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Wasserman and Mary Wasserman

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ANDREW WASSERMAN and MARY
WASSERMAN,

Plaintiffs,

vs.

JANSSEN PHARMACEUTICALS, INC.,
JOHNSON & JOHNSON, JANSSEN
RESEARCH AND DEVELOPMENT, LLC,
and DOES 1-5,

Defendants

Case No. _____

COMPLAINT

JURY TRIAL DEMANDED

Plaintiffs Andrew Wasserman and his mother, Mary Wasserman, by and through their undersigned counsel, based upon personal knowledge and the investigation of their counsel, hereby sue Defendants Janssen Pharmaceuticals, Inc., Janssen L.P. (collectively, "Janssen"), Johnson & Johnson (J&J), Janssen Research and Development, LLC ("JRD"), and Does 1-5 (cumulatively, "Defendants"), and allege:

INTRODUCTION AND SUMMARY OF ACTION

1. This case involves the unreasonably dangerous and mislabeled drug Risperdal (generic, risperidone) that Defendants manufactured, distributed, promoted and sold.

COMPLAINT

1 2. Defendants misrepresented that Risperdal is a safe and effective treatment for
2 schizophrenia and bipolar mania. In fact, Defendants knew the drug causes a host of serious side
3 effects, including the growth of enlarged breasts in boys and men, known as gynecomastia; and
4 hyperprolactinemia, the presence of abnormally high levels of prolactin (a hormone that
5 stimulates breast development and milk production in women), which has been linked to
6 gynecomastia, erectile dysfunction, infertility and other hormonal and sexual disorders in men.

7 3. Defendants failed to adequately warn doctors and consumers about these risks,
8 misrepresented the degree of risk, dismissed the severity of Risperdal-caused hyperprolactinemia
9 and gynecomastia, and even claimed that breast development in boys taking Risperdal is normal.

10 4. Defendants also engaged in an aggressive, illegal marketing campaign to promote
11 Risperdal for “off-label” uses, i.e., uses not approved as safe and effective by the U.S. Food and
12 Drug Administration (“FDA”), including the treatment of anxiety, depression and other mood
13 disorders. Defendants paid kickbacks to doctors and pharmacists, produced sham studies and
14 seeded the medical literature with ghostwritten articles promoting off-label uses.

15 5. As a result of Defendants’ illegal marketing campaign, sales skyrocketed. While
16 in 1993, J&J predicted it would take seven years for Risperdal to reach \$295 million in annual
17 sales, Risperdal sales hit \$343 million in less than two years. By 1997, Risperdal sales had
18 increased to \$589 million, making it the top selling antipsychotic drug on the market.

19 6. Defendants’ illegal activity soon drew the attention of the FDA. In 1999 and
20 again in 2004, the FDA warned Defendants it was unlawfully promoting Risperdal for
21 unapproved uses and was publishing false and misleading promotional materials by omitting
22 material information, minimizing potentially fatal risks and claiming the drug is safer than other
23 atypical antipsychotics without adequate substantiation.

24 7. Defendants ignored the FDA’s warnings. Defendants’ refusal to stop the off-
25 label promotion of Risperdal was directly related to their bottom line. J&J’s Risperdal sales for
26 2006 topped \$4.2 billion, an increase of over 17.8% over 2005. In 2007, J&J’s antipsychotics
27 franchise (primarily Risperdal) achieved sales of \$4.7 billion, an increase of 12.3% over 2006.
28 From 2003 through 2009, J&J’s revenues from Risperdal exceeded \$23.6 billion.

1 8. Defendants' illegal business practices spurred whistleblowers and investigations
2 across the country. In 2010, 2011 and 2012, judges in Louisiana, South Carolina and Arkansas
3 ordered J&J and/or Janssen to pay \$330 million, \$327 million and \$1.1 billion, respectively, after
4 juries found Defendants violated unfair trade practices laws and/or defrauded the states'
5 Medicaid systems by fraudulently exaggerating Risperdal's efficacy, illegally marketing it for
6 off-label uses, and concealing and downplaying its risks of side effects, including
7 hyperprolactinemia.

8 9. In 2012, Defendants agreed to pay more than \$2.2 billion – the largest health care
9 fraud settlement in the nation's history – to settle federal and state charges that Defendants used
10 deceptive marketing and kickbacks to promote Risperdal. The agreement included \$181 million
11 in civil fines to settle allegations Defendants illegally marketed Risperdal for off-label uses in
12 children and concealed its risks of side effects, including gynecomastia.

13 10. Plaintiff Andrew Wasserman was prescribed and took Risperdal at various times
14 from 2008 to 2013 beginning at the age of 20. During that time he developed enlarged breasts,
15 causing him severe psychological trauma and leading him to undergo a double mastectomy in
16 2011, at the age of 24. These horrific experiences scarred him for life. He also experienced
17 other side effects and injuries from taking Risperdal, including pain and swelling in his chest,
18 pain in his testicles, testicular shrinkage, erectile dysfunction, diminished semen volume and
19 sperm count (and likely infertility), loss of sex drive, damage to endocrine functions,
20 gastrointestinal problems, cellulitis (severe inflammation), impaired motor skills, depression,
21 dyssomnia (difficulty getting to sleep and staying asleep and intermittent wakefulness during the
22 night), anxiety, embarrassment, social anxiety, difficulty with physical intimacy, difficulty
23 concentrating, impaired thinking, fear, apprehension, despair, suicidality, and other emotional
24 problems. He continues to suffer from many of these conditions.

25 11. Plaintiffs bring this action for strict liability, negligence, negligence *per se*, false
26 advertising, fraudulent concealment, fraudulent misrepresentation, failure to warn, breach of
27 express and implied warranties, unfair business practices, intentional infliction of emotional
28 distress and negligent infliction of emotional distress. This action is based upon Defendants'

violations of the laws of the United States and of the State of California, including but not limited to 21 U.S.C. § 321, et seq. (the Food, Drug, and Cosmetic Act); 31 U.S.C. §§ 3729-33 and 3730(b)(1) (the False Claims Act); 21 C.F.R. 99, 200-202, 312 and 314 (federal regulations re off-label promotion); 42 U.S.C. § 1320a7b(b) (federal anti-kickback statute); 15 U.S.C. § 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), California Business and Professions Code § 17200, et seq. and § 17500; and other applicable federal and California state requirements, in the marketing and distribution of the defective and unreasonably dangerous drug Risperdal. Plaintiffs seek compensatory and punitive damages for the physical, psychological, pecuniary and related injuries for which Defendants are liable.

JURISDICTION

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 availing 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. Janssen 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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COMPLAINT

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.

1 27. At all relevant times, Defendants knew that Risperdal was no more effective and
2 considerably less safe than other antipsychotic medications, yet Defendants engaged in an
3 ongoing pattern of false and misleading conduct designed to increase Risperdal's perceived
4 therapeutic and monetary value over cheaper, safer and more effective products.

5 28. Defendants failed to disclose to physicians, patients, and Plaintiffs, and those
6 similarly situated, that Risperdal was likely to cause gynecomastia, hyperprolactenemia and
7 other medical problems, and that patients taking Risperdal are more at much higher risk for these
8 problems than patients taking similar medications.

9 29. Defendants continued to promote Risperdal as safe and effective despite patient
10 reports of adverse events, FDA warnings regarding Risperdal's dangers, and FDA requests to
11 modify the warning labels.

12 30. As a direct result of ingesting Risperdal/risperidone, Mr. Wasserman has suffered
13 severe physical and emotional injuries, including but not limited to, gynecomastia,
14 hyperprolactenemia, pain and swelling in his chest, pain in his testicles, testicular shrinkage,
15 erectile dysfunction, diminished semen volume and sperm count, loss of sex drive, damage to
16 endocrine functions, cellulitis, impaired motor skills, depression, dyssomnia, anxiety,
17 embarrassment, social anxiety, difficulty with physical intimacy, difficulty concentrating,
18 impaired thinking, fear, apprehension, despair, suicidality, and other emotional problems. He
19 continues to suffer from many of these conditions.

20 31. Defendants failed to provide sufficient warnings and instructions that would have
21 put Plaintiffs or the general public on notice of the dangers and adverse effects associated with
22 Risperdal/risperidone, including, but not limited to gynecomastia, hyperprolactenemia and other
23 medical problems.

24 32. Risperdal/risperidone was defective as marketed due to inaccurate warnings,
25 instructions and labeling in light of Defendants' knowledge the product was likely to cause
26 hyperprolactenemia, gynecomastia and other medical problems.

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1 33. When Defendants promoted Risperdal for non-approved uses, Defendants denied
2 physicians the opportunity to know that Risperdal was associated with endocrine abnormalities
3 that were greater than disclosed in the drug's label.

4 34. Defendants manufactured and promoted Risperdal/risperidone for sale within the
5 State of California and elsewhere.

6 35. Defendants promoted Risperdal to physicians and consumers within the State of
7 California and elsewhere.

8 36. Defendants knew or should have known their false advertising and unlawful
9 marketing activities in violation of the Fair Claims Act and other federal and state laws was
10 likely to and did in fact cause physicians and consumers to rely on said advertising and
11 marketing and take Risperdal/risperidone without adequate knowledge of its risks.

12 37. Defendants conducted an organized, coordinated, intentional and deliberate
13 campaign to unlawfully market and promote off-label use of Risperdal/risperidone in spite of
14 their knowledge of the risks associated therewith.

15 38. As a result of Defendants' unlawful actions, physicians and consumers were
16 deceived into using Risperdal/risperidone in lieu of first generation antipsychotic medications
17 ("FGAs") or other medications in spite of the fact that Risperdal carried additional dangerous
18 side effects and cost approximately 40-50 times as much as equally or more effective FGAs.

19 39. Defendants sought to create the image, impression and belief among consumers
20 and physicians that the use of Risperdal/risperidone was safe for humans, including children, and
21 had fewer side effects and adverse reactions than other medications; Defendants engaged in this
22 unlawful behavior despite knowing their representations were false and there was no reasonable
23 basis to believe them to be true.

24 40. Defendants repeatedly disregarded FDA warnings not to market Risperdal beyond
25 its FDA-approved uses and repeatedly promoted Risperdal as superior to other antipsychotics
26 even after the FDA expressly forbid Defendants to do so and warned Defendants for infractions.

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1 41. Defendants purposefully concealed, obfuscated, downplayed and understated the
2 health hazards and risks associated with Risperdal and actively promoted its off-label use in
3 violation of federal and California state law.

4 42. As a direct result of ingesting Risperdal/risperidone, Mr. Wasserman has suffered
5 severe physical and emotional injuries, including but not limited to, gynecomastia,
6 hyperprolactenemia, pain and swelling in his chest, pain in his testicles, testicular shrinkage,
7 erectile dysfunction, diminished semen volume and sperm count, loss of sex drive, damage to
8 endocrine functions, cellulitis, impaired motor skills, depression, dyssomnia, anxiety,
9 embarrassment, social anxiety, difficulty with physical intimacy, difficulty concentrating,
10 impaired thinking, fear, apprehension, despair, suicidality, and other emotional problems. He
11 continues to suffer from many of these conditions.

12 43. Plaintiffs file this lawsuit within the applicable limitations period of first
13 suspecting that said drug caused the appreciable harm sustained by Plaintiffs. Plaintiffs could
14 not, by the exercise of reasonable diligence, have discovered the wrongful case of Plaintiffs'
15 injuries at an earlier time because the injuries were unknown to Plaintiffs, and when the injuries
16 were discovered their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff
17 have reason to suspect, that Plaintiff had been injured, the cause of the injuries, or the tortious
18 nature of the conduct causing the injuries, until less than the applicable limitations period prior to
19 the filing of this action. Additionally, Plaintiff was prevented from discovering this information
20 sooner because Defendants herein misrepresented and continue to misrepresent to the public and
21 to the medical profession that Risperdal is safe and free from serious side effects, and Defendants
22 have fraudulently concealed facts and information that could have led Plaintiff to discover a
23 potential cause of action.

24 **CLAIMS FOR RELIEF**

25 **FIRST CAUSE OF ACTION**

26 **NEGLIGENCE**

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

COMPLAINT

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.

COMPLAINT

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, supplied 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 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.

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.

1 73. Plaintiffs claim that Risperdal lacked sufficient warnings of potential risks and
2 side effects on boys and young men.

3 74. Defendants manufactured and distributed Risperdal.

4 75. Risperdal had potential risks and side effects for boys and young men that were
5 known or knowable in the light of scientific and/or medical knowledge that was generally
6 accepted in the scientific and/or medical community at the relevant times when Defendants were
7 manufacturing and distributing Risperdal to physicians for off-label use.

8 76. The potential risks and side effects presented a substantial danger when Risperdal
9 is used or misused in an intended or reasonably foreseeable way.

10 77. The potential risks and side effects are not the type of risks and side effects that
11 ordinary consumers would recognize.

12 78. Defendants ignored the potential risks and side effects when advising doctors of
13 the benefits of Risperdal in boys and young men.

14 79. Due to the strict requirements established by the FDA for approving anti-
15 psychotic prescription drugs for any specific use, particularly in children more susceptible to
16 adverse effects, Defendants knew that Risperdal was not approved for use in children, yet
17 Defendants pushed this off-label use anyway; this is the risk-amelioration intended by
18 compliance with the FDA regulations for approval of these types of drugs in all persons,
19 especially children.

20 80. Defendants knew at all times that Risperdal was not approved by the FDA for use
21 in children or for the off-label uses for which Defendants illegally marketed the drug.

22 81. Defendants failed to adequately warn of the potential risks and side effects.

23 82. Plaintiff was harmed.

24 83. The lack of sufficient instructions and warnings were substantial factors in
25 causing Plaintiff's harm.

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COMPLAINT

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.

COMPLAINT

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 anti-psychotic 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.

111. Defendants directly or indirectly disseminated false and misleading information as a marketing scheme to increase Risperdal sales.

112. Defendants' false advertising caused the proximate harm to Plaintiff.

ELEVENTH CAUSE OF ACTION

FRAUDULENT MISREPRESENTATION

113. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set 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 off-labels 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.

1 116. Plaintiff reasonably relied on Defendants' representations because Defendants are
2 a famous producer of health products and prescription medication.

3 117. Ingesting Risperdal harmed Plaintiff.

4 118. Plaintiff's reliance on Defendants' representations was a substantial factor in
5 causing his harm.

6 **TWELFTH CAUSE OF ACTION**

7 **NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS**

8 119. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set
9 forth herein.

10 120. Defendants were negligent in their promotion and marketing of Risperdal as safe
11 as Defendants knew or reasonably should have known that the risks of serious side effects, in
12 particular gynecomastia and hyperprolactinemia, were substantially higher for patients taking
13 Risperdal than for patients taking similar medications, and that similar medications were equally
14 or more effective without carrying such high risks.

15 121. Plaintiff Andrew Wasserman suffered serious emotional distress caused by his use
16 of Risperdal/risperidone, both during the time he ingested it and continuing to present day, due to
17 the many side effects and injuries he has suffered, in particular the breast growth that required a
18 double mastectomy and the particular emotional distress of a young man faced with growing
19 enlarged breasts and enduring physical deformation, frequent pain and discomfort, and
20 diminished sexual functioning. These experiences caused Mr. Wasserman shame, humiliation,
21 anxiety, depression, social isolation and other emotional injuries.

22 122. Defendants had a duty to provide safe prescription drugs to Mr. Wasserman or
23 proper and adequate warnings of risks and side effects. Defendants were fiduciaries in the
24 delivery of properly tested medication to young men like Mr. Wasserman.

25 123. Defendants' negligence was a substantial factor in causing Mr. Wasserman's
26 serious emotional distress.

27 124. Defendants negligently caused serious injury to Mr. Wasserman by fraudulently
28 promoting off-label use of Risperdal as safe for boys and young men.

1 125. During the time Mr. Wasserman ingested Risperdal, he became withdrawn and
2 negative toward himself and others, including his mother, Plaintiff Mary Wasserman. He
3 suffered many of the physical and emotional injuries caused by his ingestion of Risperdal in
4 front of his mother. Mrs. Wasserman personally witnessed the torment that Risperdal caused her
5 son and the devastating impact it had on his relationship with her and his disposition in general.

6 126. Mrs. Wasserman was aware of the injuries and conditions her son was suffering
7 from taking Risperdal, but was ignorant of their cause.

8 127. As a proximate result of Mr. Wasserman ingesting Risperdal, Mrs. Wasserman
9 suffered serious emotional distress, including without limitation horror, anguish, fright, anxiety
10 and grief.

11 128. Ms. Wasserman's serious emotions distress was beyond that which would be
12 anticipated in a disinterested witness.

13 129. Defendants' conduct was a substantial factor in causing Mrs. Wasserman's
14 serious emotions distress.

15 **THIRTEENTH CAUSE OF ACTION**

16 **INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS**

17 130. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set
18 forth herein.

19 131. Defendants' conduct of manufacturing, distributing, marketing or promoting the
20 use of Risperdal in boys and adult men as safe for approved and off-label uses while concealing
21 information to the contrary is outrageous conduct.

22 132. Defendants acted with reckless disregard of the probability that Plaintiff Andrew
23 Wasserman would suffer emotional distress, knowing he would rely on Defendants to provide
24 his doctors accurate information about Risperdal's risks and side effects, and causing him to
25 ingest Risperdal without knowing those risks and side effects.

26 133. Plaintiff suffered severe emotional distress during the time he ingested Risperdal.

27 134. Defendants' conduct was a substantial factor in causing Plaintiff's severe
28 emotional distress.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request judgment against Defendants as follows:

1. Economic and non-economic damages in an amount exceeding \$75,000 as provided by law and supported by the evidence at trial;
2. Compensatory and punitive damages;
3. Attorneys' fees and costs;
4. Prejudgment interests and costs; and
5. Such other and further relief, including equitable relief, as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand trial by jury in this action of all issues so triable.

Dated: June 16, 2014

LAW OFFICE OF AARON MYERS

/s/ Aaron Myers

Aaron Myers
18111 Dorcich Ct.
Saratoga, CA 95070
Tel: (415) 710-3783
Fax: (415) 493-0001
Email: aaronmyerslaw@gmail.com

*Attorneys for Plaintiffs Andrew
Wasserman and Mary Wasserman*

CIVIL COVER SHEET

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 docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

Andrew Wasserman and Mary Wasserman

(b) County of Residence of First Listed Plaintiff San Francisco, California
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)
Aaron Myers (CBN 200145)
Law Office of Aaron Myers
18111 Dorcich Court
Saratoga, CA 95070
Tel.: (415) 710-3783

DEFENDANTS

Janssen Pharmaceuticals, Inc., Johnson & Johnson, Janssen Research and Development, LLC, and Does 1-5

County of Residence of First Listed Defendant Mercer, New Jersey
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)
unknown

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

- ☐ 1 U.S. Government Plaintiff ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

	PTF	DEF		PTF	DEF
Citizen of This State	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4
Citizen of Another State	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input checked="" type="checkbox"/> 5
Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6

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

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice PERSONAL INJURY <input type="checkbox"/> 365 Personal Injury - Product Liability <input checked="" type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities Employment <input type="checkbox"/> 446 Amer. w/Disabilities Other <input type="checkbox"/> 448 Education PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

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

- ☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District (specify) ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
28 U.S.C. 1332 (diversity)
Brief description of cause:
Prescription drug product liability

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION 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 Myers