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SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ALAMEDA

BRIDGETT BROWN,

Plaintiff,

vs.

JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; JANSSEN RESEARCH & DEVELOPMENT, LLC; ELI LILLY AND COMPANY; KAISER PERMANENTE; and DOES 1 through 100, inclusive,

Defendant.

Case No. 25CV119808

COMPLAINT

DEMAND FOR JURY

TABLE OF CONTENTS

INTRODUCTION

1. This is a personal injury action for damages relating to the design, manufacture, sale, marketing, advertising, promotion, testing, labeling, and packaging, of Risperdal and Zyprexa, which includes the brand name versions of Risperidone and Olanzapine, and their various generic forms (collectively "Defendants' Drugs" unless specifically identified). These drugs were manufactured and/or sold by: Eli Lilly and Johnson & Johnson Company and its subsidiaries (collectively "Defendant Drug Makers") and distributed by Kaiser Permanente ("Retailer Defendant"). Notably, consumption of Defendants' Drugs has been shown to cause breast cancer. And, as a result of consuming Defendants' Drugs, Plaintiff tragically developed breast cancer. This lawsuit seeks to hold the Defendant Drug Makers liable for their conduct in contributing to Plaintiff's development of breast cancer.

2. Defendants' Drugs are atypical antipsychotics ("atypicals"), also called "second-generation" antipsychotics ("SGAs"). The only commonality among SGAs that distinguishes them from first-generation antipsychotics ("FGAs") is that they were introduced after 1990. Pharmacologically, SGAs are a diverse group without a common distinction from FGAs and, crucially, SGAs are neither safer nor more effective than their predecessors, FGAs.

3. Defendants' Drugs were originally approved to treat severe psychiatric conditions – primarily schizophrenia. Recognizing that marketing Defendants Drugs only to patients with severe psychiatric conditions would constrain the market, Defendant Drug Makers broadened their customer base by gaining approval for mild indications in new patient populations and by illegally promoting the drugs for off-label use, *e.g.* as attention-deficit drugs for children, dementia drugs for the elderly, and "mood stabilizers." This aggressive campaign marketed Defendants' Drugs to a broad patient population as safer, more effective treatments than FGAs and other patent-expired drugs. As a result, Defendants' Drugs became blockbusters.

4. Concerns over prolonged exposure to Defendants' Drugs causing breast cancer arose as early as the drugs debuted. Specifically, Defendants' Drugs cause elevated production of prolactin—a hormone produced by the pituitary gland, primarily to promote milk production after childbirth. Abnormally high prolactin led to a condition known as "hyperprolactinemia," which is

associated with a variety of adverse health conditions including breast cancer. And, Defendant Drug Makers have known, or should have known, for decades that antipsychotics can cause breast cancer.

5. The clinical trials conducted as part of the approval stage provided early indications that consumption of Defendants' Drugs could substantially contribute to the development of hyperprolactinemia and breast cancer. In addition, following marketing and use of the product by patients, independent epidemiological studies published over the last two decades have repeatedly observed a causal association between exposure to Defendants' Drugs and breast cancer.

6. Defendant Drug Makers have never warned consumers of the risk of breast cancer. In fact, Defendants' Drug labels have, throughout the years, disclaimed any such risk, obfuscated the link between hyperprolactinemia and breast cancer, and mischaracterized the results of the studies demonstrating that Defendants' Drugs can cause breast cancer.

7. Defendant Drug Makers knew or should have known of the increased risk of breast cancer associated with consumption of these drugs and warned the public accordingly. Instead, Defendant Drug Makers obfuscated and disclaimed such risks while promoting these dangerous, expensive drugs over safer, more affordable alternatives. As a result, Defendant Drug Makers were able to profit billions while exposing unsuspecting consumers to a potent and aggressive carcinogen and tumor promoter.

PARTIES

I. Plaintiff

8. **Plaintiff Bridgett Brown** is a resident of California.

II. Defendants

A. Defendant Drug Makers

9. **Defendant Eli Lilly and Company ("Lilly")** is a citizen of Indiana, with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly manufactures, promotes, and distributes the brand name variants of Zyprexa (collectively "Zyprexa") discussed below. Lilly has controlled Zyprexa since it was first approved by the FDA in September 1996. At all relevant times, Lilly has conducted business and derived substantial revenue from designing, manufacturing, advertising, distributing, and selling Zyprexa within the United States and California,

including Alameda County.

10. **Defendant Johnson & Johnson Company ("J&J")** is a New Jersey corporation, with its principal place of business located at 1 Johnson & Johnson Plaza, New Brunswick, NJ 08933. J&J does business under the fictious name "Johnson & Johnson." At all relevant times, J&J has conducted business and derived substantial revenue from designing, manufacturing, advertising, distributing, and selling Risperdal and Invega within the United States and California, including Alameda County.

11. **Defendant Janssen Pharmaceuticals, Inc. ("JPI")** is a Pennsylvania corporation, with its principal place of business located at 1125 Trenton Harbourton Rd, Titusville, NJ 08560. The name of the entity "JPI" has changed over time.[1] JPI manufactures, promotes, and distributes the brand name variants of Risperdal (collectively "Risperdal") and Invega (collectively "Invega"), discussed below. JPI has controlled Risperdal and Invega since they were first approved by the FDA in December 1993 and December 2006, respectively. At all relevant times, JPI has conducted business and derived substantial revenue from designing, manufacturing, advertising, distributing, and selling Risperdal and Invega within the United States and California, including Alameda County. Defendant J&J is the parent company of Defendant JPI.

12. **Defendant Janssen Research & Development, LLC ("JRD")** is a New Jersey limited liability company, with its principal place of business located at 920 US Route 202, Raritan, NJ 08869 and with California offices in Fremont, La Jolla, Los Angeles, and San Francisco. Janssen Biotech, Inc., a New Jersey corporation, is the sole member of Janssen Research & Development, LLC. The name of the entity "JRD" has changed over time.[2] At all relevant times, JRD was

[1] JPI was previously named Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMJPI") until June 22, 2011. OMJPI was created in a corporate reorganization on December 31, 2007, when J&J transferred all of the assets and liabilities (except those that could not be transferred) of its wholly owned subsidiary Ortho-McNeil Pharmaceuticals, Inc. ("OMJ") to its wholly owned subsidiary Janssen Pharmaceutica, Inc. Upon reorganization, Janssen Pharmaceutica, Inc. became known as OMJPI. During this reorganization, J&J also dissolved Janssen, LP, which was previously named Janssen Pharmaceutical Products, L.P, and transferred its assets and liabilities into OMJPI. Janssen, LP was a limited partnership, with Janssen Pharmaceutica as its general partner and conducted most of its business. Janssen LP was the original co-sponsor of the Invega New Drug Application.

[2] JRD was previously named Johnson & Johnson Pharmaceutical Research & Development, L.L.C. ("JJPRD") until December 6, 2011. JJPRD had been created in a corporate reorganization in 2001, when J&J merged

responsible for clinical research and development of Risperdal and Invega, for pharmacovigilance in the U.S. pertaining to Risperdal and Invega, and for submitting regulatory reports to the U.S. Food & Drug Administration ("FDA") pertaining to Risperdal and Invega. Defendant J&J is the parent company of Defendant JRD.

13. On information and belief, JPI and JRD are wholly owned subsidiaries of J&J, belonging to the company's Johnson & Johnson Innovative Medicine ("JJIM") division. JJIM, previously called the "Janssen Pharmaceutical Companies of Johnson & Johnson," is not a distinct legal entity, but the global group of pharmaceutical companies owned by J&J.

14. Collectively, J&J, JPI, and JRD shall be referred to as "JJIM Defendants."

B. Retailer Defendant

15. **Defendant Kaiser Permanente International ("Kaiser")** is a California corporation with its headquarters and principal place of business located at One Kaiser Plaza, Oakland, CA 94612. At all relevant times, Kaiser has conducted business and derived substantial revenue from selling Defendants' Drugs within the State of California and Alameda County by operating a pharmacy which sells Defendants' Drugs. Specifically, Kaiser supplied Plaintiff with Defendants' Drugs which caused Plaintiff's injuries.

C. Doe Defendants

16. The true names and/or capacities, whether individual, corporate, partnership, associate, governmental, or otherwise, of Defendants DOES 1 through 100, inclusive, and each of them, are unknown to Plaintiff at this time, who therefore sues said Defendants by such fictitious names. Plaintiff is informed and believes, and thereon alleges, that each Defendant designated herein as a DOE caused injuries and damages proximately thereby to Plaintiff as hereinafter alleged; and that each DOE Defendant is liable to the Plaintiff for the acts and omissions alleged herein, and the resulting injuries to Plaintiff, and damages sustained by Plaintiff. Plaintiff will amend this Complaint to allege the true names and capacities of said DOE Defendants when ascertained. At all relevant times, Defendants and DOES 1 through 100, inclusive, and each of them, expected or should have

various research organizations, including McNeil Pharmaceuticals, Janssen Research Foundation, Three Dimensional Pharmaceuticals and the R.W. Johnson Pharmaceutical Research Institute.

expected that their acts would have consequences within the United States of America including the State of California and including Alameda County, said Defendants derived and derive substantial revenue therefrom.

JURISDICTION AND VENUE

17. This Court has jurisdiction over this action pursuant to California Constitution Article VI, Section 10, which grants the Superior Court "original jurisdiction in all causes except those given by statute to other trial courts."

18. This Court has general personal jurisdiction over each Defendant because each Defendant consented to jurisdiction by registering to do business in the State of California.

19. This Court has specific personal jurisdiction over each Defendant insofar as the claims asserted herein arise from and relate to Defendants' forum contacts and the exercise of personal jurisdiction complies with all Constitutional considerations of substantial justice and fair play.

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

21. There also is specific personal jurisdiction over each Defendant Drug Maker because they engaged in conduct in California. The JJIM Defendants manufactured Invega in California and conducted research on California residents that informed decisions about Defendants' Drugs and labeling.[3] Those specific acts relate to and give rise to claims against each Defendant Drug Maker.

22. Venue is proper in this Court pursuant to California Code of Civil Procedure Section 395(a) in that the headquarters and principal place of business of Defendant Kaiser is in Alameda County.

23. Plaintiff seeks relief that is within the jurisdictional limits of the Court.

[3] J&J primarily took these actions through its affiliate, Alza Corporation ("Alza"). Through Alza, J&J operated a large-scale manufacturing facility in Vacaville, California until 2022 and coordinated research crucial to developing Invega from Alza Plaza in Mountainview, California.

24. This lawsuit is not subject to removal based on the existence of a federal question. Plaintiff asserts common law and/or statutory claims under state law. These claims do not arise under the Constitution, laws, or treaties of the United States. 28 U.S.C. § 1447(c).

GENERAL ALLEGATIONS

I. Risperdal, Zyprexa, and Invega

25. Defendants marketed and sold Risperdal, Olanzapine, and Paliperidone under their respective brand names "Risperdal," "Zyprexa," and "Invega," and under related brand names for their various formulations.

A. Brand Names

26. JJIM Defendants designed, developed, manufactured, marketed, and sold Risperidone as:

a. Risperdal (risperidone), a tablet or oral solution, was approved December 29, 1993, and its patent expired September 15, 2008;

b. Risperdal (risperidone), an oral solution, was approved June 10, 1996, and its patent expired January 30, 2009;

c. Risperdal M-Tab (risperidone), an orally disintegrating tablet, was approved April 2, 2003, and its patent expired April 30, 2009; and

d. Risperdal Consta (risperidone), extended-release injection, was approved October 29, 2003, and its patent expired July 27, 2018.

27. Defendant Lilly designed, developed, manufactured, marketed, and sold Olanzapine as:

a. Zyprexa (olanzapine), a tablet formulation, was approved September 30, 1996, and its patent expired October 24, 2011;

b. Zyprexa (olanzapine), an injectable intramuscular formulation, was approved March 29, 2004, and its patent expired October 24, 2011;

c. Zyprexa Zydis (olanzapine), an orally disintegrating tablet was approved April 6, 2000, and its patent expired October 24, 2011; and

d. Zyprexa Relprevv (olanzapine pamoate), an extended-release injection, was

approved December 11, 2009, and its patent expired October 24, 2011.

28. JJIM Defendants designed, developed, manufactured, marketed, and sold Paliperidone as:

a. Invega (paliperidone), an extended-release tablet, was approved December 19, 2006 and its patent expired September 24, 2015;

b. Invega Sustenna (paliperidone palmitate), an injection released over one month, was approved July 31, 2009, and its patent expired July 6, 2021;

c. Invega Trinza (paliperidone palmitate), an injection released over three months, was approved May 18, 2015 and its patent expired July 6, 2021; and

d. Invega Hafyera (paliperidone palmitate), an injection released over six months, was approved May 18, 2015 and its patent expired July 6, 2021.

29. At all relevant times, Defendant Drug Makers, through their agents, servants, and employees, were the designer(s), developer(s), manufacturer(s), marketer(s), advertiser(s), distributor(s), and/or seller(s) of the brand name prescription drugs, Risperdal, Zyprexa, and Invega.

30. Risperdal was originally developed and approved for use in the treatment of symptoms associated with schizophrenia. Zyprexa is indicated for the treatment of schizophrenia and bipolar disorder. Invega is indicated for the treatment of schizophrenia and the treatment of schizoaffective disorder.

31. None of these drugs cures schizophrenia or any other mental health condition. Their antipsychotic mechanism is believed to be their ability to block or moderate dopamine, a chemical found in the brain. It has been hypothesized that abnormal dopamine activity is the cause of psychosis, abnormal thinking, and hallucinations.

32. Defendants' Drugs are only approved for a narrow range of severe mental health conditions, primarily schizophrenia. Because schizophrenia affects just 1% of the U.S. population, Defendants marketed the drugs for off-label indications, namely, management of "psychotic disorders." In fact, in 2009, Lilly pled guilty and agreed to pay over $1.4 billion to settle U.S. criminal and civil litigation based on the company's illegal marketing of Zyprexa – then the largest

criminal fine in U.S. history.[4] In 2013, J&J agreed to pay $2.2 billion to settle similar claims regarding Risperdal and two other drugs.

33. The Department of Justice alleged the Defendant Drug Makers promoted their drugs for off-label uses by, among other tactics, paying kickbacks to doctors and pharmacists; targeting sales calls toward child psychiatrists, adolescent mental health facilities, and nursing homes; and clouding research into safety concerns with "misinformation from a company trying to build its bottom line."[5] Defendant Drug Makers' scheme exposed the general public to a dangerous carcinogen without any proven benefit to most, and, as former U.S. Attorney General Eric Holder Jr. stated, "recklessly put at risk the health of some of the most vulnerable members of our society – including young children, the elderly, and the disabled."[6]

B. Atypical Antipsychotics

34. Risperdal, Zyprexa, and Invega are classified as atypical, or second-generation, antipsychotics. They are believed to function primarily by blocking receptors in the brain that are responsive to the neurotransmitters serotonin and dopamine.[7] Other atypical antipsychotics include Clozaril (clozapine), Seroquel (quetiapine), Geodon (ziprasidone), and Abilify (aripiprazole). Within this diverse sub-class of antipsychotics, Defendants' Drugs stand out as the SGAs most prone to induce hyperprolactinemia.[8]

35. The phrase "second-generation" suggests SGAs are more sophisticated than FGAs. However, "the FGA/SGA classification remains problematic because neither group is defined by

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[4] Press Release, U.S. Dep't of Justice, *Eli Lilly and Company Agrees to Pay $1.415 Billion to Resolve Allegations of Off-label Promotion of Zyprexa* (Jan. 15, 2009), https://www.justice.gov/archive/opa/pr/2009/January/09-civ-038.html.

[5] *Id.*; Press Release, U.S. Dep't of Justice, *Johnson & Johnson to Pay More Than $2.2 Billion to Resolve Criminal and Civil Investigations* (Nov. 4, 2013), https://www.justice.gov/archives/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations.

[6] Eric Holder, Att'y Gen., U.S. Dep't of Justice, *Attorney General Eric Holder Delivers Remarks at Johnson & Johnson Press Conference* (Nov. 4, 2013), https://www.justice.gov/archives/opa/speech/attorney-general-eric-holder-delivers-remarks-johnson-johnson-press-conference.

[7] D.M. Taylor, T.R.E. Barnes & A.H. Young, *The Maudsley Prescribing Guidelines in Psychiatry* 3-6 (14th ed. 2021).

[8] G.E. Moore, et al., *Prescribing of Antipsychotic Medication to Children and Adolescents: An Analysis of Gender and Age Differences in State Medicaid Programs*, 32 *J.* CHILD & ADOL. PSYCHOPHARMACOLOGY 116 (2022), https://doi.org/10.1089/cap.2021.0140.

Risperidone and Invega share another pharmacological similarity: the active ingredient in Invega, Paliperidone, or "9-hydroxy-risperidone," is the active metabolite of Risperdal.

anything other than time of introduction," with SGAs entering the market after 1990. "There is nothing either pharmacologically or chemically which clearly binds atypicals together as a group, save a general, but not universal, finding of preference for D2 receptors outside the striatum." Atypicals are *not* "characterized by improved efficacy over older drugs (clozapine and one or two others excepted) or the absence of hyperprolactinemia." Moreover, date of introduction differs from date of formulation – so while clozapine was first synthesized in 1959 and olanzapine was patented in 1971, they still qualify as SGAs, "apparently the most modern of antipsychotics," because they went undeveloped for decades.[9]

II. Regulatory History of Defendants' Drugs

36. Defendants' Drugs were all developed years before being released on the market, and before many so-called FGAs were developed, for the treatment of psychotic disorders as tablet formulations. In each case, the drug was developed by the manufacturer to replace an earlier blockbuster drug that was nearing patent expiration.

A. Risperdal

37. Risperidone was developed in the 1980s by Janssen Pharmaceutica, Inc., a Belgian company owned by Johnson & Johnson.[10]

38. On December 29, 1993, Defendant JPI obtained approval from the FDA (New Drug Application ("NDA") 020272) to market Risperdal oral tablets for the treatment of "manifestations of psychotic disorders" (schizophrenia) in adults.

39. For Defendant JPI, Risperdal replaced Haldol (haloperidol), an FGA. Haldol, approved by the FDA in 1967, was a "blockbuster" for J&J, until its patent expired in 1986. Because Haldol cost roughly 100 times less than patent-protected antipsychotics,[11] "[i]nexpensive generic versions of Haldol had decimated the brand name's revenues by 1992."[12]

40. To encourage patient transition, JJIM requested Risperdal's label to include certain

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[9] *Id.*
[10] Defendant JPI (Janssen Pharmaceuticals, Inc.) is the successor in interest to Janssen Pharmaceutica, Inc.
[11] J.I. Escobar & H. Marin, *Clinical Psychopharmacology: A Practical Approach*, 69 WORLD SCIENTIFIC (2013).
[12] Steven Brill, *America's Most Admired Lawbreaker*, HUFFPOST HIGHLINE. (2015), https://highline.huffingtonpost.com/miracleindustry/americas-most-admired-lawbreaker/

side-by-side comparisons of the drug and Haldol. The FDA explained this was unacceptable, because it "invites a comparison that leads to the conclusion that Risperdal has been shown to be superior to [Haldol] when, in fact, it has not."[13]

41. The branded version of Risperdal earned JJIM over $4.1 billion in 2006 as the drug approached patent expiration, accounting for roughly 18% of the company's revenue.[14]

B. Zyprexa

42. Olanzapine was originally developed by Defendant Lilly and patented as "Zyprexa" in 1971.[15]

43. Zyprexa was originally approved by the FDA in September 1996 (NDA 076000) for the treatment of "manifestations of psychotic disorders."[16]

44. For Lilly, developing Zyprexa was an attempt to replace revenues from Prozac (fluoxetine). The FDA originally approved Prozac for sale in 1987, and the drug "powered Lilly's meteoric sales growth for more than a decade. In 2000, Prozac accounted for a quarter of the company's $10.8 billion in revenues. But by the closing months of 2001, as the drug battled with new generic antidepressants, Prozac's quarterly sales had dropped 66% from the previous year."[17]

45. Lilly developed Zyprexa as part of its "Year X Plan," management's strategy to introduce a replacement for Prozac before its patent expired. Zyprexa, an antipsychotic, had a smaller patient population than Prozac, an antidepressant. Lilly, however, illegally marketed Zyprexa

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[13] *Id;* attachment titled "Temple Memo" (on file with HuffPost). https://highline.huffingtonpost.com/miracleindustry/americas-most-admired-lawbreaker/assets/documents/1/temple-memo-1993.pdf

[14] Johnson & Johnson, Form 10-K, at 35 (Feb. 20, 2007), https://d18rn0p25nwr6d.cloudfront.net/CIK-0000200406/cdb6b1de-b877-4e4f-a6b2-0a06661d5482.pdf; Johnson & Johnson, Form 10-K, at 34 (Feb. 20, 2008), https://d18rn0p25nwr6d.cloudfront.net/CIK-0000200406/14efa49c-d018-435b-a3ed-ff9f1808b807.pdf.; Angus Liu, *Entering J&J's Fiefdom, Luye Wins FDA Approval for Long-Acting Schizophrenia Drug,* FIERCE PHARMA (Jan. 23, 2024), https://www.fiercepharma.com/pharma/entering-jjs-fiefdom-luye-wins-fda-approval-long-acting-schizophrenia-drug.

[15] Taylor et al., *supra.*

[16] In March 2000, FDA approved Zyprexa for the short-term treatment of acute manic episodes associated with Bipolar I Disorder. In November 2000, FDA approved Zyprexa for the short-term treatment of schizophrenia in place of management of the manifestations of psychotic disorders, and for maintaining treatment response in schizophrenic patients who had been stable for approximately eight weeks and were then followed for a period of up to eight months.

[17] Clifton Leaf, *The Law of Unintended Consequences*, FORTUNE (June 28, 2004), https://money.cnn.com/magazines/fortune/fortune_archive/2004/06/28/374398/index.htm.

for many of Prozac's indications. The company also downplayed Zyprexa's potential side effects, settling over $1.2 billion in personal injury claims related to Zyprexa by January 2007.[18]

46. Global revenue of Olanzapine stayed above $4 billion from 2003 until 2010, accounting for nearly a quarter of Lilly's total sales before the company lost its patent in late 2011. Zyprexa played a crucial role in Lilly's march from ninth largest pharmaceutical company in 1990 by sales,[19] to its crowning as the most valuable pharmaceutical company in the world in May 2023. Over the same time, the company's stock increased roughly 50-fold.

C. Invega

47. Paliperidone, as the primary active metabolite of risperidone, was discovered around the same time as Risperidone, in the 1980s. However, the JJIM Defendants did not develop Paliperidone as a standalone drug until decades later.

48. On September 29, 2006, Invega (NDA 021999) was approved by the FDA for the treatment of Schizophrenia as extended-release oral tablets.

49. JJIM Defendants attempted to replace Risperdal's revenues, which was approaching the end of its patent protection, with revenue from Invega. Invega was approved roughly 18 months ahead of Risperdal's patent expiration in June 2008. To boost customer carryover, JJIM Defendants priced Invega *below* Risperdal until Risperdal's patent expired.

50. However, even when it debuted, Invega's comparison to its predecessor was unflattering, as an industry analyst explained at the time: "Bottom line. When all is said and done, Invega looks like Risperdal without drug-drug interactions, but with more QT interval prolongation, more tachycardia, possibly more EPS, and the same amount of hyperprolactinemia. Not a pretty picture. Get ready to be Invega'ed – I mean inveigled – by your neighborhood drug rep soon."[20]

51. Annual worldwide sales of Invega topped $4.1 billion in 2023.[21]

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[18] https://www.thecarlatreport.com/articles/1431-invega-can-you-say-patent-extender-

[19] Agnes Shanley, *Decades of Change for Top Pharmaceutical Companies*, PHARM. TECH. (Jan. 23, 2024), https://www.pharmtech.com/view/decades-change-top-pharmaceutical-companies.

[20] Daniel Carlat, *Invega: Can You Say "Patent Extender?"* THE CARLAT PSYCHIATRY REPORT (Apr. 1, 2010), https://www.thecarlatreport.com/articles/1431-invega-can-you-say-patent-extender-.

[21] Press Release, Johnson & Johnson, *Johnson & Johnson Reports Q4 and Full-Year 2023 Results* (Jan. 23, 2024), https://www.investor.jnj.com/news/news-details/2024/Johnson--Johnson-Reports-Q4-and-Full-Year-2023-Results/default.aspx.

III. Carcinogenicity of Defendants' Drugs

52. It has been well known within the scientific community since at least the 1970s that hyperprolactinemia can cause breast cancer. And, since at least the 1990s, there has been common scientific consensus that atypical antipsychotics, such as Defendants' Drugs, can cause hyperprolactinemia.

53. Moreover, over the last three decades, a wealth of publicly available, peer-reviewed epidemiological literature has shown a strong causal association between consumption of Defendants' Drugs and breast cancer.

A. Hyperprolactinemia Causes Breast Cancer

54. The carcinogenic risk of hyperprolactinemia is well known, with research into the topic going back decades.

55. In the 1970s, animal studies conclusively established a causal association between hyperprolactinemia and carcinogenicity, and by 1978, a study published in the journal CANCER RESEARCH stated, "It is unequivocal that prolactin is an influential hormone in murine mammary tumorigenesis."[22]

56. Around the same time, evidence began to accumulate that prolactin could also cause breast cancer in humans.[23] Epidemiological studies conducted in the late 1980s found that high serum prolactin levels were associated with known breast cancer risk factors such as parity status and mammographic breast density.[24]

57. Long-term prospective studies emerged in the early 1990s. The earliest long-term prospective study, Wang et al. (1992), commenced in 1968 and followed participants until 1990, examining the relationship between prolactin levels and the risk of breast cancer.[25] The authors observed a significant association in both pre- and post-menopausal women between

[22] C.W. Welsch & H. Nagasawa. *Prolactin and murine mammary tumorigenesis: a review*, 37 CANCER RES. 951 (1977) https://pubmed.ncbi.nlm.nih.gov/191183/

[23] G.C. Lachelin, et al. *Hormonal changes following hypophysectomy in humans*. 50 OBSTET. & GYNECOL, 333 (1977).

[24] D.Y. Wang, et al. *The permanent effect of reproductive events on blood prolactin levels and its relation to breast cancer risk: a population study of postmenopausal women*, EUR. J. CANCER CLIN. ONCOL 1225 (1988).

[25] D.Y. Wang, et al. *Relationship of blood prolactin levels and the risk of subsequent breast cancer*. 21 INT J EPIDEMIOL, 214-221 (1992). https://doi.org/10.1093/ije/21.2.214.

hyperprolactinemia and breast cancer. This was followed by Helzlsouer, et al. (1994), conducted between 1974 and 1991, and Hankinson, et al. (1999), conducted between 1989 and 1994, each reporting similar results.[26]

58. Today, the causal association between hyperprolactinemia and breast cancer is undisputed.[27] As a 2014 study funded by Defendant JRD admitted, "[m]ore than 95% of [breast cancer tumors] display overexpression of the prolactin receptor, and genes that are activated by this receptor are associated with tumorigenesis and cancer cell proliferation."[28] The causal association is underscored by studies of atypicals, discussed below, which found that the risk of breast cancer impacted the proportional increase of prolactin.[29]

B. Atypical Antipsychotics Cause Hyperprolactinemia

59. JJIM Defendants have been aware of the strong causal association between exposure to atypical antipsychotics and hyperprolactinemia since at least the 1990s. All FGAs, introduced before 1990, caused hyperprolactinemia.[30] In fact, since the 1970s, some clinicians recommended against the use of FGAs in patients with hyperprolactinemia or suspected breast cancer.[31]

60. Pre-approval nonclinical studies for Defendants' Drugs found a five-to-six-fold increase in prolactin for Risperdal, and a four-fold increase for Zyprexa.[32] By contrast, certain other SGAs have negligible prolactin effects – aripiprazole, in fact, decreases prolactin production.

61. In 1998, JPI executives set a brand strategy to prove that Risperdal's prolactin effects were no worse than Haldol or other FGAs.[33] The company conducted three clinical trials to support

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[26] K.J. Helzlsouer et al., A Prospective Study of Endogenous Hormones and Breast Cancer, 18 Cancer Detect. Prev. 79 (1994); S.E. Hankinson et al., Plasma Prolactin Levels and Subsequent Risk of Breast Cancer in Postmenopausal Women, 91 J. Nat'l Cancer Inst. 629 (1999), https://doi.org/10.1093/jnci/91.7.629.

[27] *See, e.g.*, T. Rahman, et al. *Antipsychotic treatment in breast cancer patients*, 171 AM. J. PSYCHIATRY, 616 (2014), https://doi.org/10.1176/appi.ajp.2013.13050650.

[28] K.Y. Tsai, et al., *Risperidone Exposure and Breast Cancer Risk: A Cohort Study Using the Taiwan National Health Insurance Research Database*, 8 J NEUROPSYCHIATRY 290 (2018), https://www.jneuropsychiatry.org/peer-review/risperidone-exposure-and-breast-cancer-risk-a-cohort-study-using-the-taiwan-national-health-insurance-research-database-12756.html.

[29] *See* Rahman et al., 171 AM. J. PSYCHIATRY 616 (2014).

[30] J.R. Bostwick, S.K. Guthrie & V.L. Ellingrod, *Antipsychotic-Induced Hyperprolactinemia*, 29 PHARMACOTHERAPY 64 (2009).

[31] *Id.*

[32] Brill at Ch. 3-4; attachment titled "Gosky re: 'perceived Weakness.'" (on file with HuffPost).

[33] *Id.*

this messaging, because, as a JPI medical adviser insisted, "we need to do more with our own data." But when results of the final trial came back in May 2002, a JPI executive concluded that it "[d]oesn't look promising." Another executive asked the researchers to withhold from publication until JPI could re-analyze the database, stating that "these results may differ slightly from what will appear in the final Clinical Study Report."[34]

62. Nevertheless, the FDA caught on to Risperdal's prolactin problem. In July 2006, when JPI sought to indicate Risperdal for the treatment of irritability associated with autism, the FDA psychiatry division again "expressed concern regarding unacceptable longer-term risks,"[35] including hyperprolactinemia. JPI argued that this concern "was not justified based on available data," but the hyperprolactinemia warning was ultimately strengthened.[36] Still, JPI never warned of the risk of breast cancer.

63. Today, the literature shows that hyperprolactinemia is common, and severe, among users of these drugs,[37] with incidence rates reaching 70% to 76.4% for Olanzapine[38] and 94.8% for Risperdal.[39] "Hyperprolactinemia is one of the most common side effects of Risperidone treatment."[40] The severity of hyperprolactinemia among users is also impressive; serum prolactin levels can increase two to three-fold for Olanzapine users and ten-fold increases for Risperdal users.[41]

C. Atypical Antipsychotics Cause Breast Cancer

64. The link between atypicals and breast cancer has been extensively studied. Since the introduction of Defendants' Drugs, mounting evidence has demonstrated that these drugs can cause

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[34] *Id, supra.*
[35] *Id.*
[36] *Id.*
[37] D. Lecic-Tosevski & M. Milosavljevic, *Community Mental Health Care in Serbia: Development and Perspectives*, 2 CONSORTIUM PSYCHIATR., 81 (2021). https://doi.org/10.17816/CP77; T.C. Chopko & C.W. Lindsley, *Classics in Chemical Neuroscience: Risperidone*, 9 ACS CHEM NEUROSCI 1520-9 (2018). https://doi.org/10.1021/acschemneuro.8b00159.
[38] M. Wudarsky, et al. *Elevated Prolactin in Pediatric Patients on Typical and Atypical Antipsychotics*, 9 J. CHILD & ADOLESC. PSYCHOPHARMACOL, 239 (1999), https://pubmed.ncbi.nlm.nih.gov/10630453/.
[39] M.T. Koch, et al. *Antipsychotic-Related Prolactin Levels and Sexual Dysfunction in Mentally Ill Youth: A 3-Month Cohort Study*, 62 J. AM. ACAD. CHILD & ADOLESC. PSYCHIATRY 1021-1050. (2023). https://doi.org/10.1016/j.jaac.2023.03.007.
[40] M. Stojkovic et al., *Risperidone Induced Hyperprolactinemia: From Basic to Clinical Studies*, 13 FRONT PSYCHIATRY 874705 (2022), https://doi.org/10.3389/fpsyt.2022.874705.
[41] T.S. Kolnikaj, et al. *Pharmacological Causes of Hyperprolactinemia.* (K.R. Feingold et al. eds., MDTEXT.COM, INC. 2024), https://www.ncbi.nlm.nih.gov/books/NBK599196/.

breast cancer and promote tumors. However, the Defendant Drug Makers ignored early warnings that their drugs were carcinogenic. The risk is particularly strong in studies evaluating higher dosages, prolonged periods of consumption, and use of prolactin-increasing antipsychotics ("PIAs").

65. Large-scale epidemiological studies emerging in the early 2000s provided clear evidence of a causal connection. Wang et al. (2002) conducted a retrospective cohort study examining over 100,000 women enrolled in New Jersey healthcare programs,[42] and found a 16% increase in breast cancer risk associated with dopamine antagonists, like Defendants' Drugs. This study concluded shortly after Risperdal's approval, which should have demonstrated to the Defendant Drug Makers that these atypicals posed a risk of breast cancer – a risk that was already well-documented in the medical and scientific literature.[43]

66. In 2007, Hippisley-Cox et al. analyzed data from 40,441 incidents of cancer in the UK's Q Research database, concluding that antipsychotic use was linked to a 55% elevated risk of breast cancer.[44] Similarly, Chou et al. (2017), studying over 90,000 cases of female breast cancer from the Taiwanese Insurance Claims Database, found nearly double the risk, or a 94% increase, of breast cancer among patients exposed to PIAs, including Risperdal and Invega.[45]

67. Studies have specifically identified exposure to Defendants' Drugs as associated with an increased risk of breast cancer. For instance, in Pottegård et al. (2018), an analysis of 60,360

[42] Specifically, the Medicaid or Pharmaceutical Assistance to the Aged and Disabled programs.
[43] Wang, Philip S et al., *Dopamine Antagonists and the Development of Breast Cancer*. Arch. Gen. Psychiatry 1147 (2002), https://doi.org/10.1001/archpsyc.59.12.1147.
[44] J. Hippisley-Cox, et al., *Risk of Malignancy in Patients with Schizophrenia or Bipolar Disorder: Nested Case-Control Study.* Arch. Gen. Psychiatry 1368 (2007). https://doi.org/10.1001/archpsyc.64.12.1368.
[45] Tsai et al. (2018), discussed later, was another study conducted using data from Taiwan's Nation Health Insurance Research Database. Although the authors concluded that "[t]here is no evidence of an increased risk of BC associated with risperidone compared to other atypical or conventional antipsychotics," the study did not include non-users as a control, nor does it mention how much more likely to develop breast cancer antipsychotic users were estimated to be. To qualify for the study, patients needed to fill at least two prescriptions of an antipsychotic within a 90-day window – beyond that, the study apparently did not measure exposure or dosage at all. Perhaps most importantly, the median follow-up time was 3.34-5.56 years, well below the recommended latency time of 6-20 years recommended for breast cancer studies. In short, this study, because of its design, was unable to detect the risk of breast cancer. Tellingly, this study was spearheaded by JRD.

breast cancer cases in the Danish Cancer Registry reported that 1,000 days or more exposure[46] to second-generation PIAs, including risperidone and olanzapine, was associated with a 52% increased risk of breast cancer.[47] This finding was replicated by George et al. (2020)—a study of 155,737 participants in the Women's Health Initiative, which concluded that extended use of atypicals substantially increased the risk of developing invasive breast cancer by 45%.[48]

68. In exploring prolactin increases, Rahman et al. (2023) provided crucial insights in an observational study of 540,737 women using data from IBM MarketScan and Medicaid Databases. The study observed that women taking high-prolactin-elevating antipsychotics such as risperidone faced a 62% increased risk of breast cancer compared to non-users. Medium-prolactin drugs like olanzapine showed a similarly alarming 54% increased risk.[49]

69. Systematic reviews and meta-analyses further consolidated the consensus. Gao et al. (2022) was a meta-analysis of 11 epidemiological studies with 1,499,001 total participants, concluding that "antipsychotic exposure is an independent risk factor for cancer." A dose response relationship was also observed—high-dose groups were 33-39% more likely to develop breast cancer than low-dose groups. And among breast cancer patients, antipsychotic use is associated with a 54% increased risk of mortality.[50] Leung et al. (2022) was a meta-analysis of 9 high-quality[51] observational studies published in Embase, PubMed and Web of Science databases, pooling data from over *two million* individuals. The study found that antipsychotic use increased breast cancer risk by 39% among the five cohort studies analyzed, and 37% among the four case-controlled studies.[52]

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[46] The actual definition of long-term use was 10,000 mg of "olanzapine equivalents." The authors standardized to different antipsychotics with this metric, using each drug's "defined daily dose," per WHO definitions. WHO considers a Defined Daily Dose (DDD) of olanzapine to be 10mg.

[47] A. Pottegård, et al., *Use of antipsychotics and risk of breast cancer: a Danish nationwide case-control study*, Brit. J. Clinical Pharmacol. 2152 (2018), https://doi.org/10.1111/bcp.13661.

[48] A. George, et al., *Psychotropic Medication Use and Postmenopausal Breast Cancer Risk*, 29 Cancer Epidemiol. Biomarkers & Prevention 254 (2020).

[49] *See* Rahman et al., 171 Am. J. Psychiatry 616 (2014).

[50] Z. Gao, et al, *Antipsychotic exposure is an independent risk factor for breast cancer: A systematic review of epidemiological evidence*, 12 Front. Oncol. 993367 (2022), https://doi.org/10.3389/fonc.2022.993367.

[51] Quality of studies was assessed using the Newcastle-Ottawa Scale. "High-quality" means 7-9 stars.

[52] J.C.N. Leung, et al. *Association of Antipsychotic Use With Breast Cancer: A Systematic Review and Meta-Analysis of Observational Studies With Over 2 Million Individuals*. 31 Epidemiol. & Psychiatric Sci. e61 (2022), https://doi.org/10.1017/S2045796022000476.

70. This consistently positive causal trend was reaffirmed by the most recent epidemiological data. Solmi et al. (2024) analyzed data from 132,061 women in Swedish nationwide medical registers (roundly regarded as among the highest quality registers for use in epidemiological studies). The authors concluded that, compared to non-users of prolactin-increasing antipsychotics, breast cancer was 20% more common among women taking a PIA[53] for one to four years, and 47% more common among those with at least five years of use, after adjustment.[54]

71. The Defendant Drug Makers have designed, funded, and/or participated in conducting at least three epidemiological studies: Reutfors et al. (2016), Tsai et al. (2018), and Kern et al. (2024).[55]

72. The two earlier studies, Reutfors et al. and Tsai et al. focused on Risperdal. Not surprisingly, the studies conclude that the drug was not associated with an increased risk of breast cancer. Both studies reached their conclusions based on comparisons of Risperdal to users of *other* PIAs, rather than users of prolactin-sparing antipsychotics or non-antipsychotic users. That said, their results, in fact, showed that breast cancer rates were higher for risperidone than other atypicals, and the association was attenuated only after adjustment. Coincidently, these studies also used databases that were also analyzed by independent researchers who concluded that Defendants' Drugs are, in fact, linked to breast cancer.[56]

73. Perhaps the most obvious defect in these studies was noted in Taipale et al. (2021). "[Some] cohort studies have not found any substantial risk increase in breast cancer associated with antipsychotic use. However, these findings are almost self-evident because of small antipsychotic exposure in these studies given that the highest cutoff of classification for cumulative exposure to any

[53] All three of Defendants' Drugs were included in the "prolactin-increasing antipsychotic group." Within that group, Olanzapine and Risperidone were the two most commonly used antipsychotics.

[54] M. Solmi, et al., *Antipsychotic Use and Risk of Breast Cancer in Women with Severe Mental Illness: Replication of a Nationwide Nested Case-Control Database Study*, 50 Schizophr. Bull. 1471 (2024), https://doi.org/10.1093/schbul/sbae058.

[55] Reutfors et al. was funded by JRD, and two of its authors were JRD employees. Tsai et al. was funded by JRD, JRD planned the study and reviewed the manuscript, three of its authors received grants from JRD, and three others were JRD employees. Kern et al. was conducted by current and former employees of JRD.

[56] *See* Solmi, et al., 50(6) Schizophr. Bull. (2024); W. Chou, et al., *Female Schizophrenia Patients and Risk of Breast Cancer: A Population-Based Cohort Study*, 188 Schizophr. Res. 165 (2017), https://doi.org/10.1016/j.schres.2017.01.019.

patient subgroup was less than 400 DDDs [*i.e.*, defined daily doses]." In other words, in studies finding no substantial increase in breast cancer risk, the flaws were "self-evident," primarily because the follow-up periods were so short that the *most* exposed cohort in any of these studies had used the drugs for roughly a year. This is well below median usage of Defendants' Drugs and well below the latency period for breast cancer.[57]

74. Lastly, the third study produced by Defendant Drug Markers, Kern et al. (2024), ("Kern") positions itself as a response to the growing research linking PIAs and breast cancer – particularly Taipale et al. (2021) and Rahman et al. (2022).[58] While Kern feigns to incorporate the criticisms of previous JRD-funded studies, it does not account for the "self-evident" flaw noted in Taipale, *i.e.* length of exposure, for which no minimum is imposed. This decision is all the stranger considering the litany of inclusion/exclusion criteria, controls for confounding, analysis variants, and data failure thresholds imposed throughout the study. While Kern contains signs of data distortion,[59] ultimately, the results of the study showed that more patients taking PIAs, including Risperdal and Invega, developed breast cancer than those taking prolactin-sparing antipsychotics. Kern only concludes in confidently "finding no association" by dismissing those results are not statistically significant.

75. Kern was published in March of 2024, and was the JJIM Defendants' final stand, a last-ditch effort to convince the FDA to dismiss the findings of independent researchers. However, Kern was followed by Solmi et al. in April 2024 and Bird et al. in December 2024 – the latter of

[57] H. Taipale, et al., *Antipsychotic Use and Risk of Breast Cancer in Women with Schizophrenia: A Nationwide Nested Case-Control Study in Finland*, 8 The Lancet. Psychiatry 833 (2021), https://doi.org/10.1016/S2215-0366(21)00241-8.

[58] Both studies are explicitly referenced throughout the paper. In the supplementary materials, the Defendants disclose, "This is a follow-up to an internal white paper regarding our position on the risk of breast cancer and use of antipsychotics based on current available evidence. The development of the white paper was triggered by a recent publication in August 2021 titled "Antipsychotic use and the risk of breast cancer in women with schizophrenia: a nationwide nested case-control study in Finland."

[59] For instance, at the outset of the study, researchers chose five databases to examine, but only present the results from one. The comparator groups, i.e. the drugs characterized as PIAs vs. non-prolactin increasing antipsychotics, are also unusual; results from Risperdal and Invega in isolation are not presented, but are instead grouped in with eight other PIAs, four of which are not established PIAs. The seven drugs prolactin-sparing group, similarly, are also composed of two drugs known to increase prolactin. Meanwhile, a third group of "moderate prolactin-increasing antipsychotics," are not presented in the final results.

which explicitly concluded that a label change was warranted.[60]

76. The overwhelming weight of the available epidemiological literature, comprised of multiple studies conducted in the United States and other countries over last couple of decades, demonstrates that consumption of Defendants' Drugs is causally associated with an increased risk of breast cancer and capable of tumor promotion. And one of the proposed mechanisms by which such carcinogenesis occurs is the significant increase of prolactin precipitated by these drugs. Notwithstanding these repeated signals, Defendant Drug Makers failed to act on the available evidence linking their products to the risk of breast cancer by informing consumers and the medical community. Instead, Defendant Drug Makers downplayed the risk, in blatant disregard for the health and safety of patients prescribed their medications.

IV. Defendants Failed to Warn of the Risk of Breast Cancer Associated with their Drugs

A. Denial of Carcinogenesis

77. Defendant Drug Makers have never warned about the risk of breast cancer. Their labels have only dismissed or obfuscated the risk. The 1996 label for Risperdal – the earliest publicly accessible label for any of Defendants' Drugs – asserted that "[n]either clinical trials nor epidemiological studies conducted to date have shown an association between chronic administration of this class of drugs and tumorigenesis in humans; the available evidence is considered too limited to be conclusive at this time." Notably, this statement appeared in the "Hyperprolactinemia" section, and not in the "Carcinogenesis" section of the label. This statement also went unchanged on Defendants' labels for all three drugs from at least as early as 1996 to January 2025, notwithstanding the mounting evidence of breast cancer risk.[61]

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[60] S.B. Bird, *Antipsychotic-Induced Hyperprolactinemia: Toxicologic Mechanism and the Increased Breast Cancer Risk*, 14 TOXICOL. REPS., 101927 (2025), https://doi.org/10.1016/j.toxrep.2025.101927.

[61] U.S. Food & Drug Admin., Drugs@FDA: FDA-Approved Drugs, Application No. 020272 (Risperdal), https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020272 (last visited Apr. 3, 2025).

U.S. Food & Drug Admin., *Drugs@FDA: FDA-Approved Drugs*, Application No. 020592 (Zyprexa), https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020592 (last visited Apr. 3, 2025).

U.S. Food & Drug Admin., *Drugs@FDA: FDA-Approved Drugs*, Application No. 021999 (Invega), https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021999 (last visited Apr. 3, 2025).

78. Defendant Drug Makers updated the label language regarding the risk of breast cancer in January 2025 – after decades of their drugs being prescribed to consumers – but the new warning still dismisses their drugs' breast cancer risk: "Published epidemiologic studies have shown inconsistent results when exploring the potential association between hyperprolactinemia and breast cancer."[62] Describing the results of the epidemiology as "inconsistent" is flatly wrong. As a recently published meta-analysis of the literature concluded: "Given this increased risk of breast cancer, stronger warnings about this increased risk are warranted, and regular monitoring of prolactin levels and breast cancer screening should be part of the management plan for these patients."[63]

B. Obfuscation of Potential Mechanisms

79. Defendants' labels also disclaim the risks and well-established adverse effects of elevated prolactin,[64] which provide the primary suspected pathway for carcinogenesis. Since at least 2006, Risperdal's label stated: "the clinical significance of elevated serum prolactin levels is unknown for most patients."[65] In 2006, in the wake of litigation regarding hyperprolactinemia's tendency to induce gynecomastia, this sentence was removed.

80. However, Defendant Drug Makers have never disclosed the connection between hyperprolactinemia and breast cancer, which has been established for decades. Worse yet, in the recent January 2025 label update, which discusses tissue studies on elevated prolactin and breast cancer, Defendant Drug Makers incorrectly state that the results of these studies are "a factor of potential importance ***if*** the prescription of these drugs is considered in a patient with previously detected breast cancer."[66] This flies in the face of established scientific evidence which demonstrates that Defendants' Drugs are capable of causing breast cancer irrespective of whether an individual previously had breast cancer.[67]

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[62] *Id.*
[63] S.B. Bird, *Antipsychotic-Induced Hyperprolactinemia: Toxicologic Mechanism and the Increased Breast Cancer Risk*, 14 TOXICOL. REPS., 101927 (2025), https://doi.org/10.1016/j.toxrep.2025.101927.
[64] *See* U.S. Food & Drug Admin., *Drugs@FDA*, Appl. Nos. 020272, 020592 & 021999.
[65] *Id.*
[66] *Id.* (emphasis added).
[67] *Id.*

C. Misrepresentation of Carcinogenesis Studies

The labels on Defendants Drugs also downplay the results of animal studies which have consistently linked elevated prolactin to breast cancer. These misrepresentations are particularly important because they appear in the only section on Defendants' Drugs labeled "Carcinogenesis" – i.e. the section intended to disclose any potential risks of cancer. The concluding sentence of this section states, "The relevance of these tumor findings in rodents to human risk is unknown."[68] In February 2021 and December 2022, the labels of Risperdal and Zyprexa, respectively, were updated to describe the relevance of these findings as "unclear."[69] Whether Defendant Drug Makers describe the relevance of these studies as "unclear" or "unknown," their descriptions are untrue.

V. The Defendant Drug Makers Knew or Should Have Known of the Breast Cancer Risk

81. During the time the Defendant Drug Makers manufactured and sold Defendants' Drugs in the United States, the weight of scientific evidence showed that the drugs exposed users to an increased risk of developing breast cancer. Defendant Drug Makers failed to disclose this risk to consumers on the drugs' labels—or through any other means—and Defendant Drug Makers failed to report these risks to the FDA.

82. Prior to and during the time Plaintiff ingested Defendants' Drugs, Defendant Drug Makers knew or should have known about studies authored by independent researchers and published in peer-reviewed scientific journals, as well as case reports related to Defendant' Drugs, that demonstrated an association between these drugs and breast cancer.

83. Despite clear evidence that their drugs can cause cancer, Defendant Drug Makers did not exercise reasonable care in ensuring the dangers of Defendants' Drugs were conveyed to consumers or the FDA.

84. Defendant Drug Makers concealed the cancer link from consumers in part by not reporting it to the FDA, which relies on drug manufacturers to bring new information regarding approved drugs like Defendants' Drugs to the agency's attention.

85. Manufacturers of an approved drug are required by regulation to submit an annual

[68] *Id.*
[69] *Id.*

report to the FDA containing, *inter alia*, new information regarding the drug's safety pursuant to 21 C.F.R. § 314.81(b)(2):

> The report is required to contain . . . [a] brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study.

86. 21 C.F.R. § 314.81(b)(2)(v) provides:

> The manufacturer's annual report also must contain copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (*e.g.*, mutagenicity) conducted by, or otherwise obtained by, the [manufacturer] concerning the ingredients in the drug product.

87. The Defendant Drug Makers ignored these regulations and, disregarding the scientific evidence available to them, failed to report to the FDA significant new information affecting the safety or labeling of Defendants' Drugs.

88. The Defendant Drug Makers knew of the risk of breast cancer associated with their drugs.

89. On information and belief, Defendant Drug Makers have not provided the relevant studies concerning the risk of breast cancer to the FDA, nor did they present the FDA with a proposed disclosure of the link between breast cancer and Defendants' Drugs.

90. Pursuant to federal regulations, the Defendant Drug Makers remain responsible for the content of its label and are charged with drafting an adequate label and ensuring that its warnings remain adequate as long as Defendants' Drugs are on the market.

91. Defendant Drug Makers were aware of the connection between hyperprolactinemia and breast cancer yet repeatedly misstated the scientific consensus in order to minimize this risk of breast cancer associated Defendants' Drugs.

92. To be clear, multiple alternative antipsychotics are available that do not pose the same risk, such as Abilify (aripiprazole), Clozaril (clozapine), Geodon (ziprasidone), and Seroquel (quetiapine).

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EXEMPLARY/PUNITIVE DAMAGES ALLEGATIONS

(Against Defendant Drug Makers)

93. Defendant Drug Makers' conduct as alleged herein was done with reckless disregard for human life, oppression, and malice. Defendants' conduct is particularly reprehensible given their drugs were directed at a vulnerable population—namely those suffering with a variety of mental health conditions, including children and the elderly.

94. Defendant Drug Makers were fully aware of the safety risks of cancer associated with their products. Nonetheless, Defendant Drug Makers deliberately crafted their label, marketing, and promotion to mislead physicians and consumers. Indeed, Defendant Drug Makers repeatedly omitted and obfuscated the risk of cancer as well as other statements and representations that hold out their drugs as safe for consumption. In actual fact, as discussed above, Defendant Drug Makers sold drugs capable of causing breast cancer and failed to disclose to physicians and consumers that their products carried such dangerous risks.

95. This was not done by accident or through some justifiable negligence. Rather, Defendant Drug Makers knew they could profit by omitting and obfuscating the risk of cancer, and that full disclosure of the true risks of their drugs would limit the amount of money Defendant Drug Makers would make selling the products. Defendant Drug Makers' objective was accomplished not only through a misleading label, but through a comprehensive scheme of selective misleading research and testing, failure to test, false advertising, and deceptive omissions as more fully alleged throughout this pleading. Patients such as Plaintiff were denied the right to make an informed decision about whether to ingest Defendant Drug Makers' products, knowing the full risks attendant to that use. Such conduct was done with conscious disregard of Plaintiff's rights.

96. Accordingly, Plaintiff requests punitive damages against the Defendant Drug Makers for the harms caused to Plaintiff.

PLAINTIFF-SPECIFIC ALLEGATIONS

97. Plaintiff consumed both brand-name and generic Risperdal and Zyprexa.

98. Plaintiff obtained Defendants' Drugs from Retailer Defendant Kaiser Permanente.

99. Plaintiff alleges that neither she nor her prescribing physicians, Michael Burton, MD

and Winston Chung, MD, knew or had reason to know, at the time the products were prescribed and ingested, that Defendants' Drugs could cause breast cancer.

100. Had Plaintiff or her prescribing physicians known about the risk of cancer, Plaintiff would not have taken Defendants' Drugs.

101. On information and belief, the medical professionals prescribing Defendants' Drugs to Plaintiff relied, both directly and indirectly, on the representations made by Defendant Drug Makers regarding the safety and side effects of Defendants' Drugs including representations on Defendants' labeling which failed to warn that Defendants' Drugs can cause breast cancer.

102. On information and belief, had these medical professionals received a warning about the risk of breast cancer posed by Defendants' Drugs, Plaintiff's prescribing physicians, like any reasonably prudent physician, would have relayed this warning to Plaintiff.

103. Had Plaintiff received this warning, Plaintiff, like any reasonably situated Plaintiff, would not have consented to treatment with Defendants' Drugs and would have requested an alternative treatment, or Plaintiff would have limited her consumption of Defendants' Drugs, and thus, Plaintiff would not have developed breast cancer.

104. As a direct and proximate result of her use of Defendants' Drugs, Plaintiff developed breast cancer and was diagnosed in approximately 2024.

105. As a direct and proximate result of her exposure to Defendant Drug Makers' products, Plaintiff suffered, and will continue to suffer, physical injury, pain, emotional distress, disfigurement, and related *sequalae*. Plaintiff asserts all applicable statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, delayed discovery, discovery rule and/or fraudulent concealment.

LIMITATION ON ALLEGATIONS

106. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

107. The allegations in this pleading are made pursuant to California law. To the extent California law imposes a duty or obligation on the Defendant Drug Makers that exceeds those required by federal law, Plaintiff does not assert such claims.

108. Additionally, Plaintiff's claims do not seek to enforce federal law. These claims are brought under California law, notwithstanding that such claims run parallel to federal law.

CAUSES OF ACTION

I. Count I: Strict Products Liability – Failure to Warn (Against All Defendants)

109. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

110. At all relevant times, Defendants were engaged in the business of manufacturing, distributing, marketing, and selling Defendants' Drugs ingested by Plaintiff and controlled their labeling.

111. The design of Defendants' Drugs is defective and unreasonably dangerous to consumers, including Plaintiff, because they cause breast cancer and do not contain adequate warnings or instructions concerning this risk. This danger, as described above, was known to Defendant Drug Makers, or scientifically knowable to Defendant Drug Makers through appropriate research and testing by known methods, at the time Defendant Drug Makers distributed, supplied or sold the products, and were not known to end users or their physicians. Any benefits associated with the use of Defendants' Drugs were outweighed by the risk of cancer and could have been obtained by the use of other, alternative treatments that could equally of more effectively reach similar results.

112. Defendants' Drugs failed to perform as safely as an ordinary consumer would expect when the product is used in a reasonably foreseeable way, as the use of Defendants' Drugs is associated with an increased risk of severe physical injury or death resulting from breast cancer. Defendants knew or should have known that the minimal warnings disseminated with Defendants' Drugs were inadequate, failed to communicate adequate information on the dangers and safe use of Defendants' Drugs, 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.

113. At all relevant times, Plaintiff used Defendants' Drugs while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics. Plaintiff could not reasonably have discovered the defects and risks associated with Defendants' Drugs prior to or at the time of Plaintiff consuming the drugs. Plaintiff and Plaintiff's physicians

relied upon the skill, superior knowledge, and judgment of Defendants to know about and disclose serious health risks associated with using Defendants' products.

114. At all relevant times, Defendants failed to warn and have wrongfully concealed information concerning the dangers of Defendants' Drugs, and further, have made false and/or misleading statements concerning the safety of Defendants' Drugs. Defendants could have provided warnings or instructions regarding the full and complete risks of Defendants' Drugs because they knew or should have known of the unreasonable risks of harm associated with the use of such products. Defendants deliberately refused to investigate, study, test, promote the safety of Defendants' Drugs, or to minimize the dangers to users and consumers of their product and to those who would foreseeably use or be harmed by Defendants' Drugs.

115. The information 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 drug. 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 Defendants' Drugs; continued to aggressively promote the efficacy of their products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Defendants' Drugs.

116. This alleged failure to warn is not limited to the information contained on Defendants' Drugs' labeling. The Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Defendants' Drugs through other non-labeling mediums, *i.e.*, Dear Healthcare Professional letters, promotion, advertisements, public service announcements, and/or public information sources. But the Defendants did not disclose these known risks through any medium.

117. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with Defendants' Drugs, Plaintiff could have avoided the risk of developing injuries and could have obtained or used alternative medication. Plaintiff's physicians,

like any reasonably prudent physicians, would have relayed this stronger warning to Plaintiff, and had Plaintiff received this warning, Plaintiff, like any objectively prudent person in Plaintiff's position, would have thereafter declined treatment with Defendants' Drugs, or reduced her exposure to Defendants' drugs. However, as a result of Defendants' concealment of the dangers posed by Defendants' Drugs, Plaintiff could not have averted her injuries.

118. The Defendants' lack of adequate warnings and instructions accompanying Defendants' Drugs were a substantial factor in causing Plaintiff's injuries. As a direct and proximate result of the Defendants' failure to provide an adequate warning of the risks of Defendants' Drugs, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

119. Defendant Drug Makers' conduct, as described above, was reckless. Defendant Drug Makers risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety problems associated with Defendants' Drugs, and suppressed this knowledge from the public. Defendant Drug Makers made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

120. **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

II. Count II: General Negligence (Against All Defendants)

121. Plaintiff incorporates by reference every allegation set forth in preceding paragraphs as if fully stated herein.

122. Defendants were engaged in the business of design, development, manufacturing, testing, advertising, marketing, promotion, labeling, warnings given, distribution, sale, and/or post-marketing safety monitoring of Defendants' Drugs, including a duty to ensure the products did not cause users to suffer from unreasonable, dangerous side effects when used alone or in foreseeable combination with other drugs.

123. Defendants owed Plaintiff, and all reasonably foreseeable users of Defendants' Drugs,

a duty to act with reasonable care because:

a. Defendants designed, manufactured, controlled, distributed, and sold their products to Plaintiff; and

b. Defendants distributed and promoted their drugs as safe and effective;

124. Defendants breached their duty by failing to use reasonable care in the design of Defendants' Drugs, by negligently designing and selling a drug with a propensity to cause breast cancer.

125. Defendants also breached their duty of care, by designing, developing, manufacturing, producing, marketing, advertising, distributing, and selling their drugs in the following respects:

a. Failure to perform adequate testing, research, and analysis concerning the safety of Defendants' Drugs, which would have shown that the drugs posed a serious risk of breast cancer, and the potential of hyperprolactinemia to stimulate tumorigenesis.

b. Failure to provide adequate and appropriate warnings to the medical community and the public, including Plaintiff's prescribing physician and Plaintiff, about the risk of breast cancer associated with Defendants' drugs.

c. When placed in the stream of commerce, Defendants' Drugs were defective in design and formulation by, *inter alia*, elevating prolactin levels and causing breast cancer, such that the product was unreasonably dangerous to an extent beyond that which an ordinary consumer would contemplate;

d. When placed in the stream of commerce, Defendants' Drugs were unreasonably dangerous in that they were hazardous and posed a risk of breast cancer when used in a reasonably anticipated manner;

e. Defendants' Drugs present a risk of harmful side effects (i.e., increased prolactin and breast cancer) that outweighs any potential utility stemming from the use of Defendants' Drugs;

f. Defendants knew or should have known at the time of marketing Defendants' Drugs that exposure could result in cancer and other severe illnesses and injuries;

g. Defendants did not conduct adequate post-marketing surveillance of Defendants'

Drugs; and

h. Defendants could have employed safer alternative designs, including, *inter alia*, a design that did not unreasonably increase prolactin levels and present a risk of breast cancer.

126. Defendants were negligent in the design, development, manufacturing, testing, advertising, marketing, promotion, labeling, warnings given, distribution, sale, and post-marketing safety monitoring of Defendants' Drugs.

127. The Defendants breached their duty by failing to use reasonable care by failing to use cost effective, reasonably feasible alternative designs. There was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Drugs

128. A reasonable company under the same or similar circumstances would have designed a safer product.

129. As a direct and proximate result of Plaintiff's ingestion of and/or injection with Defendants' Drugs, and the acts and failure to act by the Defendants, Plaintiff was caused to develop the aforesaid injuries and damages.

130. Defendants' conduct is outrageous because of willful or reckless indifference to the health and safety of Plaintiff and the public so as to justify an award of punitive damages.

131. At all relevant times, Defendants owed a duty of reasonable care to Plaintiff.

132. **WHEREFORE**, Plaintiff requests judgment for compensatory and punitive damages against the JJIM Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

III. <u>Count III: Negligence – Failure to Warn (Against All Defendants)</u>

133. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

134. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Defendants' Drugs. Defendants knew or by the exercise of reasonable care should have known that

Defendants' Drugs are not accompanied with adequate warnings or instructions concerning the dangerous characteristics of Defendants' Drugs. These actions were under the ultimate control and supervision of Defendants.

135. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, handled, stored, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce Defendants' Drugs, and in the course of same, directly advertised or marketed the products to physicians, including Plaintiff's physicians, and therefore had a duty to warn of the risks associated with the use of Defendants' Drugs.

136. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure Defendants' Drugs did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiff of dangers associated with Defendants' Drugs. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

137. At the time of manufacture and sale, Defendants could have provided warnings or instructions regarding the full and complete risks of Defendants' Drugs because they knew or should have known use of Defendants' Drugs was dangerous, harmful and injurious when used by Plaintiff in a reasonably foreseeable manner.

138. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of their product and to those who would foreseeably use or be harmed Defendants' Drugs.

139. Defendants knew or should have known that Defendants' Drugs posed a grave risk of harm but failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the products. The carcinogenic characteristics of their products, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, and were not known to end users and consumers, such as the Plaintiff.

140. Defendants further breached their duty by failing to use reasonable care to adequately warn or instruct consumers (*i.e.*, the reasonably foreseeable users) of the risks of exposure to their products. Defendants failed to warn and have wrongfully concealed information concerning the carcinogenic potential of Defendants' Drugs, and further, have made false and/or misleading statements concerning the safety of those products.

141. At all relevant times, Plaintiff was exposed to the excessive carcinogenic risk of Defendants' Drugs while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

142. Defendants knew or should have known that the minimal warnings disseminated with Defendants' Drugs were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, 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.

143. 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 Defendants' Drugs; continued to aggressively promote the efficacy of their products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Defendants' Drugs.

144. A reasonable company under the same or similar circumstances would have warned and instructed of the dangers of Defendants' Drugs.

145. This alleged failure to warn is not limited to the information contained on Defendants' Drugs labeling. The Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Defendants' Drugs through other non-labeling mediums, *i.e.*, Dear Healthcare Professional Letters, promotion, advertisements, public service announcements, and/or public information sources. But the Defendants did not disclose these known

risks through any medium.

146. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with Defendants' Drugs, Plaintiff could have avoided the risk of developing injuries and could have obtained or used alternative medication. Plaintiff's physicians, like any reasonably prudent physicians, would have relayed this stronger warning to Plaintiff, and had Plaintiff received this warning, Plaintiff, like any objectively prudent person in Plaintiff's position, would have thereafter declined treatment via Defendants' Drugs, or reduced her exposure to Defendants' drugs. However, as a result of Defendants' concealment of the dangers posed by Defendants' Drugs, Plaintiff could not have averted Plaintiff's injuries.

147. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety problems associated with Defendants' Drugs, and suppressed this knowledge from the public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

148. The Defendants' lack of adequate warnings and instructions accompanying Defendants' Drugs were a substantial factor in causing Plaintiff's injuries.

149. As a direct and proximate result of the Defendants' failure to provide an adequate warning of the risks of Defendants' Drugs, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

150. **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

IV. Count IV: Fraud (Against Defendant Drug Makers)

151. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows.

152. Defendant Drug Makers knowingly and intentionally made false and misleading statements regarding the uses, safety, and efficacy of Defendants' Drugs, and concealed, suppressed,

and omitted important information regarding the uses, safety, and efficacy of Defendants' Drugs, in general and, in treating conditions such as those of Plaintiff's, to Plaintiff, and to Plaintiff's prescribing physicians.

153. These deliberate misrepresentations and/or concealment, suppression, and omission of material facts as alleged herein, including, but not limited to:

a. Making false and misleading claims regarding the known risks of Defendants' Drugs and suppressing, failing to disclose and mischaracterizing the known risk of breast cancer associated with Defendants' Drugs;

b. Making false and misleading written and oral statements that Defendants' Drugs are more effective than other antipsychotic drugs, and omitting material information showing that Defendants' Drugs are neither safer nor more effective than other available antipsychotic drugs;

c. Misrepresenting or failing to timely and fully disclose the true results of clinical tests and studies related to Defendants' Drugs;

d. Issuing false and misleading warnings and failing to issue adequate warnings concerning the risks and dangers Defendants' Drugs which would disclose the nature and extent of the harmful side effects of Defendants' Drugs;

e. Making false and misleading claims that adequate clinical testing had been done and failing to disclose that adequate and generally accepted standards for pre-clinical and clinical testing had not been followed;

f. Making false and misleading claims that adequate, standard, and/or generally accepted methods of post-marketing safety surveillance had been performed and that Defendants' Drugs are safe and effective, and failing to disclose that adequate, standard, and/or generally accepted standards for post-marketing testing had not been done; and

g. Making false and misleading misrepresentations concerning the safety, efficacy and benefits of Defendants' Drugs as detailed in this complaint without full and adequate disclosure of the underlying facts which rendered such statements false

and misleading;

154. Specifically, Defendant Drug Makers omitted warnings regarding the risk of developing breast cancer on the labels of their products and significantly obfuscated the risk of cancer observed in the available epidemiological data, stating, "[n]either clinical trials nor epidemiological studies conducted to date have shown an association between chronic administration of this class of drugs and tumorigenesis in humans; the available evidence is considered too limited to be conclusive at this time" notwithstanding the mounting evidence of the risk of breast cancer associated with Defendants' Drugs. Plaintiff and her physicians relied upon Defendants' omissions and misrepresentations.

155. Defendant Drug Makers had a post-manufacturing and continuing duty to warn, which arose when they knew, or with reasonable care should have known, that Defendants' Drugs were associated with adverse effects which are injurious or fatal.

156. Defendant Drug Makers engaged in calculated silence despite their knowledge of the growing public acceptance of misinformation and misrepresentations regarding the uses, safety and efficacy of Defendants' Drugs, and did so because the prospect of enormous future profits caused them to ignore concerns regarding health and safety issues, all to the significant detriment of the public, including Plaintiff.

157. Defendant Drug Makers' actions as set forth herein constitute knowing misrepresentation, omission, suppression and concealment of material facts, made with the intent that regulators, physicians and consumers, including Plaintiff, would rely upon such misrepresentation, concealment, suppression or omission, in connection with the marketing, sale and use of Defendants' Drugs.

158. Regulators, physicians, and Plaintiff did not know, and could not learn, the truth concerning the uses, risks and benefits of Defendants' Drugs due to Defendants' deliberate misrepresentations and concealment, suppression and omission of material facts and important information regarding Defendants' Drugs. The facts and information misrepresented, concealed, suppressed and omitted by Defendant Drug Makers are material, and of such a nature that it can be reasonably presumed that the suppression and concealment of such facts caused, contributed to, and

was a substantial factor in the prescribing doctors' decision to prescribe Defendants' Drugs to the Plaintiff and in Plaintiff's decision to use Defendants' Drugs.

159. Plaintiff, directly and through her prescribing physicians, was induced by Defendants' misrepresentations, omissions, suppression and concealment to agree to use Defendants' Drugs.

160. As a direct and proximate result of the aforesaid fraudulent conduct by Defendant Drug Makers, Plaintiff was caused to use Defendants' Drugs and suffered the aforesaid injuries and damages.

161. **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

JURY TRIAL DEMAND

162. Plaintiff demands a trial by jury on all the triable issues within this pleading.

PRAYER FOR RELIEF

163. WHEREFORE, Plaintiff requests the Court to enter judgment in Plaintiff's favor and against the Defendants for:

a. actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;
b. exemplary and punitive damages sufficient to punish and deter the Defendants and others from future wrongful practices;
c. pre-judgment and post-judgment interest;
d. costs including reasonable attorneys' fees, court costs, and other litigation expenses; and
e. any other relief the Court may deem just and proper.

Respectfully submitted,

Dated: April 21, 2025

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