaintiff's injuries.

14 150. As a direct and proximate result of Defendants' conduct, including the inadequate
15 warnings, lack of safety information, failures to adequately research and test, and the defective and
16 dangerous nature of Depo-Provera, Plaintiff has been injured and sustained severe and permanent
17 pain, suffering, disability, mental anguish, impairment, loss of enjoyment of life, comfort, loss of
18 consortium, economic damage and other damages.

19 **COUNT II: - STRICT LIABILITY – DESIGN DEFECT**
20 **(Asserted against Manufacturer Defendants)**

21 151. Plaintiff realleges and incorporates by reference every paragraph of this Complaint as
22 though fully set forth herein.

23 152. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled,
24 packaged, handled, distributed, stored, and/or sold Depo-Provera, which was defective and
25 unreasonably dangerous to consumers, including Plaintiff, thereby placing Depo-Provera into the
26 stream of commerce. These actions were under the ultimate control and supervision of these
27 Defendants.
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1 153. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled,
2 packaged, handled, distributed, stored, and/or sold the Depo-Provera used by Plaintiff, as described
3 herein.

4 154. At all relevant times, the medication injected into Plaintiff was expected to and did
5 reach Plaintiff without a substantial change in its anticipated or expected design as manufactured,
6 tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold by the Defendants.
7 Depo-Provera was defective in design and formulation in that, when it left Defendants' control, it was
8 unreasonably dangerous, and dangerous to an extent beyond that which an ordinary consumer would
9 contemplate because of the drugs increased risk of meningioma.

10 155. Depo-Provera, as designed, manufactured, tested, marketed, labeled, packaged,
11 handled, distributed, stored, and/or sold by Defendants was defective in design and formulation in
12 that, when they left the hands of Defendants, the foreseeable risks exceeded the alleged benefits
13 associated with the drug's design and formulation.

14 156. At all relevant times, Defendants knew or had reason to know that Depo-Provera was
15 defective and were inherently dangerous and unsafe when used in the manner instructed and provided
16 by Defendants.

17 157. Therefore, at all relevant times, Depo-Provera, as designed, manufactured, tested,
18 marketed, labeled, packaged, handled, distributed, stored, and/or sold by Defendants was defective in
19 design and formulation, in one or more of the following ways:

- 20 a. Depo-Provera posed a grave risk of meningioma when used in a reasonably
21 anticipated manner;
- 22 b. Depo-Provera was not reasonably safe when used in a reasonably anticipated or
23 intended manner;
- 24 c. Depo-Provera was not sufficiently tested, investigated or studied; in particular, the
25 relationship between Depo-Provera and meningioma was not adequately tested,
26 investigated or studied.
- 26 d. The relationship between duration of use and the greater risk of meningioma
27 development was not adequately tested, investigated, or studied.
- 28 e. Depo-Provera lacked adequate and accurate warnings and instructions concerning
the risk of meningioma and the symptoms of meningioma that should be watched
for by users of Depo-Provera.

- 1 f. Defendants did not conduct adequate post-marketing surveillance of their Depo-Provera;
- 2
- 3 g. Depo-Provera was not required to use such a high dose of progesterone for effective contraception.
- 4
- 5 h. Using a high dose of progesterone unnecessarily increases the risk of meningioma while providing no increased contraceptive benefits.

6 158. Exposure to Depo-Provera presents a risk of harmful side effects that outweigh any
7 potential utility stemming from the use of the drug. The harm caused by Defendants' Depo-Provera
8 far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that
9 which an ordinary consumer would contemplate. Depo-Provera was and is more dangerous than
10 alternative products, and Defendants could have designed Depo-Provera to make it less dangerous.
11 Indeed, at the time Defendants designed Depo-Provera and its labels, the state of the industry's
12 scientific knowledge was such that a safer, less risky design or formulation and label was attainable.

13 159. Defendants could have employed safer alternative designs and formulations. Depo-
14 SubQ Provera 104 is a lower dosage version of Depo-Provera that is administered on the same time
15 schedule (every three months) as Depo-Provera and provides equivalent contraceptive function to
16 Depo-Provera. Defendants did not meaningfully promote Depo-SubQ Provera 104 out of fear that
17 doing so would spark fears about high dose Depo-Provera and reduce Depo-Provera sales.
18 Additionally, non-hormonal birth control methods were also available alternatives for some patients.

19 160. Plaintiff used Depo-Provera without knowledge of Depo-Provera's dangerous
20 characteristics. Plaintiff could not reasonably have discovered the defects and risks associated with
21 Depo-Provera before or at the time of exposure due to Defendants' suppression or obfuscation of
22 scientific information linking Depo-Provera to meningioma.

23 161. At all times relevant to this litigation, Plaintiff used and/or were exposed to the use of
24 Defendants' Depo-Provera in an intended or reasonably foreseeable manner without knowledge of
25 Depo-Provera's dangerous characteristics.

26 162. Defendants' defective design of Depo-Provera was willful, wanton, malicious, and
27 conducted with reckless disregard for the health and safety of users of Depo-Provera, including
28 Plaintiff.

1 163. The defects in Depo-Provera were substantial factors in causing Plaintiff’s injuries.
2 The defects in Depo-Provera were substantial and contributing factors in causing Plaintiff’s injuries,
3 and, but for Defendants’ misconduct and omissions, Plaintiff would not have sustained injuries.

4 164. As a direct and proximate result of Defendants’ defective design of Depo-Provera,
5 Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, mental
6 anguish, impairment, loss of enjoyment of life, comfort, loss of consortium, economic damage
7 including obligations for medical services and expenses, lost income and other damages. These losses
8 are either permanent or continuing and Plaintiff will suffer the losses in the future.

9 **COUNT III – NEGLIGENT – FAILURE TO WARN**
10 **(Asserted against All Defendants)**

11 165. Plaintiff realleges and incorporates by reference every paragraph of this Complaint as
12 though fully set forth herein.

13 166. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled,
14 packaged, handled, distributed, and sold Depo-Provera. Defendants knew or by the exercise of
15 reasonable care should have known that Depo-Provera was not accompanied by adequate warnings
16 or instructions concerning the dangerous characteristics of Depo-Provera and, particularly, the
17 dangerous increased risk of meningioma. These actions were under the ultimate control and
18 supervision of Defendants.

19 167. Defendants designed, manufactured, tested, marketed, labeled, packaged, handled,
20 distributed, stored, and/or sold, and otherwise released into the stream of commerce Depo-Provera.
21 In the course of do doing, Defendant directly marketed the products to consumers and end users,
22 including Plaintiff, and therefore had a duty to warn consumers and end users, as well as healthcare
23 providers, of the risks associated with the use of Depo-Provera.

24 168. At all relevant times, Defendants had a duty to properly design, manufacture, test,
25 market, label, package, handle, distribute, store, and sell, provide proper warnings, and take such steps
26 as necessary to ensure Depo-Provera did not cause users and consumers to suffer from unreasonable
27 and dangerous risks.
28

1 169. Defendants had a continuing duty to warn Plaintiff of dangers associated with Depo-
2 Provera. Defendants, as manufacturers and sellers of pharmaceutical medication, are held to the
3 knowledge of an expert in the field.

4 170. Defendants breached their duty by failing and deliberately refusing to investigate,
5 study, test, or promote safety or to minimize the dangers to users and consumers of their product and
6 to those who would foreseeably use or be harmed by use of Depo-Provera.

7 171. Defendants breached their duty by failing to use reasonable care to adequately warn
8 of the dangerous risks associated with use and exposure to Depo-Provera. The dangerous propensities
9 of Depo-Provera to cause or substantially contribute to meningioma were known to Defendants, or
10 scientifically knowable to Defendants. Defendants breached their duty by failing to provide warnings
11 or instructions regarding the full and complete risks of Depo-Provera because they knew or should
12 have known use of Depo-Provera was dangerous, harmful and injurious when used by Plaintiff in a
13 reasonably foreseeable manner.

14 172. At all relevant times, Plaintiff was unknowingly exposed to excessive and unnecessary
15 risk of developing meningioma while using Depo-Provera for its intended or reasonably foreseeable
16 purpose as a contraceptive. Plaintiff used Depo-Provera without knowledge of its dangerous
17 characteristics.

18 173. Manufacturer Defendants acted negligently, and breached their duties to Plaintiff,
19 through acts and omissions including the following:

- 20 a. Not issuing a warning that use of Depo-Provera may cause meningioma.
- 21 b. Not issuing a warning not to take Depo-Provera when other lower-dose or non-
22 hormonal contraceptives were an option for the patient.
- 23 c. Not issuing a warning that Depo-Provera should not be used for prolonged period
24 exceeding one year.
- 25 d. Failing to accompany Depo-Provera with proper and adequate warnings, labeling
26 and instructions concerning the drugs dangerous health risks.
- 27 e. Failing to accurately warn about the severity and potentially irreversible nature of
28 the meningioma risk posed by Depo Provera.
- f. Failing to adequately test in response to safety signals relating to meningioma risks
 with Depo-Provera use.

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- 2 g. Not instructing patients, prescribers and healthcare providers as to the need for
- 3 monitoring for meningioma symptoms when taking Depo-Provera.
- 4 h. Not instructing patients to discontinue Depo-Provera if symptoms potentially
- 5 related to the development of intracranial meningiomas arise.
- 6 i. Failing to explain the mechanism, mode and types of adverse events associated
- 7 with Depo-Provera.
- 8 j. Failing to adequately train medical care providers regarding appropriate use of
- 9 Depo-Provera.
- 10 k. Failing to advise that safer alternatives with lower effective doses of progestin exist
- 11 and provide equivalent birth control protection,

12 174. Kaiser Defendants acted negligently, and breached their duties to Plaintiff, through
13 acts and omissions including the following:

- 14 a. Failing to use reasonable and prudent care in researching, evaluating, approving
- 15 and recommending Depo-Provera as a safe contraceptive when Depo Provera
- 16 posed a greatly increased risk of developing meningioma
- 17 b. Failing to independently and objectively evaluate the scientific literature relating
- 18 to Depo Provera despite representing to patients that you Kaiser did so;
- 19 c. Placing Depo-Provera on the Kaiser drug formulary thereby signaling and
- 20 influencing doctors and healthcare providers in the Kaiser system that they
- 21 should prescribe and use Depo Provera;
- 22 d. Failing to properly and thoroughly research the scientific data and medical
- 23 literature relating to Depo-Provera to determine whether or not Depo-Provera
- 24 was safe for its intended consumer use;
- 25 e. Failing to undertake to provide adequate warnings instructions, guidelines, and
- 26 safety precautions to those persons Defendants could reasonably foresee would
- 27 use Depo-Provera;
- 28 f. Failing to undertake to disclose to Plaintiff, users/consumers, and the general
- public that use of Depo-Provera presented a risk of meningioma,
- g. Failing to warn Plaintiff, consumers, and the general public that Depo-Provera’
- risk of harm was unreasonable and that there were safer and effective alternative
- contraceptives available to Plaintiff and other consumers;
- h. Advertising, marketing, and recommending the use of Depo-Provera, while
- concealing and failing to disclose or warn of the dangers known (by Defendants)
- to be associated with or caused by the use of Depo-Provera;

- i. Continuing to disseminate information to consumers, including Plaintiff, that indicated or implied that Depo-Provera was not unsafe for regular consumer use; and
- j. Continuing to market, approve, sell and encourage the use of Depo-Provera with the knowledge that the product was unreasonably unsafe and dangerous.

175. A reasonable drug manufacturing company and a reasonable medical care services provider under the same or similar circumstance would have warned and instructed of the dangers of Depo-Provera as described in the preceding paragraph.

176. Defendants knew or should have known that the minimal warnings disseminated with Depo-Provera were inadequate, failed to communicate adequate information on the dangers of Depo-Provera use, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended, and reasonably foreseeable uses.

177. This alleged failure to warn is not limited to the information contained on Depo-Provera' labeling. Defendants were able to disclose the known risks associated with Depo-Provera through other non-labeling mediums, e.g., promotion, advertisements, public service announcements, and/or public information sources. But Defendants did not disclose these known risks through any of these means.

178. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to avoid using the product. Instead, Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to Depo-Provera, continued to aggressively promote the efficacy of Depo-Provera, even after they knew or should have known of the unreasonable risks, ; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of using Depo-Provera.

1 179. Had Defendants provided adequate warnings and instructions and properly disclosed
2 and disseminated the risks associated with their Depo-Provera, Plaintiff could have avoided the risk
3 of developing injuries and could have obtained or used alternative medication. However, as a result
4 of Defendants' concealment of the dangers posed by their Depo-Provera, Plaintiff was unable to avert
5 her injuries.

6 180. Defendants' conduct, as described above, was reckless. Defendants risked the lives of
7 consumers and users of their products, including Plaintiff, with knowledge of the safety problems
8 associated with Depo-Provera, and suppressed this knowledge from the general public. Defendants
9 made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants'
10 reckless conduct warrants an award of punitive damages.

11 181. Defendants' lack of adequate warnings and instructions accompanying their Depo-
12 Provera were a substantial factor in causing Plaintiff's injuries.

13 182. As a direct and proximate result of Defendant's negligent warnings, Plaintiff has been
14 injured and sustained severe and permanent pain, suffering, disability, mental anguish, impairment,
15 loss of enjoyment of life, comfort, loss of consortium, economic damages including obligations for
16 medical services and expenses, lost income and other damages. These losses are either permanent or
17 continuing and Plaintiff will suffer the losses in the future.

18 **COUNT IV: NEGLIGENCE – DESIGN**
19 **(Asserted against Manufacturer Defendants)**

20 183. Plaintiff realleges and incorporates by reference every paragraph of this Complaint as
21 though fully set forth herein.

22 184. Defendants owed a duty to all reasonably foreseeable users to design a safe product
23 and to provide a label that rendered the product safe and effective. Defendants' duty of care was
24 owed to consumers, physicians, healthcare providers and the general public.

25 185. Defendants breached their duty by failing to use reasonable care in the design of Depo-
26 Provera in one or more of the following ways:

- 27 a. When placed in the stream of commerce, Depo-Provera was defective in design
28 and formulation, and, consequently, dangerous to an extent beyond that which an
ordinary consumer would contemplate;

- 1 b. When placed in the stream of commerce, Depo-Provera was unreasonably
2 dangerous in that it posed a grave risk of meningioma when used in a reasonably
3 anticipated manner;
- 4 c. When placed in the stream of commerce, Depo-Provera contained unreasonably
5 dangerous design defects in that it unnecessarily exposed users to higher doses of
6 progesterone than necessary to meet its contraceptive purpose;
- 7 d. Defendants manufactured, produced, promoted, formulated, created, developed,
8 designed, distributed, and marketed, and sold Depo-Provera without undertaking
9 sufficient pre- and post-market studies and testing to determine whether or not
10 Depo-Provera were safe for their intended consumer use;
- 11 e. Defendants did not sufficiently test, investigate, the effect of dosage or of duration
12 of use of Depo-Provera on the likelihood of developing meningioma;
- 13 f. Defendants did not conduct adequate post-marketing surveillance of Depo
14 Provera;
- 15 g. Defendants did not design or manufacture Depo-Provera so as to use the lowest
16 effective dose necessarily to achieve its contraceptive purpose;
- 17 h. Defendants could have employed safer alternative designs and formulations, but
18 failed to do so;
- 19 i. Defendants failed to design and manufacture Depo-Provera so as to ensure it was
20 at least as safe and effective as other contraceptives on the market that were used
21 for the same purpose;
- 22 j. Defendants were negligent in manufacturing, producing, promoting, formulating,
23 creating, developing, designing, selling, and/or distributing Depo-Provera while
24 negligently and/or intentionally concealing and failing to disclose the results of
25 trials, tests, and studies of Depo-Provera, and, consequently, the risk of serious
26 harm associated with human use of Depo-Provera;
- 27 k. Defendants failed to use reasonable and prudent care in testing, research, and
28 development of Depo-Provera so as to avoid the risk of serious harm associated
with the prevalent use of Depo-Provera;
- l. Defendants were negligent in advertising, marketing, and recommending the use
of Depo-Provera while concealing and failing to disclose or warn of the
meningioma risk known (to Defendants) to be associated with Depo-Provera;
- m. Defendants failed to provide adequate instructions, guidelines, and safety
precautions to those persons Defendants who could reasonably be foreseen would
use Depo-Provera;
- n. Defendants failed to disclose that there were safer and effective alternative
contraceptives available to Plaintiff and other consumers;

- 1 o. Defendants systematically suppressed and downplayed evidence about the risks,
2 incidence, and prevalence of meningioma associated with Depo-Provera;
- 3 p. Defendants represented that their products were safe for their intended use when,
4 in fact, Defendants knew or should have known the products were not safe for their
5 intended purpose;
- 6 q. Defendants failed to make or propose any changes to the products' labeling or
7 other promotional materials that would alert consumers and the general public of
8 the risks, particularly the risk of meningioma; and
- 9 r. Defendants continued to manufacture and sell Depo-Provera despite knowledge
10 that the products were adulterated, misbranded, unreasonably unsafe and
11 dangerous.

12 186. Exposure to Depo-Provera presents a risk of harmful side effects that outweigh any
13 potential utility stemming from the use of the drug. The harm caused by Defendants' Depo-Provera
14 far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that
15 which an ordinary consumer would contemplate. Depo-Provera was and is more dangerous than
16 alternative products, and Defendants could have designed Depo-Provera to make it less dangerous.
17 Indeed, at the time Defendants designed Depo-Provera and its labels, the state of the industry's
18 scientific knowledge was such that a safer, less risky design or formulation and label was attainable.

19 187. Defendants could have employed safer alternative designs and formulations. Depo-
20 SubQ Provera 104 is a lower dosage version of Depo-Provera that is administered on the same time
21 schedule (every three months) as Depo-Provera and provides equivalent contraceptive function to
22 Depo-Provera. Defendants did not meaningfully promote Depo-SubQ Provera 104 out of fear that
23 doing so would spark fears about high dose Depo-Provera and reduce Depo-Provera sales. Non-
24 hormonal birth control methods were also available alternatives for some patients.

25 188. Defendants knew and/or should have known that foreseeable consumers, such as
26 Plaintiffs, would suffer injuries as a result of Defendants' failure to exercise ordinary care in the
27 manufacturing, marketing, labeling, distribution, storage, transport, and sale of Depo-Provera.

28 189. Plaintiff did not know the nature and extent of the injuries that could result from the
intended use of and/or exposure to Depo-Provera.

1 190. Defendants' conduct, as described above, was willful, wanton, malicious and
2 conducted with reckless disregard for the health and safety of users of Depo-Provera, including
3 Plaintiff. Defendants' conduct warrants an award of punitive damages. Defendants' conduct as
4 alleged herein was done with reckless disregard for human life, oppression, and malice. Defendants
5 were aware of the meningioma risks of Depo-Provera. Nonetheless, Defendants deliberately crafted
6 their label and marketing to mislead consumers. This was not done accidentally or through some
7 justifiable negligence. Rather, Defendants knew they could profit by convincing consumers that
8 Depo-Provera was harmless to humans, and that full disclosure of the true risks would limit the
9 amount of money Defendants would make selling Depo-Provera. Such conduct was done with
10 conscious disregard of Plaintiff's rights.

11 191. The defects in Defendants' Depo-Provera were substantial factors in causing
12 Plaintiff's injuries.

13 192. As a direct and proximate result of Defendant's negligent design of Depo Provera,
14 Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, mental
15 anguish, impairment, loss of enjoyment of life, comfort, loss of consortium, economic damages
16 including obligations for medical services and expenses, lost income and other damages. These losses
17 are either permanent or continuing and Plaintiff will suffer the losses in the future.

18 **COUNT V: GENERAL NEGLIGENCE**
19 **(Asserted against All Defendants)**

20 193. Plaintiff realleges and incorporates by reference every paragraph of this Complaint as
21 though fully set forth herein.

22 194. Defendants designed, manufactured, tested, marketed, labeled, packaged, handled,
23 distributed, and/or sold the Depo-Provera that was used by Plaintiff.

24 195. At all relevant times, Defendants had a duty to exercise reasonable care in the design,
25 manufacture, testing, marketing, labeling, packaging, handling, distribution, and/or sale of Depo-
26 Provera, including the duty to take all reasonable steps necessary to design, manufacture, test, market,
27 label, package, handle, distribute, store, and/or sell a product that was not unreasonably dangerous to
28 consumers and users of the product.

1 196. At all relevant times, Defendants had a duty to exercise reasonable care in the
2 marketing and sale of Depo-Provera. Defendants owed to consumers and the general public a duty
3 of care that included providing accurate, true, and correct information concerning the risks of using
4 Depo-Provera and appropriate, complete, and accurate warnings concerning the potential adverse
5 effects of Depo-Provera and, in particular, its increased risk of meningioma.

6 197. At all relevant times, Defendants knew or, in the exercise of reasonable care, should
7 have known of the hazards and dangers of Depo-Provera and its increased risk of meningioma.
8 Defendants knew or, in the exercise of reasonable care should have known, that Depo-Provera use
9 increased the risk that a woman would develop meningioma. Defendants further knew that the risk of
10 meningioma was unreasonable in relation to the purpose of the drug and in light of the availability of
11 less dangerous, alternative forms of contraception.

12 198. Defendants also knew or, in the exercise of reasonable care, should have known that
13 users and consumers of Depo-Provera were unaware of the risks and the magnitude of the risks
14 associated with use of Depo-Provera.

15 199. Defendants breached their duty of reasonable care and failed to exercise ordinary care
16 in the design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage,
17 and/or sale of Depo-Provera, in that Defendants knew or had reason to know of the defects inherent
18 in Depo Provera; knew or had reason to know that a user's or consumer's use of the products created
19 a significant risk of harm; and failed to prevent or adequately warn of these risks and injuries. Indeed,
20 Defendants deliberately refused to investigate the meningioma risk posed by Depo-Provera and still
21 has not added a meningioma warning to its US label for Depo-Provera.

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1 200. Defendants negligently failed to provide physicians and patients, such as Plaintiff,
2 with accurate warnings related to Depo-Provera. Defendants—who designed, manufactured, tested,
3 marketed, labeled, packaged, handled, distributed, stored, and/or sold Depo-Provera—were in a
4 superior position to understand the risk of meningioma presented by Depo-Provera and had a duty to
5 warn of these dangers. Yet, despite their ability and means to investigate, study, and test the products
6 and to provide adequate warnings, Defendants failed to do so. Indeed, Defendants wrongfully
7 concealed information and further made false and/or misleading statements concerning the safety and
8 use of Depo-Provera.

9 201. Manufacturer Defendants’ negligence included:

- 10 a. Failing to use reasonable and prudent care in the design, manufacture, testing,
11 marketing, labeling, packaging, handling, distribution, storage, and/or sale of
12 Depo-Provera so as to avoid the risk of serious harm associated with the prevalent
13 use of Depo-Provera;
- 13 b. Failing to design, manufacture, test, market, label, package, handle, distribute,
14 store, and/or sell Depo-Provera so as to ensure they were at least as safe and
15 effective as other contraceptives available on the market,
- 15 c. Designing, manufacturing, testing, marketing, labeling, packaging, handling,
16 distributing, storing, and/or selling Depo-Provera without thorough and adequate
17 pre- and post-market testing;
- 18 d. Failing to undertake sufficient studies and conduct necessary tests to determine
19 whether or not Depo-Provera was safe for its intended consumer use;
- 19 e. Failing to undertake to provide adequate warnings instructions, guidelines, and
20 safety precautions to those persons Defendants could reasonably foresee would
21 use Depo-Provera;
- 22 f. Failing to undertake to disclose to Plaintiff, users/consumers, and the general
23 public that use of Depo-Provera presented a risk of meningioma,
- 23 g. Failing to warn Plaintiff, consumers, and the general public that Depo-Provera’
24 risk of harm was unreasonable and that there were safer and effective alternative
25 contraceptives available to Plaintiff and other consumers;
- 26 h. Systematically suppressing or downplaying contrary evidence about the risks,
27 incidence, and prevalence of the side effects of Depo-Provera;
- 27 i. Representing that Depo-Provera was safe for its intended use when, in fact,
28 Defendants knew or should have known the product was not safe for its intended
29 purpose;

- 1 j. Declining to make or propose any changes to Depo-Provera's labeling or other
2 promotional materials that would alert consumers and the general public of the
3 meningioma risk of Depo-Provera;
- 4 k. Advertising, marketing, and recommending the use of Depo-Provera, while
5 concealing and failing to disclose or warn of the dangers known (by Defendants)
6 to be associated with or caused by the use of Depo-Provera;
- 7 l. Continuing to disseminate information to consumers, including Plaintiff, that
8 indicated or implied that Depo-Provera was not unsafe for regular consumer use;
9 and
- 10 m. Continuing to design, manufacture, test, market, label, package, handle, distribute,
11 store, and/or sell Depo-Provera with the knowledge that the product was
12 unreasonably unsafe and dangerous.

13 202. Kaiser Defendants' negligence included:

- 14 a. Failing to use reasonable and prudent care in researching, evaluating, approving
15 and recommending Depo-Provera as a safe contraceptive when Depo Provera
16 posed a greatly increased risk of developing meningioma
- 17 b. Failing to independently and objectively evaluate the scientific literature relating
18 to Depo Provera despite representing to patients that you Kaiser did so;
- 19 c. Placing Depo-Provera on the Kaiser drug formulary thereby signaling and
20 influencing to doctors and healthcare providers in the Kaiser system that they
21 should prescribe and use Depo-Provera;
- 22 d. Failing to properly and thoroughly research the scientific data and medical
23 literature relating to Depo-Provera to determine whether or not Depo-Provera was
24 safe for its intended consumer use;
- 25 e. Failing to undertake to provide adequate warnings instructions, guidelines, and
26 safety precautions to those persons Defendants could reasonably foresee would
27 use Depo-Provera;
- 28 f. Failing to undertake to disclose to Plaintiff, users/consumers, and the general
public that use of Depo-Provera presented a risk of meningioma,
- g. Failing to warn Plaintiff, consumers, and the general public that Depo-Provera'
risk of harm was unreasonable and that there were safer and effective alternative
contraceptives available to Plaintiff and other consumers;
- h. Advertising, marketing, and recommending the use of Depo-Provera, while
concealing and failing to disclose or warn of the dangers known (by Defendants)
to be associated with or caused by the use of Depo-Provera;

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- i. Continuing to disseminate information to consumers, including Plaintiff, that indicated or implied that Depo-Provera was not unsafe for regular consumer use; and
- j. Continuing to market, approve, sell and encourage the use of Depo-Provera with the knowledge that the product was unreasonably unsafe and dangerous.

203. Defendants' conduct, as described above, was reckless. Defendants regularly risked the lives of consumers and users of their products, including Plaintiff, with full knowledge of the dangers of their products. Defendants knew or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in the design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of Depo-Provera. Defendants have made conscious decisions not to redesign, re-label, warn, or inform the unsuspecting public, including Plaintiff, about those dangers. Defendants' reckless conduct therefore warrants an award of punitive damages.

204. Plaintiff did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to Depo-Provera.

205. Defendants' negligence was a substantial factor in causing Plaintiff's injuries.

206. As a direct and proximate result of Defendant's negligence, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, mental anguish, impairment, loss of enjoyment of life, comfort, loss of consortium, economic damage including obligations for medical services and expenses, lost income and other damages. These losses are either permanent or continuing and Plaintiff will suffer the losses in the future.

**COUNT VI: NEGLIGENT MISREPRESENTATION
(Asserted against all Defendants)**

207. Plaintiff realleges and incorporates by reference every allegation of this Complaint as though fully set forth herein.

1 208. Defendants falsely and fraudulently presented to the public that the Depo-Provera had
2 been tested and was safe and effective. Defendant negligently provided Plaintiff, her physician, her
3 administering health care providers, the medical community and the general public with false or
4 incorrect information or omitted or failed to disclose material information regarding the safety and
5 risk profile of Depo Provera.

6 209. Defendants made misrepresentations through advertisements, labeling materials, print
7 campaigns, commercial media, internet, and other materials. The misrepresentations distributed to
8 the public, the FDA, and Plaintiff by Defendants included, but was not limited to, websites,
9 information presented at point of sale and in marketing, information disseminated by company
10 representatives, reports, press releases, advertising campaigns, television commercials, print
11 advertisements, billboards and other commercial media containing material representations, which
12 were false and misleading, and contained omissions and concealment of the truth about the dangers
13 of the use of the Depo-Provera.

14 210. Defendants knew and had reason to know that Depo-Provera could and would cause
15 serious injury, including meningioma, and that Depo-Provera was inherently dangerous in a manner
16 that exceeded any purported, inaccurate, or otherwise downplayed warnings.

17 211. Defendants intentionally failed to warn purchasers and the public, including Plaintiff,
18 of the dangers and risk of injury. Defendants chose instead to falsely market the purported safety,
19 efficacy, and benefits of the Depo-Provera. Defendants intentionally made material
20 misrepresentations to the public, including Plaintiff, regarding the safety of Depo-Provera,
21 specifically that they did not have dangerous and/or serious adverse health safety concerns, and that
22 Depo-Provera was safe or safer than other similar products available.

23 212. In representations made to Plaintiff, her physicians, her administering health care
24 providers, the medical community and the general public and the public, Defendants fraudulently
25 concealed and intentionally or recklessly omitted the following material information about Depo-
26 Provera:

- 27 a. That the products are not as safe as other similar products available;
- 28 b. That the products are not more effective than other similar products available;

- c. That the products are not appropriately tested for safety and efficacy, including the failure to study the products as obligated under FDA rules and regulations;
- d. That the likelihood of an adverse event requiring serious medical attention with the products is much higher than with the other similar products available;
- e. That the testing and surveillance shows the products have a higher risk of adverse effects beyond those associated with other similar products available;
- f. That Defendants deliberately failed to follow up on the adverse results from studies and formal and informal reports and buried and/or misrepresented those findings;
- g. That Defendants deliberately chose to forego studies that might reveal the rate of adverse events or otherwise necessitate the need to reveal information as to adverse events to the Plaintiff or the regulatory authorities;
- h. That Defendants were aware of dangers beyond those associated with other similar products available;
- i. That the products cause dangerous and adverse health consequences, including tumors and cancer;
- j. That users of the products need to be medically monitored.

213. The representations made by Defendants were, in fact, false. These representations, and others made by Defendants, were false when made and/or made with the pretense of actual knowledge when such knowledge did not exist and were made recklessly and without regard to the true facts. When Defendants made their representations, Defendants knew and/or had reason to know that those representations were indeed false, yet Defendants negligently, willfully, wantonly, and recklessly disregarded the inaccuracies in their representations about the dangers of the Depo-Provera.

1 214. Defendants' intent and purpose in making the misrepresentations was to cause Plaintiff
2 and consumers to purchase Depo-Provera so as to increase the profits of Defendants. Defendants'
3 intended was to deceive and defraud the public and Plaintiff; to gain the confidence of the public and
4 Plaintiff; to falsely assure them of the quality and fitness for use of the Depo-Provera; and induce
5 Plaintiff, and the public to purchase and continue to use the Depo-Provera. That Defendants acted
6 with the intent of defrauding and deceiving the public to use an unreasonably danger product, Depo-
7 Provera, evinced a callous, reckless, willful, and depraved indifference to the health, safety, and
8 welfare of consumers including the Plaintiff.

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

12 216. In reliance upon Defendants' false misrepresentations, Plaintiff was induced to and
13 did use the recalled products in a pervasive manner. Plaintiff reasonably relied on revealed facts that
14 foreseeably and purposefully suppressed and concealed facts that were critical to understanding the
15 real dangers inherent in the use of the Depo-Provera. Plaintiff thereby sustained severe and personal
16 injuries and damages.

17 217. Defendants had a duty when disseminating information to the public to disseminate
18 truthful information and a parallel duty not to deceive the public, the Plaintiff, and the United States
19 Food and Drug Administration. Defendants had a duty to disclose the defective nature of the Depo-
20 Provera, including but not limited to the heightened risks of meningioma injury, and death.
21 Defendants had access to the full material facts concerning the defective nature of the products and
22 the propensity to cause serious injury and death.

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1 218. Defendants' misrepresentations and concealment and omissions of material fact were
2 done negligently, purposefully, willfully, wantonly, and/or recklessly to mislead, Defendants
3 recklessly and/or intentionally falsely represented the dangerous and serious health and safety
4 concerns inherent in the use of the Depo-Provera to the public at large, to influence the sales of
5 products known to be dangerous and defective, and/or not as safe as other alternatives. Defendants
6 willfully and intentionally failed to disclose the truth, failed to disclose material facts, and made false
7 representations to deceive and lull Plaintiff and consumers into a false sense of security, so that
8 Plaintiff and consumers would rely on Defendants' representations and Plaintiff and others would
9 request and purchase Depo-Provera. Defendants' wrongful conduct constitutes fraud, suppression,
10 concealment, and deceit and was committed and perpetrated willfully, wantonly, and/or purposefully
11 on Plaintiff.

12 219. When the representations were made, Plaintiff did not know the truth about the dangers
13 and severe health and safety risks inherent in the use of the Depo-Provera. Plaintiff did not discover
14 the true facts about the dangers and severe health and/or safety risks, nor did Plaintiff discover the
15 false representations of Defendants, nor would Plaintiff, with reasonable diligence, have discovered
16 the true facts or Defendant's misrepresentations.

17 220. Had Plaintiff known the true facts about the dangers and serious health and/or safety
18 risks of the Depo-Provera, Plaintiff would not have purchased, used, or relied on the Depo-Provera.

19 221. As a direct and proximate result of Defendant's negligent misrepresentations, Plaintiff
20 has been injured and sustained severe and permanent pain, suffering, disability, mental anguish,
21 impairment, loss of enjoyment of life, comfort, loss of consortium, economic damages including
22 obligations for medical services and expenses, lost income and other damages. These losses are either
23 permanent or continuing and Plaintiff will suffer the losses in the future.

24 **COUNT VII – FRAUD – INTENTIONAL MISREPRESENTATION**
25 **(Asserted against All Defendants)**

26 222. Plaintiff realleges and incorporates by reference every allegation of this Complaint as
27 though fully set forth herein.
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1 223. Defendants falsely represented to patients and consumers, including Plaintiff, and the
2 greater healthcare community and general public, that Depo-Provera was safe and effective for use
3 as a contraceptive.

4 224. Manufacturing Defendants represented to consumers, including Plaintiff, that Depo
5 Provera was safe with no increased risk of intracranial meningioma. The label for Depo-Provera
6 included a “Warnings” section, but failed to include a warning regarding the increased risk that the
7 patient would develop and intra-cranial meningioma.

8 225. Through its website, online advertising and other materials, Kaiser represented to
9 patients, including Plaintiff, that it screened drugs for safety and efficacy before placing them on
10 Kaiser’s drug formulary. Kaiser’s false statements included, but are not limited to, representations
11 that it performed independent reviews and evaluations of medications and chooses the “safest”
12 medications for its members.³¹ Kaiser represented that no drug, even if approved by the FDA, would
13 be added to the Kaiser formulary unless its safety was established.³²

14 226. Defendants’ representations were false. Defendants knew or should have known that
15 their representations were false when they were made; yet Defendants made the representations
16 falsely or made them recklessly and without regard for their truth. Defendants’ willful and malicious
17 conduct demonstrates a wanton disregard of the safety of Plaintiff.

18 227. Defendants intended that consumers and patients, including Plaintiff, would rely on
19 their false representations. Defendants intended that Plaintiff, the public and the medical community,
20 including Plaintiff’s prescribers and drug administrators, would recommend, prescribe, dispense and
21 purchase Depo-Provera without knowing of the drug’s propensity to cause meningioma.

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26 ³¹<https://healthy.kaiserpermanente.org/health-wellness/drug-formulary/how-it-works#:~:text=The%20Pharmacy%20and%20Therapeutics%20Committee,effective%20medications%20for%20our%20members> (last visited on October 23, 2024).

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28 ³² <https://espanol.kaiserpermanente.org/content/dam/kporg/final/documents/forms/drug-formulary-process-nw-en.pdf> (last visited on October 23, 2024).

1 228. Plaintiff reasonably relied on Defendants’ false representations and suffered severe,
2 harmful, and debilitating injuries. Plaintiff’s reliance on Defendants’ representations was a
3 substantial factor in causing her harm. In reasonable reliance on Defendants’ representations,
4 Plaintiff was caused to believe that Depo-Provera was safe and was induced to use Depo-Provera,
5 which use caused Plaintiff’s harm. Plaintiff would not have used Depo-Provera had she known the
6 truth about the dangers and risks of the product which Defendants misrepresented and concealed.

7 229. As a direct and proximate result of Defendant’s fraud, Plaintiff has been injured and
8 sustained severe and permanent pain, suffering, disability, mental anguish, impairment, loss of
9 enjoyment of life, comfort, loss of consortium, economic damages including obligations for medical
10 services and expenses, lost income and other damages. These losses are either permanent or
11 continuing and Plaintiff will suffer the losses in the future.

12 **COUNT VIII – VIOLATION OF CONSUMER PROTECTION LAWS**
13 **(Asserted against All Defendants)**

14 230. Plaintiff realleges and incorporates by reference every allegation of this Complaint as
15 though fully set forth herein.

16 231. Plaintiff brings this cause pursuant to the California Business Code’ Unfair
17 Competition Law (“UCL”). The UCL prohibits acts of “unfair competition” including any “unlawful,
18 unfair or fraudulent business act or practice.” CA Bus. & Prof. § 17200. The UCL prohibits from
19 engaging in false or misleading advertising by inducing the public to purchase products or services
20 through the use of untrue or misleading statements. CA Bus. & Prof. § 17500.

21 232. Defendants have engaged in unlawful, unfair and fraudulent business acts and
22 practices in violation of the UCL including, but not limited to, the following acts and omissions:

- 23 a. By concealing the health risks associated with Depo-Provera, including, but not
 limited to, the increased risk of meningioma.
- 24 b. By downplaying and minimizing the risks of Depo-Provera.
- 25 c. By concealing that Depo-Provera should not be used for periods greater than one
26 year.
- 27 d. By downplaying, minimizing and concealing the availability of lower dose
28 alternatives that served the same contraceptive purpose without exposing users to
 the same increase danger of meningioma.

1 e. By deceptively representing Depo-Provera as a “safe” contraceptive despite
2 Defendants knowing that Depo-Provera exposes users to dosages that are higher
3 than necessary to meet the contraceptive purpose and that increase the likelihood
4 of harm.

5 233. These acts and practices described above were and are likely to mislead the general
6 public and therefore constitute unfair business practices withing the meaning of California Business
7 & Professional Code § 17200 as well as unfair, deceptive untrue and misleading advertising as
8 prohibited by California Business & Professions Code § 17500.

9 234. Defendants' unfair and fraudulent business acts and practices are unfair because they
10 induce consumers to purchase and use Depo-Provera without accurate information regarding the
11 products characteristics and risks and without the opportunity to make an informed decision whether
12 other contraceptive products present safer options that would meet the consumer’s needs. Defendants'
13 unfair and fraudulent business acts and practices caused Plaintiff to purchase Depo-Provera.

14 235. Defendants' misrepresentations and omissions as alleged herein were consistent with
15 and part of its scheme to maximize profits at the expense of public health.

16 236. Plaintiff has suffered injury and lost money as a result of Defendants' unlawful, unfair
17 and fraudulent business practices.

18 237. Plaintiff seek to enjoin further unlawful, unfair and fraudulent acts or practices by
19 Defendants under Bus. & Prof. Code § 17200. Plaintiff requests that this Court enter such orders or
20 judgments as may be necessary to enjoin Defendants from continuing their unfair and deceptive
21 practices and to restore to Plaintiff any money it acquired by unfair competition, including restitution
22 and/or disgorgement, as provided in Bus. & Prof. Code § 17203 and Bus. & Prof. Code § 3345. The
23 requested injunction under the UCL will primarily benefit the interests of the general public. It will
24 have the primary purpose and effect of prohibiting acts that threaten injury to members of the public
25 who have or will be exposed to Depo-Provera.
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1 238. Defendants' conduct, as described herein, is unfair because it is immoral, unethical,
2 unscrupulous, oppressive, and substantially injurious. The gravity of the harm resulting from
3 Defendants' conduct far outweighs any conceivable utility of this conduct. There are reasonably
4 available alternatives, including alternatives manufactured by Pfizer itself, that would further
5 Defendants' stated purpose of providing safe contraceptives, without unnecessarily exposing women
6 to an increased risk of meningioma.

7 239. Defendants' conduct in connection with Depo-Provera was also impermissible and
8 illegal in that it created a likelihood of confusion and misunderstanding because the Defendants
9 misleadingly, falsely and/or deceptively misrepresented and omitted numerous material facts
10 regarding, among other things, the utility, benefits, safety, efficacy, and advantages of Depo-Provera.

11 240. Plaintiff could not have reasonably avoided injury from Defendants' unfair conduct.
12 Plaintiff did not know, and had no reasonable means of learning, that Depo-Provera could cause
13 meningioma.

14 **COUNT IX – BREACH OF EXPRESS WARRANTY**
15 **(Asserted against Manufacturer Defendants)**

16 241. Plaintiff realleges and incorporates by reference every allegation of this Complaint as
17 though fully set forth herein.

18 242. At all relevant times, Defendants were in the business of researching, testing,
19 developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing,
20 and/or promoting Depo-Provera and placed it in the stream of commerce in a defective and
21 unreasonably dangerous condition. These actions were under the ultimate control and supervision of
22 Defendants.
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1 243. Defendants expressly represented and warranted to the purchasers of their products,
2 by and through statements made by Defendants in labels, publications, package inserts, on the internet
3 and through other written materials intended for consumers and the general public, that Depo-Provera
4 was safe to human health, effective, fit, and proper for its intended use as a contraceptive. Defendants
5 advertised, labeled, marketed, and promoted Depo-Provera, representing the quality to consumers and
6 the public in such a way as to induce their purchase or use, thereby making an express warranty that
7 Depo-Provera would conform to Defendants' representations.

8 244. Defendants expressly represented and warranted to the purchasers of their products,
9 by and through statements made by Defendants in labels, publications, package inserts, on the internet
10 and through other written materials intended for consumers and the general public, that Depo-Provera
11 was safe to human health, effective, fit, and proper for its intended use as a contraceptive. Defendants
12 advertised, labeled, marketed, and promoted Depo-Provera, representing the quality to consumers and
13 the public in such a way as to induce their purchase or use, thereby making an express warranty that
14 Depo-Provera would conform to Defendants' representations.

15 245. These express representations include incomplete warnings and instructions that
16 purport, but fail, to include the complete array of risks associated with use of Depo-Provera.
17 Defendants knew and/or should have known that the risks expressly included in Depo-Provera
18 warnings and labels did not, and still do not, accurately or adequately set forth the risks of developing
19 the serious meningioma complained of herein. Nevertheless, Defendants expressly represented that
20 Depo-Provera was safe and effective and also that it was safe and effective for use for prolonged
21 periods of time.

22 246. The representations about Depo-Provera, as set forth herein, contained or constituted
23 affirmations of fact or promises made by the seller to the buyer, which related to the goods and became
24 part of the basis of the bargain, creating an express warranty that the goods would conform to the
25 representations.

26 247. Defendants placed Depo-Provera into the stream of commerce for sale and
27 recommended its use to physicians, consumers and the public without adequately warning of the true
28 risks of developing meningiomas associated with the use of Depo-Provera.

1 248. Defendants breached these warranties because, among other things, Depo-Provera was
2 defective, dangerous, and unfit for use, did not contain labels representing the true and adequate
3 nature of the risks associated with their use, and was not merchantable or safe for its intended,
4 ordinary, and foreseeable uses and purpose.

5 249. Plaintiff and her physicians and administering healthcare providers, detrimentally
6 relied on the express warranties and representations of Defendants concerning the safety and/or risk
7 profile of Depo-Provera and agreed to have the product injected into her body Plaintiff reasonably
8 relied upon Defendants to disclose known defects, risks, dangers, and side effects of Depo-Provera
9 Physicians would not have prescribed, and Plaintiff would not have agreed to use Depo-Provera had
10 Defendants properly disclosed the risks associated with the product -- either through advertising,
11 labeling, or any other form of disclosure

12 250. Defendants had sole access to material facts concerning the nature of the risks
13 associated with Depo-Provera, as expressly stated within their warnings and labels, and knew that
14 consumers and users such as Plaintiff could not have reasonably discovered that the risks expressly
15 included in Depo-Provera' warnings and labels were inadequate and inaccurate.

16 251. Plaintiff had no knowledge of the falsity or incompleteness of Defendants' statements
17 and representations concerning Depo-Provera. Plaintiff used Depo Provera without knowledge that
18 the drug was not safe and well-tolerated as Defendants had warranted. Plaintiff was unaware that
19 Depo Provera increased the risk of significant and irreparable damage due to development of
20 meningioma.

21 252. Plaintiff used and/or was exposed to Depo-Provera as designed, manufactured, tested,
22 marketed, labeled, packaged, handled, distributed, stored, sold, or otherwise released into the stream
23 of commerce by Defendants.

24 253. Had the warnings, labels, advertisements, or promotional material for Depo-Provera
25 accurately and adequately set forth the true risks associated with the use of such products, including
26 Plaintiff's injuries, rather than expressly excluding such information and warranting that Depo-
27 Provera was safe for its intended use, Plaintiff could have avoided the injuries complained of herein.

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1 263. The Defendants breached various implied warranties concerning Depo-Provera,
2 including the following particulars:

- 3 a. Defendants represented through their labeling, advertising, marketing materials,
4 detail persons, seminar presentations, publications, notice letters, and regulatory
5 submissions that the products are safe and fraudulently withheld and concealed
6 information about the substantial risks of serious injury associated with use;
7
8 b. Defendants represented that the products are safe or safer than other alternative
9 products and fraudulently concealed information, which demonstrated it was not
10 as safe or safer than alternatives available on the market;
11
12 c. The Defendants represented that the products were as efficacious than other
13 alternative treatments and fraudulently concealed information about the true
14 efficacy; and
15
16 d. In reliance upon the implied warranties, Plaintiff used the products as prescribed
17 in the foreseeable manner normally intended, recommended, promoted, and
18 marketed by the Defendants.

19 264. Defendants breached their implied warranties to Plaintiff in that Depo-Provera is not
20 of merchantable quality, safe and/or fit for intended use, or adequately tested, in violation of common
21 law principles.

22 265. As a direct and proximate result of the breaches of warranty, Plaintiff has been injured
23 and sustained severe and permanent pain, suffering, disability, mental anguish, impairment, loss of
24 enjoyment of life, comfort, loss of consortium, economic damages and other damages. These losses
25 are either permanent or continuing and Plaintiff will suffer the losses in the future.

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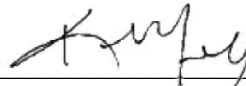
PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

- i. That process issue and the Defendants be served in accordance with the Federal Rules of Civil Procedure;
- ii. Compensatory damages, including but not limited to medical expenses, lost wages, pain and suffering, and diminished quality of life they are deemed entitled to in an amount to be determined by the jury;
- iii. Special damages, including all expenses, incidental past and future expenses, medical expenses, and loss of earnings and earning capacity in an amount to be determined by the jury;
- iv. Statutory damages as provided by law;
- v. Punitive damages in an amount to be determined by the jury;
- vi. Pre- and post-judgment interest as allowed by law;
- vii. Reasonable attorneys’ fees and costs, as provided by law;
- viii. Such other relief as this Court may deem just and proper.

DATED: November 15, 2024

KBM LAW CORP.



KAREN BARTH MENZIES, ESQ.

-AND-

MATTHEWS & ASSOCIATES

**DAVID P. MATTHEWS, ESQ.
MARK E. CHAVEZ, ESQ.
BRITTNIE C. PANETTA, ESQ.**

Counsel for Plaintiff, Madison Le

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DEMAND FOR JURY TRIAL

A trial by jury is hereby demanded by Plaintiff.

DATED: November 15, 2024

KBM LAW CORP.



KAREN BARTH MENZIES, ESQ.

-AND-

MATTHEWS & ASSOCIATES

DAVID P. MATTHEWS, ESQ.
MARK E. CHAVEZ, ESQ.
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Counsel for Plaintiff, Madison Le