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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

BRIDGETT BROWN, Plaintiff, v. JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; JANSSEN RESEARCH & DEVELOPMENT, LLC; ELI LILLY AND COMPANY; CHEPLAPHARM ARZNEIMITTEL GMBH; KAISER PERMANENTE INTERNATIONAL; and DOES 1 through 100, inclusive, Defendants.	Case No. 3:25-cv-04318 **NOTICE OF REMOVAL OF ACTION UNDER 28 U.S.C. SECTION 1441(b) (DIVERSITY)** **(JURY TRIAL DEMANDED)** Action Filed:

Pursuant to 28 U.S.C. §§ 1332, 1441, and 1446, Defendants Johnson & Johnson,[1] Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, and Eli Lilly and Company

[1] Johnson & Johnson denies that it is a properly named Defendant in this action, as it did not design, manufacture, label, market, distribute, or sell Risperdal®, risperidone, Invega, or paliperidone. Johnson & Johnson is a parent and holding company that is a separate and distinct legal entity from Defendants Janssen Pharmaceuticals, Inc. and Janssen Research & Development, LLC (together, now known as Johnson & Johnson Innovative Medicine ("JJIM" or the "JJIM Defendants")).

(collectively the "Removing Defendants")[2] hereby give notice of removal of this action, *Brown v. Johnson & Johnson, et al.*, from the Superior Court of the State of California, County of Alameda, Case Number 25CV119808, to the United States District Court for the Northern District of California (Oakland Division).

The United States District Court for the Northern District of California has original subject matter jurisdiction with respect to this civil action pursuant to 28 U.S.C. §§ 1332(a) and 1441 because there is complete diversity between Plaintiff and all of the properly joined Removing Defendants, and the amount in controversy exceeds $75,000, exclusive of interest and costs. In support of removal, Removing Defendants state as follows:

I. THE STATE COURT ACTION

1. Plaintiff Bridgett Brown filed this action, *Brown v. Johnson & Johnson et al.*, Case Number 25CV119808 (hereafter the "State Court Action"), in the Superior Court of the State of California, County of Alameda on April 21, 2025. The original Complaint in the State Court Action names Johnson & Johnson, Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, and Eli Lilly and Company as defendants. Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., and Janssen Research & Development, LLC, were served with the original Complaint on April 24, 2025. Eli Lilly and Company was also served on April 24, 2025. None of the Removing Defendants have appeared or pled in the State Court Action.

2. Plaintiff filed an Amended Complaint[3] on May 12, 2025, adding Cheplapharm

[2] By removing this case from state court, Removing Defendants do not waive, and specifically reserve, any defense available to them, including those available under Federal Rule of Civil Procedure 12. *See Great Am. Ins. Co. of New York v. Nippon Yusen Kaisha*, No. 13-CV-00031, 2013 WL 3850675, at *3 (N.D. Cal. May 10, 2013); *see also Vinegar v. U.S. Marshals Serv.,* No. CIV. 95-0199-R, 1996 WL 227860, at *8 (S.D. Cal. Mar. 27, 1996) (stating that certain defenses were not waived upon removal and that "[a]ctions removed to federal court from state court are to proceed as if they had been commenced in federal court.").

[3] Subsequent citations to Plaintiff's Complaint in this pleading are to the Amended Complaint, which was filed on May 12, 2025. Defendants Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC and Eli Lilly and Company were served with the Amended Complaint on May 13, 2025. Johnson & Johnson was served with the Amended Complaint on May 14, 2025. Removing Defendants reserve all rights and do not waive any defense available to them by virtue of Plaintiff's filing of an Amended Complaint.

Arzneimittel GMBH ("Cheplapharm"), a German company, as a defendant. The docket does not reflect that Cheplapharm has been served, appeared, or pled in the State Court Action.

3. Plaintiff broadly alleges in the Amended Complaint that Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Eli Lilly and Company, and Cheplapharm failed to warn of the risk of breast cancer purportedly associated with the use of certain pharmaceutical drugs, Risperdal and Zyprexa. *See* Plaintiff's First Amended Complaint ("Am. Compl.") ¶¶ 77-78, 109-120. She asserts causes of action sounding in strict liability, general negligence, negligent failure to warn, and fraud based on Defendants' design, manufacture, sale, marketing, advertising, promotion, testing, labeling, and packaging, of Risperdal and Zyprexa. *See generally id*. ¶¶ 109-161.

4. Plaintiff further alleges that she was diagnosed with breast cancer in 2024 as a result of her use of Risperdal and Zyprexa. *See id*. ¶ 104.

5. Plaintiff alleges that as a direct and proximate result of her exposure to Risperdal and Zyprexa, she "suffered, and will continue to suffer, physical injury, pain, emotional distress, disfigurement, and related sequalae." *Id*. ¶ 105. Plaintiff asserts that due to the Removing Defendants' alleged failure to provide adequate warnings alongside Risperdal and Zyprexa, "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." *Id*. ¶¶ 118, 149. Plaintiff requests compensatory and punitive damages due to Defendants' alleged "willful or reckless indifference to the health and safety of Plaintiff and the public." *Id*. ¶ 130.

6. Plaintiff's Complaint also names Kaiser Permanente International as a defendant (hereafter, "Kaiser") and alleges that Kaiser distributed and supplied Plaintiff with Risperdal and Zyprexa. *See* Am. Compl. ¶¶ 1, 15, 98. However, under California law, a pharmacy cannot be held liable for simply filling a prescription, absent allegations it filled the prescription improperly—which are not asserted here. Therefore, Kaiser is an improper defendant and its citizenship should be disregarded for purposes of diversity jurisdiction under the theory of fraudulent joinder.

7. Further, as set forth more fully below, this case is properly removed to this Court pursuant to 28 U.S.C. § 1441 because this Court has subject-matter jurisdiction over this action under 28 U.S.C. § 1332, as the amount in controversy exceeds $75,000, exclusive of interest and costs, and there is complete diversity between all properly joined parties.

II. REMOVAL IS PROPER BECAUSE THE COURT HAS ORIGINAL SUBJECT MATTER JURISDICTION PURSUANT TO 28 U.S.C. §§ 1332(a) AND 1441.

8. This Court has diversity jurisdiction pursuant to 28 U.S.C. § 1332(a) because this is a civil action between the properly joined citizens of different states in which the amount in controversy exceeds $75,000, exclusive of interest and costs.

A. Complete Diversity of Citizenship Exists Between Plaintiff and Properly Joined Defendants.

9. Plaintiff Bridgett Brown is a resident of California. *See* Am. Compl. ¶ 8.

10. Defendant Eli Lilly and Company ("Lilly") is a citizen and resident of Indiana, with its principal place of business located at 893 S Delaware Street, Lilly Corporate Center, Indianapolis, Indiana 46285. *See* Am. Compl. ¶ 9. *Hertz Corp. v. Friend*, 559 U.S. 77, 93 (2010) (holding that a corporation is a citizen of its place of incorporation and its "principal place of business," which is "the actual center of direction, control, and coordination" of the corporation's activities).

11. Defendant Johnson & Johnson ("J&J") is a citizen and resident of New Jersey, with its principal place of business located at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey, 08933. *See* Am. Compl. ¶ 10.

12. Defendant Janssen Pharmaceuticals, Inc. ("JPI") is a citizen and resident of Pennsylvania and New Jersey, with its principal place of business located at 1125 Trenton Harbourton Road, Titusville, New Jersey 08560. *See id.* ¶ 11.

13. Defendant Janssen Research & Development, LLC ("JRD"), a limited liability company, is a citizen and resident of New Jersey, with its principal place of business located at 920 US Route 202, Raritan, New Jersey, 08869. *See* Am. Compl. ¶ 12. Janssen Biotech, Inc., a New Jersey corporation, with a principal place of business in Pennsylvania, is the sole member of Janssen Research & Development, LLC. *Id.*; *see also Johnson v. Columbia Props. Anchorage, LP*, 437 F.3d 894, 899 (9th Cir. 2006) ("[A]n LLC is a citizen of every state of which its owners/members are

citizens.").

14. Defendant Kaiser Permanente International is a California corporation with its headquarters and principal place of business located at One Kaiser Plaza, Oakland, California, 94612. *See* Am. Compl. ¶ 15. As set forth fully below, Kaiser has been improperly named and therefore its citizenship should be disregarded for diversity purposes.

15. Defendant Cheplapharm is a German corporation with its headquarters and principal place of business located at Ziegelhof 24, Greifswald, Germany.[4] To date, Cheplapharm has not been joined and served in this action and does not need to consent to removal. *See* 18 U.S.C. § 1446(b)(2)(A) ("When a civil action is removed solely under section 1441(a), all defendants who have been properly joined and served must join in or consent to the removal of the action.").

16. Plaintiff has also named "DOES 1-100" as putative defendants in this case. *See id.* ¶ 16. Pursuant to 28 U.S.C. § 1441(b)(1), "the citizenship of defendants sued under fictitious names shall be disregarded" for purposes of determining diversity of citizenship.

17. Thus, Plaintiff is diverse from all Defendants, with the exception of Kaiser, whose citizenship should be disregarded.

B. Kaiser is Fraudulently Joined and Should Be Disregarded for Purposes of Diversity Jurisdiction.

18. The presence of Kaiser in this case does not defeat diversity jurisdiction because it is fraudulently joined. *McCabe v. General Foods Corp.*, 811 F.2d 1336, 1339 (9th Cir. 1987). "Joinder is fraudulent [i]f the plaintiff fails to state a cause of action against a resident defendant, and the failure is obvious according to the settled rules of the state." *Hunter v. Philip Morris USA*, 582 F.3d 1039, 1043 (9th Cir. 2009) (citations and internal quotation marks omitted). "While

[4] Plaintiff erroneously asserts that "J&J has conducted business and derived substantial revenue from selling Zyprexa within the United States and California, including Alameda County." *See* Am. Compl. ¶ 10. This appears to be a typo, as the paragraph in which it appears relates to defendant Cheplapharm Arzneimittel CgmH. In fact, J&J is a parent and holding company that does not design, manufacture, label, market, distribute, or sell any pharmaceutical products, nor have Defendants Janssen Pharmaceuticals, Inc. or Janssen Research & Development, LLC ever been responsible for the design, manufacture, label, marketing, distribution, or sale of Zyprexa at any time.

Plaintiffs are in no way required to prove their case, by the same token they cannot avoid a finding of fraudulent joinder by asserting a mere hypothetical possibility of a cause of action against the resident defendant." *Higley v. Cessna Aircraft Co*., No. CV-10-3345-GHK, 2010 WL 3184516, at *2 (C.D. Cal. July 21, 2010) (quotations and citation omitted). A defendant may prove fraudulent joinder by showing that a plaintiff has no "reasonable probability" of recovery against a non-diverse defendant. *See Ritchey v. Upjohn Drug Co.*, 139 F.3d 1313, 1320 (9th Cir. 1998) (hospital fraudulently joined in pharmaceutical products liability case); *McCabe*, 811 F.2d at 1339 ("If the plaintiff fails to state a cause of action against a resident defendant, and the failure is obvious according to the settled rules of the state, the joinder of the resident defendant is fraudulent.").

19. As set forth fully below, Plaintiff fails to assert any viable claims under California law against Kaiser, nor do Plaintiff's allegations against Kaiser satisfy federal pleading requirements. Under Ninth Circuit authority, Kaiser has been fraudulently joined, as there is no reasonable probability of recovery against it by Plaintiff.

1. Plaintiff's Claims Against Kaiser Will Fail Under California Law.

20. Kaiser is a health care system and provider of pharmacy services to patients, including Plaintiff. *See* Am. Compl. ¶¶ 1, 15.

21. Plaintiff alleges that she obtained Risperdal and Zyprexa, from Kaiser in its capacity as a pharmacy. *See id*. ¶¶ 1, 15, 98. She does not otherwise set forth any specific factual allegations about Kaiser or explain how Kaiser's actions or inactions support her claims.

22. Plaintiff appears to assert three causes of action "Against All Defendants," including Kaiser: Strict Products Liability – Failure to Warn (Count I), General Negligence (Count II), and Negligence – Failure to Warn (Count III). *See id*. ¶¶ 109-120; 121-132; 133-150; 151-161. None of these causes of action are viable against Kaiser under California law.

23. ***First***, Plaintiff's Strict Products Liability – Failure to Warn claim focuses on "the [defendants'] business of manufacturing, distributing, marketing, and selling" the drugs at issue, including the purported defect in the warnings associated with those drugs. *See* Am. Compl. ¶ 110. These allegations cannot support a cause of action against Kaiser under California law.

24. As the California Supreme Court held in *Murphy v. E.R. Squibb & Sons, Inc.*, 710

P.2d 247 (Cal. 1985), strict liability for defective pharmaceutical products does not extend to the pharmacies that dispense drugs to patients. *Id.* at 251. The *Murphy* court reasoned that "[t]he pharmacist is in the business of selling prescription drugs, and [its] role begins and ends with the sale." *Id*. Liability should not attach to pharmacies, the court explained, because if individuals or entities that do not manufacture, label or design prescription products are held liable, they "might restrict availability [of important medications] by refusing to dispense drugs which pose even a potentially remote risk of harm, although such medications may be essential to the health or even the survival of patients." *Id*. at 253.

25. The Northern District of California and its sister district courts have followed *Murphy* consistently since it was decided nearly 30 years ago. *See, e.g.*, *Dodich v. Pfizer Inc*., No. C 18-02764 WHA, 2018 WL 3584484, at *9 (N.D. Cal. July 26, 2018) ("Pharmacists are not strictly liable for defects of prescription medicines in California"); *S.K. v. CaremarkPCS Pennsylvania Mail Pharmacy, L.L.C*., No. 221CV05154MCSGJS, 2022 WL 20273643, at *3 (C.D. Cal. Mar. 7, 2022) (dismissing pharmacy defendants from case and holding that "[t]he clear import of *Murphy* is that pharmacies are not to be named in strict liability product liability actions involving alleged defective drugs."); *Grove v. Bayer Corp.*, No. SACV091509AGMLGX, 2010 WL 11595821, at *2 (C.D. Cal. Feb. 23, 2010) ("Removing Defendants correctly assert that pharmacies are shielded from strict liability in California."). Accordingly, Plaintiff's Count I fails against Kaiser.

26. ***Second***, Plaintiff's General Negligence claim against "All Defendants," including Kaiser, does not alter this analysis or impact its result because Plaintiff's theory appears to be premised on vague allegations regarding, *inter alia*, the design, manufacture, testing, marketing, labeling, and sale of the products. *See* Am. Compl. ¶¶ 121-126. But Plaintiff alleges only that she filled her Risperdal and Zyprexa prescriptions at Kaiser—not that Kaiser designed, manufactured, tested, marketed, or labeled those prescription medications. As such, none of the alleged conduct asserted in Count II can be attributed to Kaiser, and Plaintiff has no "reasonable probability" of recovering against Kaiser for General Negligence.

27. Nor does Plaintiff allege that Kaiser improperly rendered pharmacy healthcare services to her. Even if she had, such a claim would similarly fail, as the proper cause of action to

assert such misconduct against a pharmacy in California law is under a professional negligence theory pursuant to the Medical Injury Compensation Reform Act (MICRA), not as a general negligence claim. Cal. Civ. Code § 3333.1.

28. "Professional negligence" is defined by MICRA as "a negligent act or omission to act by a health care provider in the rendering of professional services, which act or omission is the proximate cause of a personal injury or wrongful death, provided that such services are within the scope of services for which the provider is licensed and which are not within any restriction imposed by the licensing agency or licensed hospital." *Id.* California courts decline to entertain such claims under a general negligence theory, as Plaintiff appears to assert here. *See Goldsmith v. CVS Pharmacy, Inc.*, No. CV 20-00750-AB (JCX), 2020 WL 3966004, at *7 (C.D. Cal. May 5, 2020) (quoting *Flowers v. Torrance Mem'l Hosp. Med. Ctr.*, 8 Cal. 4th 992, 999 (1994)) (stating that MICRA explicitly governs "'professional negligence' against 'health care providers,'" including pharmacies); *CaremarkPCS Pennsylvania Mail Pharmacy, L.L.C.*, 2022 WL 20273643, at *3 ("Pursuant to the statutory regime established in MICRA, the proper vehicle to sue a defendant pharmacy for its allegedly negligent actions is by way of a professional negligence theory [. . .] the Court declines to entertain the negligent product liability claim against Caremark as an appropriate avenue for relief.").

29. ***Third*,** Plaintiff has no "reasonable probability" of recovering against Kaiser for Negligence – Failure to Warn (Count III). For one, a pharmacy has no independent duty to warn of adverse reactions from consumption of pharmaceutical products. For another, a pharmacy cannot be held liable for failing to warn of a purported risk that Plaintiff contends has been fraudulently concealed (as asserted in Count IV).

30. Under California law, a pharmacy does not have a duty to warn of adverse effects resulting from consumption of prescription drugs. *Corcoran v. CVS Health Corp.*, 169 F. Supp. 3d 970, 989 (N.D. Cal. 2016) ("[A]bsent special circumstances, courts refuse to extend [a pharmacist's duty] to encompass a duty to warn or an affirmative duty to counsel customers on the side effects of prescription drugs."). Instead, "[p]harmacists have a duty of care to *accurately fill* a prescription." *Id.* Moreover, "[t]his duty has been construed narrowly, and absent special circumstances, courts

refuse to extend it to encompass a duty to warn or an affirmative duty to counsel customers on the side effects of prescription drugs." *Id.* (internal citations omitted) (emphasis in original). Accordingly, Kaiser owed no duty to warn of any alleged risk of breast cancer related to Risperdal or Zyprexa, and thus, Plaintiff's Count III fails against Kaiser.

31. So too with respect to Plaintiff's Count IV. There, Plaintiff alleges that the drug manufacturers—not Kaiser—fraudulently concealed the risks of Risperdal and Zyprexa. Am. Compl. ¶¶ 158. Plaintiff does not otherwise allege that Kaiser was aware of any purported breast cancer risk associated with those medications. *Id*. ¶¶ 99-102. "This allegation directly undermines and contradicts the idea that" Kaiser "had knowledge or reason to know of alleged defects" related to Risperdal or Zyprexa, as a pharmacy cannot warn of a latent risk that was concealed and not knowable. *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, No. C02-423R, 2002 WL 34418423, at *3 (W.D. Wash. Nov. 27, 2002). As such, Plaintiff's negligent failure to warn claim against Kaiser will necessarily fail. *See, e.g.*, *id.* ("For example, the complaint alleges that the manufacturer defendants concealed material facts regarding PPA through product packaging, labeling, advertising, promotional campaigns and materials, and other methods. This allegation directly undermines and contradicts the idea that [the retailer,] Bill's Dollar Store had knowledge or reason to know of alleged defects.").

32. Indeed, courts in and outside of the Ninth Circuit have dismissed negligent failure to warn claims against a pharmacy when fraudulent concealment is alleged for this very reason. *In re Rezulin,* 133 F. Supp. 2d 272, 290 (S.D.N.Y. 2001) (finding "purely tendentious" the plaintiffs' failure-to-warn allegations against pharmacists because the plaintiffs' central theory of liability against defendant-manufacturers was that they "hid the dangers of Rezulin . . . from everyone."); *In re Baycol Prods. Litig.*, No. 1431 (MJD/JGL), 2004 WL 1118642, at *2 (D. Minn. May 17, 2004) (finding the plaintiffs fraudulently joined non-diverse defendants because "[t]he gravamen" of the complaint "is that Bayer and GSK withheld pertinent information, and sold a dangerous product" and thus, their failure-to-warn claims against physician and clinic defendants had "no reasonable basis in fact."). Thus, Plaintiff's Count III is not viable against Kaiser, either.

33. Because Plaintiff "fails to state a cause of action against" Kaiser, the lone California

defendant, and because "the failure is obvious according to the settled rules of th[is] state[,]" Kaiser is fraudulently joined and its citizenship should not be considered for purposes of diversity jurisdiction. *Hunter*, 582 F.3d at 1043.

2. Kaiser Is Fraudulently Joined Because Plaintiffs Fail to Satisfy Federal Rule of Civil Procedure 8(a).

34. There is yet another reason the Court should find Plaintiff fraudulently joined Kaiser: her allegations against it are utterly bereft of factual detail and thus do not satisfy the basic pleading requirements of Fed. R. Civ. P. 8, suggesting further that there are no viable claims possible against Kaiser. *See Joyner v. Bank of Am. Home Loans Servicing, LP*, 473 F. App'x 724, 725 (9th Cir. 2012) (applying federal pleading standards to complaint following removal from state court).

35. Plaintiff references Kaiser in only three substantive paragraphs of her 164-paragraph Complaint, and only through boilerplate allegations that generally identify it as a pharmacy at which Plaintiff filled her prescriptions. *See* Am. Compl. ¶¶ 1, 15, 98. She does not otherwise tie Kaiser's conduct to her claims.

36. Nowhere in the Complaint does Plaintiff "specifically allege" the role Kaiser had in allegedly causing her breast cancer. Instead, she asserts her claims collectively "Against All Defendants," which fails to meet the federal pleading standards of Rule 8(a). *See Sollberger v. Wachovia Securities, LLC*, No. CV 09-0766, 2010 WL 2674456, at *4 (C.D. Cal. June 30, 2010) (claims not plausibly alleged where "the plaintiff uses the omnibus term 'Defendants' throughout a complaint by grouping defendants together without identifying what the particular defendants specifically did wrong.").

37. Courts evaluate the legitimacy of allegations asserted in "shotgun" pleadings, such as this one, to analyze whether a defendant is fraudulently joined. For example, in *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, the court—applying Ninth Circuit standards to the plaintiffs' motion to remand—found the plaintiffs fraudulently joined the non-diverse retailer defendant where they plaintiffs clearly directed their allegations at the over-the-counter drug manufacturers, not at the retailer. 2002 WL 34418423, at *2. The court noted that, "while 'defendants' are alleged to have been aware . . . of numerous scientific journal articles, incident

reports, medical textbooks, and other reports containing information as to risks of [product] consumption," none of those allegations likely applied to the non-diverse retailer. *Id.* Viewing the complaint as a whole—including that it referred collectively to all "defendants" and pleaded fraudulent concealment claims against the manufacturers that contradicted their failure-to-warn theory against the retailer—the court determined that the plaintiffs directed their complaint against the "manufacturers alone" and thus failed to assert any viable claims against that non-diverse party. *Id.* at *3–4.

38. So too here. Throughout the Complaint, Plaintiff refers to Defendants in lump format, and—aside from a few boilerplate jurisdictional allegations—fails to allege any specific facts as to Kaiser's individual conduct. In so doing, it is impossible for the manufacturer Defendants to discern which claims Plaintiff asserts against them, and which she asserts against Kaiser. As in *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, when taken a whole, the Complaint focuses on awareness of the evolution of scientific literature and the risks of breast cancer, which cannot reasonably be construed to apply to Kaiser, the non-diverse defendant. 2002 WL 34418423, at *2.

39. Under the fraudulent joinder doctrine, where "'the plaintiff fails to state a cause of action against a resident defendant, and the failure is obvious according to the settled rules of the state[,]'" courts must disregard that defendant's citizenship. *Morris v. Princess Cruises, Inc*., 236 F.3d 1061, 1067 (9th Cir. 2001) (quoting *McCabe*, 811 F.2d 1336, 1339). That is the case here. Because Plaintiff's Strict Liability, Negligence, and Negligent Failure to Warn claims are not viable under ***any set of facts*** against Kaiser, given that strict liability claims cannot be advanced against a pharmacy (see *Murphy*, *supra*) and a pharmacy has no duty to warn of adverse side effects from prescription medications under California law (and, indeed, cannot warn of concealed risks), it is fraudulently joined and removal is proper under 28 U.S.C. §§ 1332, 1441, and 1446.

C. The Amount in Controversy Exceeds the $75,000 Threshold.

40. The initial pleading does not set forth the dollar amount requested, under 28 U.S.C. § 1446(c)(2)(B). However, removal of this action is proper because the amount in controversy exceeds $75,000.00, exclusive of interests and costs.

41. Here, Plaintiff alleges that, "as a result of consuming Defendants' Drugs, Plaintiff

tragically developed breast cancer." Am. Compl. ¶ 1. Plaintiff alleges that she has "suffered, and will continue to suffer, physical injury, pain, emotional distress, disfigurement, and related sequalae." *Id.* ¶ 105. Plaintiff further alleges that she, "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." *Id.* ¶¶ 118, 149. Plaintiff requests compensatory and punitive damages due to Defendants' alleged "willful or reckless indifference to the health and safety of Plaintiff and the public. *Id.* ¶ 130. In the Ninth Circuit, those allegations provide a sufficient basis on which to find Plaintiff's Complaint satisfies the amount-in-controversy requirement under Section 1446(c)(2)(B).

42. When a plaintiff does not allege a specific amount of damages in the complaint, the defendant must demonstrate the likelihood that the plaintiff's claims each exceed $75,000, exclusive of interest and costs. *See Valdez v. Allstate Ins. Co*., 372 F.3d 1115 (9th Cir. 2004); *Gaus v. Miles, Inc.*, 980 F.2d 564, 566 (9th Cir. 1992). To meet that requirement, a removing defendant need only show that the amount in controversy "more likely than not" exceeds the jurisdictional amount of $75,000. *Sanchez v. Monumental Life Ins. Co*., 102 F.3d 398, 404 (9th Cir. 1996); *Singer v. State Farm Mut. Auto. Ins. Co*., 116 F.3d 373, 376 (9th Cir. 1997). When the amount in controversy is not specified in the complaint, the court may consider the facts alleged in the complaint as well as in the notice of removal. *See Simmons v. PCR Tech*., 209 F. Supp. 2d 1029, 1031 (N.D. Cal. 2002); 28 U.S.C. § 1446(c)(2).

43. "In measuring the amount in controversy, 'a court must assume that the allegations of the complaint are true and assume that a jury will return a verdict for the plaintiff on all claims made in the complaint.'" *Korn v. Polo Ralph Lauren Corp.*, 536 F. Supp. 2d 1199, 1205, 1205 (E.D. Cal. 2008) (quoting *Kenneth Rothschild Trust v. Morgan Stanley Dean Witter*, 199 F. Supp. 2d 993, 1001 (C.D. Cal. 2002)). To determine the amount in controversy, a district court considers claims for general damages, pain and suffering, out-of-pocket loss, emotional distress, punitive damages, attorneys' fees, and other categories of damages that Plaintiff alleges here. *See Richmond v. Allstate Ins. Co*., 897 F. Supp. 447, 449-50 (S.D. Cal. 1995). And the "amount in controversy is not measured by the low end of an open-ended claim, but rather by a reasonable reading of the value

of the rights being litigated." *Kenneth Rothschild Trust*, 199 F. Supp. 2d at 1001.

44. Courts regularly find that the amount-in-controversy requirement is apparent from the face of the complaint where, as here, a plaintiff alleges serious bodily injury. *See, e.g.*, *Campbell v. Bridgestone/Firestone, Inc*., 2006 WL 707291, at *2–3 (E.D. Cal. Mar. 17, 2006) (amount-in-controversy met where complaint asserted strict products liability, negligence, and breach of warranty claims against multiple defendants and requested compensatory damages, hospital and medical expenses, general damages, and loss of earnings); *Geographic Expeditions, Inc. v. Estate of Lhotka*, 599 F.3d 1102, 1107–08 (9th Cir. 2010) (amount-in-controversy satisfied where complaint requested damages for, among other things, negligence medical expenses, and other damage categories).

45. Jury verdicts within the Ninth Circuit and California further support a conclusion that Plaintiff's claims readily meet the $75,000 threshold based on analogous claims and injuries. *See Georges vs. Novartis Pharm. Corp*., No. 06-CV-05207 (C.D. Cal. 2013) (awarding $2,162,000 for suit alleging that oncology medication caused osteonecrosis of the jaw); *In re Actos Prod. Liab. Cases*, No. JCCP4696 (Cal. Sup. Ct. 2013) ($6,500,000 judgment awarded in claim that plaintiff developed bladder cancer following consumption of Type II Diabetes medication). California appellate courts also have affirmed compensatory and punitive damages awards higher than $75,000 in products liability cases where serious personal injuries were alleged. *See, e.g.*, *Karlsson v. Ford Motor Co*., 45 Cal. Rptr. 3d 265, 268 (Ct. App. 2006) (affirming award of over $30 million to plaintiff who suffered a broken spine in a car crash because of a defective seat belt).

46. Given the breadth of Plaintiff's alleged injuries (including breast cancer) and scope of damages sought, the amount in controversy in this matter exceeds $75,000, exclusive of interest and costs, as required by 28 U.S.C. § 1332(a).

III. ALL OTHER REMOVAL REQUIREMENTS ARE MET.

47. This Notice of Removal is timely under 28 U.S.C. § 1446(b)(3) because the Complaint was the first pleading from which Removing Defendants could ascertain that the case was removable, and this Notice is filed within 30 days of service of the Summons and Complaint (which occurred on April 25, 2025). *See Murphy Bros. v. Michetti Pipe Stringing, Inc.*, 526 U.S.

344 (1999).

48. The Superior Court of the State of California, County of Alameda is located within the United States District Court for the Northern District of California. *See* 28 U.S.C. §1441(a).

49. Neither the Removing Defendants, nor Cheplapharm are citizens of the State of California, the State where this action was brought. *See* 28 U.S.C. §1441(b).

50. It is well-settled that co-defendants who are fraudulently joined need not join in the removal. *See Borusk v. Mass Mut. Life Ins. Co.,* No. C 03-630 VRW, 2003 U.S. Dist. LEXIS 25259, at *7–8 (N.D. Cal. Sept. 4, 2003). As set forth above, Kaiser is fraudulently joined. Therefore, it need not consent to removal.

51. Additionally, only defendants that are "properly joined and served" must consent to removal. Here, Cheplapharm is a German corporation that, upon information and belief, has not yet been served.

52. No previous application has been made for the release requested herein.

53. This Notice of Removal is in compliance with Rule 11 of the Federal Rules of Civil Procedure.

54. Copies of all pleadings filed and orders received in this matter are attached as **Exhibit A**.

55. The written notice required by 28 U.S.C. § 1446(d) will be promptly filed in the Superior Court of the State of California, County of Alameda, and will be promptly served on counsel of record for Plaintiff.

56. Removing Defendants do not waive any legal defenses and expressly reserve their rights to raise any and all legal defenses in subsequent proceedings.

57. Removal of this action is not prohibited by 28 U.S.C. § 1445.

IV. DEMAND FOR JURY TRIAL.

58. The Removing Defendants hereby demand a separate jury trial on all claims and issues so triable.

WHEREFORE, Removing Defendants hereby remove this action from the Superior Court of the State of California, County of Alameda, Case Number 25CV119808, to the United States

District Court for the Northern District of California (Oakland Division).

Dated: May 20, 2025

BARNES & THORNBURG LLP

By: */S/ Mihran Yezbekyan*
Robyn S. Maguire
Mihran Yezbekyan
Erin M. Gilmore

Attorneys for Defendant JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; JANSSEN RESEARCH & DEVELOPMENT, LLC

Dated: May 20, 2025

KING & SPALDING LLP

By: */S/ Matthew J. Blaschke*
Matthew J. Blaschke

Attorney for Defendant ELI LILLY AND COMPANY

SIGNATURE ATTESTATION

"I hereby attest that I have on file all holographic signatures corresponding to any signatures indicated by a conformed signature (/S/) within this e-filed document."

Dated: May 20, 2025

BARNES & THORNBURG LLP

By: */S/ Mihran Yezbekyan*
Robyn S. Maguire
Mihran Yezbekyan
Erin M. Gilmore

Attorneys for Defendant JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; JANSSEN RESEARCH & DEVELOPMENT, LLC

EXHIBIT A

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address):
Conor Kennedy (SBN: 354542)
Wisner Baum LLP, 11111 Santa Monica Blvd., Suite 1750, Los Angeles, CA 90025

TELEPHONE NO.: (310) 207-3233 FAX NO. (Optional): (310) 820-7444
E-MAIL ADDRESS: ckennedy@wisnerbaum.com
ATTORNEY FOR (Name): Plaintiff Bridgett Brown

FOR COURT USE ONLY

ELECTRONICALLY FILED
Superior Court of California,
County of Alameda
04/21/2025 at 06:04:05 PM
By: Milagros Cortez,
Deputy Clerk

SUPERIOR COURT OF CALIFORNIA, COUNTY OF ALAMEDA
STREET ADDRESS: 1225 Fallon Street
MAILING ADDRESS: same as above
CITY AND ZIP CODE: Oakland, CA 94612
BRANCH NAME: Rene C. Davidson Courthouse

CASE NAME:
Bridgett Brown v. Johnson & Johnson, et al.

CIVIL CASE COVER SHEET

[x] **Unlimited** (Amount demanded exceeds $25,000)
[ ] **Limited** (Amount demanded is $25,000 or less)

Complex Case Designation
[ ] Counter [ ] Joinder
Filed with first appearance by defendant (Cal. Rules of Court, rule 3.402)

CASE NUMBER: 25CV119808
JUDGE:
DEPT.:

Items 1–6 below must be completed (see instructions on page 2).

1. Check **one** box below for the case type that best describes this case:

Auto Tort
- [ ] Auto (22)
- [ ] Uninsured motorist (46)

Other PI/PD/WD (Personal Injury/Property Damage/Wrongful Death) Tort
- [ ] Asbestos (04)
- [x] Product liability (24)
- [ ] Medical malpractice (45)
- [ ] Other PI/PD/WD (23)

Non-PI/PD/WD (Other) Tort
- [ ] Business tort/unfair business practice (07)
- [ ] Civil rights (08)
- [ ] Defamation (13)
- [ ] Fraud (16)
- [ ] Intellectual property (19)
- [ ] Professional negligence (25)
- [ ] Other non-PI/PD/WD tort (35)

Employment
- [ ] Wrongful termination (36)
- [ ] Other employment (15)

Contract
- [ ] Breach of contract/warranty (06)
- [ ] Rule 3.740 collections (09)
- [ ] Other collections (09)
- [ ] Insurance coverage (18)
- [ ] Other contract (37)

Real Property
- [ ] Eminent domain/Inverse condemnation (14)
- [ ] Wrongful eviction (33)
- [ ] Other real property (26)

Unlawful Detainer
- [ ] Commercial (31)
- [ ] Residential (32)
- [ ] Drugs (38)

Judicial Review
- [ ] Asset forfeiture (05)
- [ ] Petition re: arbitration award (11)
- [ ] Writ of mandate (02)
- [ ] Other judicial review (39)

Provisionally Complex Civil Litigation (Cal. Rules of Court, rules 3.400–3.403)
- [ ] Antitrust/Trade regulation (03)
- [ ] Construction defect (10)
- [ ] Mass tort (40)
- [ ] Securities litigation (28)
- [ ] Environmental/Toxic tort (30)
- [ ] Insurance coverage claims arising from the above listed provisionally complex case types (41)

Enforcement of Judgment
- [ ] Enforcement of judgment (20)

Miscellaneous Civil Complaint
- [ ] RICO (27)
- [ ] Other complaint *(not specified above)* (42)

Miscellaneous Civil Petition
- [ ] Partnership and corporate governance (21)
- [ ] Other petition *(not specified above)* (43)

2. This case [x] is [ ] is not complex under rule 3.400 of the California Rules of Court. If the case is complex, mark the factors requiring exceptional judicial management:
   a. [x] Large number of separately represented parties
   b. [ ] Extensive motion practice raising difficult or novel issues that will be time-consuming to resolve
   c. [x] Substantial amount of documentary evidence
   d. [ ] Large number of witnesses
   e. [ ] Coordination with related actions pending in one or more courts in other counties, states, or countries, or in a federal court
   f. [ ] Substantial postjudgment judicial supervision
3. Remedies sought *(check all that apply)*: a. [x] monetary b. [ ] nonmonetary; declaratory or injunctive relief c. [x] punitive
4. Number of causes of action *(specify)*: 4 (four)
5. This case [ ] is [x] is not a class action suit.
6. If there are any known related cases, file and serve a notice of related case. *(You may use form CM-015.)*

Date: April 21, 2025
Conor J. Kennedy
(TYPE OR PRINT NAME)

(SIGNATURE OF PARTY OR ATTORNEY FOR PARTY)

NOTICE

- Plaintiff must file this cover sheet with the first paper filed in the action or proceeding (except small claims cases or cases filed under the Probate Code, Family Code, or Welfare and Institutions Code). (Cal. Rules of Court, rule 3.220.) Failure to file may result in sanctions.
- File this cover sheet in addition to any cover sheet required by local court rule.
- If this case is complex under rule 3.400 et seq. of the California Rules of Court, you must serve a copy of this cover sheet on all other parties to the action or proceeding.
- Unless this is a collections case under rule 3.740 or a complex case, this cover sheet will be used for statistical purposes only.

Form Adopted for Mandatory Use
Judicial Council of California
CM-010 [Rev.September 1, 2021]

Cal. Rules of Court, rules 2.30, 3.220, 3.400–3.403, 3.740;
Cal. Standards of Judicial Administration, std. 3.10
www.courts.ca.gov

INSTRUCTIONS ON HOW TO COMPLETE THE COVER SHEET

CM-010

To Plaintiffs and Others Filing First Papers. If you are filing a first paper (for example, a complaint) in a civil case, you **must** complete and file, along with your first paper, the Civil Case Cover Sheet contained on page 1. This information will be used to compile statistics about the types and numbers of cases filed. You must complete items 1 through 6 on the sheet. In item 1, you must check **one** box for the case type that best describes the case. If the case fits both a general and a more specific type of case listed in item 1, check the more specific one. If the case has multiple causes of action, check the box that best indicates the **primary** cause of action. To assist you in completing the sheet, examples of the cases that belong under each case type in item 1 are provided below. A cover sheet must be filed only with your initial paper. Failure to file a cover sheet with the first paper filed in a civil case may subject a party, its counsel, or both to sanctions under rules 2.30 and 3.220 of the California Rules of Court.

To Parties in Rule 3.740 Collections Cases. A "collections case" under rule 3.740 is defined as an action for recovery of money owed in a sum stated to be certain that is not more than $25,000, exclusive of interest and attorney's fees, arising from a transaction in which property, services, or money was acquired on credit. A collections case does not include an action seeking the following: (1) tort damages, (2) punitive damages, (3) recovery of real property, (4) recovery of personal property, or (5) a prejudgment writ of attachment. The identification of a case as a rule 3.740 collections case on this form means that it will be exempt from the general time-for-service requirements and case management rules, unless a defendant files a responsive pleading. A rule 3.740 collections case will be subject to the requirements for service and obtaining a judgment in rule 3.740.

To Parties in Complex Cases. In complex cases only, parties must also use the Civil Case Cover Sheet to designate whether the case is complex. If a plaintiff believes the case is complex under rule 3.400 of the California Rules of Court, this must be indicated by completing the appropriate boxes in items 1 and 2. If a plaintiff designates a case as complex, the cover sheet must be served with the complaint on all parties to the action. A defendant may file and serve no later than the time of its first appearance a joinder in the plaintiff's designation, a counter-designation that the case is not complex, or, if the plaintiff has made no designation, a designation that the case is complex.

CASE TYPES AND EXAMPLES

Auto Tort
- Auto (22)–Personal Injury/Property Damage/Wrongful Death
- Uninsured Motorist (46) *(if the case involves an uninsured motorist claim subject to arbitration, check this item instead of Auto)*

Other PI/PD/WD (Personal Injury/ Property Damage/Wrongful Death) Tort
- Asbestos (04)
  - Asbestos Property Damage
  - Asbestos Personal Injury/ Wrongful Death
- Product Liability *(not asbestos or toxic/environmental)* (24)
- Medical Malpractice (45)
  - Medical Malpractice–Physicians & Surgeons
- Other Professional Health Care Malpractice
- Other PI/PD/WD (23)
  - Premises Liability (e.g., slip and fall)
  - Intentional Bodily Injury/PD/WD (e.g., assault, vandalism)
  - Intentional Infliction of Emotional Distress
  - Negligent Infliction of Emotional Distress
  - Other PI/PD/WD

Non-PI/PD/WD (Other) Tort
- Business Tort/Unfair Business Practice (07)
- Civil Rights (e.g., discrimination, false arrest) *(not civil harassment)* (08)
- Defamation (e.g., slander, libel) (13)
- Fraud (16)
- Intellectual Property (19)
- Professional Negligence (25)
  - Legal Malpractice
  - Other Professional Malpractice *(not medical or legal)*
- Other Non-PI/PD/WD Tort (35)

Employment
- Wrongful Termination (36)
- Other Employment (15)

Contract
- Breach of Contract/Warranty (06)
  - Breach of Rental/Lease Contract *(not unlawful detainer or wrongful eviction)*
  - Contract/Warranty Breach–Seller Plaintiff *(not fraud or negligence)*
  - Negligent Breach of Contract/ Warranty
  - Other Breach of Contract/Warranty
- Collections (e.g., money owed, open book accounts) (09)
  - Collection Case–Seller Plaintiff
  - Other Promissory Note/Collections Case
- Insurance Coverage *(not provisionally complex)* (18)
  - Auto Subrogation
  - Other Coverage
- Other Contract (37)
  - Contractual Fraud
  - Other Contract Dispute

Real Property
- Eminent Domain/Inverse Condemnation (14)
- Wrongful Eviction (33)
- Other Real Property (e.g., quiet title) (26)
  - Writ of Possession of Real Property
  - Mortgage Foreclosure
  - Quiet Title
  - Other Real Property *(not eminent domain, landlord/tenant, or foreclosure)*

Unlawful Detainer
- Commercial (31)
- Residential (32)
- Drugs (38) *(if the case involves illegal drugs, check this item; otherwise, report as Commercial or Residential)*

Judicial Review
- Asset Forfeiture (05)
- Petition Re: Arbitration Award (11)
- Writ of Mandate (02)
  - Writ–Administrative Mandamus
  - Writ–Mandamus on Limited Court Case Matter
  - Writ–Other Limited Court Case Review
- Other Judicial Review (39)
  - Review of Health Officer Order
  - Notice of Appeal–Labor Commissioner Appeals

Provisionally Complex Civil Litigation (Cal. Rules of Court Rules 3.400–3.403)
- Antitrust/Trade Regulation (03)
- Construction Defect (10)
- Claims Involving Mass Tort (40)
- Securities Litigation (28)
- Environmental/Toxic Tort (30)
- Insurance Coverage Claims *(arising from provisionally complex case type listed above)* (41)

Enforcement of Judgment
- Enforcement of Judgment (20)
  - Abstract of Judgment (Out of County)
- Confession of Judgment *(non-domestic relations)*
- Sister State Judgment
- Administrative Agency Award *(not unpaid taxes)*
- Petition/Certification of Entry of Judgment on Unpaid Taxes
- Other Enforcement of Judgment Case

Miscellaneous Civil Complaint
- RICO (27)
- Other Complaint *(not specified above)* (42)
  - Declaratory Relief Only
  - Injunctive Relief Only *(non-harassment)*
  - Mechanics Lien
  - Other Commercial Complaint Case *(non-tort/non-complex)*
  - Other Civil Complaint *(non-tort/non-complex)*

Miscellaneous Civil Petition
- Partnership and Corporate Governance (21)
- Other Petition *(not specified above)* (43)
  - Civil Harassment
  - Workplace Violence
  - Elder/Dependent Adult Abuse
  - Election Contest
  - Petition for Name Change
  - Petition for Relief From Late Claim
  - Other Civil Petition

F. ADDENDUM TO CIVIL CASE COVER SHEET

Short Title: Bridgett Brown v. Johnson & Johnson, et al. **Case Number:**

CIVIL CASE COVER SHEET ADDENDUM

THIS FORM IS REQUIRED IN ALL NEW UNLIMITED CIVIL CASE FILINGS IN THE SUPERIOR COURT OF CALIFORNIA, COUNTY OF ALAMEDA

[X] Oakland, Rene C. Davidson Alameda County Courthouse (446)
[ ] Hayward Hall of Justice (447)
[ ] Pleasanton, Gale-Schenone Hall of Justice (448)

Civil Case Cover Sheet Category	Civil Case Cover Sheet Case Type	Alameda County Case Type (check only one)
Auto Tort	Auto tort (22)	[ ] 34 Auto tort (G) **Is this an uninsured motorist case? [ ] yes [ ] no**
Other PI /PD / WD Tort	Asbestos (04)	[ ] 75 Asbestos (D)
	Product liability (24)	[X] 89 Product liability (not asbestos or toxic tort/environmental) (G)
	Medical malpractice (45)	[ ] 97 Medical malpractice (G)
	Other PI/PD/WD tort (23)	[ ] 33 Other PI/PD/WD tort (G)
Non - PI /PD / WD Tort	Bus tort / unfair bus. practice (07)	[ ] 79 Bus tort / unfair bus. practice (G)
	Civil rights (08)	[ ] 80 Civil rights (G)
	Defamation (13)	[ ] 84 Defamation (G)
	Fraud (16)	[ ] 24 Fraud (G)
	Intellectual property (19)	[ ] 87 Intellectual property (G)
	Professional negligence (25)	[ ] 59 Professional negligence - non-medical (G)
	Other non-PI/PD/WD tort (35)	[ ] 03 Other non-PI/PD/WD tort (G)
Employment	Wrongful termination (36)	[ ] 38 Wrongful termination (G)
	Other employment (15)	[ ] 85 Other employment (G)
		[ ] 53 Labor comm award confirmation
		[ ] 54 Notice of appeal - L.C.A.
Contract	Breach contract / Wrnty (06)	[ ] 04 Breach contract / Wrnty (G)
	Collections (09)	[ ] 81 Collections (G)
	Insurance coverage (18)	[ ] 86 Ins. coverage - non-complex (G)
	Other contract (37)	[ ] 98 Other contract (G)
Real Property	Eminent domain / Inv Cdm (14)	[ ] 18 Eminent domain / Inv Cdm (G)
	Wrongful eviction (33)	[ ] 17 Wrongful eviction (G)
	Other real property (26)	[ ] 36 Other real property (G)
Unlawful Detainer	Commercial (31)	[ ] 94 Unlawful Detainer - commercial **Is the deft. in possession**
	Residential (32)	[ ] 47 Unlawful Detainer - residential **of the property?**
	Drugs (38)	[ ] 21 Unlawful detainer - drugs **[ ] Yes [ ] No**
Judicial Review	Asset forfeiture (05)	[ ] 41 Asset forfeiture
	Petition re: arbitration award (11)	[ ] 62 Pet. re: arbitration award
	Writ of Mandate (02)	[ ] 49 Writ of mandate **Is this a CEQA action (Publ.Res.Code section 21000 et seq) [ ] Yes [ ] No**
	Other judicial review (39)	[ ] 64 Other judicial review
Provisionally Complex	Antitrust / Trade regulation (03)	[ ] 77 Antitrust / Trade regulation
	Construction defect (10)	[ ] 82 Construction defect
	Claims involving mass tort (40)	[ ] 78 Claims involving mass tort
	Securities litigation (28)	[ ] 91 Securities litigation
	Toxic tort / Environmental (30)	[ ] 93 Toxic tort / Environmental
	Ins covrg from cmplx case type (41)	[ ] 95 Ins covrg from complex case type
Enforcement of Judgment	Enforcement of judgment (20)	[ ] 19 Enforcement of judgment
		[ ] 08 Confession of judgment
Misc Complaint	RICO (27)	[ ] 90 RICO (G)
	Partnership / Corp. governance (21)	[ ] 88 Partnership / Corp. governance (G)
	Other complaint (42)	[ ] 68 All other complaints (G)
Misc. Civil Petition	Other petition (43)	[ ] 06 Change of name
		[ ] 69 Other petition

SUPERIOR COURT OF CALIFORNIA COUNTY OF ALAMEDA	Reserved for Clerk's File Stamp FILED Superior Court of California County of Alameda 04/21/2025 Chad Finke, Executive Officer / Clerk of the Court By: _____ Deputy M. Cortez
COURTHOUSE ADDRESS: Rene C. Davidson Courthouse Administration Building, 1221 Oak Street, Oakland, CA 94612	
PLAINTIFF: Bridgett Brown	
DEFENDANT: Johnson & Johnson et al	
NOTICE OF CASE MANAGEMENT CONFERENCE	CASE NUMBER: 25CV119808

TO THE PLAINTIFF(S)/ATTORNY(S) FOR PLAINTIFF(S) OF RECORD:

You are ordered to serve all named defendants and file proofs of service on those defendants with the court within 60 days of the filing of the complaint (Cal. Rules of Court, 3.110(b)).

Give notice of this conference to all other parties and file proof of service.

Your Case Management Conference has been scheduled on:

Date: 08/19/2025 Time: 8:30 AM Dept.: 21

Location: Rene C. Davidson Courthouse
Administration Building, 1221 Oak Street, Oakland, CA 94612

TO DEFENDANT(S)/ATTORNEY(S) FOR DEFENDANT(S) OF RECORD:

The setting of the Case Management Conference does not exempt the defendant from filing a responsive pleading as required by law, you must respond as stated on the summons.

TO ALL PARTIES who have appeared before the date of the conference must:

Pursuant to California Rules of Court, 3.725, a completed Case Management Statement (Judicial Council form CM-110) must be filed and served at least 15 calendar days before the Case Management Conference. The Case Management Statement may be filed jointly by all parties/attorneys of record or individually by each party/attorney of record.

Meet and confer, in person or by telephone as required by Cal. Rules of Court, rule 3.724.

Post jury fees as required by Code of Civil Procedure section 631.

If you do not follow the orders above, the court may issue an order to show cause why you should not be sanctioned under Cal. Rules of Court, rule 2.30. Sanctions may include monetary sanctions, striking pleadings or dismissal of the action.

The judge may place a Tentative Case Management Order in your case's on-line register of actions before the conference. This order may establish a discovery schedule, set a trial date or refer the case to Alternate Dispute Resolution, such as mediation or arbitration. Check the court's eCourt Public Portal for each assigned department's procedures regarding tentative case management orders at https://eportal.alameda.courts.ca.gov.

Expedited Jury Trials

If the parties agree, they may try the case in an Expedited Jury Trial. Code of Civ. Proc. § 630.01 et seq. In short, the parties would agree to the following: 8 jurors (6 must agree); 3 peremptory challenges per side; 5-hour time limit per side, unless otherwise agreed and approved; one to two court days for completion, unless otherwise agreed and approved; high/low arrangement option; and limited right to appeal. For additional information, please see the following links:

- EJT-010-INFO* Expedited Jury Trial Information Sheet (ca.gov)
- EJT-008 Agreement of Parties (Mandatory Expedited Jury Trial Procedures) (ca.gov)
- EJT-020 [Proposed] Consent Order for Voluntary Expedited Jury Trial (ca.gov)

SUPERIOR COURT OF CALIFORNIA COUNTY OF ALAMEDA	Reserved for Clerk's File Stamp FILED Superior Court of California County of Alameda 04/21/2025 Chad Finke, Executive Officer / Clerk of the Court By: _____ Deputy M. Cortez
COURTHOUSE ADDRESS: Rene C. Davidson Courthouse 1225 Fallon Street, Oakland, CA 94612	
PLAINTIFF/PETITIONER: Bridgett Brown	
DEFENDANT/RESPONDENT: Johnson & Johnson et al	
CERTIFICATE OF MAILING	CASE NUMBER: 25CV119808

I, the below-named Executive Officer/Clerk of the above-entitled court, do hereby certify that I am not a party to the cause herein, and that on this date I served the attached document upon each party or counsel named below by placing the document for collection and mailing so as to cause it to be deposited in the United States mail at the courthouse in Oakland, California, one copy of the original filed/entered herein in a separate sealed envelope to each address as shown below with the postage thereon fully prepaid, in accordance with standard court practices.

J. Conor Kennedy
Wisner Baum, LLP
11111 Santa Monica Blvd, Suite 1750
Los Angeles, CA 90025

Pedram Esfandiary
Wisner Baum, LLP
11111 Santa Monica Blvd., Suite 1750
Los Angeles, CA 90025

Monique A. Alarcon
Wisner Baum, LLP
11111 Santa Monica Blvd., Suite 1750
Los Angeles, CA 90025

Bijan Esfandiari
Wisner Baum, LLP
11111 Santa Monica Blvd., Suite 1750
Los Angeles, CA 90025

Chad Finke, Executive Officer / Clerk of the Court

Dated: 04/23/2025

By:

M. Cortez, Deputy Clerk

CERTIFICATE OF MAILING

Bijan Esfandiari (SBN: 223216)
besfandiari@wisnerbaum.com
Monique Alarcon (SBN: 311650)
malarcon@wisnerbaum.com
Pedram Esfandiary (SBN: 312569)
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Los Angeles, CA 90025
Tel: (310) 207-3233
Fax: (310) 820-7444

Counsel for Plaintiff

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

[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

[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

[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

[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. Count III: Negligence – Failure to Warn (Against All Defendants)

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

WISNER BAUM, LLP

Conor Kennedy (SBN: 354542)
ckennedy@wisnerbaum.com
Bijan Esfandiari (SBN: 223216)

besfandiari@wisnerbaum.com
Monique Alarcon (SBN: 311650)
malarcon@wisnerbaum.com
Pedram Esfandiary (SBN: 312569)
pesfandiary@wisnerbaum.com
11111 Santa Monica Blvd., Suite 1750
Los Angeles, CA 90025
Tel: (310) 207-3233
Fax: (310) 820-7444

Counsel for Plaintiff

SUM-100

SUMMONS
(CITACION JUDICIAL)

NOTICE TO DEFENDANT:
(AVISO AL DEMANDADO):
JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; JANSSEN RESEARCH & DEVELOPMENT, LLC; ELI LILLY AND COMPANY; KAISER PERMANENTE; and DOES 1 through 100, inclusive

YOU ARE BEING SUED BY PLAINTIFF:
(LO ESTÁ DEMANDANDO EL DEMANDANTE):
BRIDGETT BROWN

FOR COURT USE ONLY
(SOLO PARA USO DE LA CORTE)

ELECTRONICALLY FILED
Superior Court of California
County of Alameda
04/21/2025
Chad Finke, Executive Officer / Clerk of the Court
By: M. Cortez Deputy

NOTICE! You have been sued. The court may decide against you without your being heard unless you respond within 30 days. Read the information below.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the court to hear your case. There may be a court form that you can use for your response. You can find these court forms and more information at the California Courts Online Self-Help Center (*www.courtinfo.ca.gov/selfhelp*), your county law library, or the courthouse nearest you. If you cannot pay the filing fee, ask the court clerk for a fee waiver form. If you do not file your response on time, you may lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney referral service. If you cannot afford an attorney, you may be eligible for free legal services from a nonprofit legal services program. You can locate these nonprofit groups at the California Legal Services Web site (*www.lawhelpcalifornia.org*), the California Courts Online Self-Help Center (*www.courtinfo.ca.gov/selfhelp*), or by contacting your local court or county bar association. **NOTE:** The court has a statutory lien for waived fees and costs on any settlement or arbitration award of $10,000 or more in a civil case. The court's lien must be paid before the court will dismiss the case.
¡AVISO! *Lo han demandado. Si no responde dentro de 30 días, la corte puede decidir en su contra sin escuchar su versión. Lea la información a continuación.*

*Tiene 30 DÍAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito en esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que procesen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de California (*www.sucorte.ca.gov*), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no puede pagar la cuota de presentación, pida al secretario de la corte que le dé un formulario de exención de pago de cuotas. Si no presenta su respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.*

*Hay otros requisitos legales. Es recomendable que llame a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a un servicio de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sitio web de California Legal Services, (*www.lawhelpcalifornia.org*), en el Centro de Ayuda de las Cortes de California, (*www.sucorte.ca.gov*) o poniéndose en contacto con la corte o el colegio de abogados locales. AVISO: Por ley, la corte tiene derecho a reclamar las cuotas y los costos exentos por imponer un gravamen sobre cualquier recuperación de $10,000 ó más de valor recibida mediante un acuerdo o una concesión de arbitraje en un caso de derecho civil. Tiene que pagar el gravamen de la corte antes de que la corte pueda desechar el caso.*

The name and address of the court is:
(El nombre y dirección de la corte es): Rene C. Davidson Courthouse
Superior Court of California, County of Alameda
1225 Fallon Street, Oakland, CA 94612

CASE NUMBER:
(Número del Caso): 25CV119808

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:
(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):
Conor J. Kennedy, Wisner Baum LLP, 11111 Santa Monica Boulevard, Suite 1750, Los Angeles, CA 90025
(310) 207-3233; ckennedy@wisnerbaum.com

DATE: *(Fecha)* 04/21/2025 Chad Finke, Executive Officer / Clerk of the Court
Clerk, by *(Secretario)* M. Cortez, Deputy *(Adjunto)*

(For proof of service of this summons, use Proof of Service of Summons *(form POS-010).)*
(Para prueba de entrega de esta citatión use el formulario Proof of Service of Summons, *(POS-010)).*

[SEAL]

NOTICE TO THE PERSON SERVED: You are served
1. ☐ as an individual defendant.
2. ☐ as the person sued under the fictitious name of *(specify):*
3. ☐ on behalf of *(specify):*
   under: ☐ CCP 416.10 (corporation) ☐ CCP 416.60 (minor)
   ☐ CCP 416.20 (defunct corporation) ☐ CCP 416.70 (conservatee)
   ☐ CCP 416.40 (association or partnership) ☐ CCP 416.90 (authorized person)
   ☐ other *(specify):*
4. ☐ by personal delivery on *(date):*

Form Adopted for Mandatory Use
Judicial Council of California
SUM-100 [Rev. July 1, 2009]

SUMMONS

Code of Civil Procedure §§ 412.20, 465
www.courtinfo.ca.gov

Bijan Esfandiari (SBN: 223216)
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Fax: (310) 820-7444

Counsel for Plaintiff

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

Assigned for Complex Determination to the Honorable Judge Somnath Raj Chatterjee
Department 21

NOTICE OF ASSOCIATION OF COUNSEL – STEVEN BRADY

Action Filed: April 21, 2025
Trial Date: TBD

TO THE HONORABLE JUDGE, THE COURT AND ALL PARTIES OF RECORD:

PLEASE TAKE NOTICE THAT the law firm of BRADY LAW GROUP, hereby associates as attorneys of record for Plaintiff Bridgett Brown, as co-counsel with WISNER BAUM, LLP in the above-mentioned matter. Please add BRADY LAW FIRM to your service lists as follows:

Steven Brady, Esq. (SBN. 116651)
mail@bradylawgroup.com
Brady Law Group
1015 Irwin Street, Suite A
San Rafael, CA 94901
Telephone: (415) 459-7300
Fax: (415) 459-7303

Request is made that both our firms be added to all service lists and that all pleadings, correspondence and other relevant documents and communications be directed to both the law firms Brady Law Firm and Wisner Baum, LLP.

Dated: April 29, 2025

Respectfully submitted,

WISNER BAUM, LLP

Pedram Esfandiary (SBN: 312569)
pesfandiary@wisnerbaum.com
Conor Kennedy (SBN: 354542)
ckennedy@wisnerbaum.com
Bijan Esfandiari (SBN: 223216)
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Monique Alarcon (SBN: 311650)
malarcon@wisnerbaum.com
11111 Santa Monica Blvd., Suite 1750
Los Angeles, CA 90025
Tel: (310) 207-3233
Fax: (310) 820-7444

Counsel for Plaintiff

PROOF OF SERVICE

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES.

I am employed in the county of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is: 11111 Santa Monica Blvd, Suite 1750, Los Angeles, CA 90025.

On April 29, 2025, I served the following document(s):

NOTICE OF ASSOCIATION OF COUNSEL – STEVEN BRADY

on the interested parties in this action by placing a true copy thereof enclosed in sealed envelopes addressed as follows:

[X] **VIA U.S. MAIL:** I am readily familiar with the firm's practice of collection and processing correspondence for mailing. Under that practice it would be deposited with the U.S. postal service on that same day with postage thereon fully prepaid at Los Angeles, California in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if postal cancellation date or postage meter date is more than one day after date of deposit for mailing an affidavit.

I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

Executed on April 29, 2025 at Los Angeles, California.

Valeriya Adlivankina

SERVICE LIST

Eli Lilly And Company
c/o National Registered Agents, Inc.
330 N Brand Blvd
Glendale, CA 91203

Janssen Pharmaceuticals, Inc.
c/o CT Corporation System
330 N Brand Blvd
Glendale, CA 91203

Janssen Research & Development, LLC
c/o CT Corporation System
330 N Brand Blvd
Glendale, CA 91203

Johnson & Johnson
c/o CT Corporation System
820 Bear Tavern Road
West Trenton, NJ 08628

Kaiser Permanente International
c/o CSC - Lawyers Incorporating Service
2710 Gateway Oaks Drive
Sacramento, CA 95833

Attorney or Party without Attorney:
Conor Kennedy (SBN: 354542)
WISNER BAUM
11111 Santa Monica Boulevard, Suite 1750
Los Angeles, CA 90025
Telephone No: (310) 207-3233
Attorney For: Plaintiff

Ref. No. or File No.:

For Court Use Only

ELECTRONICALLY FILED
Superior Court of California,
County of Alameda
04/29/2025 at 03:25:50 PM
By: Maria Alvarado,
Deputy Clerk

Insert name of Court, and Judicial District and Branch Court:
SUPERIOR COURT OF THE STATE OF
CALIFORNIA FOR THE COUNTY OF ALAMEDA

Plaintiff: BRIDGETT BROWN
Defendant: JOHNSON & JOHNSON, et al

PROOF OF SERVICE SUMMONS	*Hearing Date:*	*Time:*	*Dept/Div:*	*Case Number:* 25CV119808

1. *At the time of service I was at least 18 years of age and not a party to this action.*

2. I served copies of the Summons; Complaint; Civil Case Cover Sheet, Civil Case Cover Sheet Addendum; Notice Of Case Management Conference

3. *a. Party served:* ELI LILLY AND COMPANY
   b. Person served: Jacqueline, authorized to accept for CT Corporation System, Inc., Agent for Service of Process

4. *Address where the party was served:* 330 North Brand Boulevard Suite 700, Glendale, CA 91203

5. *I served the party:*
   a. **by personal service.** I personally delivered the documents listed in item 2 to the party or person authorized to receive service of process for the party (1) on *(date)*: Thu, Apr 24 2025 (2) at *(time)*: 12:40 PM
   (1) [X] **(business)**
   (2) [ ] **(home)**
   (3) [ ] **(other)** :

6. The "Notice to the Person Served" (on the summons) was completed as follows:
   a. [ ] as an individual defendant.
   b. [ ] as the person sued under the fictitious name of *(specify)*:
   c. [ ] as occupant.
   d. [X] On behalf of *(specify)*: ELI LILLY AND COMPANY
   under the following Code of Civil Procedure section:

[X] 416.10 (corporation)	[ ] 415.95 (business organization, form unknown)
[ ] 416.20 (defunct corporation)	[ ] 416.60 (minor)
[ ] 416.30 (joint stock company/association)	[ ] 416.70 (ward or conservatee)
[ ] 416.40 (association or partnership) 416.50	[ ] 416.90 (authorized person)
[ ] (public entity)	[ ] 415.46 (occupant)
[ ] other:	

Plaintiff:	BRIDGETT BROWN	*Case Number:*	
Defendant:	JOHNSON & JOHNSON, et al	25CV119808	

Recoverable cost Per CCP 1033.5(a)(4)(B)

7. **Person who served papers**
   a. Name: Douglas Forrest
   b. Address: **FIRST LEGAL**
      1517 W. Beverly Blvd.
      LOS ANGELES, CA 90026
   c. Telephone number: (213) 250-1111
   d. **The fee** for service was: $60.25
   e. I am:
      (1) ☐ not a registered California process server.
      (2) ☐ exempt from registration under Business and Professions Code section 22350(b).
      (3) ☒ a registered California process server:
         (i) ☐ owner ☐ employee ☒ independent contractor
         (ii) Registration No: 5141
         (iii) County: Los Angeles

8. ***I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.***

04/25/2025
(Date)

Douglas Forrest

Attorney or Party without Attorney:	For Court Use Only
Conor Kennedy (SBN: 354542) WISNER BAUM 11111 Santa Monica Boulevard, Suite 1750 Los Angeles, CA 90025 Telephone No: (310) 207-3233 Attorney For: Plaintiff	ELECTRONICALLY FILED Superior Court of California, County of Alameda 04/29/2025 at 05:10:05 PM By: Maria Alvarado, Deputy Clerk
Ref. No. or File No.:	
Insert name of Court, and Judicial District and Branch Court: SUPERIOR COURT OF THE STATE OF CALIFORNIA FOR THE COUNTY OF ALAMEDA	
Plaintiff: BRIDGETT BROWN Defendant: JOHNSON & JOHNSON., et al	

PROOF OF SERVICE SUMMONS	Hearing Date:	Time:	Dept/Div:	Case Number: 25CV119808

1. *At the time of service I was at least 18 years of age and not a party to this action.*

2. I served copies of the Summons and Complaint; Notice Of Case Management Conference; Civil Case Cover Sheet, Civil Case Cover Sheet Addendum

3. *a. Party served:* JOHNSON & JOHNSON
   b. Person served: Dosiree Mims, Authorized to Accept Service for CT Corporation System, Agent for Service of Process

4. *Address where the party was served:* 820 Bear Tavern Road, West Trenton, NJ 08628

5. *I served the party:*
   a. **by personal service.** I personally delivered the documents listed in item 2 to the party or person authorized to receive service of process for the party (1) on *(date)*: Thu, Apr 24 2025 (2) at *(time)*: 12:00 PM
   (1) [X] **(business)**
   (2) [ ] **(home)**
   (3) [ ] **(other)** :

6. The "Notice to the Person Served" (on the summons) was completed as follows:
   a. [ ] as an individual defendant.
   b. [ ] as the person sued under the fictitious name of *(specify)*:
   c. [ ] as occupant.
   d. [X] On behalf of *(specify)*: JOHNSON & JOHNSON
   under the following Code of Civil Procedure section:

[X] 416.10 (corporation)	[ ] 415.95 (business organization, form unknown)
[ ] 416.20 (defunct corporation)	[ ] 416.60 (minor)
[ ] 416.30 (joint stock company/association)	[ ] 416.70 (ward or conservatee)
[ ] 416.40 (association or partnership)	[ ] 416.90 (authorized person)
[ ] 416.50 (public entity)	[ ] 415.46 (occupant)
[ ] other:	

Plaintiff: BRIDGETT BROWN *Defendant:* JOHNSON & JOHNSON., et al	*Case Number:* 25CV119808

Recoverable cost Per CCP 1033.5(a)(4)(B)

7. **Person who served papers**
   a. Name: Aziza Amer
   b. Address: **FIRST LEGAL**
      1517 W. Beverly Blvd.
      LOS ANGELES, CA 90026
   c. Telephone number: (213) 250-1111
   d. **The fee** for service was: $319.25
   e. I am:
      (1) [X] not a registered California process server.
      (2) [ ] exempt from registration under Business and Professions Code section 22350(b).
      (3) [ ] a registered California process server:
         (i) [ ] owner [ ] employee [ ] independent contractor
         (ii) Registration No:
         (iii) County:

8. *I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.*

04/25/2025
(Date)

Aziza Amer

Attorney or Party without Attorney:
Conor Kennedy (SBN: 354542)
WISNER BAUM
11111 Santa Monica Boulevard, Suite 1750
Los Angeles, CA 90025
Telephone No: (310) 207-3233
Attorney For: Plaintiff

Ref. No. or File No.: 259-1-0039

For Court Use Only

ELECTRONICALLY FILED
Superior Court of California,
County of Alameda
04/29/2025 at 04:58:45 PM
By: Maria Alvarado,
Deputy Clerk

Insert name of Court, and Judicial District and Branch Court:
SUPERIOR COURT OF THE STATE OF CALIFORNIA FOR THE COUNTY OF ALAMEDA

Plaintiff: BRIDGETT BROWN
Defendant: JOHNSON & JOHNSON., et al

PROOF OF SERVICE SUMMONS	*Hearing Date:*	*Time:*	*Dept/Div:*	*Case Number:* 25CV119808

1. *At the time of service I was at least 18 years of age and not a party to this action.*

2. I served copies of the Summons; Complaint; Civil Case Cover Sheet, Civil Case Cover Sheet Addendum; Notice Of Case Management Conference

3. *a. Party served:* JANSSEN PHARMACEUTICALS, INC.
   b. Person served: Jacqueline Mejia, authorized to accept for CT Corporation System, Inc., Agent for Service of Process

4. *Address where the party was served:* 330 North Brand Boulevard Suite 700, Glendale, CA 91203

5. *I served the party:*
   a. **by personal service.** I personally delivered the documents listed in item 2 to the party or person authorized to receive service of process for the party (1) on *(date)*: Thu, Apr 24 2025 (2) at *(time)*: 12:40 PM
   (1) [X] **(business)**
   (2) [ ] **(home)**
   (3) [ ] **(other)** :

6. The "Notice to the Person Served" (on the summons) was completed as follows:
   a. [ ] as an individual defendant.
   b. [ ] as the person sued under the fictitious name of *(specify)*:
   c. [ ] as occupant.
   d. [X] On behalf of *(specify)*: JANSSEN PHARMACEUTICALS, INC. under the following Code of Civil Procedure section:
   - [X] 416.10 (corporation)
   - [ ] 416.20 (defunct corporation)
   - [ ] 416.30 (joint stock company/association)
   - [ ] 416.40 (association or partnership) 416.50
   - [ ] (public entity)
   - [ ] other:
   - [ ] 415.95 (business organization, form unknown)
   - [ ] 416.60 (minor)
   - [ ] 416.70 (ward or conservatee)
   - [ ] 416.90 (authorized person)
   - [ ] 415.46 (occupant)

Plaintiff:	BRIDGETT BROWN	*Case Number:*	
Defendant:	JOHNSON & JOHNSON., et al	25CV119808	

Recoverable cost Per CCP 1033.5(a)(4)(B)

7. **Person who served papers**
   a. Name: Douglas Forrest
   b. Address: **FIRST LEGAL**
      1517 W. Beverly Blvd.
      LOS ANGELES, CA 90026
   c. Telephone number: (213) 250-1111
   d. **The fee** for service was: $144.07
   e. I am:
      (1) ☐ not a registered California process server.
      (2) ☐ exempt from registration under Business and Professions Code section 22350(b).
      (3) ☒ a registered California process server:
         (i) ☐ owner ☐ employee ☒ independent contractor
         (ii) Registration No: 5141
         (iii) County: Los Angeles

8. ***I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.***

04/25/2025
(Date)

Douglas Forrest

Attorney or Party without Attorney:
Conor Kennedy (SBN: 354542)
WISNER BAUM
11111 Santa Monica Boulevard, Suite 1750
Los Angeles, CA 90025
Telephone No: (310) 207-3233
Attorney For: Plaintiff

Ref. No. or File No.: 259-1-0039

For Court Use Only

ELECTRONICALLY FILED
Superior Court of California,
County of Alameda
04/29/2025 at 04:58:55 PM
By: Maria Alvarado,
Deputy Clerk

Insert name of Court, and Judicial District and Branch Court:
SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF ALAMEDA

Plaintiff: BRIDGETT BROWN
Defendant: JOHNSON & JOHNSON., et al

PROOF OF SERVICE SUMMONS	*Hearing Date:*	*Time:*	*Dept/Div:*	*Case Number:* 25CV119808

1. *At the time of service I was at least 18 years of age and not a party to this action.*

2. I served copies of the Summons; Complaint; Civil Case Cover Sheet, Civil Case Cover Sheet Addendum; Notice Of Case Management Conference

3. *a. Party served:* JANSSEN RESEARCH & DEVELOPMENT, LLC
   b. Person served: Jacqueline Mejia, authorized to accept for CT Corporation System, Inc., Agent for Service of Process

4. *Address where the party was served:* 330 North Brand Boulevard Suite 700, Glendale, CA 91203

5. *I served the party:*
   a. **by personal service.** I personally delivered the documents listed in item 2 to the party or person authorized to receive service of process for the party (1) on *(date)*: Thu, Apr 24 2025 (2) at *(time)*: 12:40 PM
   (1) [X] **(business)**
   (2) [ ] **(home)**
   (3) [ ] **(other)** :

6. The "Notice to the Person Served" (on the summons) was completed as follows:
   a. [ ] as an individual defendant.
   b. [ ] as the person sued under the fictitious name of *(specify)*:
   c. [ ] as occupant.
   d. [X] On behalf of *(specify)*: JANSSEN RESEARCH & DEVELOPMENT, LLC
   under the following Code of Civil Procedure section:
   - [ ] 416.10 (corporation)
   - [ ] 416.20 (defunct corporation)
   - [ ] 416.30 (joint stock company/association)
   - [ ] 416.40 (association or partnership)
   - [ ] 416.50 (public entity)
   - [X] other: limited liability company
   - [ ] 415.95 (business organization, form unknown)
   - [ ] 416.60 (minor)
   - [ ] 416.70 (ward or conservatee)
   - [ ] 416.90 (authorized person)
   - [ ] 415.46 (occupant)

Plaintiff: BRIDGETT BROWN *Defendant:* JOHNSON & JOHNSON., et al	*Case Number:* 25CV119808

Recoverable cost Per CCP 1033.5(a)(4)(B)

7. **Person who served papers**
   a. Name: Douglas Forrest
   b. Address: **FIRST LEGAL**
      1517 W. Beverly Blvd.
      LOS ANGELES, CA 90026
   c. Telephone number: (213) 250-1111
   d. **The fee** for service was: $60.25
   e. I am:
      (1) ☐ not a registered California process server.
      (2) ☐ exempt from registration under Business and Professions Code section 22350(b).
      (3) ☒ a registered California process server:
         (i) ☐ owner ☐ employee ☒ independent contractor
         (ii) Registration No: 5141
         (iii) County: Los Angeles

8. ***I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.***

04/25/2025
(Date)

Douglas Forrest

Attorney or Party without Attorney: Conor Kennedy (SBN: 354542) WISNER BAUM 11111 Santa Monica Boulevard, Suite 1750 Los Angeles, CA 90025 *Telephone No:* (310) 207-3233 *Attorney For:* Plaintiff *Ref. No. or File No.:* 259-1-0039	***For Court Use Only*** **ELECTRONICALLY FILED** Superior Court of California, County of Alameda **04/29/2025 at 05:04:02 PM** By: Maria Alvarado, Deputy Clerk
Insert name of Court, and Judicial District and Branch Court: SUPERIOR COURT OF THE STATE OF CALIFORNIA FOR THE COUNTY OF ALAMEDA	
Plaintiff: BRIDGETT BROWN, *Defendant:* JOHNSON & JOHNSON, et al.,	

PROOF OF SERVICE SUMMONS	*Hearing Date:*	*Time:*	*Dept/Div:*	*Case Number:* 25CV119808

1. *At the time of service I was at least 18 years of age and not a party to this action.*

2. I served copies of the Summons; Complaint; Civil Case Cover Sheet, Civil Case Cover Sheet Addendum; Notice of Case Management Conference

3. *a. Party served:* KAISER PERMANENTE
   b. Person served: Koy Saechao, Authorized to Accept Service for CSC Lawyers Incorporating Service, Agent for Service of Process

4. *Address where the party was served:* 2710 Gateway Oaks Drive Suite 150N, Sacramento, CA 95833

5. *I served the party:*
   a. **by personal service.** I personally delivered the documents listed in item 2 to the party or person authorized to receive service of process for the party (1) on *(date)*: Thu, Apr 24 2025 (2) at *(time)*: 10:40 AM
   (1) [X] **(business)**
   (2) [ ] **(home)**
   (3) [ ] **(other)** :

6. The "Notice to the Person Served" (on the summons) was completed as follows:
   a. [ ] as an individual defendant.
   b. [ ] as the person sued under the fictitious name of *(specify)*:
   c. [ ] as occupant.
   d. [X] On behalf of *(specify)*: KAISER PERMANENTE
   under the following Code of Civil Procedure section:

[X] 416.10 (corporation)	[ ] 415.95 (business organization, form unknown)
[ ] 416.20 (defunct corporation)	[ ] 416.60 (minor)
[ ] 416.30 (joint stock company/association)	[ ] 416.70 (ward or conservatee)
[ ] 416.40 (association or partnership) 416.50	[ ] 416.90 (authorized person)
[ ] (public entity)	[ ] 415.46 (occupant)
[ ] other:	

Plaintiff: BRIDGETT BROWN, *Defendant:* JOHNSON & JOHNSON, et al.,	*Case Number:* 25CV119808

Recoverable cost Per CCP 1033.5(a)(4)(B)

7. **Person who served papers**
   a. Name: Michael Morris
   b. Address: **FIRST LEGAL**
      1517 W. Beverly Blvd.
      LOS ANGELES, CA 90026
   c. Telephone number: (213) 250-1111
   d. **The fee** for service was: $245.17
   e. I am:
      (1) ☐ not a registered California process server.
      (2) ☐ exempt from registration under Business and Professions Code section 22350(b).
      (3) ☒ a registered California process server:
         (i) ☐ owner ☐ employee ☒ independent contractor
         (ii) Registration No: 2012-33
         (iii) County: Sacramento

8. ***I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.***

04/24/2025
(Date)

Michael Morris

Bijan Esfandiari (SBN: 223216)
besfandiari@wisnerbaum.com
Monique Alarcon (SBN: 311650)
malarcon@wisnerbaum.com
Pedram Esfandiary (SBN: 312569)
pesfandiary@wisnerbaum.com
Conor Kennedy (SBN: 354542)
ckennedy@wisnerbaum.com
WISNER BAUM, LLP
11111 Santa Monica Blvd., Suite 1750
Los Angeles, CA 90025
Tel: (310) 207-3233
Fax: (310) 820-7444

Counsel for Plaintiff

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; CHEPLAPHARM ARZNEIMITTEL GMBH; KAISER PERMANENTE INTERNATIONAL; and DOES 1 through 100, inclusive,

Defendant.

Case No. 25CV119808

FIRST AMENDED 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, Cheplapharma, 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 CHEPLAPHARM Arzneimittel GmbH ("Cheplapharm")** is a German limited liability company, headquartered in Greifswald, Germany. In July 2023, Lilly sold the rights for its Zyprexa portfolio to Cheplapharm.[1] The deal obligated Cheplapharm to purchase Zyprexa products manufactured by Lilly at a standalone selling price,[2] and Lilly has continued to manufacture and market Zyprexa in the U.S after the deal. Cheplapharm also sells Zyprexa products manufactured and distributed by its U.S. Partner, H2-Pharma.[3] At all relevant times, J&J has conducted business and derived substantial revenue from selling Zyprexa within the United States and California, including Alameda County.

11. **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.

12. **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.[4] JPI manufactures, promotes, and distributes the

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[1] Lilly sold the global rights to all Zyprexa products, outside of South Korea.

[2] Eli Lilly and Company. (2023). *Form 10-K for the fiscal year ended December 31, 2023*. U.S. Securities and Exchange Commission. https://www.sec.gov/ix?doc=/Archives/edgar/data/0000059478/000059478240000065/lly-20231231.htm Eli Lilly and Company. (2024). *Form 10-K for the fiscal year ended December 31, 2024*. U.S. Securities and Exchange Commission. https://www.sec.gov/ix?doc=/Archives/edgar/data/0000059478/000059478250000067/lly-20241231.htm

[3] 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).

[4] 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.

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.

13. **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.[5] At all relevant times, JRD was 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.

14. 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.

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

B. Retailer Defendant

16. **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

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

pharmacy which sells Defendants' Drugs. Specifically, Kaiser supplied Plaintiff with Defendants' Drugs which caused Plaintiff's injuries.

C. Doe Defendants

17. 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 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

18. 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."

19. 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.

20. 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.

21. 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.

22. 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.[6] Those specific acts relate to and give rise to claims against each Defendant Drug Maker.

23. 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.

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

25. 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

26. Defendant Drug Makers 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

27. 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

[6] 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.

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

28. Defendants Lilly and Cheplapharm designed, developed, manufactured, marketed, and sold Olanzapine as:[7]

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;

d. Zyprexa Relprevv (olanzapine pamoate), an extended-release injection, was approved December 11, 2009, and its patent expired October 24, 2011; and

e. Symbyax (fluoxetine hydrochloride and olanzapine), an oral capsule, was approved Dec. 24, 2003, and its patent expired June 19, 2012. Symbyax combines olanzapine with fluoxetine, a selective serotonin reuptake inhibitor.

29. 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.

30. At all relevant times, Defendant Drug Makers, through their agents, servants, and

[7] As described above, Defendant Lilly sold the worldwide rights to the Zyprexa portfolio, outside of South Korea, to Defendant Cheplapharm in July 2023, however in compliance with the deal, Lilly continued to manufacture and market Zyprexa in the U.S. on behalf of Cheplapharm.

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.

31. 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.

32. 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.

33. 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.[8] In 2013, J&J agreed to pay $2.2 billion to settle similar claims regarding Risperdal and two other drugs.

34. 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."[9] 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 –

[8] 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.

[9] *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.

including young children, the elderly, and the disabled."[10]

B. Atypical Antipsychotics

35. 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.[11] 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.[12]

36. The phrase "second-generation" suggests SGAs are more sophisticated than FGAs. However, "the FGA/SGA classification remains problematic because neither group is defined by 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.[13]

II. Regulatory History of Defendants' Drugs

37. 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

[10] 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.

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

[12] 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.

[13] *Id.*

formulations. In each case, the drug was developed by the manufacturer to replace an earlier blockbuster drug that was nearing patent expiration.

A. Risperdal

38. Risperidone was developed in the 1980s by Janssen Pharmaceutica, Inc., a Belgian company owned by Johnson & Johnson.[14]

39. 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.

40. 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,[15] "[i]nexpensive generic versions of Haldol had decimated the brand name's revenues by 1992."[16]

41. To encourage patient transition, JJIM requested Risperdal's label to include certain 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."[17]

42. 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.[18]

B. Zyprexa

43. Olanzapine was originally developed by Defendant Lilly and patented as "Zyprexa" in

[14] Defendant JPI (Janssen Pharmaceuticals, Inc.) is the successor in interest to Janssen Pharmaceutica, Inc.
[15] J.I. Escobar & H. Marin, *Clinical Psychopharmacology: A Practical Approach*, 69 WORLD SCIENTIFIC (2013).
[16] Steven Brill, *America's Most Admired Lawbreaker*, HUFFPOST HIGHLINE. (2015), https://highline.huffingtonpost.com/miracleindustry/americas-most-admired-lawbreaker/
[17] *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
[18] 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.

1971.[19]

44. Zyprexa was originally approved by the FDA in September 1996 (NDA 076000) for the treatment of "manifestations of psychotic disorders."[20]

45. 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."[21]

46. 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 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.[22]

47. 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,[23] 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

48. 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

[19] Taylor et al., *supra*.
[20] 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.
[21] 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.
[22] https://www.thecarlatreport.com/articles/1431-invega-can-you-say-patent-extender-
[23] Agnes Shanley, *Decades of Change for Top Pharmaceutical Companies*, PHARM. TECH. (Jan. 23, 2024), https://www.pharmtech.com/view/decades-change-top-pharmaceutical-companies.

Paliperidone as a standalone drug until decades later.

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

50. 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.

51. 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."[24]

52. Annual worldwide sales of Invega topped $4.1 billion in 2023.[25]

III. Carcinogenicity of Defendants' Drugs

53. 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.

54. 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

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

56. In the 1970s, animal studies conclusively established a causal association between

[24] 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-.

[25] 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.

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."[26]

57. Around the same time, evidence began to accumulate that prolactin could also cause breast cancer in humans.[27] 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.[28]

58. 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.[29] The authors observed a significant association in both pre- and post-menopausal women between 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.[30]

59. Today, the causal association between hyperprolactinemia and breast cancer is undisputed.[31] 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."[32] The causal association is

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

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

[28] 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).

[29] 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.

[30] 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.

[31] *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.

[32] 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.

underscored by studies of atypicals, discussed below, which found that the risk of breast cancer impacted the proportional increase of prolactin.[33]

B. Atypical Antipsychotics Cause Hyperprolactinemia

60. 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.[34] In fact, since the 1970s, some clinicians recommended against the use of FGAs in patients with hyperprolactinemia or suspected breast cancer.[35]

61. 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.[36] By contrast, certain other SGAs have negligible prolactin effects – aripiprazole, in fact, decreases prolactin production.

62. In 1998, JPI executives set a brand strategy to prove that Risperdal's prolactin effects were no worse than Haldol or other FGAs.[37] The company conducted three clinical trials to support 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."[38]

63. 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,"[39] including hyperprolactinemia. JPI argued that this concern "was not justified based on available data," but the hyperprolactinemia warning was ultimately strengthened.[40] Still, JPI never warned of the risk of

[33] *See* Rahman et al., 171 AM. J. PSYCHIATRY 616 (2014).
[34] J.R. Bostwick, S.K. Guthrie & V.L. Ellingrod, *Antipsychotic-Induced Hyperprolactinemia,* 29 PHARMACOTHERAPY 64 (2009).
[35] *Id.*
[36] Brill at Ch. 3-4; attachment titled "Gosky re: 'perceived Weakness.'" (on file with HuffPost).
[37] *Id.*
[38] *Id, supra.*
[39] *Id.*
[40] *Id.*

breast cancer.

64. Today, the literature shows that hyperprolactinemia is common, and severe, among users of these drugs,[41] with incidence rates reaching 70% to 76.4% for Olanzapine[42] and 94.8% for Risperdal.[43] "Hyperprolactinemia is one of the most common side effects of Risperidone treatment."[44] 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.[45]

C. Atypical Antipsychotics Cause Breast Cancer

65. 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 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").

66. 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,[46] 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.[47]

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[41] 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.

[42] 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/.

[43] 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.

[44] 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.

[45] 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/.

[46] Specifically, the Medicaid or Pharmaceutical Assistance to the Aged and Disabled programs.

[47] 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.

67. 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.[48] 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.[49]

68. 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 breast cancer cases in the Danish Cancer Registry reported that 1,000 days or more exposure[50] to second-generation PIAs, including risperidone and olanzapine, was associated with a 52% increased risk of breast cancer.[51] 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%.[52]

69. 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

[48] 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.

[49] 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.

[50] 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.

[51] 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.

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

olanzapine showed a similarly alarming 54% increased risk.[53]

70. 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.[54] Leung et al. (2022) was a meta-analysis of 9 high-quality[55] 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.[56]

71. 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[57] for one to four years, and 47% more common among those with at least five years of use, after adjustment.[58]

72. 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.

[53] *See* Rahman et al., 171 Am. J. Psychiatry 616 (2014).
[54] 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.
[55] Quality of studies was assessed using the Newcastle-Ottawa Scale. "High-quality" means 7-9 stars.
[56] 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.
[57] 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.
[58] 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.

(2024).[59]

73. 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.[60]

74. 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 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.[61]

75. 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).[62] While Kern feigns to incorporate the

[59] 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.

[60] *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.

[61] 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.

[62] 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

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,[63] 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.

76. 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 which explicitly concluded that a label change was warranted.[64]

77. 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.

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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."

[63] 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.

[64] 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.

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

A. Denial of Carcinogenesis

78. 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.[65]

79. 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."[66] 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."[67]

B. Obfuscation of Potential Mechanisms

80. Defendants' labels also disclaim the risks and well-established adverse effects of

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[65] 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).

[66] *Id.*

[67] 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.

elevated prolactin,[68] 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."[69] In 2006, in the wake of litigation regarding hyperprolactinemia's tendency to induce gynecomastia, this sentence was removed.

81. 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."[70] 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.[71]

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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."[72] In February 2021 and December 2022, the labels of Risperdal and Zyprexa, respectively, were updated to describe the relevance of these findings as "unclear."[73] 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

[68] *See* U.S. Food & Drug Admin., *Drugs@FDA*, Appl. Nos. 020272, 020592 & 021999.
[69] *Id.*
[70] *Id.* (emphasis added).
[71] *Id.*
[72] *Id.*
[73] *Id.*

82. 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.

83. 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.

84. 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.

85. 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.

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

87. 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.

88. 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.

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

90. 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.

91. 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.

92. 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.

93. 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)

94. 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.

95. 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.

96. 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.

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

PLAINTIFF-SPECIFIC ALLEGATIONS

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

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

100. 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.

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

102. 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.

103. 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.

104. 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.

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

106. 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

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

108. 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.

109. 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)

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

111. 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.[74]

[74] As described above, Defendant Lilly sold the worldwide rights to the Zyprexa portfolio, outside of South Korea, to Defendant Cheplapharm in July 2023, however in compliance with the deal, Lilly continued to manufacture and market Zyprexa in the U.S. on behalf of Cheplapharm. For the purposes of this allegation, Lilly controlled Zyprexa pre-sale, and Cheplapharm controlled Zyprexa post-sale.

112. 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.

113. 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.

114. 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.

115. 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.

116. 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.

117. 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.

118. 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.

119. 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.

120. 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.

121. **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)

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

123. 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.

124. 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;

125. 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.

126. 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.

127. 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.

128. 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

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

130. 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.

131. 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.

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

133. **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. Count III: Negligence – Failure to Warn (Against All Defendants)

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

135. 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.

136. 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.

137. 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.

138. 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.

139. 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.

140. 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.

141. 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.

142. 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.

143. 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.

144. 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.

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

146. 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.

147. 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.

148. 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.

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

150. 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.

151. **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)

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

153. 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.

154. 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;

155. 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.

156. 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.

157. 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.

158. 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.

159. 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.

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

161. 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.

162. **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

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

PRAYER FOR RELIEF

164. 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;

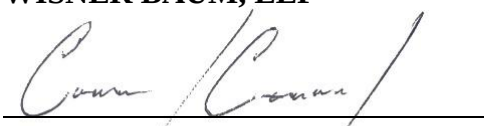
d. costs including reasonable attorneys' fees, court costs, and other litigation expenses; and

e. any other relief the Court may deem just and proper.

Respectfully submitted,

Dated: May 9, 2025

WISNER BAUM, LLP



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Tel: (310) 207-3233
Fax: (310) 820-7444

Counsel for Plaintiff

SUM-100

AMENDED SUMMONS
(CITACION JUDICIAL)

NOTICE TO DEFENDANT:
(AVISO AL DEMANDADO):
JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; JANSSEN RESEARCH & DEVELOPMENT, LLC; ELI LILLY AND COMPANY; CHEPLAPHARM ARZNEIMITTEL GMBH; KAISER PERMANENTE INTERNATIONAL; and DOES 1 through 100, inclusive

YOU ARE BEING SUED BY PLAINTIFF:
(LO ESTÁ DEMANDANDO EL DEMANDANTE):
BRIDGETT BROWN

FOR COURT USE ONLY
(SOLO PARA USO DE LA CORTE)

ELECTRONICALLY FILED
Superior Court of California
County of Alameda
05/12/2025
Chad Finke, Executive Officer / Clerk of the Court
By: D. Franklin Deputy

NOTICE! You have been sued. The court may decide against you without your being heard unless you respond within 30 days. Read the information below.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the court to hear your case. There may be a court form that you can use for your response. You can find these court forms and more information at the California Courts Online Self-Help Center (*www.courtinfo.ca.gov/selfhelp*), your county law library, or the courthouse nearest you. If you cannot pay the filing fee, ask the court clerk for a fee waiver form. If you do not file your response on time, you may lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney referral service. If you cannot afford an attorney, you may be eligible for free legal services from a nonprofit legal services program. You can locate these nonprofit groups at the California Legal Services Web site (*www.lawhelpcalifornia.org*), the California Courts Online Self-Help Center (*www.courtinfo.ca.gov/selfhelp*), or by contacting your local court or county bar association. **NOTE:** The court has a statutory lien for waived fees and costs on any settlement or arbitration award of $10,000 or more in a civil case. The court's lien must be paid before the court will dismiss the case.
¡AVISO! *Lo han demandado. Si no responde dentro de 30 días, la corte puede decidir en su contra sin escuchar su versión. Lea la información a continuación.*

*Tiene 30 DÍAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito en esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que procesen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de California (*www.sucorte.ca.gov*), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no puede pagar la cuota de presentación, pida al secretario de la corte que le dé un formulario de exención de pago de cuotas. Si no presenta su respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.*

*Hay otros requisitos legales. Es recomendable que llame a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a un servicio de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sitio web de California Legal Services, (*www.lawhelpcalifornia.org*), en el Centro de Ayuda de las Cortes de California, (*www.sucorte.ca.gov*) o poniéndose en contacto con la corte o el colegio de abogados locales. AVISO: Por ley, la corte tiene derecho a reclamar las cuotas y los costos exentos por imponer un gravamen sobre cualquier recuperación de $10,000 ó más de valor recibida mediante un acuerdo o una concesión de arbitraje en un caso de derecho civil. Tiene que pagar el gravamen de la corte antes de que la corte pueda desechar el caso.*

The name and address of the court is:
(El nombre y dirección de la corte es): Rene C. Davidson Courthouse
Superior Court of California, County of Alameda
1225 Fallon Street, Oakland, CA 94512

CASE NUMBER:
(Número del Caso): 25CV119808

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:
(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):
Conor J. Kennedy, Wisner Baum LLP, 11111 Santa Monica Boulevard, Suite 1750, Los Angeles, CA 90025
(310) 207-3233; ckennedy@wisnerbaum.com

DATE:
(Fecha) 05/12/2025 Chad Finke, Executive Officer / Clerk of the Court
Clerk, by *(Secretario)* D. Franklin, Deputy *(Adjunto)*

(For proof of service of this summons, use Proof of Service of Summons *(form POS-010).)*
(Para prueba de entrega de esta citatión use el formulario Proof of Service of Summons, *(POS-010)).*

[SEAL]

NOTICE TO THE PERSON SERVED: You are served
1. ☐ as an individual defendant.
2. ☐ as the person sued under the fictitious name of *(specify):*
3. ☐ on behalf of *(specify):*
   under: ☐ CCP 416.10 (corporation) ☐ CCP 416.60 (minor)
   ☐ CCP 416.20 (defunct corporation) ☐ CCP 416.70 (conservatee)
   ☐ CCP 416.40 (association or partnership) ☐ CCP 416.90 (authorized person)
   ☐ other *(specify):*
4. ☐ by personal delivery on *(date)*:

Form Adopted for Mandatory Use
Judicial Council of California
SUM-100 [Rev. July 1, 2009]

SUMMONS

Code of Civil Procedure §§ 412.20, 465
www.courtinfo.ca.gov

CIVIL COVER SHEET - for people without lawyers only

See Civil Local Rule 3-2 (amended April 28, 2025), which requires the filing of a civil cover sheet only by those unrepresented by counsel.

I. PLAINTIFF(S)

BRIDGETT BROWN

County of Residence of First Listed Plaintiff: California
Leave blank in cases where United States is plaintiff.

Attorney or Pro Se Litigant Information *(Firm Name, Address, and Telephone Number)*

Bijan Esfandiari (SBN: 223216), WISNER BAUM, LLP, 11111 Santa Monica Blvd., Suite 1750
Los Angeles, CA 90025, (310) 207-3233

DEFENDANT(S)

JOHNSON & JOHNSON et al.

County of Residence of First Listed Defendant: Middlesex County, NJ
Use ONLY in cases where United States is plaintiff.

Defendant's Attorney's Name and Contact Information *(if known)*

MIHRAN YEZBEKYAN (SBN 322233), 2029 Century Park East, Suite 300
Los Angeles, California 90067-2904, (310) 284-3880

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ U.S. Government Plaintiff
- ☐ Federal Question *(U.S. Government Not a Party)*
- ☐ U.S. Government Defendant
- ☒ Diversity

III. CAUSE OF ACTION

Cite the U.S. Statute under which you are filing: *(Use jurisdictional statutes only for diversity)*

28 U.S.C. §§ 1332, 1441, and 1446

Brief description of case: Products liability and personal injury action related to Plaintiffs' consumption of certain pharmaceutical drugs, Rispe

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT

- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY

- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY

- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury -Medical Malpractice

PERSONAL INJURY

- ☐ 365 Personal Injury – Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY

- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS

- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities–Employment
- ☐ 446 Amer. w/Disabilities–Other
- ☐ 448 Education

PRISONER PETITIONS

HABEAS CORPUS

- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

OTHER

- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee– Conditions of Confinement

FORFEITURE/PENALTY

- ☐ 625 Drug Related Seizure of Property 21 USC § 881
- ☐ 690 Other

LABOR

- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION

- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY

- ☐ 422 Appeal 28 USC § 158
- ☐ 423 Withdrawal 28 USC § 157

PROPERTY RIGHTS

- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent–Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY

- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS

- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS–Third Party 26 U.S.C. § 7609

OTHER STATUTES

- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC § 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced & Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

- ☐ Original Proceeding
- ☒ Removed from State Court
- ☐ Remanded from Appellate Court
- ☐ Reinstated or Reopened
- ☐ Transferred from Another District
- ☐ Multidistrict Litigation–Transfer
- ☐ Multidistrict Litigation–Direct File

VI. FOR DIVERSITY CASES ONLY: CITIZENSHIP OF PRINCIPAL PARTIES

(Place an "X" in One Box for Plaintiff and One Box for Defendant)

Plaintiff	Defendant	
☒	☐	Citizen of California
☐	☐	Citizen of Another State
☐	☐	Citizen or Subject of a Foreign Country
☐	☐	Incorporated or Principal Place of Business In California
☐	☒	Incorporated and Principal Place of Business In Another State
☐	☐	Foreign Nation

VII. REQUESTED IN COMPLAINT

- ☑ Check if the complaint contains a **jury demand.**
- ☐ Check if the complaint contains a **monetary demand**. Amount:
- ☐ Check if the complaint seeks **class action** status under Fed. R. Civ. P. 23.
- ☐ Check if the complaint seeks a **nationwide injunction** or Administrative Procedure Act vacatur.

VIII. RELATED CASE(S) OR MDL CASE

Provide case name(s), number(s), and presiding judge(s).

IX. DIVISIONAL ASSIGNMENT pursuant to Civil Local Rule 3-2

(Place an "X" in One Box Only) ☒ SAN FRANCISCO/OAKLAND ☐ SAN JOSE ☐ EUREKA-MCKINLEYVILLE

DATE 05/20/2025 **SIGNATURE OF ATTORNEY OR PRO SE LITIGANT** /S/ Mihran Yezbekyan

COMPLETING THE CIVIL COVER SHEET

Complete the form as follows:

I. Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.

Attorney/Pro Se Litigant Information. Enter the firm name, address, telephone number, and email for attorney of record or pro se litigant. If there are several individuals, list them on an attachment.

II. Jurisdiction. Under Federal Rule of Civil Procedure 8(a), pleadings must establish the basis of jurisdiction. If multiple bases for jurisdiction apply, prioritize them in the order listed:

(1) *United States plaintiff*. Jurisdiction based on 28 U.S.C. §§ 1345 and 1348 for suits filed by the United States, its agencies or officers.

(2) *United States defendant.* Applies when the United States, its agencies, or officers are defendants.

(3) *Federal question*. Select this option when jurisdiction is based on 28 U.S.C. § 1331 for cases involving the U.S. Constitution, its amendments, federal laws, or treaties (but use choices 1 or 2 if the United States is a party).

(4) *Diversity of citizenship.* Select this option when jurisdiction is based on 28 U.S.C. § 1332 for cases between citizens of different states and complete Section VI to specify the parties' citizenship. Note: Federal question jurisdiction takes precedence over diversity jurisdiction.

III. Cause of Action. Enter the statute directly related to the cause of action and give a brief description of the cause. Do not cite jurisdictional statutes unless jurisdiction is based on diversity. Example: U.S. Civil Statute: 47 U.S.C. § 553. Brief Description: Unauthorized reception of cable service.

IV. Nature of Suit. Check one of the boxes. If the case fits more than one nature of suit, select the most definitive or predominant.

V. Origin. Check one of the boxes:

(1) *Original Proceedings*. Cases originating in the United States district courts.

(2) *Removed from State Court*. Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C. § 1441. When the petition for removal is granted, check this box.

(3) *Remanded from Appellate Court*. Check this box for cases remanded to the district court for further action, using the date of remand as the filing date.

(4) *Reinstated or Reopened*. Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

(5) *Transferred from Another District*. Check this box for cases transferred under Title 28 U.S.C. § 1404(a). Do not use this for within-district transfers or multidistrict litigation (MDL) transfers.

(6) *Multidistrict Litigation Transfer*. Check this box when a multidistrict (MDL) case is transferred into the district under authority of Title 28 U.S.C. § 1407.

(7) *Multidistrict Litigation Direct File.* Check this box when a multidistrict litigation case is filed in the same district as the Master MDL docket.

VI. Residence (citizenship) of Principal Parties. Mark for each principal party *only* if jurisdiction is based on diversity of citizenship.

VII. Requested in Complaint.

(1) *Jury demand.* Check this box if plaintiff's complaint demanded a jury trial.

(2) *Monetary demand*. For cases demanding monetary relief, check this box and enter the actual dollar amount being demanded.

(3) *Class action.* Check this box if plaintiff is filing a class action under Federal Rule of Civil Procedure 23.

(4) *Nationwide injunction.* Check this box if plaintiff is seeking a nationwide injunction or nationwide vacatur pursuant to the Administrative Procedures Act.

VIII. Related Cases. If there are related pending case(s), provide the case name(s) and number(s) and the name(s) of the presiding judge(s). If a short-form MDL complaint is being filed, furnish the MDL case name and number.

IX. Divisional Assignment. Identify the divisional venue according to Civil Local Rule 3-2: "the county in which a substantial part of the events or omissions which give rise to the claim occurred or in which a substantial part of the property that is the subject of the action is situated." Note that case assignment is made without regard for division in the following case types: Property Rights (Patent, Trademark and Copyright), Prisoner Petitions, Securities Class Actions, Anti-Trust, Bankruptcy, Social Security, and Tax.

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Attorneys for Defendant
JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; JANSSEN RESEARCH & DEVELOPMENT, LLC

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

BRIDGETT BROWN,

Plaintiff,

v.

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

Defendants.

Case No. 3:25-cv-04318

CERTIFICATE OF SERVICE OF NOTICE TO ADVERSE PARTY OF REMOVAL TO FEDERAL COURT

Case Removed: May 20, 2025

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

I, Monica Martinez, certify and declare as follows:

28. I am over the age of 18 years and not a party to this litigation.

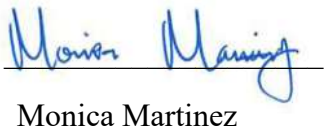
29. My business address is 2029 Century Park East, Suite 300, which is located in the city, county and state where the mailing described below took place.

30. On May 20, 2025, I served by electronic mail via my electronic service address (Monica.Martinez@btlaw.com) and through First Legal, a copy of the Notice to Adverse Party of

Removal to Federal Court dated May 20, 2025, addressed to Plaintiff's attorney of record, Bijan Esfandiari. Copies of the conformed face page and certificate of service are attached to this Certificate.

31. I declare under penalty of perjury that the above is true and correct.

32. Executed this 20th day of May, 2025.



Monica Martinez