FDA Prohibition of Off-Label Marketing and Promotion

124. "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 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).

125. 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).

126. 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.

127. 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.

128. 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.

129. 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 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.

130. 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.

131. 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 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.

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

133. 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 providing support for CME programs that advocated off-label uses of Risperdal and/or Invega.

PLAINTIFFS' USE OF DRUG PRODUCTS

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

135. 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 and/or long-lasting weight gain, hyperprolactinemia, gynecomastia (abnormal development of breasts in males), galactorrhea (lactation), precocious puberty, 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.

136. 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.

137. 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.

138. 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 efficacious for treatment of Adult Plaintiffs' and the Minor Plaintiffs' condition, and had said physicians 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 efficacious 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 rapid and/or long-lasting weight gain, hyperglycemia, diabetes mellitus, precocious puberty, hyperprolactinemia, gynecomastia, and tardive dyskinesia and other serious adverse 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 rapid and/or long-lasting weight gain, diabetes mellitus, precocious puberty, 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.

139. 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.

140. 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)

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

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

143. 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 and/or long-lasting weight gain, hyperprolactinemia, gynecomastia, precocious puberty, 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.

144. 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.

145. 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 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 and/or long-lasting weight gain, hyperglycemia, diabetes mellitus, diabetic ketoacidosis, hyperosmolar coma, death, pancreatitis, hyperprolactinemia, gynecomastia, tardive dyskinesia, precocious puberty, 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;

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 and/or long-lasting weight gain, hyperprolactinemia, gynecomastia, diabetes mellitus, tardive dyskinesia, and potentially fatal side effects;

   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;

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.

146. 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.

147. 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 the Janssen Defendants)

148. Plaintiff(s) incorporate by reference all other paragraphs of this Second Amended

Master Complaint as if fully set forth herein and further allege as follows.

149. The Janssen 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.

150. At all relevant time to this lawsuit, the Janssen 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. The Janssen Defendants' duties included, but were not limited to, carefully and properly designing, testing, studying and manufacturing Rispedal.

151. The Janssen 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;

d. Utilized false and misleading claims, including ghost-writing, 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 in the design and formulation stage of Risperdal's development.

152. 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.

153. 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.

154. Although the Janssen Defendants knew or should have known that Risperdal caused unreasonably dangerous side effects, which many uses would be unable to remedy by any means, the Janssen Defendants continued to market this drug when there were safer and less expensive alternatives available.

155. The Janssen Defendants knew or should have known that consumers, like Plaintiffs, would suffer injury as a result of Janssen's failure to exercise ordinary care, as described above. Janssen, as a manufacturer of drug products, is held to the level of knowledge of an expert in the field.

156. As a direct and proximate result of the Janssen 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 the Janssen Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT III
FRAUD
(Against All Defendants)

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

158. 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.

159. 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 known risks of Risperdal and/or Invega, including, but not limited to, rapid and/or long-lasting weight gain, hyperprolactinemia, gynecomastia, diabetes mellitus, diabetic ketoacidosis, tardive dyskinesia, precocious puberty, and death;

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

160. 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.

161. 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.

162. 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.

163. 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.

164. 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.

165. 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.

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

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

168. 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.

169. 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 Defendants knew or should have known that warnings and other clinically relevant information and data which they distributed regarding the risks of Risperdal were inadequate.

170. 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.

171. Despite the fact that the Janssen Defendants knew or should have known that Risperdal and/or Invega were associated with rapid and/or long-lasting weight gain,

hyperprolactinemia, gynecomastia (abnormal development of breasts in males), galactorrhea (lactation), precocious puberty, 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, 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.

172. 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, precocious puberty, tardive dyskinesia, extrapyramidal symptoms, diabetes, and rapid and/or long-lasting 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.

173. 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.

174. 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.

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

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

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

178. As a direct and proximate result of ingestion of 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)

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

180. 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.

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

182. 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.

183. 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.

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

185. 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.

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

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

188. 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.

189. 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 VI
BREACH OF EXPRESS WARRANTY
(Against the Janssen Defendants)

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

191. 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.

192. 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.

193. 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.

194. 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)

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

196. 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.

197. 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.

198. 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.

199. 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.

200. 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)

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

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

203. 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.

204. 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

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

205. 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)

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

207. 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.

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

209. 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.

210. 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

h. Engaging in other fraudulent or deceptive conduct which creates likelihood of

confusion or of misunderstanding, as alleged in this Complaint.

211. 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 interest at the legal rate.

COUNT X
CONSPIRACY
(Against All Defendants)

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

213. 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.

214. 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.

215. 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.*, 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.

216. 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.

217. 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)

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

219. 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.

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

221. 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.

222. 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

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, 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 Second Amended Master Complaint as if fully set forth herein and further allege as follows.

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 Second Amended Master Complaint as if fully set forth herein and further allege as follows.

a. 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.

b. 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.

c. 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.

d. 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.

e. 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;

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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Attorneys for Plaintiffs

DATED: April 4, 2012

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: April 5, 2012