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PROTHONOTARY FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
Filed and Attested by
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03 SEP 2010 01:22 pm
R. WEISS

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IN RE: RISPERDAL® LITIGATION	:	**PHILADELPHIA COUNTY COURT OF COMMON PLEAS TRIAL DIVISION**
Plaintiff(s),	:	
v.	:	**MARCH TERM, 2010 No. 296**
Ortho-McNeil-Janssen Pharmaceuticals, Inc, f/k/a Janssen Pharmaceutica, Inc., Johnson & Johnson Company, Johnson & Johnson Pharmaceutical Research and Development, L.L.C., Excerpta Medica, Inc., and Elsevier Inc.,	:	
Defendants.	:	

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NOTICE TO DEFEND

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, yon must take action within twenty (20) days **after this complaint and notice are served by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you** fail to do so the case may proceed without you and a judgment may be **entered against you by the court without further notice for any money** claimed in the complaint or for any other claim or relief requested by the **plaintiff. You may lose money or property or other rights important to you.**

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER.

Case ID: 100300296

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THIS IS NOT AN ARBITRATION MATTER.
ASSESSMENT OF DAMAGES HEARING IS REQUIRED.
JURY TRIAL DEMANDED.

IN RE: RISPERDAL® LITIGATION	:	**PHILADELPHIA COUNTY COURT OF COMMON PLEAS TRIAL DIVISION**
Plaintiff(s),	:	
v.	:	**MARCH TERM, 2010 No. 296**
Ortho-McNeil-Janssen Pharmaceuticals, Inc, f/k/a Janssen Pharmaceutica, Inc., Johnson & Johnson Company, Johnson & Johnson Pharmaceutical Research and Development, L.L.C., Excerpta Medica, Inc., and Elsevier Inc.,	:	
Defendants.	:	

PLAINTIFFS' FIRST AMENDED MASTER
LONG-FORM COMPLAINT AND JURY DEMAND

Plaintiffs, by and through their undersigned counsel, hereby submit this First Amended Master Complaint on behalf of all Plaintiffs and, if applicable, Plaintiffs' spouses, children, decedents, and/or wards who were injured and/or suffered damages on account of their or their family member's ingestion of the antipsychotic drug, Risperdal® (risperidone), in any of its forms, including Risperdal CONSTA® (a long-acting injectable form of risperidone) and/or

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IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

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Philadelphia, Pennsylvania (215) 238-1701

AVISO

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usetd tiene veinte (20) dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta **asentar una comparesencia escrita o en persona o con un abogado y** entregar **a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no Ademas, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros Derechos importantes para usted.**

LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA SCRITA ABAJO. ESTA OFICINA LE PUEDE AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

SI USTED NO TIENE DINERO SUFICIENTE PARA OBTENER UN ABOGADO, ESTA OFICINA PUEDE HACER PREVISIONES PARA DARLE INFORMACION PARA OBTENER UN ABBOGADO O PUEDE ASISTER CON INFORMACION DE AGENCIAS QUE PUEDEN OFRECER SERVICIOS LEGALES A PERSONAS ELEGIBLE A HONORARIOS REDUCIDOS O SIN HONORARIOS NINGUNOS.

ASOCIACIÓN DE LICENCIADOS DE FILADELFIA. SERVICIO DE REFERENCIA E INFORMACIÓN LEGAL
One Reading Center
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Invega® (paliperidone),[1] designed, developed, tested, labeled, packaged, distributed, marketed, and sold throughout the United States by the Janssen Defendants (as defined below) and co-promoted by the Excerpta Medica Defendants (as defined below) and who are represented by any Plaintiffs' counsel who has signed onto or agreed to the Master Long-Form Complaint and, by operation of such order, all allegations pleaded herein are deemed pleaded in any "Short-Form" Complaint hereinafter filed. Plaintiffs, by and through their attorneys, complaining of the Defendants Ortho-McNeil-Janssen Pharmaceuticals, Inc. f/k/a Janssen Pharmaceutica, Inc., Johnson & Johnson Company d/b/a Johnson & Johnson, Johnson & Johnson Pharmaceutical Research and Development, L.L.C. (sometimes hereinafter collectively referred to as "Janssen" or the "Janssen Defendants"), Excerpta Medica Inc. and Elsevier Inc. (sometimes hereinafter collectively referred to as the "Excerpta Medica Defendants") (Janssen Defendants and Excerpta Medica Defendants may be collectively referred to as "Defendants"), jointly and severally, for their causes of action against said Defendants allege and state as follows:

PLAINTIFFS

1. The "Minor Plaintiffs" referred to herein are minor children who ingested and/or were injected with the Janssen Defendants' drug products, Risperdal and/or Invega, and who, as a result of their use of Risperdal and/or Invega, developed one or more of the following serious and/or permanent adverse effects: rapid weight gain, hyperprolactinemia, gynecomastia (abnormal development of breasts in males), galactorrhea (lactation), pituitary tumors, microadenomas of the pituitary gland, breast cancer, osteoporosis, decreased bone mineral density, metabolic syndrome, dyslipidemia, hypertension, diabetes mellitus, diabetic ketoacidosis (DKA), hyperosmolar coma, hyperglycemia, glucose dysregulation, insulin insufficiency, insulin resistance, pancreatitis, tardive dyskinesia, extrapyramidal symptoms, involuntary movement

1 Risperdal, in any and all of its formulations, will be referred to as "Risperdal."

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disorders, dyskinesia, dystonia, akathisia, parkinsonism, neuroleptic malignant syndrome (NMS) and/or other related conditions. The Minor Plaintiffs are represented in these actions by one or both parents, or guardians ("Guardian Plaintiffs"), who are their next friends pursuant to Pennsylvania Rule of Civil Procedure 2026.

2. The "Guardian Plaintiffs" referred to herein are competent adults and the mothers, fathers and/or guardians of the Minor Plaintiffs in these actions. They bring these actions individually and on behalf of the Minor Plaintiffs to recover, among other things, medical and other expenses related to treatment resulting from their child's injuries due to their ingestion of, and/or being injected with, Risperdal and special damages.

3. The "Adult Plaintiffs" referred to herein are individuals who ingested and/or were injected with the Janssen Defendants' drug products, Risperdal and/or Invega, and who, as a result of their use of Risperdal and/or Invega, developed one or more of the following serious and/or permanent adverse effects: rapid weight gain, hyperprolactinemia, gynecomastia (abnormal development of breasts in males), galactorrhea (lactation), pituitary tumors, microadenomas of the pituitary gland, breast cancer, osteoporosis, decreased bone mineral density, metabolic syndrome, dyslipidemia, hypertension, diabetes mellitus, diabetic ketoacidosis (DKA), hyperosmolar coma, hyperglycemia, glucose dysregulation, insulin insufficiency, insulin resistance, pancreatitis, tardive dyskinesia, extrapyramidal symptoms, involuntary movement disorders, dyskinesia, dystonia, akathisia, parkinsonism, neuroleptic malignant syndrome (NMS) and/or other related conditions.

4. "Plaintiffs" as used herein refers to the Minor Plaintiffs, Guardian Plaintiffs, and/or the Adult Plaintiffs, collectively.

DEFENDANTS

5. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. (hereinafter "OMJ"),

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formerly known as Janssen Pharmaceutica Inc., is a Pennsylvania corporation with substantial offices in suburban Philadelphia, and is duly qualified to do business in the Commonwealth of Pennsylvania. OMJ does business in the Commonwealth of Pennsylvania and other states by, among other things, designing, developing, testing, manufacturing, labeling, packaging, distributing, marketing, selling and/or profiting from Risperdal and/or Invega. On information and belief, OMJ is a wholly-owned subsidiary of Defendant Johnson & Johnson.

6. At all times mentioned herein, OMJ was responsible for Risperdal and/or Invega From time to time, the name of the entity has changed.

7. Several affiliates have provided OMJ and the other Janssen Defendants with support in the development and distribution of Risperdal and/or Invega. These affiliates include Johnson & Johnson Pharmaceutical Research & Development, L.L.C., Ortho-McNeil Pharmaceuticals, Inc., Janssen Ortho-McNeil Pharmaceutica Services, Pharmaceutical Sourcing-Group Americas, Pharmaceutical Group Strategic Marketing, Janssen Pharmaceutica N.V., Janssen Ortho LLC, Janssen Medical Affairs, L.L.C., and Ortho-McNeil Janssen Scientific Affairs LLC. All of these entities are subsidiaries or divisions of Defendants OMJ and/or Johnson & Johnson, do business in the Commonwealth of Pennsylvania, and are subject to jurisdiction in this Commonwealth.

8. On information and belief, Johnson & Johnson is a fictitious name adopted by Defendant Johnson & Johnson Company (hereinafter, "Johnson & Johnson"), a New Jersey corporation with its principal place of business in New Jersey. Johnson & Johnson does business in the Commonwealth of Pennsylvania and other states by, among other things, designing, developing, testing, manufacturing, labeling, packaging, distributing, marketing, selling and/or profiting from Risperdal and/or Invega in the Commonwealth of Pennsylvania and throughout the United States.

9. On information and belief, Defendant Johnson & Johnson Pharmaceutical Research

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& Development, L.L.C. ("JJPRD") is a New Jersey limited liability company that has offices in Spring House, Pennsylvania and Exton, Pennsylvania. JJPRD was responsible for clinical research and development of Risperdal and/or Invega, for pharmacovigilance in the United States pertaining to Risperdal and/or Invega, and for submitting regulatory reports to the United States Food & Drug Administration ("FDA") pertaining to Risperdal and/or Invega.

10. On information and belief, Defendant Excerpta Medica Inc. ("Excerpta Medica") is a New York corporation that provides services, including, but not limited to, medical communication services, as further detailed below, to pharmaceutical manufacturers, including the Janssen Defendants. On information and belief, Defendant Excerpta Medica is a wholly-owned subsidiary of Defendant Elsevier Inc.

11. Defendant Elsevier Inc. ("Elsevier") is a New York corporation that provides services to pharmaceutical manufacturers, including the Janssen Defendants. Defendant Elsevier is engaged in the business of publishing scholarly books and journals in many fields of science and social science, including but not limited to those specifically identified in this action.

12. The Janssen Defendants acted in concert with one another and/or with the Excerpta Medica Defendants in the Commonwealth of Pennsylvania and throughout the United States to fraudulently convey false and misleading information concerning the safety and efficacy of Risperdal and/or Invega and to conceal the risks of serious adverse events, including weight gain, diabetes mellitus, pancreatitis, metabolic syndrome, hyperprolactinemia, gynecomastia, tardive dyskinesia and other adverse effects associated with Risperdal and/or Invega from the FDA, the public, Plaintiffs, physicians and other healthcare providers. These concerted efforts resulted in significant harm to consumers of Risperdal and/or Invega, including Plaintiffs. But for the actions of Defendants, individually, jointly, and in concert with one another, Plaintiffs would not have ingested, or permitted injection of, Risperdal and/or Invega. Defendants' tortious actions

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make them each individually liable and responsible for Plaintiffs' injuries and damages as described herein from the ingestion and/or injection of Risperdal and/or Invega.

VENUE AND JURISDICTION

13. Plaintiffs have suffered injuries and damages arising out of the use of the antipsychotic medications -- Risperdal and/or Invega.

14. Venue is proper in this County because Defendant OMJ is a Pennsylvania corporation, resides in this County for venue purposes and regularly conducts business in this County. *See* Pa.R.C.P. 2179, as amended by 2003 Supreme Court of Pennsylvania Order.

15. This Court has jurisdiction over Defendant OMJ, a wholly-owned subsidiary of Defendant Johnson & Johnson, because OMJ is a Pennsylvania corporation and conducts substantial business in the Commonwealth of Pennsylvania, committed torts in whole or in part in the Commonwealth of Pennsylvania, has had systematic and continuous contacts with the Commonwealth of Pennsylvania, specifically within this County, has agents and representatives which can be found in this County, and/or has otherwise engaged in misconduct in this County. Defendant is amenable to service by a Pennsylvania court and the exercise of jurisdiction over it comports with due process.

16. This Court has jurisdiction over Defendant JJPRD, a New Jersey limited liability company, because JJPRD has significant offices in Spring House, Pennsylvania and Exton, Pennsylvania, conducts substantial business in the Commonwealth of Pennsylvania, committed torts in whole or in part in the Commonwealth of Pennsylvania, and has systematic and continuous contacts with the Commonwealth of Pennsylvania.

17. This Court has jurisdiction over Defendant Johnson & Johnson, a New Jersey corporation, because Defendant Johnson & Johnson conducts substantial business in the Commonwealth of Pennsylvania, committed torts in whole or in part in the Commonwealth of

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Pennsylvania, has systematic and continuous contacts with the Commonwealth of Pennsylvania, has agents and representatives which can be found in this Commonwealth, and/or has otherwise engaged in conduct subjecting said Defendant to the reach of the applicable long-arm statute. Said Defendant is subject to service by a Pennsylvania court, and the exercise of jurisdiction over said Defendant comports with due process.

18. This Court has jurisdiction over Defendant Excerpta Medica because Excerpta Medica conducts substantial business in the Commonwealth of Pennsylvania, committed torts in whole or in part in the Commonwealth of Pennsylvania, has systematic and continuous contacts with the Commonwealth of Pennsylvania, has agents and representatives which can be found in this Commonwealth, and/or has otherwise engaged in conduct subjecting said Defendant to the reach of the applicable long-arm statute. Said Defendant is subject to service by a Pennsylvania court, and the exercise of jurisdiction over said Defendant comports with due process.

19. This court has jurisdiction over Defendant Elsevier because Defendant Elsevier conducts substantial business in the Commonwealth of Pennsylvania, committed torts in whole or in part in the Commonwealth of Pennsylvania, has systematic and continuous contacts with the Commonwealth of Pennsylvania, has agents and representatives which can be found in this Commonwealth, and/or has otherwise engaged in conduct subjecting said Defendant to the reach of the applicable long-arm statute. Said Defendant is subject to service by a Pennsylvania court, and the exercise of jurisdiction over said Defendant comports with due process.

20. This suit is brought to recover damages and other relief, and the costs of suit, including reasonable attorney and expert fees, for the damages Plaintiffs have sustained as a result of Defendants' acts and omissions in excess of the jurisdictional limits of all lower courts in the Commonwealth of Pennsylvania.

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GENERAL ALLEGATIONS

Risperdal and Invega Products

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

22. Risperdal is an antipsychotic medication, belonging to a class of drugs which have become known as "atypical" or "second generation" ("SGA") antipsychotics. Other atypical antipsychotics include Clozaril (clozapine), Seroquel (quetiapine), Zyprexa (olanzapine), Geodon (ziprasidone), Abilify (aripiprazole), and Invega (paliperidone) (the active ingredient of which is 9-hydroxy-risperidone, the active metabolite of risperidone), all of which began coming onto the market in 1989.

23. Risperdal was originally developed and approved for use in the treatment of symptoms associated with schizophrenia. However, Risperdal does not cure schizophrenia or any other mental health condition. The pharmacologic action of Risperdal is unknown but is thought to be dependent on its ability to block or moderate the level of dopamine, a chemical found in the brain that in excessive amounts is believed to cause abnormal thinking and hallucinations.

24. Risperdal and/or Invega can and do cause serious and sometimes fatal injuries to the metabolic, cerebrovascular, neurologic, and endocrine systems and to organs such as the brain, liver, and pancreas in some patients. Adverse effects include, but are not limited to, rapid weight gain, hyperprolactinemia, gynecomastia (abnormal development of breasts in males), galactorrhea (lactation), pituitary tumors, microadenomas of the pituitary gland, breast cancer, osteoporosis, decreased bone mineral density, metabolic syndrome, dyslipidemia, hypertension, diabetes mellitus, diabetic ketoacidosis (DKA), hyperosmolar coma, hyperglycemia, glucose

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dysregulation, insulin insufficiency, insulin resistance, pancreatitis, tardive dyskinesia, extrapyramidal symptoms, involuntary movement disorders, dyskinesia, dystonia, akathisia, parkinsonism, and/or other related conditions. Complications of diabetes mellitus include ketoacidosis, hyperosmolar coma, heart disease, infection, neuropathy, blindness, seizures, and death.

25. The branded version of Risperdal earned Janssen $2.5 billion in 2007, the last full year for which Janssen enjoyed patent protection for Risperdal. The before-mentioned $2.5 billion accounted for more than 6% of Johnson & Johnson's company-wide sales.

False and Misleading Promotional Activities

26. Sections 502(a) and 201(n) of the Federal Food, Drug, and Cosmetic Act (the "FDCA") (21 U.S.C. §§ 352(a) and 321(n)) require Janssen to fully and accurately disclose information relating to hyperprolactinemia, gynecomastia, hyperglycemia, diabetes mellitus, ketoacidosis, tardive dyskinesia and other adverse effects in the Risperdal and/or Invega package insert (PI) and other labeling, and to include adequate warnings concerning these and other risks in promotional materials for Risperdal and/or Invega.

27. Sections 502(a) and 201(n) of the FDCA (21 U.S.C. §§ 352(a) and 321(n)) prohibit Janssen from minimizing these risks, and from promulgating misleading claims that Risperdal and/or Invega is safer than other antipsychotic medications on the market.

28. Janssen has violated, and continues to violate, Sections 502(a) and 201(n) of the FDCA (21 U.S.C. §§ 352(a) and 321(n)) by omitting information concerning these risks from the Risperdal and/or Invega Package Insert ("PI") and other labeling, and by utilizing and/or distributing promotional materials that were false and misleading in that they minimized the risks of these serious adverse events, failed to advise physicians to monitor patients for these adverse events, and otherwise falsely claimed that Risperdal and/or Invega was safer and more

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efficacious than other antipsychotic medications on the market.

29. On information and belief, Janssen engaged in promotional activities that were not only false and misleading as to the safety and efficacy of Risperdal and/or Invega, but, in many cases, were designed to illegally expand the use of Risperdal and/or Invega for off-label uses, without scientific proof of drug products' safety and efficacy in treating such disorders, so as to increase sales and profits at the expense of the safety, health, and well-being of the public, including Plaintiffs, by means of the following, including, but not limited to:

a. Manipulating clinical trials to produce results favorable to Risperdal and/or Invega;

b. Failing to publish or report negative studies concerning Risperdal and/or Invega to the FDA or to publish the results in the medical literature;

c. Ghostwriting medical journal articles, pertaining to Risperdal and/or Invega, *i.e.*, utilizing hired medical writers, who are not researchers or scientists, to write articles and then submitting them to selected opinion or "thought" leaders to attach their names to them as authors without making any meaningful contribution to the article, to lend false credence to these articles;

d. Presenting false and misleading studies and reports concerning Risperdal and/or Invega at professional meetings by means of posters and abstracts;

e. Publishing the same studies and/or selected portions of the same studies in multiple journals to create a false impression of scientific acceptability of Risperdal and/or Invega for a variety of uses (a practice known as "salami science");

f. Failing to file accurate and timely reports of adverse events and abnormal laboratory values seen in Risperdal and/or Invega clinical trials with the FDA;

g. Failing to publish accurate reports of adverse events and abnormal laboratory values in articles concerning Risperdal and/or Invega clinical trials;

h. Failing to file accurate and timely reports of post-marketing adverse events with the FDA;

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i. Failing to publish accurate reports of post-marketing adverse events in articles concerning Risperdal and/or Invega;

j. Failing to recognize signal evidencing association between Risperdal and/or Invega and adverse events in post-marketing adverse event reports;

k. Conducting marketing and promotion of Risperdal and/or Invega for off-label use under the guise of continuing medical education;

l. Utilizing "advisory boards" to conduct marketing and promotion of Risperdal and/or Invega;

m. Paying large sums to key opinion leaders to tout Risperdal and/or Invega as treatment for a variety of disorders;

n. Marketing Risperdal and/or Invega as "broad spectrum" antipsychotics;

o. Hiring consultants involved in creating treatment algorithms in order to achieve favorable treatment of Risperdal and/or Invega in those algorithms;

p. Giving lucrative contracts for "clinical research" as a reward to high prescribers of Risperdal and/or Invega;

q. Distributing promotional materials such as sales aids (including, but not limited to, children's Lego-like blocks in bright colors adorned with the Risperdal logo), journal ads, display panels, brochures, letters, flashcards, calendars, and computer programs regarding Risperdal and/or Invega which were false, misleading, and/or lacking in fair balance; and

r. Coordinating, with consultants, marketing executives, medical staff, healthcare professionals and scientists, to off-label market and promote Risperdal for the treatment of the following off-label uses in children: Attention-Deficit/Hyperactivity Disorder (ADHD), Obsessive-Compulsive Disorder (OCD), Oppositional-Defiant Disorder (ODD), Conduct Disorder (CD), Disruptive Behavior Disorder (DBD), Tourette's syndrome, and pervasive development disorders (PDD), among others.

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History of Risperdal Label Changes and FDA's Reprimands to Janssen

Schizophrenia and Bipolar Disorder

30. On December 29, 1993, Janssen obtained approval from the FDA to market Risperdal oral tablets for the treatment of "manifestations of psychotic disorders" (schizophrenia) in adults with a target dosage of 4 to 6 milligrams per day.

31. In September 2000, the FDA requested that the label be changed to more clearly indicate that Risperdal was only approved for use in treating schizophrenia in adults.

32. The Janssen Defendants delayed making this recommended change until two years later, in 2002.

33. The FDA subsequently approved Risperdal in other formulations for the treatment of schizophrenia in adults — on June 10, 1996, the FDA approved Risperdal oral solution; on April 2, 2003, the FDA approved the Risperdal M-Tab for adults; and on October 29, 2003 the FDA approved Risperdal Consta®, a long-acting injection of Risperdal.

34. On December 4, 2003, the FDA approved additional uses of Risperdal oral tablets, Risperdal oral solution and Risperdal M-Tab as monotherapy for the short-term treatment of acute manic or mixed episodes associated with bipolar I disorder, and as combination therapy, with Lithium or Valproate, for the short-term treatment of acute manic or mixed episodes associated with bipolar I disorder in adults.

Irritability in Autistic Disorder

35. In October 2006, Risperdal was approved for the treatment of irritability associated with autistic disorder in children and adolescents (between the ages of 5 and 16), including symptoms of aggression towards others, deliberate self-injuriousness, temper tantrums and quickly changing moods. Risperdal has only been approved for the treatment of irritability associated with autistic disorder in children and adolescents, and not the whole Autistic

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Spectrum Disorder – *i.e.*, the wider variation of autistic symptoms including withdrawal from social interactions, problems communicating, and repetitive behaviors. Risperdal has not been approved for children younger than 5 or those older than 16 years for irritability associated with autistic disorder.

Schizophrenia and Mania Associated with Bipolar I in Children and Adolescents

36. On August 22, 2007, Risperdal received approval from the FDA for the treatment of schizophrenia in adolescents ages 13-17 years, and for the short-term treatment of acute manic or mixed episodes associated with bipolar I disorder in children and adolescents ages 10-17 years.

FDA Communications

37. In January 1999, the FDA sent a letter to Janssen regarding promotional materials and activities for the marketing of Risperdal Tablets that had been reviewed by the Division of Drug Marketing, Advertising and Communications ("DDMAC") as part of its monitoring and surveillance program. In particular, the DDMAC letter concerned a campaign that marketed Risperdal for use in geriatric patients. These materials included, but were not limited to, sales aids, journal ads, a display panel, brochures, and a letter, a flashcard, a calendar, and a computer program, which DDMAC concluded were false, misleading, and/or lacking in fair balance, and in violation of the FDCA and the regulations promulgated thereunder.

38. As of July 1999, the Risperdal label still contained no warnings concerning diabetes mellitus or hyperglycemia. Under the "adverse reactions" section, the label mentioned that micturation disturbances and weight gain were twice as common with Risperdal-treated patients as for placebo-treated patients. Under the section entitled, "Other Events Observed During Pre-Marketing Clinical Trials," the label stated that there was a positive ($p<0.5$) trend for weight gain with the percentage of patients having weight change of at least 7% body weight being 18% for Risperdal vs. 9% for placebo. The only place in the label at that time that even mentioned

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diabetes mellitus was on page 19 of 24, under "other events" and "metabolic and nutritional disorders," and no indication of any association with Risperdal or the true severity or frequency of diabetes mellitus or hyperglycemia or the need for blood glucose monitoring was mentioned.

39. In September 2000, the FDA requested that the Janssen Defendants change the indication in the labeling and package insert for Risperdal to more clearly state that the only approved use for Risperdal was in the "treatment of schizophrenia" in adults. Presumably, the FDA was concerned about the lack of adequate studies to support the ever-expanding uses being promoted by the Janssen defendants for Risperdal. Despite repeated requests from the FDA, the Janssen Defendants refused to make this change until 2002.

40. As early as 2001, at the FDA's insistence, the label for Risperdal was modified to include a statement that "The safety and effectiveness in children have not been established." However, Defendants continued to actively market and promote Risperdal and/or Invega for off-label uses in children.

41. On information and belief, despite the addition of language to the Risperdal label designed to restrict off-label and scientifically unproven and potentially dangerous uses of Risperdal, Janssen continued to promote the off-label, unapproved use of Risperdal for children as young as 3 years of age, for a variety of unapproved uses, including but not limited to, autism, Attention-Deficit/Hyperactivity Disorder (ADHD), Obsessive-Compulsive Disorder (OCD), Oppositional-Defiant Disorder (ODD), Conduct Disorder (CD), Disruptive Behavior Disorder (DBD), Tourette's syndrome, Post-Traumatic Stress Disorder (PTSD), pervasive development disorders (PDD), and other conditions by the afore-mentioned means.

42. In November 2002, the FDA approved a label change providing for the addition of the term "hyperglycemia" to the "ADVERSE REACTIONS: Post-Introduction Reports" section

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of the Risperdal label. Prior to that there was no mention of hyperglycemia in post-marketing reports in the Risperdal label. This deliberate exclusion of the existence of case reports of hyperglycemia in no way constituted an adequate warning to prescribers or consumers regarding the true risk of diabetes mellitus with Risperdal.

43. In 2003, a researcher at the FDA identified 131 distinct cases of risperidone-associated diabetes or hyperglycemia in the FDA spontaneous reporting database. A total of seven cases appeared in three publications. Of the patients with risperidone-associated hyperglycemia (monotherapy), seventy-eight (78) had newly diagnosed hyperglycemia, forty-six (46) had exacerbation of preexisting disease, and seven (7) could not be classified. Janssen never warned the FDA, physicians or consumers of the mounting number of reported cases of diabetes or hyperglycemia or that these case reports were associated with Risperdal.

44. In September 2003, the FDA required that a "WARNING" be added to the label for all atypical antipsychotics, including Risperdal, regarding the association of hyperglycemia and diabetes with this class of drugs and the need for medical monitoring of certain patients.

45. Although the new warning was approved in November 2003, Janssen did not add the warning to the Risperdal label until January 2004.

46. Prior to that time the label was defective in that it failed to advise prescribing doctors or the public, including Plaintiffs that Risperdal was associated with hyperglycemia, diabetes, and related conditions; that patients on Risperdal should undergo fasting blood sugar tests before and during treatment if they have risk factors for diabetes or develop "symptoms" of hyperglycemia; and that treatment should be stopped if symptoms of hyperglycemia or diabetes mellitus appeared. In fact, this label is still defective in that it does not contain a black box warning for diabetes; does not clearly state that Risperdal is associated with hyperglycemia, diabetes mellitus, and related conditions; fails to state the true incidence of those conditions in

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Risperdal patients; and recommends blood glucose testing only for patients with "risk factors" and those who develop "symptoms" of hyperglycemia.

47. On November 10, 2003, Janssen sent a false and misleading "Dear Healthcare Provider Letter" (the "DHCPL Letter") to all health care professionals likely to prescribe Risperdal that deliberately minimized the risk of hyperglycemia and diabetes and omitted the warning to monitor certain patients on Risperdal.

48. On April 19, 2004, DDMAC issued a Warning Letter to Janssen concerning the false and misleading DHCPL Letter and required Janssen to send out a new letter with corrections (the "FDA Warning Letter").

49. According to the FDA, the DHCPL Letter "misleadingly omits material information about Risperdal, minimizes potentially fatal risks associated with the drug, and claims superior safety to other drugs in its class without adequate substantiation, in violation of Sections 502(a) and 201(n) of the Act (21 U.S.C. §§ 352(a) and 321(n)."

50. In response to the FDA Warning Letter, Janssen, on April 28, 2004, submitted a revised "Dear Healthcare Provider Letter" to the FDA for review, as well as an action plan to "address the issues raised in the [FDA] Warning letter."

51. However, the FDA, on May 27, 2004, rejected Janssen's "proposed corrective DHCP letter" and told Janssen that the letter did not "adequately address the issues raised in DDMAC's April 19, 2004 Warning Letter."

52. In response to the second FDA letter, Janssen mailed, on July 21, 2004, a revised Dear Health Care Provider letter (the "Revised HCP Letter"), which contained the following statement:

> The [FDA's] Warning Letter concludes that Janssen disseminated a Risperdal Dear Health Care Provider (DHCP) [Letter] dated November 10, 2003 that **omitted material information about Risperdal**, **minimized potentially fatal risks**, and made **misleading claims** suggesting superior safety to other

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> atypical antipsychotics **without adequate substantiation**, in violation of the Federal Food, Drug and Cosmetic Act.

See Exhibit A (emphasis added).

53. The Revised HCP Letter also stated:

> Specifically, **the Warning letter stated that the DHCP letter omitted important information regarding hyperglycemia and diabetes**, including the potential consequences and the recommendation of regular glucose control monitoring that was added to the approval product labeling for Risperdal; minimized the potentially fatal risks of hyperglycemia-related adverse events such as ketoacidosis, hyperosmolar comas and death; minimized the importance of blood glucose monitoring; **suggested that Risperdal did not increase the risk of diabetes**, contraindicating the Warning in the revised product labeling; and **made misleading claims** suggesting that Risperdal has a lower risk of hyperglycemia and diabetes than other atypical antipsychotics without adequate substantiation which is inconsistent with the Prescribing Information for Risperdal

See id. (emphasis added).

54. Prior to and during the time that Plaintiffs ingested and/or were injected with Risperdal, Janssen knew or should have known about articles written by independent researchers and published in peer-reviewed scientific journals that reported epidemiological studies as well as case reports related to Risperdal that demonstrated an association between atypical antipsychotics, including Risperdal, and serious and life-threatening adverse effects, including, but not limited to: new onset or aggravation of diabetes mellitus and development of dangerously high blood sugar levels, *i.e.* hyperglycemia; glucose dysregulation; ketoacidosis; pancreatitis; weight gain; hyperprolactinemia; gynecomastia, particularly in boys; and tardive dyskinesia, a serious movement disorder which can lead to permanent disability and disfigurement. Janssen, however, failed and refused to include this information in Risperdal labeling.

55. On information and belief, the Janssen Defendants pushed back vigorously in response to any article critical of Risperdal, utilizing key opinion leaders friendly to Risperdal

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and Janssen as surrogates to submit correspondence attacking such articles.

56. Despite problems with efficacy and safety, the Janssen Defendants and their network of supporters promoted the on-label and off-label use of Risperdal.

57. On information and belief, the Janssen Defendants failed and refused to timely and properly report information concerning spontaneous adverse event reports to the FDA, physicians, and consumers.

58. Recently, an FDA Pediatric Advisory Panel voted unanimously that the labeling for another atypical antipsychotic, Abilify, was inadequate because the label did not "adequately reflect [the] possible pediatric risk of excessive weight gain." Plaintiffs allege herein that Risperdal's label contains similar inadequacies.

59. The Janssen Defendants knew, or in the exercise of reasonable diligence should have known, that the risk of new-onset diabetes mellitus or hyperglycemia associated with Risperdal and/or Invega is significantly higher than with older, cheaper, equally effective "typical" antipsychotic drugs, such as haloperidol and perphenazine.

60. The Janssen Defendants' marketing efforts were designed and implemented to create the false impression in physicians' minds that Risperdal and/or Invega are safe and effective for their patients, and that they are more efficacious and carry a lower risk of harmful side effects and adverse reactions than other available treatments.

The Excerpta Medica Defendants Assist in the Fraud

61. Excerpta Medica advertises itself as a full-service medical communications *agency*. Its website lists its range of services, including strategic consultancy, publication planning and medical education.

62. The Excerpta Medica Defendants claim to help pharmaceutical clients achieve their objectives by ensuring that health-care professionals, patients, and consumers have information

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to make decisions regarding medical care and treatment options. In fact, the information provided was false and misleading and lacking in fair balance.

63. On information and belief, the Excerpta Medica Defendants have delivered medical communications to healthcare professional, patients and consumers for more than 60 years.

64. On information and belief, the Janssen Defendants, by and through their officers, directors, servants, employees, and agents met with medical writers and officers, directors, servants, employees, and agents of the Excerpta Medica Defendants, by videoconference, telephone and email, and in person, to discuss and agree on plans to create, publish, distribute, and present posters, abstracts, medical journal articles, and oral and written presentations at Janssen-sponsored events, at professional meetings, and as part of purported CMEs.

65. To implement their scheme promoting the efficacy and safety of Risperdal, the Excerpta Medica Defendants, in partnership with the Janssen Defendants, developed a publication strategy whereby Excerpta Medica would generate favorable articles touting Risperdal, including its off-label uses. Because federal regulations put conduct prohibitions in place to guard against drug manufacturers' control over such articles, the publications had to appear as if they emanated from autonomous physicians who were independently investigating Risperdal.

66. One medical communications company defines "publication planning" as "gaining product adoption and usage through the systematic, planned dissemination of key messages and data to appropriate target audiences at the optimum time using the most effective communication channels."

67. On information and belief, with limited clinical support, Excerpta Medica established Risperdal and/or Invega more prominently within the antipsychotic marketplace by:

a. Positioning Risperdal and/or Invega as a prominent player in the antipsychotic

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market as a "broad spectrum antipsychotic";

b. Increasing the base of clinical support for off-label uses of Risperdal and/or Invega;

c. Establishing Risperdal and/or Invega as an attractive therapeutic option to a much larger customer base; and

d. Building physician awareness of the conditions for which Janssen was seeking approved indications.

68. To perform these tasks, Excerpta Medica employed other medical marketing companies, physicians and ghostwriters to produce seemingly unbiased and independent publications regarding Risperdal.

69. The Excerpta Medica Defendants, in partnership with the Janssen Defendants, assembled a portfolio of articles to be published in the medical community that promoted Risperdal and the need for and efficacy of the drug.

70. The portfolio of articles assembled by the Defendants was primarily written by medical writers or educators in the employ of Excerpta Medica, then academic authors were approached by Excerpta Medica to become the named "authors" of such articles. This practice, known as "ghost writing," is purposefully calculated to create a positive "buzz" in the medical community that appears to emanate from an unbiased perspective, giving the article and the glowing conclusions about Risperdal stated therein, false credibility. Accordingly, psychiatric thought was "shaped" though the academic arena to create dissatisfaction in the market, and to establish a "need" for and create a desire for Risperdal.

71. Upon information and belief, the Excerpta Medica Defendants did not allow the listed "authors" of these articles to either see the data from the clinical trials or provide any meaningful input into the writing of the articles. In fact, the Excerpta Medica Defendants had exclusive responsibility for drafting and revising the articles.

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72. Numerous accounts of Excerpta Medica's various actions in the pharmaceutical field have drawn attention to the company's activities, which have included placing ghost-written articles for pharmaceutical companies as well as producing industry-sponsored journals.

73. For example, Susanna Dodgson, a free-lance medical writer who holds a doctorate in physiology, says she was hired in 2002 by Excerpta Medica to write an article about Defendant J&J's anemia drug, Eprex.

74. The focus of the article was a J&J-sponsored study measuring whether Eprex patients could do well taking the drug once a w week.

75. Dr. Dodgson told *The Wall Street Journal* that she was instructed to emphasize the "main message of the study" -- that 79.3% of people with anemia had done well on a once-a-week Eprex dose. However, according to study results provided to Dr. Dodgson, only 63.2% of patients responded well as defined by the original study protocol, according to a report she was provided.

76. The Eprex study eventually appeared in the journal Clinical Nephrology, highlighting the 79.3% figure without mentioning the lower one. The article did not acknowledge Dr. Dodgson or Excerpta Medica.

77. Excerpta Medica drew from its extensive experience in publishing to create company-sponsored publications that focused on providing ostensibly scientific, clinically pertinent, and timely information on off-label and unapproved uses of Risperdal and/or Invega.

78. These publications were created to build awareness of diseases and conditions for which Risperdal and/or Invega were not approved, and to prepare the specialist and primary care markets for potential future indications. They were also designed to establish the Janssen Defendants as one of the industry's authorities on psychiatric diseases. The information was presented by opinion leaders through:

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a. Poster presentations;

b. Abstracts;

c. Clinical journal articles;

d. Pathophysiology articles;

e. Case reports;

f. Literature reviews;

g. Correspondence to journal editors;

h. Continuing Medical Education (CME); and

i. Responses to clinical queries.

79. Posters, abstracts and promotional reprints were prepared by the Excerpta Medica Defendants for Janssen's use at professional meetings, and the clinical content was complemented with high-quality photographic images, giving each issue a very professional and attractive appearance.

80. Publications were released to audiences in Europe and Canada where U.S. physicians were expected to be exposed to such materials.

81. Additionally, upon information and belief, at all relevant times, Excerpta Medica was, and is, accredited by the Accreditation Council for Continuing Medical Education ("ACCME") to provide continuing medical education to physicians.

82. For example, Excerpta Medica offered a CME program, entitled "*Broadening Horizons: Advances in Understanding the Etiology, Effect and Treatment of Anxiety Disorders*" in 2004 and 2005. At least three of the five programs that formed this CME were funded by the Janssen Research Foundation, J&J and/or some other Janssen subsidiary. One of the presentations, entitled "*Treating Anxiety: Current Therapies and Beyond*" was presented by a physician who served as a member of Janssen's Advisory Board and discussed the use of

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atypical antipsychotics, including Risperdal, for "adjunctive anxiety therapy." Risperdal is not approved to treat anxiety disorders. The written supplement for this CME carries a copyright owned by Elsevier Inc.

83. Excerpta Medica also offered a CME in the same time period entitled "*Atypical Antipsychotic Drug Augmentation in Resistant Major Depression Disorder*." Again, Risperdal is not approved to treat resistant major depression disorder, and Elsevier Inc. owned the copyright for the written materials that accompanied the CME. Three of the four presenters received funding, served as consultants and/or were on the speaker's bureaus for various Janssen/J&J entities.

84. The Excerpta Medica website touts, among others, the following Risperdal-related abstracts (that pre-date any FDA approval of Risperdal for these conditions):

a. From a September 2003 European College of Neuropsycopharmacology Congress in the Czech Republic – "Risperidone monotherapy in acute bipolar mania." Upon information and belief, this study was funded by Janssen Pharmceeutica; and

b. From an October 2004 European College of Neuropsycopharmacology Congress in Sweden – "Comparative open-label trial of atypical neuroleptics in children and adolescents with bipolar disorder." This article was authored by Joseph Biederman, M.D., from Massachusetts General Hospital, who is being investigated by various governmental and/or academic entities. The abstract concludes: "This pilot, open-label study suggests that atypical neuroleptics reduce manic symptomatology in children and adolescents with bipolar disorder. **This study suggests that this effect is strongest for risperidone**." (emphasis added).

85. Dr. Biederman and/or Massachusetts General Hospital received millions of dollars in

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contracts and funding for Janssen-sponsored work promoting the treatment of bipolar disorder in children as young as 2 years and promoting the use of Risperdal in treating various mental illnesses in children and adolescents in 2003-2005.

86. Upon information and belief, Dr. Biederman prescribed Risperdal to children in the treatment of Pediatric Bipolar Disorder (PBD). However, PBD did not exist in the Diagnostic and Statistical Manual of Mental Health Disorders IV (DSM IV).

87. The commercial and authoritative value to the Janssen Defendants of Dr. Biederman's prescribing habits, and his support for Risperdal and other atypical antipsychotics, was acknowledged internally at Janssen in a March 2002 email. That e-mail describes Dr. Biedeman's program at a "pediatric seminar" attended by more than 1,000 physicians about the validity of "pediatric mania" and the utility of Risperdal:

> I think this is a clear example of the utility of partnering with a group such as MGH [Massachusetts General Hospital], who has the potential of reaching and having a significant impact upon the field of child and adolescent psychiatry with these types of professional activities in non-sponsored venues.

88. A 2007 article in Current Therapeutic Research, an Elsevier publication, contained an article about a study done in Vancouver, British Columbia, concerning Risperdal. Excerpta Medica holds the copyright on this article.

89. The relationship between the Excerpta Medica Defendants and the Janssen Defendants was essentially that of partners in these enterprises to promote Risperdal nationally and throughout the world.

90. Excerpta Medica is an inspired choice by pharmaceutical companies, including the Janssen Defendants, because it is a branch of the academic publisher, Defendant Elsevier, which publishes many of the world's most prestigious science journals.

91. As part of Elsevier, Excerpta Medica was able to leverage the resources of the world's largest medical and scientific publisher to market, promote and advertise Risperdal for

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off-label and on-label uses.

92. Excerpta Medica helped achieve Janssen's marketing objectives via strategic communications solutions in the following areas:

a. Medical education;

b. Publication planning;

c. Interactive solutions; and

d. Outreach efforts to healthcare professionals, patients and consumers.

93. Excerpta Medica understood that Janssen programs grounded in strategic thinking required a strong team of creators at Excerpta Medica — people who understood the business and could get the job done.

94. The Excerpta Medica Defendants offered an integrated team of experienced professionals to facilitate, plan, and support Janssen marketing objectives at each phase of the product life cycle for Risperdal and/or Invega.

95. Upon information and belief, during the time of its relationship with Janssen, the Excerpta Medica Defendants had more than 120 employees with scientific, business, logistical, and online expertise in the industry.

96. The Excerpta Medica Defendants offered turnkey execution of initiatives across all projects and life-cycle phases for Risperdal and/or Invega.

97. The Excerpta Medica Defendants were able to leverage the extensive resources of Elsevier to strengthen Janssen plans for the off-label promotion of Risperdal and/or Invega.

FDA Prohibition of Off-Label Marketing and Promotion

98. "Off-label" prescribing of drugs occurs when a drug is prescribed by a medical professional for use beyond those contained in the drug's FDA-approved uses. This includes prescribing a drug for a condition not indicated on the label, treating the indicated condition at a

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different dose or frequency than specified in the label, or treating a different patient population (e.g. treating a child with the drug when the drug is approved to treat adults).

99. Pursuant to the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), an off-label use of a drug can cease to be off-label only if the manufacturer conducts studies and submits a new drug application demonstrating to the satisfaction of the FDA that the product is safe and effective for the proposed new use or uses. 21 U.S.C. § 360aaa(b) and (c).

100. Under the FDA laws and regulations, (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose, and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling (which, by definition, includes all drug manufacturer promotional and advertising material) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352.

101. Congress and the FDA also prohibited manufacturers from employing indirect methods to accomplish the same end. Specifically, Congress and the FDA promulgated laws and regulations designed to regulate two of the most prevalent indirect promotional strategies: (1) manufacturer dissemination of medical and scientific publications concerning the off-label uses of their products, and (2) manufacturer support for Continuing Medical Education ("CME") programs that advocate off-label uses of their drugs.

102. With regard to the first practice, disseminating written information, the FDA permits a manufacturer to disseminate information regarding off-label usage only in response to an "unsolicited request from a health care practitioner." 21 U.S.C. §360aaa-6.

103. In any other circumstance, a manufacturer cannot disseminate information concerning the off-label uses of a drug to health care practitioners, pharmacy benefit managers, health insurance issuers, group health plans, or federal and state government agencies unless

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such information is fair and balanced and the manufacturer meets the following conditions:

a. The information concerns a drug that has been approved, licensed and cleared for marketing by the FDA;

b. The information is in the form of an unabridged copy of a peer-reviewed scientific or medical journal article or reprint, or an unabridged reference publication that pertains to a clinical investigation involving the drug and that is considered scientifically sound by experts who are qualified to evaluate the product's safety or effectiveness;

c. The information does not pose a significant risk to the public health;

d. The information is not false or misleading; and

e. The information is not derived from clinical research conducted by another manufacturer, unless permission is received from that manufacturer.

See 21 C.F.R. § 201.6(a). *See also* 21 U.S.C. §§ 360aaa, 360aaa-1.

104. With regard to the second practice – manufacturer involvement in CME programs – the FDA's examination of these practices led to the publication of an agency enforcement policy in 1997, entitled, "Guidance for Industry: Industry-Supported Scientific and Educational Activities." 62 Fed. Reg. 64,074, 64,093, 1997 WL 740420 (F.R.)(1997). This guidance document states that CME programs must be truly independent of the drug companies, and sets forth a number of factors that the FDA will consider in determining whether a program is "free from the supporting company's influence and bias." *Id.* The promotion of off-label drug uses at a CME program which fails the test of "independence" violates Congress' off-label marketing restrictions.

105. Off-label uses of Risperdal continue to increase. According to a 2006 analysis published in the Archives of Internal Medicine (*see Boost for Off-Label Drug Use*, Wall Street

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Journal, February 16, 2008) Risperdal was used off-label 66% of the time in 2006. Today, according to published market research data, as much as 70% of the prescriptions for Risperdal are for off-label use. Off-label prescribing has clearly propelled Risperdal sales.

106. On information and belief, the Janssen Defendants and the Excerpta Medica Defendants have used similar tactics to promote Invega for off-label uses.

107. On information and belief, the Janssen Defendants and the Excerpta Medica Defendants materially violated the laws and regulations governing off-label promotional activities, labeling and misbranding as well as the applicable standard of care in promoting use of Risperdal and/or Invega for unapproved uses in adults, in children and adolescents, and in the elderly by improperly disseminating medical and scientific publications concerning off-label uses of Risperdal and/or Invega and support for CME programs that advocated off-label uses of Risperdal and/or Invega.

PLAINTIFFS' USE OF DRUG PRODUCTS

108. The Adult Plaintiffs and the Minor Plaintiffs were prescribed, ingested and/or were injected with Risperdal and/or Invega at various times.

109. While using said drug product, and as a direct and proximate result thereof, the Adult Plaintiffs and the Minor Plaintiffs developed one or more of the following serious and/or permanent adverse effects: rapid weight gain, hyperprolactinemia, gynecomastia (abnormal development of breasts in males), galactorrhea (lactation), pituitary tumors, microadenomas of the pituitary gland, breast cancer, osteoporosis, decreased bone mineral density, metabolic syndrome, dyslipidemia, hypertension, diabetes mellitus, diabetic ketoacidosis (DKA), hyperosmolar coma, hyperglycemia, glucose dysregulation, insulin insufficiency, insulin resistance, pancreatitis, tardive dyskinesia, extrapyramidal symptoms, involuntary movement disorders, dyskinesia, dystonia, akathisia, parkinsonism, neuroleptic malignant syndrome (NMS)

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and/or other related conditions.

110. As a result of said injuries, Plaintiffs have suffered significant bodily and mental injury, pain and suffering, mental anguish, disfigurement, embarrassment, and inconvenience, have been caused to incur past and future medical expenses, will be required in some cases to undergo mastectomy (surgery) to remove the breasts, and will suffer loss of earning capacity in the future.

111. The Adult Plaintiffs and the Minor Plaintiffs used Risperdal and/or Invega manufactured and distributed by Janssen that had reached the Adult Plaintiffs and the Minor Plaintiffs without substantial change in said drug product's condition since the drugs were manufactured or sold.

112. On information and belief, the Adult Plaintiffs' and the Minor Plaintiffs' prescribing physicians would not have prescribed Risperdal and/or Invega to Adult Plaintiffs and the Minor Plaintiffs had the Janssen Defendants provided said physicians with an appropriate and adequate warning regarding the risks associated with the ingestion of Risperdal and/or Invega and the fact that there were not adequate well-controlled studies showing that Risperdal and/or Invega were safe and effective for treatment of Adult Plaintiffs' and the Minor Plaintiffs' condition, and had said physician not received information and promotional materials from the Janssen Defendants and/or materials produced by the Excerpta Medica Defendants suggesting that Risperdal and/or Invega were safe and effective for use in treating children and adolescents or in treating Plaintiffs' condition. Further, Plaintiffs' prescribing physicians would have changed the way in which they treated the condition for which Plaintiffs were being treated, would have warned patients, including Plaintiffs, about the signs and symptoms of serious adverse effects of Risperdal and/or Invega, would have discussed the risks of weight gain, hyperglycemia, diabetes mellitus, hyperprolactinemia, gynecomastia, and tardive dyskinesia and other serious adverse

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events, and would have permitted patients to chose whether to be treated with Risperdal and/or Invega or not after considering the risks, and, if the patients decided to take Risperdal and/or Invega, Plaintiffs' prescribing physician would have more effectively monitored the Plaintiffs' physical appearance and weight, and would have performed or requested regular physical examinations and laboratory tests, while Plaintiffs were on Risperdal and/or Invega had said Defendants appropriately and adequately disclosed the risks of weight gain, diabetes mellitus, hyperprolactinemia, gynecomastia, and tardive dyskinesia, and death associated with Risperdal and/or Invega and/or had the Janssen Defendants appropriately and adequately warned of the need for initial and/or periodic monitoring of patients on Risperdal and/or Invega.

113. Plaintiffs would not have taken, and Plaintiffs' parents or guardians would not have allowed Plaintiffs to take, Risperdal and/or Invega if the Janssen Defendants had properly disclosed the risks associated with Risperdal and/or Invega, and Plaintiffs and/or Plaintiffs' parents or guardians would have requested and/or followed the prescribing physicians' advice as to the risks and benefits of Risperdal and/or Invega, and/or requested and/or obtained initial and/or regular examinations and blood monitoring had the Janssen Defendants appropriately and adequately warned of the risks and the need for initial and/or regular monitoring of patients taking Risperdal and/or Invega.

114. Plaintiffs have performed all conditions precedent to the bringing of each of the causes of action described herein below.

COUNT I
NEGLIGENCE
(Against the Janssen Defendants)

115. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further allege as follows.

116. The Janssen Defendants had a duty to exercise reasonable care in the design,

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development, manufacturing, testing, advertising, marketing, promotion, labeling, warnings given, distribution, sale, and post-marketing safety monitoring of Risperdal and/or Invega, including a duty to insure that the products did not cause users to suffer from unreasonable, dangerous side effects when used alone or in foreseeable combination with other drugs.

117. The Janssen Defendants failed to perform adequate testing concerning the safety of Risperdal and/or Invega which would have shown that Risperdal and/or Invega posed a serious risk of rapid weight gain, hyperprolactinemia, gynecomastia, tardive dyskinesia, and other adverse effects which would have permitted adequate and appropriate warnings to have been given by Janssen to prescribing physicians and the consuming public, including Plaintiffs.

118. The Janssen Defendants failed to effectively warn users and physicians that non-pharmacological intervention and/or other medications, including other atypical antipsychotic medications, should be the first or exclusive method of treating Plaintiffs' condition.

119. The Janssen Defendants were negligent in the design, development, manufacturing, testing, advertising, marketing, promotion, labeling, warnings given, distribution, sale, and post-marketing safety monitoring of Risperdal and/or Invega in that, among other things, they:

a. Failed to design Risperdal and/or Invega so as to properly minimize effects on receptors that were known to be associated with certain serious adverse effects;

b. Failed to develop Risperdal and/or Invega properly so as to minimize the proliferation of new uses for which there was little or no scientific evidence of safety and efficacy;

c. Failed to manufacture Risperdal and/or Invega properly so as to minimize adulteration and variances in product strength and quality as well as errors in administration, and failed to package in such a way as to adequately warn

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prescribers and users of limited efficacy, lack of evidence for unapproved uses, and serious adverse effects;

d. Failed to conduct adequate pre-clinical and clinical testing to determine the safety of Risperdal and/or Invega, including failure to adequately train clinical investigators as to the risks and benefits of Risperdal and/or Invega and proper methods of monitoring patients;

e. Failed to perform adequate and proper post-marketing safety surveillance for Risperdal and/or Invega which would have revealed an association between Risperdal and/or Invega and serious and life-threatening adverse effects including but not limited to rapid weight gain, hyperglycemia, diabetes mellitus, diabetic ketoacidosis, hyperosmolar coma, death, pancreatitis, hyperprolactinemia, gynecomastia, tardive dyskinesia, extrapyramidal symptoms, and other serious and life-threatening side effects, all of which existed and were known or, in the exercise of due diligence, should have been known by Janssen; and, to the extent that Janssen learned of such adverse effects, it failed to report them to the FDA, physicians, and patients and/or concealed such information from them;

f. Illegally promoted off-label uses of Risperdal and/or Invega for which there was little or no scientific evidence of safety and efficacy;

g. Promoted Risperdal and/or Invega by means of false and misleading claims, failing to include fair balance between risks and benefits, and encouraging off-label uses in advertisements, professional meetings, medical journal articles, advisory meetings, promotional speaking, continuing medical education, leave-behinds at prescribers' offices, detailing, and by other methods and materials;

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h. Failed to label Risperdal and/or Invega so as to convey knowledge concerning Risperdal and/or Invega' approved uses, risks, and benefits in an accurate and timely manner, and to update labeling as necessary;

i. Failed to warn the FDA, prescribing physicians, and users, including Plaintiffs, of the true risks of adverse events associated with Risperdal and/or Invega;

j. Failed to distribute Risperdal and/or Invega properly so as to include adequate warnings and restrictions on unapproved uses;

k. Failed to conduct sales of Risperdal and/or Invega properly in that Janssen sales representatives made false and misleading statements to prescribers concerning approved and unapproved uses, risks and benefits of Risperdal and/or Invega;

l. Failed to provide adequate training and education to, and failed to adequately supervise, its sales representatives so as to prevent them from making false and misleading statements to prescribers concerning approved and unapproved uses, risks and benefits of Risperdal and/or Invega; and encouraged such illegal activities by means of sales promotions, contests, and bonuses;

m. Failed to accompany Risperdal and/or Invega with proper warnings regarding serious adverse side effects associated with the use of Risperdal and/or Invega;

n. Failed to warn Plaintiffs, prior to use of Risperdal and/or Invega, either directly or indirectly (through Plaintiffs' prescribing physician), orally or in writing, about the following:

    i. The signs and symptoms of known serious adverse events including but not limited to rapid weight gain, hyperprolactinemia, gynecomastia, diabetes mellitus, tardive dyskinesia, and potentially fatal side effects;

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ii. The need for diagnostic tests to be performed on the patient prior to and during use of Risperdal and/or Invega to discover and ensure against serious or potentially fatal side effects; and

iii. The need for comprehensive, regular medical monitoring to ensure early discovery of serious or potentially fatal side effects;

o. Failed to warn that the risks associated with the ingestion and/or injection of Risperdal and/or Invega exceeded the risks of other available forms of treatment for Plaintiffs' condition;

p. Failed to effectively warn about the increased danger and potentially fatal relationship in combining the use of Risperdal and/or Invega either together or with various other drugs or use in treatment of Plaintiffs' condition;

q. Marketed Risperdal and/or Invega despite the fact that the risks of the drug were so high and the benefits of the drug were so speculative that no reasonable pharmaceutical company, exercising due care, would have done so;

r. Represented or knowingly omitted, suppressed, or concealed material facts regarding the safety and efficacy of Risperdal and/or Invega from the FDA, prescribing physicians and the consuming public;

s. Remained silent despite their knowledge of the growing public acceptance of misinformation and misrepresentations regarding both the safety and efficacy of ingestion and/or injection of Risperdal and/or Invega and did so because the prospect of huge profits outweighed health and safety issues, all to the significant detriment of Plaintiffs;

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t. Failed to perform their post-manufacturing and continuing duty to warn which arose when they knew, or with reasonable certainty should have known, that their drug was being prescribed in a fatal or injurious combination or manner; and

u. Were otherwise careless, negligent, grossly negligent, reckless, and acted with willful and wanton disregard for the rights of Plaintiffs.

120. As a direct and proximate result of Plaintiffs' ingestion of and/or injection with Risperdal and/or Invega, and the acts and failure to act by the Janssen Defendants, Plaintiffs were caused to develop the aforesaid injuries and damages.

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

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against the Janssen Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT II
NEGLIGENCE
(Design Defect)
(Against All Defendants)

122. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further allege as follows.

123. Defendants are liable to Plaintiffs for the injuries and damages sustained by Plaintiffs due to their negligent design and/or formulation of Risperdal and/or Invega.

124. At all relevant time to this lawsuit, Defendants owed a duty to consumers, including Plaintiffs and their health care providers, to assess, manage and communicate the risks, dangers and adverse effects of Risperdal. Defendants' duties included, but were not limited to, carefully and properly designing, testing, studying and manufacturing Rispedal.

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125. Defendants negligently and carelessly breached the above-described duties to Plaintiffs by negligently and carelessly:

a. Failing to use ordinary care in designing, testing, and manufacturing Risperdal and/or Invega;

b. Failing to design Risperdal and/or Invega so as to properly minimize effects on receptors that were known to be associated with certain serious adverse effects;

c. Failing to develop Risperdal and/or Invega properly so as to minimize the proliferation of new uses for which there was little or no scientific evidence of safety and efficacy; and

d. Utilizing false and misleading data and facts in publication planning, professional meetings, medical journal articles (including submitting ghost-written articles controlled by Excerpta Medica), advisory meetings, clinical trials, clinical studies, and by other methods and materials in the design and formulation stage of Risperdal's development.

126. The Risperdal and/or Invega manufactured, distributed, and/or supplied by Janssen was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceeded the benefits associated with the design or formulation.

127. Alternatively, the Risperdal and/or Invega manufactured and/or distributed and/or supplied by Janssen was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers and/or distributors, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than other atypical antipsychotic drugs.

128. Although Defendants knew or should have known that Risperdal caused unreasonably

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dangerous side effects, which many uses would be unable to remedy by any means, Defendants continued to market this drug when there were safer and less expensive alternatives available.

129. Defendants knew or should have known that consumers, like Plaintiffs, would suffer injury as a result of Defendants' failure to exercise ordinary care, as described above. Janssen, as a manufacturer of drug products, and Excerpta Medica, as its partner, are held to the level of knowledge of an expert in the field.

130. As a direct and proximate result of Defendants' negligent acts and/or omissions, Plaintiffs suffered injuries and damages, as set forth in their individual Complaints.

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against all Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT III
FRAUD
(Against All Defendants)

131. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further allege as follows.

132. All Defendants knowingly and intentionally made false and misleading statements regarding the uses, safety, and efficacy of Risperdal and/or Invega, and/or concealed, suppressed, and omitted important information regarding the uses, safety, and efficacy of Risperdal and/or Invega, in general, and in treating conditions such as those of Plaintiffs, to Plaintiffs' and to Plaintiffs' prescribing physicians.

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

a. Making false and misleading claims regarding the known risks of Risperdal and/or Invega and/or suppressing, failing to disclose and mischaracterizing the

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known risks of Risperdal and/or Invega, including, but not limited to, rapid weight gain, hyperprolactinemia, gynecomastia, diabetes mellitus, diabetic ketoacidosis, tardive dyskinesia, and death;

b. Making false and misleading written and oral statements that Risperdal and/or Invega are more effective than other antipsychotic drugs and/or omitting material information showing that Risperdal and/or Invega are no more effective than other available antipsychotic drugs;

c. Misrepresenting or failing to timely and fully disclose the true results of clinical tests and studies related to Risperdal and/or Invega;

d. Issuing false and misleading warnings and/or failing to issue adequate warnings concerning the risks and dangers of ingesting and/or being injected with Risperdal and/or Invega which would disclose the nature and extent of the harmful side effects of Risperdal and/or Invega;

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

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

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

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false and misleading; and

h. Insisting on confidentiality agreements in other litigation concerning Risperdal and refusing to produce documents unless Plaintiffs in that litigation agreed, then over-designating nearly every document produced as confidential, despite the absence of any reasonable expectation that such documents were trade secrets or that they required protection to avoid any particular harm to Defendants, which was done for the improper purpose of preventing the public from learning about the true risks of adverse effects associated with Risperdal.

134. Defendants had a post-manufacturing and continuing duty to warn, which arose when they knew, or with reasonable care should have known, that Risperdal and/or Invega were associated with adverse effects which are injurious or fatal.

135. Defendants engaged in calculated silence despite their knowledge of the growing public acceptance of misinformation and misrepresentations regarding the uses, safety and efficacy of Risperdal and/or Invega, and did so because the prospect of enormous future profits caused them to ignore concerns regarding health and safety issues, all to the significant detriment of the public, including Plaintiffs.

136. Defendants' actions as set forth herein constitute knowing misrepresentation, omission, suppression and concealment of material facts, made with the intent that the FDA, physicians and consumers, including Plaintiffs, would rely upon such misrepresentation, concealment, suppression or omission, in connection with the marketing, sale and use of Risperdal and/or Invega.

137. In the alternative, Defendants failed to exercise reasonable care in ascertaining the accuracy of the information they provided regarding the safety of Risperdal and communicating that information to Plaintiffs and their physicians.

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138. At the time of the Defendants' fraudulent misrepresentations and active concealment, Plaintiffs and their physicians were not aware of the falsity of the foregoing representations, nor were they aware that material facts concerning Risperdal had been concealed or omitted. In reliance upon the Defendants' misrepresentations, Plaintiffs and their physicians were use Risperdal.

139. The FDA, physicians and Plaintiffs did not know, and could not learn, the truth concerning the uses, risks and benefits of Risperdal and/or Invega due to Janssen's deliberate misrepresentations and concealment, suppression and omission of material facts and important information regarding Risperdal and/or Invega. The facts and information misrepresented, concealed, suppressed and omitted by Janssen are material, and of such a nature that it can be reasonably presumed that the suppression and concealment of such facts caused, contributed to, and/or was a substantial factor in the prescribing doctors' decision to prescribe Risperdal and/or Invega to Plaintiffs and in Plaintiffs' decision to use Risperdal and/or Invega and/or to give them to their children.

140. The reliance of Plaintiffs and their physicians upon Defendants' misrepresentations were justified, among other reasons, because said misrepresentations and omissions were made by individuals and entities who were in a poison to know the true facts concerning Risperdal, while Plaintiffs and their physicians were not in a position to know the true facts.

141. Plaintiffs, directly and/or through their prescribing physicians, were induced by Defendants' misrepresentations, omissions, suppression and concealment to agree to use and to have their children use Risperdal and/or Invega.

142. As a direct and proximate result of the aforesaid fraudulent conduct by Defendants, Plaintiffs and/or their children were caused to use Risperdal and/or Invega and suffered the aforesaid injuries and damages.

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

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against all Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT IV
STRICT PRODUCT LIABILITY
(Failure to Warn)
(Against the Janssen Defendants)

144. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further allege as follows.

145. The Risperdal and/or Invega manufactured and/or distributed and/or supplied by Janssen was defective and unreasonably dangerous due to inadequate post-marketing warnings or instructions because Janssen failed to provide adequate warnings to users or consumers of Risperdal and/or Invega and continued to aggressively promote these dangerous and defective drug products.

146. The Janssen Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and, further, the Janssen Defendant knew or should have known that warnings and other clinically relevant information and date which they distributed regarding the risks of Risperdal were inadequate.

147. Plaintiffs did not have the same knowledge as the Janssen Defendants and no adequate warning or other clinically relevant information and date was communicated to them or their physicians.

148. Despite the fact that the Janssen Defendants knew or should have known that Risperdal and/or Invega were associated with rapid weight gain, hyperprolactinemia, gynecomastia (abnormal development of breasts in males), galactorrhea (lactation), pituitary

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tumors, microadenomas of the pituitary gland, breast cancer, osteoporosis, decreased bone mineral density, metabolic syndrome, dyslipidemia, hypertension, diabetes mellitus, diabetic ketoacidosis (DKA), hyperosmolar coma, hyperglycemia, glucose dysregulation, insulin insufficiency, insulin resistance, pancreatitis, tardive dyskinesia, extrapyramidal symptoms, involuntary movement disorders, dyskinesia, dystonia, akathisia, parkinsonism, neuroleptic malignant syndrome (NMS) and/or other related conditions, the Janssen Defendants recklessly, negligently, and with willful and wanton indifference to the health and safety of consumers including Plaintiffs, failed to provide an adequate warning and/or clinically relevant information and data with regard to the above-identified conditions.

149. Despite the fact that the Janssen Defendants knew or should have known that Risperdal and/or Invega were/are associated with the above-identified conditions, including, but not limited to, hyperprolactinemia, gynecomastia and galactorrhea, tardive dyskinesia, extrapyramidal symptoms, diabetes, and rapid weight gain, the label for Risperdal failed, and continues to fail, to include an adequate warning as to the true risks of these adverse effects associated with Risperdal and/or Invega.

150. Despite the fact that the Janssen Defendants knew or should have known that Risperdal and/or Invega are associated with hyperprolactinemia, gynecomastia and galactorrhea in Janssen clinical trials, that information was deliberately withheld from prescribing physicians and the public until at least October 2006, when it appeared in the label for Risperdal and/or Invega.

151. Even now, the warnings in the labeling for Risperdal and/or Invega are inadequate and fail to include significant information in Janssen's possession regarding postmarketing adverse event reports of these and related adverse events.

152. Despite the warnings, if any, in the label for Risperdal and/or Invega, the Janssen

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Defendants intentionally downplayed and minimized any such warnings in promotional materials, CME, presentations at medical meetings, and in visits by sales representatives to doctors' offices so as to cause doctors and patients, including Plaintiffs, to remain unaware of the true nature and extent of serious side effects of Risperdal and/or Invega.

153. Plaintiffs did not have the same knowledge as the Janssen Defendants and no adequate warning or otherwise clinically relevant information and date were communicated to them or to their physicians.

154. As a result of the foregoing, Risperdal and Invega are both defective and unreasonably dangerous drug products.

155. As a direct and proximate result of ingestion or injection with of Risperdal and/or Invega and the aforesaid acts and failure to act by Janssen, Plaintiffs were caused to suffer the aforesaid injuries and damages. Janssen's conduct is outrageous because of reckless indifference to the health and safety of Plaintiffs and the public so as to justify an award of punitive damages.

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against the Janssen Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT V
STRICT PRODUCT LIABILITY
(Design Defect)
(Against the Janssen Defendants)

156. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further allege as follows.

157. The Janssen Defendants are liable to Plaintiffs for the injuries and damages sustained by Plaintiffs due to the defective design and/or formulation of Risperdal and/or Invega.

158. The Janssen Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field.

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159. The Risperdal and/or Invega manufactured, distributed, and/or supplied by Janssen was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceeded the benefits associated with the design or formulation.

160. Alternatively, the Risperdal and/or Invega manufactured and/or distributed and/or supplied by Janssen was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers and/or distributors, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than other atypical antipsychotic drugs.

161. There existed, at all times material hereto, safer alternative medications.

162. Janssen did not perform adequate testing on Risperdal and/or Invega. Adequate testing would have shown that Risperdal and/or Invega cause serious adverse effects with respect to which full and proper warnings that accurately and fully reflected symptoms, scope and severity should have been made.

163. The Risperdal and/or Invega ingested by Plaintiffs was defective at the time it was distributed by the Janssen Defendants or left their control..

164. The Risperdal and/or Invega ingested by Plaintiffs reached them without substantial change in the condition in which it was sold.

165. As a direct and proximate result of Plaintiffs' ingestion of and/or injection with Risperdal and/or Invega and the defects in the Risperdal and/or Invega, Plaintiffs suffered the aforesaid injuries and damages.

166. Janssen's conduct is outrageous because of reckless indifference to the health and safety of Plaintiffs and the public so as to justify an award of punitive damages.

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against

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the Janssen Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT VI
BREACH OF EXPRESS WARRANTY
(Against the Janssen Defendants)

167. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further allege as follows.

168. The Janssen Defendants expressly warranted that Risperdal and/or Invega are safe and effective and that Risperdal and/or Invega were well tolerated in adequate and well-controlled clinical studies.

169. Risperdal and/or Invega do not conform to these express representations because Risperdal and/or Invega are not safe and both cause high levels of serious, life-threatening side effects.

170. As a direct and proximate result of Plaintiffs' ingestion of and/or injection with Risperdal and/or Invega and the aforesaid acts and failure to act by Janssen, Plaintiffs were caused to develop the aforesaid injuries and damages.

171. The Janssen Defendants' conduct is outrageous because of reckless indifference to the health and safety of Plaintiffs and the public so as to justify an award of punitive damages.

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against the Janssen Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT VII
BREACH OF IMPLIED WARRANTY
(Against the Janssen Defendants)

172. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further allege as follows.

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173. At the time the Janssen Defendants marketed, sold and distributed Risperdal and/or Invega for use by Plaintiffs and the consuming population, Janssen knew of the use for which Risperdal and/or Invega were intended and impliedly warranted Risperdal and/or Invega to be of merchantable quality and safe and fit for such use.

174. Plaintiffs reasonably relied upon the skill and judgment of Janssen as to whether Risperdal and/or Invega were of merchantable quality and safe and fit for their intended use.

175. Contrary to such implied warranty, Risperdal and/or Invega were not of merchantable quality or safe or fit for their intended use, because Risperdal and/or Invega were and are unreasonably dangerous and unfit for the ordinary purposes for which it was used as described above.

176. As a direct and proximate result of Plaintiffs' ingestion of Risperdal and/or Invega and the aforesaid acts and failure to act by the Janssen Defendants, Plaintiffs were caused to suffer the aforesaid injuries and damages.

177. The Janssen Defendants' conduct is outrageous because of reckless indifference to the health and safety of the Plaintiffs and the public so as to justify an award of punitive damages.

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against the Janssen Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT VIII
VIOLATION OF PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW 73 P.S. § 201-1
(Against All Defendants)

178. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further allege as follows.

179. All Defendants financed, assisted, supported and participated in the promotion and use of Risperdal in order to create a demand for the drug.

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180. All Defendants deliberately misrepresented the safety of Risperdal and intentionally concealed the risks attendant to use of the drug. Through their misrepresentations, Defendant intentionally affected the decisions of consumer and their health care providers to purchase, prescribe and use Risperdal, and to exclude the options of not using a drug product or using a substantially cheaper alternative drug from the same class.

181. All Defendants, while engaged in the conduct and practices identified above, committed one or more violations of state laws related to unfair or deceptive acts or practices, including, but not limited to, the following:

a. Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of Risperdal and/or Invega;

b. Causing likelihood of confusion or of misunderstanding as to affiliation, connection or association with, or certification by, another, of Risperdal and/or Invega;

c. Representing that Risperdal and/or Invega have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have;

d. Representing that Janssen authors and speakers do not have a sponsorship, approval, status, affiliation or connection that they do have;

e. Representing that Risperdal and/or Invega are of a particular standard, quality or grade;

f. Disparaging the goods, services or business of other pharmaceutical manufacturers by false or misleading representation of fact;

g. Failing to comply with the terms of a written guarantee or warranty given to the buyer at, prior to or after a contract for the purchase of goods or services is made; and

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h. Engaging in other fraudulent or deceptive conduct which creates likelihood of confusion or of misunderstanding, as alleged in this Complaint.

182. Plaintiffs have suffered injuries and damages as a direct and proximate result of Defendants' statements in the advertising and promotional activities to Plaintiffs and their medical providers, as described above.

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against all Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT IX
UNFAIR AND DECEPTIVE TRADE PRACTICES
(Against All Defendants)

183. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further allege as follows.

184. Under state laws, Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion and sale of drug products.

185. All Defendants financed, assisted, supported and participated in the promotion and use of Risperdal in order to create a demand for the drug.

186. All Defendants deliberately misrepresented the safety of Risperdal and intentionally concealed the risks attendant to use of the drug. Through their misrepresentations, Defendant intentionally affected the decisions of consumer and their health care providers to purchase, prescribe and use Risperdal, and to exclude the options of not using a drug product or using a substantially cheaper alternative drug from the same class.

187. All Defendants, while engaged in the conduct and practices identified above, committed one or more violations of state laws related to unfair or deceptive acts or practices,

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including, but not limited to, the following:

a. Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of Risperdal and/or Invega;

b. Causing likelihood of confusion or of misunderstanding as to affiliation, connection or association with, or certification by, another, of Risperdal and/or Invega;

c. Representing that Risperdal and/or Invega have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have;

d. Representing that Janssen authors and speakers do not have a sponsorship, approval, status, affiliation or connection that they do have;

e. Representing that Risperdal and/or Invega are of a particular standard, quality or grade;

f. Disparaging the goods, services or business of other pharmaceutical manufacturers by false or misleading representation of fact;

g. Failing to comply with the terms of a written guarantee or warranty given to the buyer at, prior to or after a contract for the purchase of goods or services is made; and

h. Engaging in other fraudulent or deceptive conduct which creates likelihood of confusion or of misunderstanding, as alleged in this Complaint.

188. Plaintiffs have suffered injuries and damages as a direct and proximate result of Defendants' statements in the advertising and promotional activities to the Plaintiffs' medical providers, as described above.

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against all Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and

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interest at the legal rate.

COUNT X
CONSPIRACY
(Against All Defendants)

189. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further allege as follows.

190. The Janssen Defendants and the Excerpta Medica Defendants, in a combination of two or more persons, acted with a common purpose to do an illegal act and/or to do a lawful act by unlawful means or for an unlawful purpose. Specifically, all Defendants violated the FDCA and parallel state acts and state common law by selling, marketing, promoting and distributing a drug product that was misbranded and/or unadulterated under the applicable statutes, including the FDCA.

191. Defendants conspired to recruit and use, and did use, academicians and other influential persons in the medical community as "key opinion leaders" to serve as named authors and presenters, despite the fact that the authors and presenters had little or no personal involvement in research on Risperdal and/or Invega, or in the analysis of data, or in the actual authorship of these materials.

192. These meetings were held for an illegal purpose, *i.e.*, the promotion of off-label uses of Risperdal and/or Invega and the creation of false and misleading promotional materials designed to create a false impression in the minds of physicians that Risperdal and/or Invega are safe and effective for a variety of uses, labeled and unlabeled, that Risperdal and/or Invega are "broad spectrum antipsychotics," that Risperdal and/or Invega were safe and effective in the treatment of children and adolescents (prior to approval of any use in children and adolescents in the United States), and that Risperdal and/or Invega were safe and effective in the treatment of conditions for which Risperdal and/or Invega have never been approved in the United States, *i.e.*,

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autism, Attention-Deficit/Hyperactivity Disorder (ADHD), Obsessive-Compulsive Disorder (OCD), Oppositional-Defiant Disorder (ODD), Conduct Disorder (CD), Disruptive Behavior Disorder (DBD), Tourette's syndrome, Post-Traumatic Stress Disorder (PTSD), pervasive development disorders (PDD), and substance abuse.

193. All Defendants acted with a common purpose to negligently, intentionally and/or fraudulently withhold information regarding the safety of Risperdal for the purpose of earning profits at the expense of Plaintiffs' health.

194. Plaintiffs and other consumers have been damaged as a direct and proximate result of Defendants' concerted actions, as alleged above.

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against all Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT XI
PUNITIVE DAMAGES
(Against All Defendants)

195. Plaintiffs and other consumers have been damaged as a direct and proximate result of Defendants' concerted actions, as alleged above.

196. Plaintiffs are entitled to punitive damages because Defendants' actions were reckless and without regard for the public's safety and welfare. Defendants misled both the medical community and the public at large, including Plaintiffs and their physicians, by making false representation about and concealing pertinent information regarding Risperdal. Defendants downplayed, understated and disregarded its knowledge of the serious and permanent side effects associated with the use of Risperdal, including gynecomastia, despite information demonstration the product was unreasonably dangerous.

197. The conduct of Defendants in designing, testing, manufacturing, promoting,

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advertising, selling, labeling, marketing, and distributing Risperdal, and in failing to warn Plaintiffs and other members of the public of the dangers inherent in the use of Risperdal, which were known to Defendants, was attended by circumstances of fraud, malice, or willful and wanton conduct, done heedlessly and recklessly without regard to consequences, or of the rights and safety of other, including Plaintiffs.

198. At all times material hereto, Defendants had a duty to exercise reasonable care in the design, manufacture, testing, research and development, processing, advertising, marketing, labeling, packaging, distribution, promotion and sale of Risperdal.

199. Defendants breached their duty and were wanton and reckless in their actions, misrepresentations, and omissions toward the public generally, and Plaintiffs specifically, in the following ways:

a. Defendants actually knew of Risperdal's defective nature, as set forth herein, but continued to design, manufacture, market and sell Risperdal so as to maximize sales and profits at the expense of the health and safety of the consuming public, including Plaintiffs, and in the conscious disregard of the foreseeable harm caused by Risperdal.

b. Defendants spent millions of dollars a year aggressively marketing Risperdal, but devoted far less attention to conducting significant pre-clinical testing, clinical testing, comparison testing, and adequate post-marketing surveillance of this drug.

c. Defendants violated state and/or federal laws by selling and distributing a drug product that was misbranded and/or adulterated under the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 *et seq.* and parallel state Food, Drug and Cosmetic Acts and state common law; and

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d. Defendants continued to promote the safety of Risperdal, while providing no warnings at all about the unreasonable risk to consumers of gynecomastia and/or diabetes associated with it, even after Defendants knew of that risk from multiple studies.

196. Defendants knew that Risperdal had unreasonably dangerous risks and caused serious side effects of which Plaintiffs and their physicians would not be aware. Defendants nevertheless advertised, marketed, distributed, and sold medicine knowing that there were safer methods and products available.

197. Defendants' above-described actions were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiffs and the public.

198. One or more of the aforementioned violations of law by Defendants were committed with reckless disregard for the safety of the public and of Plaintiffs as a product user.

199. One or more of the aforementioned violations of law by Defendants were committed willfully and deliberately, and caused substantial financial injury to the consuming public and Plaintiffs.

200. As a direct and proximate result of the wanton and reckless actions and inactions of Defendants as set forth above, Plaintiffs are entitled to punitive damages.

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against all Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT XII
MEDICAL EXPENSES INCURRED BY PARENT
(Against All Defendants)

201. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further allege as follows.

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202. By reason of the foregoing, Plaintiff's (mother, father, child) has (have) necessarily paid and has (have) become liable to pay for medical aid, treatment, attendance and medications, and will necessarily incur further expense of a similar nature in the future.

203. Said Plaintiffs incurred expenses for doctors' visits, prescriptions for Risperdal and/or Invega, and examination, testing, and treatment in an effort to cure Plaintiffs of injuries sustained as a result of their use of Risperdal and/or Invega, incurred travel expenses in connection with same, and lost time from work and income, all as a proximate and direct result of the wrongful acts of Defendants, and will continue to do so in the future.

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against all, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT XIII
LOSS OF CONSORTIUM
(Against All Defendants)

204. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further allege as follows.

205. At all time relevant hereto, Plaintiffs' spouses ("Plaintiffs' Spouse") and/or family members ("Family Member Plaintiffs") have suffered injuries and losses as a result of Plaintiffs' injuries.

206. Spouse Plaintiffs and/or Family Member Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment and for medications, and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' conduct.

207. Spouse Plaintiffs and/or Family Member Plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

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208. For all Spouse Plaintiffs, Plaintiffs allege his/her marital relationship has been impaired and depreciated, and the marital association between husband and wife has been altered.

209. Spouse Plaintiffs and/or Family Members Plaintiffs have suffered great emotional pain and mental anguish.

WHEREFORE, Plaintiffs request judgment for compensatory and punitive damages against all, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

205. The running of any statute of limitation has been tolled by reason of Defendants' fraudulent conduct. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiffs and Plaintiffs' prescribing physicians the true risks associated with taking Risperdal.

206. As a result of Defendants' fraudulent actions, Plaintiffs and Plaintiffs' prescribing physicians were unaware and could not reasonably have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

WHEREFORE, Plaintiffs request trial by jury and that the Court grant them the following relief against Defendants, jointly and severally, on all counts of this Complaint including:

a. Money Damages representing fair, just and reasonable compensation for their respective common law and statutory claims;

b. Punitive and/or Treble Damages pursuant to state law;

c. Disgorgement of profits and restitution of all costs;

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d. Attorneys' fees pursuant to state law;

e. Pre-judgment and post-judgment interests as authorized by law on the judgments which enter on Plaintiffs' behalf;

f. Cost of suit; and

g. Such other relief as is deemed just and appropriate.

Respectfully submitted,

SHELLER, P.C.

/s/ Stephen A. Sheller
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Jamie L. Sheller, Esquire
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Attorneys for Plaintiffs

DATED: September 3, 2010

DEMAND FOR JURY TRIAL

Demand is hereby made for a trial by jury.

/s/ Brian J. McCormick, Jr.
Brian J. McCormick, Jr., Esquire
SHELLER, P.C.

Attorney for Plaintiffs

DATED: September 3, 2010

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