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**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA**

9 BENJAMIN A. VERKEST and LORI L.
10 MCKEE-CALLANAN,

11 Plaintiffs,

12 vs.

13 JANSSEN PHARMACEUTICALS, INC.
14 also known as ORTHO-NCNEIL-
15 JANSSEN PHARMACEUTICALS,
16 INC.; JANSSEN PHARMACEUTICA,
17 INC.; JANSSEN LP; JOHNSON &
18 JOHNSON, INC., JOHNSON &
19 JOHNSON PHARMACEUTICAL
20 RESEARCH AND DEVELOPMENT,
21 LLC, and "JOHN DOE" 1-5 (said names
22 being fictitious, as the true names are
23 presently unknown), in their individual
24 and official capacities,

25 Defendants.

Case No. '14CV0106 JM JMA

COMPLAINT

JURY TRIAL DEMANDED

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PRELIMINARY STATEMENT

1. Plaintiff Benjamin A. Verkest and his mother, Plaintiff Lori L. McKee Callanan ("Plaintiffs"), by and through their undersigned counsel, 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, negligent infliction of emotional distress, intentional infliction of emotional distress, and reckless endangerment.

1 This action is based upon Defendants' violations of the laws of the United States
2 and of the State of California, including, but not limited to, 21 U.S.C. § 321, et seq.
3 (the Federal Food, Drug, and Cosmetic Act), 31 U.S.C. §§ 3729-33; 3730(b)(1)
4 (the False Claims Act), the Code of Federal Regulations (off-label promotion), 42
5 U.S.C. 1320a7b(b) (the federal anti-kickback statute), Section 13(b)(2)(A)(B) of
6 the Securities and Exchange Act (15 U.S.C. § 78m(b)(2)(A)(B)), 21 U.S.C. §§
7 331(a), 333(a)(1) and 352(f)(1)) (introduction of misbranded drugs into interstate
8 commerce), California Business and Professions Code § 17200, *et seq.* and §
9 17500, and other applicable federal and California state requirements, in the
10 manufacture, marketing and distribution of a defective and unreasonably
11 dangerous medication, *to wit*, Risperdal, which is also known by the generic name
12 risperidone (hereinafter "Risperdal" or "Risperdal/risperidone"). Plaintiffs seek
13 compensatory, equitable, injunctive, punitive, and declaratory relief for the
14 debilitating physical, psychological, pecuniary and related injuries for which
15 Defendants are liable. Based upon personal knowledge and upon the investigation
16 of their counsel, Plaintiffs respectfully allege the following:

17 2. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332
18 because there is complete diversity of citizenship between Plaintiffs and each
19 Defendant and because the amount in controversy exceeds \$75,000.00. This Court
20 has personal jurisdiction over each Defendant pursuant to federal law and Cal.
21 Code Civ. Proc. §410.10 due to Defendants' substantial, continuous and systematic
22 presence and activity in California and due to Defendants' purposeful availment of
23 the laws and privileges associated therewith.

24 3. Venue is properly laid in the United States District Court for the
25 Southern District of California pursuant to 28 U.S.C. §1391(a) because the events
26 giving rise to the claims alleged herein substantially occurred within the
27 geographical boundaries of the District.

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1 4. This action arises in connection with Defendants' unlawful marketing
2 and promotion of the defective and unreasonably dangerous prescription
3 medication Risperdal, which was taken by Plaintiff Verkest from 1997 to 2001. As
4 a proximate result of Defendants' unlawful actions, Plaintiff Verkest suffered
5 serious and debilitating physical, psychological, pecuniary and related injuries,
6 including permanent disfigurement, significant and severe weight gain, diabetes
7 mellitus, hyperglycemia, hyperprolactinemia, enuresis, damage to his sexual and
8 endocrine functions, gynecomastia, impaired motor skills, dyssomnia, anxiety,
9 embarrassment, difficulty concentrating, agitation, and impaired thinking, medical
10 expenses, lost and/or diminished earning capacity and psychological trauma.
11 Furthermore, as a proximate result of Defendants' unlawful actions, Plaintiff
12 McKee-Callanan suffered various damages including, but not limited to, severe
13 emotional distress, lost wages, inconvenience, medical expenses, and other
14 damages. Plaintiffs seek, *inter alia*, compensatory, equitable, injunctive, punitive
15 and declaratory relief for their injuries.

16 **BACKGROUND**

17 5. Plaintiff Benjamin A. Verkest is a 22 year old male, and a resident
18 and citizen of the City of San Marcos, County of San Diego, and State of
19 California. Plaintiff Lori L. McKee-Callanan is the biological mother of Plaintiff
20 Verkest, and was at all times relevant hereto Plaintiff's Verkest's natural and legal
21 parent and guardian.

22 6. At all times relevant to the acts alleged herein, Plaintiffs resided
23 within the geographic confines of the Southern District of California.

24 7. Plaintiff Verkest resides with his mother Plaintiff McKee-Callanan,
25 and additional family members.

26 8. In or about 1996, at about five years of age, Plaintiff Verkest began
27 experiencing behavioral and psychological issues.

1 9. In or about November of 1997, at about six years of age, Plaintiff
2 Verkest was prescribed and began to use Risperdal; Plaintiff continued to use
3 Risperdal until approximately April of 2001, roughly one month before his tenth
4 birthday.

5 10. During the time period that Plaintiff Verkest took Risperdal from
6 1997 to 2001, he experienced numerous serious side effects, including significant
7 weight gain, enlarged nipples, and development of enlarged breasts.

8 11. Upon discontinuing Risperdal in or about April of 2001, Plaintiff
9 Verkest experienced numerous deleterious effects, including increased aggression,
10 acting out, and other emotional and behavioral problems.

11 12. Plaintiff Verkest has continued to experience negative effects
12 resulting from his use of Risperdal from 2001 to the present, including
13 gynecomastia, delayed onset of puberty, delayed and/or incomplete sexual
14 development, impaired motor skills, dyssomnia, enuresis, diabetes and/or
15 diabetes-related symptoms, and other physical health issues and emotional
16 disturbances.

17 13. Defendant Johnson & Johnson, Inc. ("J&J") is a New Jersey
18 corporation with its principal place of business in New Jersey. Defendant J&J
19 manufactures, markets, and sells a wide range of pharmaceutical, medical and
20 related products. J&J is qualified to do business in California and does business in
21 California.

22 14. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc., also known
23 as Janssen Pharmaceutica, Inc., and/or Janssen, LP, ("OMJPI") is a Pennsylvania
24 corporation with its principal place of business in New Jersey.

25 15. Defendant Johnson & Johnson Pharmaceutical Research and
26 Development, LLC ("J&JPRD") is a New Jersey limited liability company, whose
27 sole member is Centocor Research & Development, Inc., a Pennsylvania
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1 corporation with its principal place of business in Pennsylvania. Medtronic Puerto
2 Rico Operations Co. is a wholly-owned subsidiary of Defendant Medtronic, Inc.,
3 existing by virtue of the laws of the Cayman Islands, with its principal place of
4 business at Road 149, km 56.3, Box 6001, Villalba, PR.

5 16. Defendants "John Doe" 1-5 are directors, officers, managers,
6 employees, agents, contractors, subsidiaries and/or closely related entities of the
7 named and/or their subsidiaries who, at all times relevant to the allegations herein,
8 acted within the scope of their authority and on behalf of the other Defendants.

9 **FACTUAL ALLEGATIONS**

10 17. At all times relevant hereto, Defendants owned a patent on the
11 prescription drug Risperdal, which was approved by the Federal Food and Drug
12 Administration ("FDA") in or around 1993. Defendants did during such times
13 manufacture, create, design, test, label, sterilize, distribute, supply, prescribe,
14 market, sell, advertise, purport to warn, purport to consult, and otherwise distribute
15 in interstate commerce and in the State of California the product known as
16 Risperdal.

17 18. In or about 1997 and thereafter, Defendants made false and
18 misleading statements about the safety, cost and effectiveness of Risperdal and
19 improperly influenced doctors and officials to promote and prescribe the
20 medication.

21 19. In or about 1999, Defendants received a warning letter from the FDA
22 regarding marketing Risperdal in a manner that was misleading, false and lacking
23 in fair balance.

24 20. In or about 2001, Defendants were required by the FDA to change the
25 labeling of Risperdal to include a statement that the safety and effectiveness of the
26 drug in children had not been established.

27 21. Documents released in connection with settlements, judgments and
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1 plea agreements reached with the U.S. Department of Justice and various state
2 attorneys general reflect that Defendants have concealed and/or minimized
3 Risperdal's side effects and exaggerated Risperdal's effectiveness.

4 22. The New York Times has reported that between 1993 and 2008, more
5 than 1,200 children have suffered serious complications in connection with taking
6 Risperdal/risperidone, including 31 deaths.

7 23. On or about April 13, 2011, U.S. District Judge Gladys Kessler
8 entered a Final Judgment against Defendant Johnson & Johnson in Civil Action
9 No. 11-0686 in the U.S. District Court for the District of Columbia; the Final
10 Judgment determined that Defendant Johnson & Johnson was "liable for
11 disgorgement of \$38,227,826, representing profits gained as a result of the conduct
12 alleged in the Complaint" brought by the U.S. Securities and Exchange
13 Commission which alleged improper influence and failure to maintain proper
14 records and accounting procedures.

15 24. That at all times relevant herein, Risperdal was widely and falsely
16 advertised and promoted by JPI/JLP/J&J/JOHN DOE Defendants as a safe and
17 effective treatment for Schizophrenia and Bipolar Disorder, and was falsely
18 promoted by Defendants as a safe and effective treatment for non-FDA approved
19 uses, such as for depressive symptoms, PTSD and MDD, and that
20 JPI/JLP/J&J/JOHN DOE Defendants minimized and/or covered up the risk posed
21 to patients taking Risperdal as prescribed and for those taking Risperdal for non-
22 FDA approved uses, such as for depressive symptoms, Major Depression and
23 PTSD.

24 25. That at all times relevant hereto, JPI/JLP/J&J/JOHN DOE Defendants
25 knew that the product Risperdal was defective and that Risperdal was likely to
26 cause hyperprolactenemia, gynecomastia, diabetes, excessive weight gain,
27 gastrointestinal problems, urinary incontinence, fecal incontinence and other
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1 medical problems.

2 26. At all times relevant hereto, JPI/JLP/J&J/JOHN DOE Defendants
3 knew that Risperdal was no more effective and considerably less safe than other
4 antipsychotic medications, yet engaged in an ongoing pattern of false and
5 misleading conduct designed to increase Risperdal's perceived therapeutic and
6 monetary value over cheaper, safer and more effective products.

7 27. JPI/JLP/J&J/JOHN DOE Defendants failed to disclose to physicians,
8 patients, or Plaintiffs, and those similarly situated, that Risperdal was likely to
9 cause hyperprolactenemia, gynecomastia, diabetes, excessive weight gain,
10 gastrointestinal problems, urinary incontinence, fecal incontinence and other
11 medical problems.

12 28. Defendants continued to promote Risperdal as safe and effective
13 despite patient reports of adverse events, FDA warnings regarding Risperdal's
14 dangers, and FDA requests to modify the warning labels.

15 29. As a direct result of ingesting Risperdal/Risperidone, Plaintiff Verkest
16 has suffered severe physical and emotional injuries, including, but not limited to,
17 hyperprolactenemia, gynecomastia, diabetes, excessive weight gain,
18 gastrointestinal problems, urinary incontinence, fecal incontinence and other
19 medical problems, fear, apprehension, despair, suicidality, social anxiety and other
20 emotional problems.

21 30. Defendants failed to provide sufficient warnings and instructions that
22 would have put Plaintiffs or the general public on notice of the dangers and
23 adverse effects associated with Risperdal/Risperidone, including, but not limited
24 to, hyperprolactenemia, gynecomastia, diabetes, excessive weight gain,
25 gastrointestinal problems, urinary incontinence, fecal incontinence and other
26 medical problems.

1 31. Risperdal/Risperidone were defective as marketed due to inaccurate
2 warnings, instructions, and labeling in light of Defendants' knowledge that the
3 product was likely to cause hyperprolactenemia, gynecomastia, diabetes, excessive
4 weight gain, gastrointestinal problems, urinary incontinence, fecal incontinence
5 and other medical problems.

6 32. Defendants manufactured and promoted Risperdal/Risperidone for
7 sale within the State of California and elsewhere.

8 33. Defendants promoted Risperdal to physicians and consumers within
9 the State of California and elsewhere.

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

15 35. Defendants conducted an organized, coordinated, intentional and
16 deliberate campaign to unlawfully market and promote off-label use of
17 Risperdal/risperidone in spite of the risks associated therewith.

18 36. As a result of Defendants' unlawful actions, Risperdal became
19 Defendants' best-selling drug.

20 37. As a result of Defendants' unlawful actions, physicians and consumers
21 were deceived into using Risperdal/risperidone in lieu of first generation
22 antipsychotic medications ("FGAs" or other medications in spite of the fact that
23 Risperdal carried additional dangerous side effects, was not approved for pediatric
24 use until 2006, and cost approximately 40-50 times as much as FGAs which were
25 equally or more effective.

26 38. Defendants sought to create the image, impression and belief among
27 consumers and physicians that the use of Risperdal/risperidone was safe for
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1 humans, including children, and that it had fewer side effects and adverse reactions
2 than other medications; Defendants engaged in this unlawful behavior despite
3 knowing that their representations were false and that there was no reasonable
4 basis to believe them to be true.

5 39. Defendants purposefully concealed, obfuscated, downplayed and
6 understated the health hazards and risks associated with Risperdal and actively
7 promoted its off-label pediatric use in violation of federal and California state law.

8 **CLAIMS FOR RELIEF**

9 **FIRST CAUSE OF ACTION**

10 **NEGLIGENCE**

11 40. Plaintiffs hereby incorporate by reference all preceding paragraphs as
12 if fully set forth herein.

13 41. Defendants owed Plaintiffs a legal duty of care.

14 42. Defendants knew or should have known that there was a foreseeable
15 risk that Plaintiff would suffer harmful side effects from Risperdal/risperidone and
16 the resulting damages alleged herein.

17 43. Defendants failed to act reasonably or with ordinary prudence.

18 44. It was reasonable for Plaintiffs to rely on Defendants' representations
19 as to the safety and effectiveness of Risperdal/risperidone and Plaintiffs did so rely.

20 45. But for Defendants' breach of duty owed to Plaintiffs, and Plaintiffs'
21 detrimental reliance thereon, Plaintiffs would not have suffered the harm alleged
22 herein.

23 46. As a direct and proximate result of Defendants' wrongful conduct,
24 Plaintiffs have suffered and will continue to suffer severe physical injuries and/or
25 death, severe emotional distress, mental anguish, economic losses and other
26 damages for which they are entitled to compensatory, equitable and other lawfully
27 available relief in an amount to be proven at trial.
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2 **SECOND CAUSE OF ACTION**

3 **BREACH OF EXPRESS WARRANTY**

4 47. Plaintiffs hereby incorporate by reference all preceding paragraphs as
5 if fully set forth herein.

6 48. At all times mentioned herein, Defendants expressly warranted to
7 Plaintiffs by and through statements made by Defendants or their authorized agents
8 or sales representatives, orally and in publications, package inserts and other
9 written materials intended for physicians, medical patients and the general public,
10 that the aforementioned products were safe, effective, fit and proper for their
11 intended use.

12 49. In utilizing the aforementioned products, Plaintiffs relied on the skill,
13 judgment, representations and foregoing express warranties of the Defendants, and
14 each of them. Said warranties and representations were false in that the
15 aforementioned products were not safe and were unfit for the uses for which they
16 were intended.

17 50. As a result of the foregoing breach of express warranties by the
18 Defendants, Plaintiffs suffered injuries and damages as alleged herein.

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20 **THIRD CAUSE OF ACTION**

21 **BREACH OF IMPLIED WARRANTY**

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23 51. Plaintiffs hereby incorporate by reference all preceding paragraphs as
24 if fully set forth herein.

25 52. At all times mentioned herein, Defendants expressly warranted to
26 Plaintiffs by and through statements made by Defendants or their authorized agents
27 or sales representatives, orally and in publications, package inserts and other
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1 written materials intended for physicians, medical patients and the general public,
2 that the aforementioned products were safe, effective, fit and proper for their
3 intended use.

4 53. In utilizing the aforementioned products, Plaintiffs relied on the skill,
5 judgment, representations and foregoing express warranties of the Defendants, and
6 each of them. Said warranties and representations were false in that the
7 aforementioned products were not safe and were unfit for the uses for which they
8 were intended.

9 54. As a result of the foregoing breach of express warranties by the
10 Defendants, Plaintiffs suffered injuries and damages as alleged herein.

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12 **FOURTH CAUSE OF ACTION**

13 **VIOLATION OF CAL. BUS. CODE § 17500, et seq.**

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15 55. Plaintiffs hereby incorporate by reference all preceding paragraphs as
16 if fully set forth herein.

17 56. At all times mentioned herein, Defendants expressly warranted to
18 Plaintiffs by and through statements made by Defendants or their authorized agents
19 or sales representatives, orally and in publications, package inserts and other
20 written materials intended for physicians, medical patients and the general public,
21 that the aforementioned products were safe, effective, fit and proper for their
22 intended use.

23 57. In utilizing the aforementioned products, Plaintiffs relied on the skill,
24 judgment, representations and foregoing express warranties of the Defendants, and
25 each of them. Said warranties and representations were false in that the
26 aforementioned products were not safe and were unfit for the uses for which they
27 were intended.

1 58. As a result of the foregoing breach of express warranties by the
2 Defendants, Plaintiffs suffered injuries and damages as alleged herein.

3 **FIFTH CAUSE OF ACTION**
4 **FRAUDULENT CONCEALMENT**

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6 59. Plaintiffs hereby incorporate by reference all preceding paragraphs as
7 if fully set forth herein.

8 60. Defendants and Plaintiffs were in a fiduciary relationship, wherein
9 Defendants manufactured, supplier and actively promoted a dangerous and
10 untested prescription drug to young children;

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12 61. Defendants intentionally concealed that they had not conducted proper
13 tests and did not know of the risks and side effects of Risperdal, thereby
14 intentionally failed to disclose important facts to Plaintiffs;

15 62. Defendants were in the unique position to know that they did not have
16 generally accepted test results of the effects of Risperdal on young children

17 63. Plaintiffs did not know that Defendants lacked generally accepted
18 testing results about the potential risks and side effects of young children taking
19 Risperdal.

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21 64. Defendants intended to deceive Plaintiffs by concealing these facts;

22 65. Plaintiffs reasonably relied on Defendants' assertions, as passed on by
23 their doctors;

24 66. Plaintiff was harmed by Defendants' fraudulent concealment;

25 67. Defendants' concealment was a substantial factor in causing
26 Plaintiffs' harm.
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SIXTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY-FAILURE TO WARN

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3 68. Plaintiffs hereby incorporate by reference all preceding paragraphs as
4 if fully set forth herein.

5 69. Plaintiffs claim that Risperdal lacked sufficient warnings of potential
6 risks and side effects on young children.

7 70. Defendants manufactured and distributed Risperdal;

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9 71. Risperdal had potential risks and side effects for young boys that were
10 known or knowable in the light of scientific and/or medical knowledge that was
11 generally accepted in the scientific and/or medical community at the relevant times
12 when Defendants were manufacturing and distributing Risperdal to physicians for
13 off-label use with children;

14 72. The potential risks and side effects presented a substantial danger
15 when Risperdal is used or misused in an intended or reasonably foreseeable way;

16 73. The potential risks and side effects are not the type of risks and side
17 effects that ordinary consumers would recognize;

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19 74. The potential risks and side effects were ignored by Defendants when
20 advising doctors of the benefits of Risperdal in young boys;

21 75. Due to the strict requirements established by the FDA for approving
22 anti-psychotic prescription drugs for any specific use, particularly in young
23 children more susceptible to adverse effects, Defendants knew that Risperdal was
24 not approved for use in young children, and yet they pushed this off-label use
25 anyway – this is the risk-amelioration intended by compliance with the FDA
26 regulations for approval of these types of drugs in all persons, especially children.

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28 76. Defendants knew at all times that Risperdal was not approved by the

1 FDA for use by children.

2 77. Defendants failed to adequately warn of the potential risks and side
3 effects;

4 78. Plaintiffs were harmed;

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6 79. The lack of sufficient instructions and warnings were substantial
7 factors in causing Plaintiffs' harm.

8 **SEVENTH CAUSE OF ACTION**
9 **NEGLIGENCE-FAILURE TO WARN**

10 80. Plaintiffs hereby incorporate by reference all preceding paragraphs as
11 if fully set forth herein.

12 81. Plaintiffs claim that Defendants were negligent by not using
13 reasonable care to warn about Risperdal's dangerous condition or about facts that
14 made Risperdal likely to be dangerous.

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16 82. Defendants manufactured and distributed Risperdal from 1993 to
17 present day.

18 83. Defendants knew or reasonably should have known that Risperdal
19 was dangerous or was likely to be dangerous when used or misused in a reasonably
20 foreseeable manner;

21 84. Defendants knew or reasonably should have known that users would
22 not realize the danger;

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24 85. Defendants failed to adequately warn of the danger or instruct on the
25 safe use of Risperdal;

26 86. A reasonable manufacturer and distributor under the same or similar
27 circumstance would have warned of the danger or instructed on the safe use of
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1 Risperdal;

2 87. Plaintiffs used Risperdal as instructed

3 88. Plaintiffs were harmed;

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5 89. Defendants' failure to warn was a substantial factor in causing
6 Plaintiffs' harm.

7 **EIGHTH CAUSE OF ACTION**

8 **NEGLIGENCE PER SE**

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10 90. Plaintiffs hereby incorporate by reference all preceding paragraphs as
11 if fully set forth herein.

12 91. Defendants violated inter alia Federal Food, Drug and Cosmetic Act,
13 21 U.S.C. s. 301 et seq., Cal. Civil Code ss. 1709 and 1770, Cal. Bus. and Prof.
14 Code ss. 17200 et seq., 17500 et seq. and 4052 et seq., Cal. Civil Code s. 1791 et
15 seq (Song-Beverly Consumer Warranty Act), 21 C.F.R. 99.101 et seq., Cal. Health
16 and Safety Code ss. 110390 and 110290, and Cal

17
18 92. Defendants were not excused from complying with the
19 aforementioned laws.

20 93. Defendants' violation of the aforementioned laws are, and each
21 violation is, the proximate cause and substantial factor in causing Plaintiffs' harm.

22 94. Plaintiffs' injuries are resulted from an occurrence of the nature which
23 the aforementioned laws were designed to prevent;

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25 95. Plaintiffs are the type of individuals that the aforementioned laws are
26 intended to protect.

27 96. Defendants' conducts substantially deviates from the standard of care
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1 an anti-psychotic prescription drug manufacturer and distributor owes to children,
2 giving rise to gross negligence or recklessness.

3 **NINTH CAUSE OF ACTION**

4 **NEGLIGENT MISREPRESENTATION**

5 97. Plaintiffs hereby incorporate by reference all preceding paragraphs as
6 if fully set forth herein.

7 98. Defendants represented to Plaintiffs, doctors and the wider medical
8 community that Risperdal was safe for young children.

9 99. Defendants' representations were not true, as Defendants had no
10 approved use from the FDA for the use of Risperdal in children, and either did not
11 know of the harm because they failed to adequately test the drug in children, or
12 knew of the risks and side effects but marketed

13 100. Regardless of whether Defendants honestly believed that the
14 representations were true, Defendants had no reasonable grounds for believing the
15 representations were true when they made the statements;
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17 101. Defendants intended that Plaintiffs rely on the representations;
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19 102. Plaintiffs reasonably relied on Defendants' representations;
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21 103. Plaintiffs' reliance on Defendants' representations was a substantial
22 factor in causing their harm.'

23 **TENTH CAUSE OF ACTION**

24 **FALSE ADVERTISING**

25 104. Plaintiffs hereby incorporate by reference all preceding paragraphs as
26 if fully set forth herein.

27 105. Defendants violated Cal. Bus. and Prof. Code s. 17500 et seq. by
28 publicly make false and misleading statements in promotion and marketing

1 Risperdal to California doctors and patients, including Plaintiffs.

2 106. Defendants knew or should have known through the exercise of
3 reasonable care under the circumstances that the aforementioned statements were
4 false and misleading because Defendants had no way of knowing the whether or
5 not such statements were true without conducting proper studies.

6 107. Defendants directly or indirectly disseminated false and misleading
7 information as a marketing scheme to increase sales in the market of antipsychotic
8 prescriptions to children.

9 108. Defendants' false advertising caused the proximate harm to Plaintiffs.

11 **ELEVENTH CAUSE OF ACTION**

12 **FRAUDULENT MISREPRESENTATION**

13 109. Plaintiffs hereby incorporate by reference all preceding paragraphs as
14 if fully set forth herein.

15 110. Defendants represented to Plaintiffs or their doctors that Risperdal
16 was safe for young children;

17 111. Defendants knew at the time they made such representations that they
18 were false because they had not conducted proper tests and did not know of the
19 risks and side effects of Risperdal, and therefore could not know what the risks and
20 side effects were.

21 112. Defendants intended for Plaintiffs to rely on their representations in
22 order for their scheme to sell off-label Risperdal to children, including Plaintiffs.

23 113. Plaintiffs reasonably relied on Defendants' representations because
24 Defendants are a famous producer of health products and prescription medication.

25 114. Plaintiffs were harmed by ingesting Risperdal.
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1 115. Plaintiffs' reliance on Defendants' representations was a substantial
2 factor in causing their harm.

3 **TWELFTH CAUSE OF ACTION**

4 **NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS**

5 116. Plaintiffs hereby incorporate by reference all preceding paragraphs as
6 if fully set forth herein.

7 117. Defendants were negligent in their promotion and marketing of off-
8 label use of Risperdal as safe for children because Defendants did not know and
9 could not know of the risks or side effects such use would cause Plaintiff Verkest
10 because Defendants had not conducted proper testing of the medication as per
11 FDA rules.

12 118. Plaintiff Verkest suffered serious emotional distress caused by the off-
13 label use of Risperdal both during the time he ingested it and continuing to present
14 day due to inter alia gynecomastia and the bullying and emotional distress of a
15 young boy growing up with breasts.

16 119. Plaintiff Verkest has been constantly bullied, cannot conduct himself
17 like most boys or men due to the physical deformation caused by the off-label use
18 of Risperdal – this has caused him shame, humiliation, physical bullying,
19 emotional bullying anxiety and more. No person should have to endure this.

20 120. Defendants had a duty to provide safe prescription drugs to Plaintiff
21 Verkest or proper and adequate warnings of risks and side effects – Defendants
22 were fiduciaries in the delivery of properly tested medication to young boys like
23 Plaintiff Verkest.

24 121. Defendants' negligence was a substantial factor in causing Plaintiff
25 Verkest's serious emotional distress.
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1 122. Defendants negligently cause serious injury to Plaintiff Verkest by
2 fraudulently promoting off-label use of Risperdal as safe for young boys.

3 123. During the time that Plaintiff Verkest ingested Risperdal, his behavior
4 became serious destructive and at times violent toward himself and others,
5 including Plaintiff McKee-Callanan.

6 124. During the time that Plaintiff Verkest ingested Risperdal, he was
7 publicly humiliated by many persons in front of his mother, Plaintiff McKee-
8 Callanan.

9 125. Plaintiff McKee-Callanan personally witnessed the torment Risperdal
10 caused her son, the violence it caused him to act upon towards Plaintiff McKee-
11 Callanan, the bullying and ridicule by others towards Plaintiff Verkest due to the
12 effects of taking Risperdal.

13 126. Plaintiff McKee-Callanan was then aware of the effects that Risperdal
14 was causing injury to Plaintiff Verkest.

15 127. Plaintiff McKee-Callanan suffered serious emotional distress,
16 including without limitation horror, anguish, fright, anxiety, grief, humiliation,
17 shame, etc. as proximate result thereof;
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19 128. Plaintiff McKee-Callanan's serious emotions distress was beyond that
20 which would be anticipated in a disinterested witness.

21 129. Defendants' conduct was a substantial factor in causing Plaintiff
22 McKee-Callanan's serious emotions distress.
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24 **THIRTEENTH CAUSE OF ACTION**

25 **INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS**

26 130. Plaintiffs hereby incorporate by reference all preceding paragraphs as
27 if fully set forth herein.
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1 131. Defendants' conduct of manufacturing, distributing, marketing or
2 promoting the off-label use of Risperdal in children as safe without conducting
3 proper, FDA-approved trials to understand what the risks and side effects were is
4 outrageous conduct;

5 132. Defendants acted with reckless disregard of the probability that
6 Plaintiff would suffer emotional distress, knowing that Plaintiff was a young boy
7 and the risks and side effects of testing conducted on adults would likely be equal
8 to or greater than those in adults; and in the causing of Plaintiffs to ingest Risperdal
9 without knowing the risks and side effects;

10 133. Plaintiffs suffered severe emotional distress during the time he
11 ingested the off-label use of Risperdal, and continuing to present day to the
12 gynecomastia that haunts him personally and elicits taunting and bullying from
13 others – no person should have to endure this.

14 134. Defendants' conduct was a substantial factor in causing Plaintiffs'
15 severe emotional distress.
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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.

Dated: January 15, 2014

THE LAW OFFICE OF CRISTOPHER G.
SABOL

/s/ Cristopher G. Sabol

Cristopher G. Sabol
Attorney for Plaintiffs

LAW OFFICE OF CRISTOPHER G.
SABOL
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West Hollywood, CA 90046
Tel: 323-383-1155
Attorneys for Plaintiffs

CIVIL COVER SHEET

'14CV0106 JM JMA

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 Benjamin Verkest and Lori McKee-Callanan
(b) County of Residence of First Listed Plaintiff San Diego, CA
(c) Attorneys (Firm Name, Address, and Telephone Number) Christopher G. Sabol, Esq. (SBN 251317) 7985 Santa Monica Blvd., Ste. 10980 West Hollywood, CA 90046 - 323.383.1155

DEFENDANTS Janssen Pharmaceuticals, Inc. a/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc.; Janssen LP; Johnson & Johnson, Inc.; Johnson & Johnson Pharmaceutical Resear
County of Residence of First Listed Defendant Mercer, NJ
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
2 U.S. Government Defendant
3 Federal Question (U.S. Government Not a Party)
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
Citizen of This State X 1 1 Incorporated or Principal Place of Business In This State 4 4
Citizen of Another State 2 2 Incorporated and Principal Place of Business In Another State 5 X 5
Citizen or Subject of a Foreign Country 3 3 Foreign Nation 6 6

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

Table with 5 columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes various legal categories like Insurance, Personal Injury, Labor, etc.

V. ORIGIN (Place an "X" in One Box Only)
X 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. s. 1332
Brief description of cause: Diversity of citizenship

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: X Yes 0 No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE n/a DOCKET NUMBER

DATE 01/15/2014 SIGNATURE OF ATTORNEY OF RECORD /s/Cristopher Sabol

FOR OFFICE USE ONLY RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE