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7	Wasserman and Mary Wasserman						
8	UNITED STATES DISTRICT COURT						
9	NORTHERN DISTRICT OF CALIFORNIA						
10	SAN FRANCISCO DIVISION						
11	SAN PRANCISCO DI VISION						
12	ANDREW WASSERMAN and MARY	Case No.					
	WASSERMAN,						
13	Plaintiffs,	COMPLAINT					
14	VS.						
15	JANSSEN PHARMACEUTICALS, INC.,	JURY TRIAL DEMANDED					
16	JOHNSON & JOHNSON, JANSSEN						
17	RESEARCH AND DEVELOPMENT, LLC, and DOES 1-5,						
18	Defendants						
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20	Plaintiffs Andrew Wasserman and his mother, Mary Wasserman, by and through their						
21	undersigned counsel, based upon personal knowledge and the investigation of their counsel,						
22	hereby sue Defendants Janssen Pharmaceuticals, Inc., Janssen L.P. (collectively, "Janssen"),						
23	Johnson & Johnson (J&J), Janssen Research and Development, LLC ("JRD"), and Does 1-5						
24	(cumulatively, "Defendants"), and allege:						
25	INTRODUCTION AND SUMMARY OF ACTION						
26	1. This case involves the unreasonably dangerous and mislabeled drug Risperdal						
27	(generic, risperidone) that Defendants manufactured, distributed, promoted and sold.						
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- 2. Defendants misrepresented that Risperdal is a safe and effective treatment for schizophrenia and bipolar mania. In fact, Defendants knew the drug causes a host of serious side effects, including the growth of enlarged breasts in boys and men, known as gynecomastia; and hyperprolactinemia, the presence of abnormally high levels of prolactin (a hormone that stimulates breast development and milk production in women), which has been linked to gynecomastia, erectile dysfunction, infertility and other hormonal and sexual disorders in men.
- 3. Defendants failed to adequately warn doctors and consumers about these risks, misrepresented the degree of risk, dismissed the severity of Risperdal-caused hyperprolactinemia and gynecomastia, and even claimed that breast development in boys taking Risperdal is normal.
- 4. Defendants also engaged in an aggressive, illegal marketing campaign to promote Risperdal for "off-label" uses, i.e., uses not approved as safe and effective by the U.S. Food and Drug Administration ("FDA"), including the treatment of anxiety, depression and other mood disorders. Defendants paid kickbacks to doctors and pharmacists, produced sham studies and seeded the medical literature with ghostwritten articles promoting off-label uses.
- 5. As a result of Defendants' illegal marketing campaign, sales skyrocketed. While in 1993, J&J predicted it would take seven years for Risperdal to reach \$295 million in annual sales, Risperdal sales hit \$343 million in less than two years. By 1997, Risperdal sales had increased to \$589 million, making it the top selling antipsychotic drug on the market.
- 6. Defendants' illegal activity soon drew the attention of the FDA. In 1999 and again in 2004, the FDA warned Defendants it was unlawfully promoting Risperdal for unapproved uses and was publishing false and misleading promotional materials by omitting material information, minimizing potentially fatal risks and claiming the drug is safer than other atypical antipsychotics without adequate substantiation.
- 7. Defendants ignored the FDA's warnings. Defendants' refusal to stop the off-label promotion of Risperdal was directly related to their bottom line. J&J's Risperdal sales for 2006 topped \$4.2 billion, an increase of over 17.8% over 2005. In 2007, J&J's antipsychotics franchise (primarily Risperdal) achieved sales of \$4.7 billion, an increase of 12.3% over 2006. From 2003 through 2009, J&J's revenues from Risperdal exceeded \$23.6 billion.

- 8. Defendants' illegal business practices spurred whistleblowers and investigations across the country. In 2010, 2011 and 2012, judges in Louisiana, South Carolina and Arkansas ordered J&J and/or Janssen to pay \$330 million, \$327 million and \$1.1 billion, respectively, after juries found Defendants violated unfair trade practices laws and/or defrauded the states' Medicaid systems by fraudulently exaggerating Risperdal's efficacy, illegally marketing it for off-label uses, and concealing and downplaying its risks of side effects, including hyperprolactinemia.
- 9. In 2012, Defendants agreed to pay more than \$2.2 billion the largest health care fraud settlement in the nation's history to settle federal and state charges that Defendants used deceptive marketing and kickbacks to promote Risperdal. The agreement included \$181 million in civil fines to settle allegations Defendants illegally marketed Risperdal for off-label uses in children and concealed its risks of side effects, including gynecomastia.
- 10. Plaintiff Andrew Wasserman was prescribed and took Risperdal at various times from 2008 to 2013 beginning at the age of 20. During that time he developed enlarged breasts, causing him severe psychological trauma and leading him to undergo a double mastectomy in 2011, at the age of 24. These horrific experiences scarred him for life. He also experienced other side effects and injuries from taking Risperdal, including pain and swelling in his chest, pain in his testicles, testicular shrinkage, erectile dysfunction, diminished semen volume and sperm count (and likely infertility), loss of sex drive, damage to endocrine functions, gastrointestinal problems, cellulitis (severe inflammation), impaired motor skills, depression, dyssomnia (difficulty getting to sleep and staying asleep and intermittent wakefulness during the night), anxiety, embarrassment, social anxiety, difficulty with physical intimacy, difficulty concentrating, impaired thinking, fear, apprehension, despair, suicidality, and other emotional problems. He continues to suffer from many of these conditions.
- 11. Plaintiffs bring this action for strict liability, negligence, negligence *per se*, false advertising, fraudulent concealment, fraudulent misrepresentation, failure to warn, breach of express and implied warranties, unfair business practices, intentional infliction of emotional distress and negligent infliction of emotional distress. This action is based upon Defendants'

1 violations of the laws of the Unites States and of the State of California, including but not limited 2 to 21 U.S.C. § 321, et seq. (the Food, Drug, and Cosmetic Act); 31 U.S.C. §§ 3729-33 and 3 3730(b)(1) (the False Claims Act); 21 C.F.R. 99, 200-202, 312 and 314 (federal regulations re 4 off-label promotion); 42 U.S.C. § 1320a7b(b) (federal anti-kickback statute); 15 U.S.C. § 5 78m(b)(2)(A)(B) (section 13(b)(2)(A)(B) of the Securities and Exchange Act); 21 U.S.C. §§ 331(a), 333(a)(1) and 352(f)(1)) (introduction of misbranded drugs into interstate commerce), 6 7 California Business and Professions Code § 17200, et seq. and § 17500; and other applicable 8 federal and California state requirements, in the marketing and distribution of the defective and 9 unreasonably dangerous drug Risperdal. Plaintiffs seek compensatory and punitive damages for

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**JURISDICTION** 

the physical, psychological, pecuniary and related injuries for which Defendants are liable.

12. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiffs and each Defendant and the amount in controversy exceeds \$75,000. This Court has personal jurisdiction over each Defendant pursuant to federal law and Cal. Code Civ. Proc. § 410.10 due to Defendants' substantial, continuous and systematic presence and activity in California and purposeful availment of the laws and privileges associated therewith.

**VENUE** 

13. Venue is properly laid in the United States District Court for the Northern District of California pursuant to 28 U.S.C. § 1391(a) because the events which give rise to the claims alleged herein substantially occurred within the geographical boundaries of the District.

#### INTRADISTRICT ASSIGNMENT

14. This action is properly assigned to the San Francisco Division pursuant N.D. Cal. Civil Local Rule 3-2(c) because a substantial part of the events and omissions which give rise to claims alleged herein occurred in the County of San Francisco.

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#### **PARTIES**

- 15. Plaintiff Andrew Wasserman is a 27 year-old male. He has resided in the City and County of San Francisco, California, since mid-2011. Before that he lived in the Cities of Covina and Northridge in Los Angeles County, California.
- 16. Plaintiff Mary Wasserman is Andrew's biological mother. At all relevant times, Mrs. Wasserman resided in the City of Covina in Los Angeles County, California, and was Andrew's natural and legal parent and guardian with whom he lived part of the time he was taking Risperdal.
- 17. Defendant Janssen Pharmaceuticals, Inc. ("Janssen"), is a Pennsylvania corporation with its principal place of business in New Jersey. Jannsen Pharmaceuticals, Inc., is a wholly owned subsidiary of J&J, and is the successor in interest to Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and Janssen, L.P.
- 18. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Jersey. J&J manufactures, markets and sells a wide range of pharmaceutical, medical and related products. J&J is qualified to do business in California and does business in California.
- 19. Defendant Janssen Research and Development, LLC ("JRD") is a New Jersey limited liability corporation with its principal place of business in Pennsylvania, and is the successor-in-interest to Johnson & Johnson Research and Development, LLC. Centocor Research & Development, Inc., is the 100% shareholder of JRD. Centocor Research & Development, Inc., is incorporated in Pennsylvania with its principle place of business in Pennsylvania.
- 20. Defendants "John Doe" 1-5 are directors, officers, managers, employees, agents, contractors, subsidiaries and/or closely related entities of the named and/or their subsidiaries who, at all times relevant to the allegations herein, acted within the scope of their authority and on behalf of the other Defendants.

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#### FACTUAL ALLEGATIONS

- 21. At all relevant times, Defendants owned a patent on Risperdal/risperidone. Defendants did during such times create, design, manufacture, test, label, distribute, supply, prescribe, market, sell, advertise, purport to warn, purport to consult, and otherwise distribute in interstate commerce and in the State of California the product known as Risperdal/risperidone.
- 22. The FDA first approved Risperdal in 1993 to treat schizophrenia in adults. Shortly after, J&J noted in an internal report: "Schizophrenia represents only 35 percent of antipsychotic prescriptions... Aggressive expansion of Risperdal use in other indications is therefore mandatory." To that end, beginning no later than about 1997 and continuing for over a decade thereafter, Defendants made false and misleading statements about the safety, cost and effectiveness of Risperdal and engaged in an aggressive illegal marketing campaign to improperly influence doctors and officials to promote and prescribe the drug for both approved and off-label uses.
- 23. In 2003, the FDA approved Risperdal to treat schizophrenia in adults and mania associated with bipolar disorder in adults. In 2007 the FDA approved Risperdal to treat schizophrenia in children.
- 24. Documents released in connection with settlements, judgments and plea agreements reached with the U.S. Department of Justice and various state attorneys general from 2010 to 2013 evidence that Defendants have concealed and/or minimized Risperdal's side effects, exaggerated its effectiveness and illegally marketed it for off-label uses.
- 25. At all relevant times, Defendants falsely advertised and promoted Risperdal as a safe and effective treatment for schizophrenia and bipolar mania; illegally promoted Risperdal as a safe and effective treatment for off-label uses, including depressive symptoms, major depressive disorder and PTSD; and minimized and/or covered up the risks of side effects posed to patients taking Risperdal as prescribed for such approved and non-approved uses.
- 26. At all relevant times, Defendants knew that Risperdal was defective and likely to cause gynecomastia, hyperprolactenemia and other medical problems.

- 27. At all relevant times, Defendants knew that Risperdal was no more effective and considerably less safe than other antipsychotic medications, yet Defendants engaged in an ongoing pattern of false and misleading conduct designed to increase Risperdal's perceived therapeutic and monetary value over cheaper, safer and more effective products.
- 28. Defendants failed to disclose to physicians, patients, and Plaintiffs, and those similarly situated, that Risperdal was likely to cause gynecomastia, hyperprolactenemia and other medical problems, and that patients taking Risperdal are more at much higher risk for these problems than patients taking similar medications.
- 29. Defendants continued to promote Risperdal as safe and effective despite patient reports of adverse events, FDA warnings regarding Risperdal's dangers, and FDA requests to modify the warning labels.
- 30. As a direct result of ingesting Risperdal/risperidone, Mr. Wasserman has suffered severe physical and emotional injuries, including but not limited to, gynecomastia, hyperprolactenemia, pain and swelling in his chest, pain in his testicles, testicular shrinkage, erectile dysfunction, diminished semen volume and sperm count, loss of sex drive, damage to endocrine functions, cellulitis, impaired motor skills, depression, dyssomnia, anxiety, embarrassment, social anxiety, difficulty with physical intimacy, difficulty concentrating, impaired thinking, fear, apprehension, despair, suicidality, and other emotional problems. He continues to suffer from many of these conditions.
- 31. Defendants failed to provide sufficient warnings and instructions that would have put Plaintiffs or the general public on notice of the dangers and adverse effects associated with Risperdal/risperidone, including, but not limited to gynecomastia, hyperprolactenemia and other medical problems.
- 32. Risperdal/risperidone was defective as marketed due to inaccurate warnings, instructions and labeling in light of Defendants' knowledge the product was likely to cause hyperprolactenemia, gynecomastia and other medical problems.

- 33. When Defendants promoted Risperdal for non-approved uses, Defendants denied physicians the opportunity to know that Risperdal was associated with endocrine abnormalities that were greater than disclosed in the drug's label.
- 34. Defendants manufactured and promoted Risperdal/risperidone for sale within the State of California and elsewhere.
- 35. Defendants promoted Risperdal to physicians and consumers within the State of California and elsewhere.
- 36. Defendants knew or should have known their false advertising and unlawful marketing activities in violation of the Fair Claims Act and other federal and state laws was likely to and did in fact cause physicians and consumers to rely on said advertising and marketing and take Risperdal/risperidone without adequate knowledge of its risks.
- 37. Defendants conducted an organized, coordinated, intentional and deliberate campaign to unlawfully market and promote off-label use of Risperdal/risperidone in spite of their knowledge of the risks associated therewith.
- 38. As a result of Defendants' unlawful actions, physicians and consumers were deceived into using Risperdal/risperidone in lieu of first generation antipsychotic medications ("FGAs") or other medications in spite of the fact that Risperdal carried additional dangerous side effects and cost approximately 40-50 times as much as equally or more effective FGAs.
- 39. Defendants sought to create the image, impression and belief among consumers and physicians that the use of Risperdal/risperidone was safe for humans, including children, and had fewer side effects and adverse reactions than other medications; Defendants engaged in this unlawful behavior despite knowing their representations were false and there was no reasonable basis to believe them to be true.
- 40. Defendants repeatedly disregarded FDA warnings not to market Risperdal beyond its FDA-approved uses and repeatedly promoted Risperdal as superior to other antipsychotics even after the FDA expressly forbid Defendants to do so and warned Defendants for infractions.

- 41. Defendants purposefully concealed, obfuscated, downplayed and understated the health hazards and risks associated with Risperdal and actively promoted its off-label use in violation of federal and California state law.
- 42. As a direct result of ingesting Risperdal/risperidone, Mr. Wasserman has suffered severe physical and emotional injuries, including but not limited to, gynecomastia, hyperprolactenemia, pain and swelling in his chest, pain in his testicles, testicular shrinkage, erectile dysfunction, diminished semen volume and sperm count, loss of sex drive, damage to endocrine functions, cellulitis, impaired motor skills, depression, dyssomnia, anxiety, embarrassment, social anxiety, difficulty with physical intimacy, difficulty concentrating, impaired thinking, fear, apprehension, despair, suicidality, and other emotional problems. He continues to suffer from many of these conditions.
- 43. Plaintiffs file this lawsuit within the applicable limitations period of first suspecting that said drug caused the appreciable harm sustained by Plaintiffs. Plaintiffs could not, by the exercise of reasonable diligence, have discovered the wrongful case of Plaintiffs' injuries at an earlier time because the injuries were unknown to Plaintiffs, and when the injuries were discovered their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that Plaintiff had been injured, the cause of the injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants herein misrepresented and continue to misrepresent to the public and to the medical profession that Risperdal is safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

#### **CLAIMS FOR RELIEF**

#### **FIRST CAUSE OF ACTION**

#### **NEGLIGENCE**

44. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

- 45. Defendants owed Plaintiff Andrew Wasserman a legal duty of care.
- 46. Defendants knew or should have known that there was a foreseeable risk that Plaintiff would suffer harmful side effects from Risperdal/risperidone and the resulting damages alleged herein.
  - 47. Defendants failed to act reasonably or with ordinary prudence.
- 48. It was reasonable for Plaintiff to rely on Defendants' representations as to the safety and effectiveness of Risperdal/risperidone and Plaintiffs did so rely.
- 49. But for Defendants' breach of duty owed to Plaintiff, and Plaintiff's detrimental reliance thereon, Plaintiffs would not have suffered the harm alleged herein.
- 50. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which he is entitled to compensatory, equitable and other lawfully available relief in an amount to be proven at trial.

# SECOND CAUSE OF ACTION BREACH OF EXPRESS WARRANTY

- 51. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
- 52. At all times mentioned herein, Defendants expressly warranted to Plaintiff
  Andrew Wasserman by and through statements made by Defendants or their authorized agents or
  sales representatives, orally and in publications, package inserts and other written materials
  intended for physicians, medical patients and the general public, that the aforementioned
  products were safe, effective, fit and proper for their intended use.
- 53. In utilizing the aforementioned products, Plaintiff relied on the skill, judgment, representations and foregoing express warranties of the Defendants, and each of them. Said warranties and representations were false in that the aforementioned products were not safe and were unfit for the uses for which they were intended.
- 54. As a result of the foregoing breach of express warranties by the Defendants, Plaintiff suffered injuries and damages as alleged herein.

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## THIRD CAUSE OF ACTION

#### **BREACH OF IMPLIED WARRANTY**

- 55. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
- 56. At all times mentioned herein, Defendants expressly warranted to Plaintiff
  Andrew Wasserman by and through statements made by Defendants or their authorized agents or
  sales representatives, orally and in publications, package inserts and other written materials
  intended for physicians, medical patients and the general public, that the aforementioned
  products were safe, effective, fit and proper for their intended use.
- 57. In utilizing the aforementioned products, Plaintiff relied on the skill, judgment, representations and foregoing express warranties of the Defendants, and each of them. Said warranties and representations were false in that the aforementioned products were not safe and were unfit for the uses for which they were intended.
- 58. As a result of the foregoing breach of express warranties by the Defendants, Plaintiff suffered injuries and damages as alleged herein.

#### FOURTH CAUSE OF ACTION

#### VIOLATION OF CAL. BUS. CODE § 17500, et seq.

- 59. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
- 60. At all times mentioned herein, Defendants expressly warranted to Plaintiff
  Andrew Wasserman by and through statements made by Defendants or their authorized agents or
  sales representatives, orally and in publications, package inserts and other written materials
  intended for physicians, medical patients and the general public, that the aforementioned
  products were safe, effective, fit and proper for their intended use.
- 61. In utilizing the aforementioned products, Plaintiff relied on the skill, judgment, representations and foregoing express warranties of the Defendants, and each of them. Said

warranties and representations were false in that the aforementioned products were not safe and were unfit for the uses for which they were intended.

62. As a result of the foregoing breach of express warranties by the Defendants, Plaintiff suffered injuries and damages as alleged herein.

#### FIFTH CAUSE OF ACTION

#### FRAUDULENT CONCEALMENT

- 63. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
- 64. Defendants and Plaintiff Andrew Wasserman were in a fiduciary relationship, wherein Defendants manufactured, supplier and actively promoted a dangerous and untested prescription drug to boys and young men.
- 65. Defendants intentionally concealed test results showing that the risks of serious side effects, in particular gynecomastia and hyperprolactinemia, were substantially higher for boys and young men taking Risperdal than for those taking similar medications.
- 66. Defendants were in the unique position to know that risks of serious side effects, in particular gynecomastia and hyperprolactinemia, were substantially higher for patients taking Risperdal than for patients taking similar medications.
- 67. Plaintiff did not know that Defendants knew that he risks of serious side effects, in particular gynecomastia and hyperprolactinemia, were substantially higher for boys and young men taking Risperdal than for those taking similar medications.
  - 68. Defendants intended to deceive Plaintiff by concealing these facts.
  - 69. Plaintiff reasonably relied on Defendants' assertions, as passed on by his doctors.
  - 70. Plaintiff was harmed by Defendants' fraudulent concealment.
  - 71. Defendants' concealment was a substantial factor in causing Plaintiff's harm.

#### SIXTH CAUSE OF ACTION

#### STRICT PRODUCTS LIABILITY-FAILURE TO WARN

72. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

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- 73. Plaintiffs claim that Risperdal lacked sufficient warnings of potential risks and side effects on boys and young men.
  - 74. Defendants manufactured and distributed Risperdal.
- 75. Risperdal had potential risks and side effects for boys and young men that were known or knowable in the light of scientific and/or medical knowledge that was generally accepted in the scientific and/or medical community at the relevant times when Defendants were manufacturing and distributing Risperdal to physicians for off-label use.
- 76 The potential risks and side effects presented a substantial danger when Risperdal is used or misused in an intended or reasonably foreseeable way.
- 77. The potential risks and side effects are not the type of risks and side effects that ordinary consumers would recognize.
- 78. Defendants ignored the potential risks and side effects when advising doctors of the benefits of Risperdal in boys and young men.
- 79. Due to the strict requirements established by the FDA for approving antipsychotic prescription drugs for any specific use, particularly in children more susceptible to adverse effects, Defendants knew that Risperdal was not approved for use in children, yet Defendants pushed this off-label use anyway; this is the risk-amelioration intended by compliance with the FDA regulations for approval of these types of drugs in all persons, especially children.
- 80. Defendants knew at all times that Risperdal was not approved by the FDA for use in children or for the off-label uses for which Defendants illegally marketed the drug.
  - 81. Defendants failed to adequately warn of the potential risks and side effects.
  - 82. Plaintiff was harmed.
- 83. The lack of sufficient instructions and warnings were substantial factors in causing Plaintiff's harm.

### SEVENTH CAUSE OF ACTION

#### **NEGLIGENCE-FAILURE TO WARN**

- 84. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
- 85. Plaintiffs claim that Defendants were negligent by not using reasonable care to warn about Risperdal's dangerous condition or about facts that made Risperdal likely to be dangerous.
  - 86. Defendants manufactured and distributed Risperdal from 1993 to present day.
- 87. Defendants knew or reasonably should have known that Risperdal was dangerous or was likely to be dangerous when used or misused in a reasonably foreseeable manner.
- 88. Defendants knew or reasonably should have known that users would not realize the danger.
- 89. Defendants failed to adequately warn of the danger or instruct on the safe use of Risperdal.
- 90. A reasonable manufacturer and distributor under the same or similar circumstance would have warned of the danger or instructed on the safe use of Risperdal.
  - 91. Plaintiff used Risperdal as instructed.
  - 92. Plaintiff was harmed.
  - 93. Defendants' failure to warn was a substantial factor in causing Plaintiff's harm.

#### EIGHTH CAUSE OF ACTION

#### **NEGLIGENCE PER SE**

- 94. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
- 95. Defendants violated inter alia Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., Cal. Civil Code §§ 1709 & 1770, Cal. Bus. & Prof. Code §§ 17200 et seq., 17500 et seq. and 4052 et seq., Cal. Civil Code § 1791 et seq. (Song-Beverly Consumer Warranty Act), 21 C.F.R. 99.101 et seq., and Cal. Health and Safety Code §§ 110390 and 110290.
  - 96. Defendants were not excused from complying with the aforementioned laws.

- 97. Defendants' violations of the aforementioned laws are, and each violation is, the proximate cause and substantial factor in causing Plaintiff Andrew Wasserman's harm.
- 98. Plaintiff's injuries are resulted from an occurrence of the nature, which the aforementioned laws were designed to prevent.
  - 99. Plaintiff is the type of individual the aforementioned laws are intended to protect.
- 100. Defendants' conducts substantially deviates from the standard of care an antipsychotic prescription drug manufacturer and distributor owes to children, giving rise to gross negligence or recklessness.

#### NINTH CAUSE OF ACTION

#### **NEGLIGENT MISREPRESENTATION**

- 101. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
- 102. Defendants represented to Plaintiff Andrew Wasserman, doctors and the wider medical community that Risperdal was safe for boys and adult men.
- 103. Defendants' representations were not true, as Defendants knew or reasonably should have known that the risks of serious side effects, in particular gynecomastia and hyperprolactinemia, were substantially higher for patients taking Risperdal than for patients taking similar medications, and that similar medications were equally or more effective without carrying such high risks.
- 104. Regardless of whether Defendants honestly believed that the representations were true, Defendants had no reasonable grounds for believing the representations were true when they made the statements.
  - 105. Defendants intended that Plaintiffs rely on the representations.
  - 106. Plaintiff reasonably relied on Defendants' representations.
- 107. Plaintiff's reliance on Defendants' representations was a substantial factor in causing his harm.

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### TENTH CAUSE OF ACTION

#### FALSE ADVERTISING

- 108. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
- 109. Defendants violated Cal. Bus. & Prof. Code s. 17500 et seq. by publicly making false and misleading statements in promotion and marketing Risperdal to California doctors and patients, including Plaintiff Andrew Wasserman.
- 110. Defendants knew or should have known through the exercise of reasonable care under the circumstances that the aforementioned statements were false and misleading as Defendants knew that the risks of serious side effects, in particular gynecomastia and hyperprolactinemia, were substantially higher for patients taking Risperdal than for patients taking similar medications, and that similar medications were equally or more effective without carrying such high risks.
- Defendants directly or indirectly disseminated false and misleading information 111. as a marketing scheme to increase Risperdal sales.
  - 112. Defendants' false advertising caused the proximate harm to Plaintiff.

#### **ELEVENTH CAUSE OF ACTION**

#### FRAUDULENT MISREPRESENTATION

- Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set 113. forth herein.
- 114. Defendants represented to Plaintiff Andrew Wasserman and/or his doctors that Risperdal is safe to treat schizophrenia and bipolar mania in boys and young men, and for offlabels uses.
- 115. Defendants knew at the time they made such representations that they were false as Defendants knew that the risks of serious side effects, in particular gynecomastia and hyperprolactinemia, were substantially higher for patients taking Risperdal than for patients taking similar medications, and that similar medications were equally or more effective without carrying such high risks. Defendants intended for Plaintiff to rely on their representations.

- 116. Plaintiff reasonably relied on Defendants' representations because Defendants are a famous producer of health products and prescription medication.
  - 117. Ingesting Risperdal harmed Plaintiff.
- 118. Plaintiff's reliance on Defendants' representations was a substantial factor in causing his harm.

#### TWELFTH CAUSE OF ACTION

#### **NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS**

- 119. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
- 120. Defendants were negligent in their promotion and marketing of Risperdal as safe as Defendants knew or reasonably should have known that the risks of serious side effects, in particular gynecomastia and hyperprolactinemia, were substantially higher for patients taking Risperdal than for patients taking similar medications, and that similar medications were equally or more effective without carrying such high risks.
- 121. Plaintiff Andrew Wasserman suffered serious emotional distress caused by his use of Risperdal/risperidone, both during the time he ingested it and continuing to present day, due to the many side effects and injuries he has suffered, in particular the breast growth that required a double mastectomy and the particular emotional distress of a young man faced with growing enlarged breasts and enduring physical deformation, frequent pain and discomfort, and diminished sexual functioning. These experiences caused Mr. Wasserman shame, humiliation, anxiety, depression, social isolation and other emotional injuries.
- 122. Defendants had a duty to provide safe prescription drugs to Mr. Wasserman or proper and adequate warnings of risks and side effects. Defendants were fiduciaries in the delivery of properly tested medication to young men like Mr. Wasserman.
- 123. Defendants' negligence was a substantial factor in causing Mr. Wasserman's serious emotional distress.
- 124. Defendants negligently caused serious injury to Mr. Wasserman by fraudulently promoting off-label use of Risperdal as safe for boys and young men.

- 125. During the time Mr. Wasserman ingested Risperdal, he became withdrawn and negative toward himself and others, including his mother, Plaintiff Mary Wasserman. He suffered many of the physical and emotional injuries caused by his ingestion of Risperdal in front of his mother. Mrs. Wasserman personally witnessed the torment that Risperdal caused her son and the devastating impact it had on his relationship with her and his disposition in general.
- 126. Mrs. Wasserman was aware of the injuries and conditions her son was suffering from taking Risperdal, but was ignorant of their cause.
- 127. As a proximate result of Mr. Wasserman ingesting Risperdal, Mrs. Wasserman suffered serious emotional distress, including without limitation horror, anguish, fright, anxiety and grief.
- 128. Ms. Wasserman's serious emotions distress was beyond that which would be anticipated in a disinterested witness.
- 129. Defendants' conduct was a substantial factor in causing Mrs. Wasserman's serious emotions distress.

#### **THIRTEENTH CAUSE OF ACTION**

## INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

- 130. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
- 131. Defendants' conduct of manufacturing, distributing, marketing or promoting the use of Risperdal in boys and adult men as safe for approved and off-label uses while concealing information to the contrary is outrageous conduct.
- 132. Defendants acted with reckless disregard of the probability that Plaintiff Andrew Wasserman would suffer emotional distress, knowing he would rely on Defendants to provide his doctors accurate information about Risperdal's risks and side effects, and causing him to ingest Risperdal without knowing those risks and side effects.
  - 133. Plaintiff suffered severe emotional distress during the time he ingested Risperdal.
- 134. Defendants' conduct was a substantial factor in causing Plaintiff's severe emotional distress.

PRAYER FOR RELIEF 1 2 WHEREFORE, Plaintiffs request judgment against Defendants as follows: 3 1. Economic and non-economic damages in an amount exceeding \$75,000 as provided by law and supported by the evidence at trial; 4 Compensatory and punitive damages; 5 2. Attorneys' fees and costs; 3. 6 Prejudgment interests and costs; and 4. 7 Such other and further relief, including equitable relief, as the Court may deem 5. 8 just and proper. 9 **DEMAND FOR JURY TRIAL** 10 Plaintiffs demand trial by jury in this action of all issues so triable. 11 12 13 Dated: June 16, 2014 LAW OFFICE OF AARON MYERS 14 /s/ Aaron Myers 15 Aaron Myers 16 18111 Dorcich Ct. Saratoga, CA 95070 17 Tel: (415) 710-3783 Fax: (415) 493-0001 18 Email: aaronmyerslaw@gmail.com 19 Attorneys for Plaintiffs Andrew 20 Wasserman and Mary Wasserman 21 22 23 24 25 26 27 28

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# ${\it Case 3:} 14\text{-cv-}02729 {\it VPocument 1} {\it Spile 106}/12/14 \quad {\it Page 1 of 1}$

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil decket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

purpose of initiating the civil de	ocket sheet. (SEE INSTRUCTIONS ON NEXT PA	GE OF THIS F	ORM.)	774, is required for the use of	the Clerk of Court for the			
I. (a) PLAINTIFFS Andrew Wasserm	an and Mary Wasserman		DEFENDANTS Janssen Pharmaceuticals, Inc., Johnson & Johnson, Janssen Research and Development, LLC, and Does 1-5					
(b) County of Residence of First Listed Plaintiff San Francisco, Cali: (EXCEPT IN U.S. PLAINTIFF CASES)			County of Residence of First Listed Defendant Mercer, New Jersey (IN U.S. PLAINTIFF CASES ONLY)					
(E)	CEFT IN U.S. FLAINTIFF CASES)		NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.					
Aaron Myers (CBN 20 Law Office of Aaron 1 1811 Dorcich Court Saratoga, CA 95070 Tel.: (415) 710-3783	Myers		Attorneys (If Known) unknown					
II. BASIS OF JURISDICTION (Place an "X" in One Box Only)  III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff								
☐ 1 U.S. Government Plaintiff	☐ 3 Federal Question (U.S. Government Not a Party)	Citi	(For Diversity Cases Only) PT zen of This State					
2 U.S. Government Defendant	☑ 4 Diversity (Indicate Citizenship of Parties in Item III)	Citi	zen of Another State	2				
Citizen or Subject of a 3 Foreign Nation 6 Foreign Country								
IV. NATURE OF SUIT	(Place an "X" in One Box Only) TORTS	T	CODERTUDE/DENALTY	DANIZDUDTOV	OTHER STATUTES			
110 Insurance	PERSONAL INJURY PERSONAL IN		625 Drug Related Seizure	BANKRUPTCY  422 Appeal 28 USC 158	OTHER STATUTES  375 False Claims Act			
☐ 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	☐ 310 Airplane ☐ 365 Personal Inj ☐ 315 Airplane Product ☐ Liability ☐ 367 Health Care ☐ 320 Assault, Libel & Pharmaceut	ury - bility	of Property 21 USC 881 590 Other  LABOR 710 Fair Labor Standards Act 720 Labor/Management Relations 740 Railway Labor Act 751 Family and Medical Leave Act	□ 423 Withdrawal 28 USC 157  PROPERTY RIGHTS □ 820 Copyrights □ 830 Patent □ 840 Trademark  SOCIAL SECURITY □ 861 HIA (1395ff) □ 862 Black Lung (923) □ 863 DIWC/DIWW (405(g)) □ 864 SSID Title XVI □ 865 RSI (405(g))	□ 400 State Reapportionment □ 410 Antitrust □ 430 Banks and Banking □ 450 Commerce □ 460 Deportation □ 470 Racketeer Influenced and Corrupt Organizations □ 480 Consumer Credit □ 490 Cable/Sat TV □ 850 Securities/Commodities/ Exchange □ 890 Other Statutory Actions □ 891 Agricultural Acts □ 893 Environmental Matters □ 895 Freedom of Information Act			
REAL PROPERTY	Medical Malpractice  CIVIL RIGHTS PRISONER PET		790 Other Labor Litigation 791 Employee Retirement	FEDERAL TAX SUITS	☐ 896 Arbitration ☐ 899 Administrative Procedure			
□ 210 Land Condemnation □ 220 Foreclosure □ 230 Rent Lease & Ejectment □ 240 Torts to Land □ 245 Tort Product Liability □ 290 All Other Real Property	□ 440 Other Civil Rights □ 441 Voting □ 442 Employment □ 443 Housing/ Accommodations □ 445 Amer. w/Disabilities Employment □ 446 Amer. w/Disabilities Other □ 448 Education □ 448 Education □ 550 Civil Rights Conditions of Confinement	ty 4  & Other 4  litition lee -	Income Security Act  IMMIGRATION  462 Naturalization Application  465 Other Immigration  Actions	□ 870 Taxes (U.S. Plaintiff or Defendant) □ 871 IRS—Third Party 26 USC 7609	Act/Review or Appeal of Agency Decision  950 Constitutionality of State Statutes			
V. ORIGIN (Place an "X" in One Box Only)  1 Original Proceeding 2 Removed from Proceeding State Court 3 Remanded from Appellate Court 4 Reinstated or Reopened 5 Transferred from 6 Multidistrict Another District (specify)								
VI. CAUSE OF	Cite the U.S. Civil Statute under which you 28 U.S.C. 1332 (diversity)	are filing (1	Do not cite jurisdictional statut	tes unless diversity):				
ACTION  Brief description of cause: Prescription drug product liability								
VII. REQUESTED IN COMPLAINT: CHECK IF THIS IS A CLASS ACTIO UNDER RULE 23, F.R.Cv.P.			DEMAND \$ CHECK YES only if demanded in complaint:  JURY DEMAND: ☑ Yes ☐ No					
VIII. RELATED CASE(S) IF ANY    See instructions): JUDGE   DOCKET NUMBER								
IX. DIVISIONAL ASSIGNMENT (Civil L.R. 3-2)								
(Place an "X" in One Box Only) (x) SAN FRANCISCO/OAKLAND () SAN JOSE () EUREKA								
DATE SIGNATURE OF ATTORNEY OF RECORD								
6/12/2014	/s/ Aaron Myer	S						