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MONTANA FIRST JUDICIAL COURT LEWIS AND CLARK COUNTY

MIKE MCGRATH, ATTORNEY GENERAL OF THE STATE OF MONTANA, ex rel THE STATE OF MONTANA, Plaintiff, v. JANSSEN, LP, JANSSEN ORTHO, LLC, JANSSEN PHARMACEUTICA, INC., and ASTRAZENECA PHARMACEUTICALS, LP, Defendants.	Case No. CDV 2008 104 **COMPLAINT**

The State of Montana, by and through the Attorney General of the State of Montana, Mike McGrath, makes the following claims against Defendants:

INTRODUCTION

1. This is a civil action for damages, civil penalties and injunctive relief for violations of the Montana Food Drug and Cosmetic Act, the Montana Consumer Protection Act, The Montana False Claims Act and other state common law and statutory causes of action stated herein brought by the Montana Attorney General in the exercise of his constitutional, common law, and statutory powers against Janssen, L.P., Janssen Ortho, LLC, Janssen Pharmaceutica, Inc. (collectively "Janssen") and AstraZeneca Pharmaceuticals, LP ("AstraZeneca"). This action seeks damages and other monetary and injunctive relief by reason of Defendants' wrongful and illegal design, testing, marketing, sales and promotion of the atypical antipsychotics risperidone (known as Risperdal) and quetiapine (known as Seroquel) which, when sold in Montana, were in defective condition and unreasonably dangerous.

2. Risperdal and Seroquel were unreasonably dangerous and in defective condition because of their causal association with development of diabetes, diabetes-related conditions, including weight gain, and other serious, even life threatening medical conditions. Janssen and AstraZeneca failed to warn – and affirmatively misled – physicians, citizen-users, and others in the medical community regarding Risperdal's and Seroquel's dangers and defective condition.

3. Since Janssen launched Risperdal in 1996 and AstraZeneca launched Seroquel in 1997, the companies have engaged in false and misleading marketing, advertising and sales campaigns to promote these drugs for non-medically indicated uses. Janssen and AstraZeneca (hereinafter "Defendants") successfully deceived physicians, citizen-users, and others in the medical community regarding the comparative safety, efficacy and superiority of Risperdal and Seroquel over traditional or other atypical antipsychotics in order to achieve greater market share

by expanding the use of Risperdal and Seroquel beyond the miniscule patient population for which Risperdal and Seroquel were approved as a drug therapy by the FDA.

4. Risperdal's and Seroquel's FDA-approved uses (prior to October 20, 2006) were limited to adult schizophrenia and short-term treatment of acute manic episodes associated with Bipolar I Disorder. Janssen and AstraZeneca aggressively marketed and promoted Risperdal and Seroquel for non-medically indicated uses for which the efficacy and safety of the drugs has never been established. For example, Defendants actively marketed Risperdal and Seroquel for the treatment of various conditions or symptoms in *children* who had not been diagnosed with schizophrenia or Bipolar I Disorder; treatment in the *elderly*, primarily for dementia or disruptive behaviors; and treatment in minors and adults for broad, vague symptoms encompassing a myriad of mental afflictions such as anxiety and depression.

5. A January 2007 report by the Agency for Healthcare Research and Quality ("2007 AHRQ Report") entitled *Efficacy and Comparative Effectiveness of Off-Label Use of Atypical Antipsychotics,* states that Risperdal is being widely prescribed for non-medically indicated uses, including treatment for Autistic Spectrum Disorders for adults, dementia, depression for patients who do not benefit from selective serotonin reuptake inhibitors ("SSRI"), Obsessive-Compulsive Disorder ("OCD") for patients who do not respond adequately to SSRI therapy, Post-Traumatic Stress Disorder, Personality Disorders, Tourette's Syndrome, Alzheimer's disease, anxiety, Attention Deficit Disorder, Attention Deficit Hyperactivity Disorder, sleep disorders, anger management, and mood enhancement or mood stabilization. As discussed herein, most, if not all, of these non-medically indicated uses have been expressly promoted by Janssen or have resulted from Janssen's deceptive marketing campaign.

6. Janssen's unlawful marketing, advertising and promotion propelled Risperdal to a

27% share of the market for atypical antipsychotics in 2006, transforming Risperdal into one of the best selling prescription drugs in 2006 with $4.2 billion in sales.

7. AstraZeneca's unlawful marketing, advertising and promotion of Seroquel was similarly effective. Seroquel captured a 22% share of the market in 2006 with $3.4 billion in sales, making it AstraZeneca's number one prescription product.

8. Less than 2% percent of the United States population falls within Risperdal's and Seroquel's FDA-approved indications. Further, the drug therapeutic category of antipsychotics is comprised of numerous traditional and atypical antipsychotic safer alternatives. Nonetheless, Risperdal's and Seroquel's combined annual sales exceed $7 billion.

9. As a result of Janssen's and AstraZeneca's improper, false, and misleading marketing of these atypical antipsychotic drugs, the State of Montana and its citizens and other entities were injured and damaged, including some of whom suffered serious injuries, illnesses, diseases or death after taking Defendants' antipsychotic drugs and others who were caused to spend money on these drugs that were not medically indicated and that actually caused injury, disability and death. Defendants knew or should have known of the dangerous, defective condition of these drugs, but failed to warn Montana physicians, particularly primary care physicians, citizen-users, and others in the medical community, of those risks. Janssen and AstraZeneca further knew that many of the citizen-users were Montana Medicaid recipients and knew or should have known that the State of Montana would expend state funds through the Montana Department of Public Health and Human Services ("DPHHS") for purchasing Defendants' antipsychotic drugs for non-medically accepted indications.

10. As a result of the above and foregoing actions by Defendants Janssen and AstraZeneca, Plaintiff seeks: a) damages for medical care and treatment for injuries caused or

contributed to by the unreasonably dangerous, defective condition of these drugs; b) recovery of the funds expended by the State of Montana through the DPHHS and by its citizens and other entities for purchasing the prescription drugs Seroquel and Risperdal for non-medically accepted indications; and c) injunctive relief solely within the geographic boundaries of the State of Montana, against the ongoing conduct of Defendants Janssen and AstraZeneca which continues to proximately cause the State of Montana and its citizenry irreparable harm.

PARTIES

Plaintiff

11. Plaintiff, the State of Montana, is a body politic created by the Constitution and laws of the State of Montana; and as such, it is not a citizen of any state. Mike McGrath is the duly-elected and present Attorney General of the State of Montana. The Attorney General brings this action in the exercise of his statutory and common law powers.

Defendants

12. Defendant Janssen, L.P. is a New Jersey limited partnership with a principal place of business located at 1125 Trenton-Harbourton Road, Titusville, NJ 08560. Janssen, L.P. is a wholly-owned subsidiary of Johnson & Johnson. Janssen, L.P. manufactured and marketed the drug risperidone under the brand name Risperdal throughout the entire United States, including Montana. Janssen, L.P. is duly licensed and in good-standing to legally conduct business in the State of Montana, specifically Lewis and Clark County.

13. Defendant Janssen Ortho, LLC ("Janssen Ortho") is incorporated in Delaware, and has its principal place of business at One Johnson & Johnson Plaza, New Brunswick, NJ 08933. Janssen Ortho is a wholly-owned subsidiary of Johnson & Johnson. Janssen Ortho manufactured and marketed the drug risperidone under the brand name Risperdal throughout the entire United States, including Montana. Janssen Ortho is duly licensed and in good-standing to

legally conduct business in the State of Montana, specifically Lewis and Clark County.

14. Defendant Janssen Pharmaceutica, Inc. ("Janssen Pharma") is incorporated in Pennsylvania, with a principal place of business located at 1125 Trenton-Harbourton Road, Titusville, NJ 08560. Janssen Pharma is a wholly-owned subsidiary of Johnson & Johnson. Janssen Pharma manufactured and marketed the drug risperidone under the brand name Risperdal throughout the entire United States, including Montana. Janssen Pharma is duly licensed and in good-standing to legally conduct business in the State of Montana, specifically Lewis and Clark County.

15. Defendant AstraZeneca Pharmaceuticals, LP is a Delaware limited partnership with a principal place of business located in Wilmington, Delaware. AstraZeneca Pharmaceuticals, LP ("AstraZeneca") is the U.S. subsidiary of a Swedish entity, AstraZeneca PLC, which has corporate headquarters in the United Kingdom, and Research and Development headquarters in Sweden. AstraZeneca manufactured and marketed the drug quetiapine under the brand name Seroquel throughout the entire United States, including Montana. AstraZeneca is duly licensed and in good-standing to legally conduct business in the State of Montana, specifically Lewis and Clark County.

JURISDICTION AND VENUE

16. This is a civil action for damages and civil penalties for violations of the Montana Food, Drug, and Cosmetic Act (Montana FDCA), Mont. Code Ann. § 50-31-101, *et seq.* (2006); the Montana Consumer Protection Act, Mont. Code Ann. § 30-14-101, *et seq.* (2006); the Montana False Claims Act, Mont. Code Ann. § 17-8-403, *et seq.* (2006); and other statutory and common law causes of action stated herein. This court has subject matter jurisdiction and personal jurisdiction pursuant to Mont. Code Ann. § 3-5-302 and Mont. Code Ann. Ch. 20, Rule 4B.

17. The instant Complaint does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C. § 1332. Likewise, federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by the instant Complaint, as it sets forth herein exclusively viable state law claims against Defendants. Nowhere herein does Plaintiff plead, expressly or implicitly, any cause of action or request any remedy which is founded upon federal law. The issues presented in the allegations of the instant well-pleaded Complaint do not implicate significant federal issues; do not turn on the substantial interpretation of federal law; nor do they raise a substantial federal question. Specifically, Plaintiff expressly avers that the only causes of action claimed, and the only remedies sought herein, are for those founded upon the statutory, common and decisional laws of the State of Montana. Likewise, the instant, well-pleaded Complaint exclusively seeks the recovery of damages solely for the State of Montana, its citizens and other entities, and is specifically not seeking recovery of any damages on behalf of the United States, the federal government or any of its agencies. Further, assertion of federal jurisdiction over the claims made herein would improperly disturb the congressionally approved balance of federal and state responsibilities. Accordingly, any improvident and dilatory attempt by Defendants to remove this case to federal court would be without a reasonable legal basis in fact or law.

FDA APPROVED INDICATIONS

18. A company wishing to market a new drug must seek the approval of the Food & Drug Administration ("FDA") by completing a New Drug Application ("NDA"). Based upon the submissions of the drug companies in support of a NDA, the FDA renders a determination whether the submitted information is consistent with its regulatory guidelines for approval, i.e., that the drug is safe and effective for each of its intended uses when administered at specified dosages.

Risperdal

19. On December 29, 1993 Risperdal was approved by the FDA for the treatment of adult schizophrenia and for the treatment of acute manic or mixed episodes of Bipolar I Disorder, which afflict less than 1% of the U.S. population. With less than 1% of U.S. population also diagnosed with adult schizophrenia, less than 2% of persons in the U.S. suffered from the diseases and disorders for which Risperdal was the approved drug therapy following initial FDA approval. Because of the chronic nature of adult schizophrenia, Risperdal is prescribed as a long-term drug therapy.

20. Thirteen (13) years later, in October 2006, Risperdal was approved by the FDA for the treatment of children and adolescents aged 5 to 16 years who were diagnosed with irritability associated with autism, including symptoms of aggression toward others, deliberate self-injury, tantrums, and sudden mood changes. Minors who suffer from this condition comprise less than .5% of the U.S. population.

21. In August 2007, the FDA approved Risperdal for the treatment of schizophrenia in adolescents, ages 13-17, and for the short-term treatment of manic or mixed episodes of Bipolar I Disorder in children and adolescents ages 10 to 17.

22. Even with the additional indications for which Risperdal was approved in October 2006 and August 2007, only a minute portion of the U.S. population suffers from the conditions Risperdal is FDA-approved to treat. However, annual sales of Risperdal in 2006 were $4.2 billion.

Seroquel

23. AstraZeneca obtained approval from the FDA to market Seroquel tablets for treatment of adults with schizophrenia in September 1997. On January 12, 2004 the FDA approved Seroquel tablets for treatment of adults with acute mania associated with Bipolar I

Disorder and combination therapy with lithium or divalproex for acute manic episodes associated with Bipolar I Disorder. In October 2006, Seroquel tablets were approved for treatment of adults with major depressive episodes associated with bipolar disorder.

24. Since Seroquel's additional indications were approved in October 2006, only a minor fraction of the U.S. population suffer from the conditions for which Seroquel is FDA-approved. However, annual sales of Seroquel in 2006 were $3.4 billion.

FRAUDULENT AND UNLAWFUL MARKETING ACTIVITIES

25. The Defendants illegally marketed and promoted Risperdal and Seroquel for non-FDA approved uses including, *inter alia*, the following:

(a) Treatment of the elderly for dementia, anxiety, sleep disorders, depression and various other mood and behavioral disorders not caused by adult schizophrenia or Bipolar I Disorder;

(b) Treatment of children and adolescents for general mood and behavior disorders, attention deficit disorder, attention deficit hyper-activity disorder, depression, sleeplessness, and for the general treatment of autism; and

(c) Treatment of the general patient population for other mood and sleep disorders and symptoms not caused by adult schizophrenia, Bipolar I Disorder and autism.

26. Defendants falsely represented that they were seeking FDA approval for the unapproved uses described above, and that there was a sufficient body of medical evidence warranting FDA approval for those uses.

27. To implement this deceptive, fraudulent and unlawful marketing campaign, Janssen and AstraZeneca used their marketing department, sales managers and field sales force to: a) fund clinical research studies, publications, and authors; b) advertise directly to physicians; and c) promote Risperdal and Seroquel to treat general symptoms of mood and

behavioral disorders.

COMPANY-FUNDED CLINICAL RESEARCH STUDIES, PUBLICATIONS AND AUTHORS

28. Janssen and AstraZeneca controlled the majority of the clinical trial processes for these drugs from design and implementation through data analysis and publication. These trials were essentially devices to mispromote their products. Defendants abused the clinical trial device by failing to publish negative results, using multiple outcome measures, selectively presenting only positive studies, publishing positive study results multiple times, and excluding subjects from the analysis who would "tarnish" a study's positive results.

29. Defendants' contrived, self-funded studies were materially misleading in that they failed to employ proper scientific methodology, clinical research techniques and data interpretation, neglected to accurately report results in conducting these studies to support their promotional campaign, and distorted the data derived from their flawed studies in their publication of that data.

30. The methodological deficiencies in these studies intentionally injected bias into the results, thereby guaranteeing favorable results for Risperdal and Seroquel. Defendants' research and publishing activities offered biased, flawed scientific evidence to mislead the medical community in the promotion of Risperdal and Seroquel for non-FDA approved purposes.

31. The flawed clinical studies manufactured otherwise absent "evidence" of Risperdal's and Seroquel's comparative efficacy and safety, failed to disclose material facts about the morbid and potentially fatal side-effects of Risperdal and Seroquel, and endorsed the drugs for dangerous unapproved indications.

32. Janssen and AstraZeneca also constructed a portfolio of articles for the medical

community that promoted Risperdal and Seroquel. The articles were primarily written by a medical writing or education agency, academic authors were then approached to become the named "authors," of such articles. This practice, known as "ghost writing," was purposefully calculated to create a positive "buzz" in the medical community that appears to emanate from an unbiased perspective, giving false credibility to the article and the glowing conclusions about Risperdal and Seroquel. Accordingly, psychiatric thought was "shaped" through the academic arena to create dissatisfaction in the market, establish a "need," and create a desire for the drugs.

DIRECT TO PHYSICIAN ADVERTISING

33. Janssen and AstraZeneca have engaged in marketing efforts calculated to deceive, among others, physicians and pharmacists into favoring Risperdal and Seroquel over other prescription drugs.

34. Janssen and AstraZeneca have funded and hosted scores of events during which trained and pre-approved doctors promote and market the efficacy and safety of Risperdal and Seroquel for unapproved and non-medically indicated uses.

35. Janssen and AstraZeneca provide financial payments and items of substantial value to participant and attendee physicians to induce them to listen to the marketing pitch, to prescribe Risperdal and Seroquel for unapproved and non-medically indicated uses, and to recommend such use of Risperdal and Seroquel to other physicians.

36. Financial incentives provided to physicians by Defendants include, but are not limited to, free samples of Risperdal and Seroquel, expensive dinners and vacations at lavish accommodations in return for choosing to prescribe the drugs, grants under the guise that the grant is for research purposes, and drug trials where physicians are paid to conduct clinical trials of Risperdal and Seroquel.

37. Defendants have also published misleading advertisements in leading and widely

distributed medical journals, including journals that are mailed free of charge to psychiatrists and neurologists throughout the United States. These advertisements are materially misleading and calculated to deceive in that they specifically cite to studies which Defendants use to "support" their claims about, *inter alia*, Risperdal's and Seroquel's "Proven Efficacy" and "Trusted Tolerability." Contrary to Defendants' representations, these company-financed, flawed and biased studies do not support their promotional claims. Rather, the research and/or the researchers' conclusion that ostensibly underscored the references were misleading, biased, invalid, and inconsistent with the data.

38. In April 2007, AstraZeneca's misleading sales and marketing practices toward physicians were exposed when AstraZeneca fired Michael Zubillaga, a regional sales director, after Mr. Zubillaga described oncologists' offices as "a bucket of money" from which salespeople can "grab a handful." Anonymous AstraZeneca employees revealed that managers like Zubillaga had been pushing sales representatives to make unfounded and improper representations about their drugs.

SYMPTOM-BASED MARKETING

39. To further expand the market share of Risperdal and Seroquel, Janssen and AstraZeneca exploited their knowledge that some symptoms of schizophrenia and Bipolar I Disorder overlap with other illnesses. Accordingly, Janssen and AstraZeneca attempted to undermine and circumvent the marketing limitations set by the limited approved uses of these drugs by devising a marketing campaign focused on Risperdal's and Seroquel's efficacy in treating a variety of common *symptoms* relating to mood and behavioral disturbances, such as depression, agitation, sleeplessness and anxiety.

40. Janssen's and AstraZeneca's marketing of Risperdal and Seroquel for other types of anxiety disorders such as panic disorder, generalized anxiety disorder and obsessive

compulsive disorder have helped to convince more and more people that they have a mental disorder that needs treatment. In the process, the companies have capitalized on this by creating a market for Risperdal and Seroquel in areas where atypical antipsychotics were formerly not frequently used. The common factor is the identification of a diagnosis or concept that is constituted by behaviors and emotions that have a substantial overlap with normal experience.

41. By and through these types of deceptive conduct, Janssen and AstraZeneca caused the State of Montana, its citizens and other entities to unnecessarily pay large sums of money for Risperdal and Seroquel that were improperly prescribed due to Defendants' fraudulent marketing scheme.

FRAUDULENT AND UNLAWFUL ACTS REGARDING SAFETY AND EFFICACY

42. In executing their marketing scheme, Defendants also misrepresented the safety and efficacy of Risperdal and Seroquel for the unapproved uses described in paragraph 25 by misrepresenting, minimizing or concealing certain serious adverse consequences of Risperdal and Seroquel, which made the drugs unsuitable for said uses when compared to other, less costly FDA-approved drug therapies. Risperdal's and Seroquel's serious adverse consequences include the following:

(a) Neuroleptic Malignant Syndrome (NMS), a serious condition which may cause death or respiratory failure, cardiovascular collapse, myoglobinuric renal failure, arrhythmias, rhabdomyolylsis, pneumonia, seizures, or diffuse intravascular coagulation;

(b) Weight gain, obesity;

(c) Diabetes Mellitus, Type 2;

(d) Hypercholesterolemia;

(e) Hypertriglyceridemia;

(f) Kidney disease, renal failure;

(g) Long-term dialysis, kidney transplantation;

(h) Peripheral vascular disease, including ischemic changes leading to amputation;

(i) Hypertension;

(j) Increased risk of certain cancers as a result of weight gain;

(k) Dementia, including multi-infarct type;

(l) Metabolic syndrome;

(m) Cardiovascular disease, including premature heart attacks and stroke, and thromboembolic disease;

(n) Cardiac arrhythmias;

(o) Acute onset extrapyramidal symptoms, including akathesia and Parkinsonism;

(p) Long-term neurological dysfunction including dystonias and tardive dyskinesia ("TD");

(q) Psychosis;

(r) Hypothyroidism;

(s) Degenerative arthritis from excessive weight gain and immobility;

(t) Depression as a consequence of chronic disease; and

(u) Long-term physical and mental disability as a result of chronic disease.

43. Further, Defendants knew, or recklessly disregarded the fact that Risperdal's and Seroquel's lack of efficacy and serious long- and short-term side effects made the drugs totally unsuitable as a drug therapy for the unapproved uses described in paragraph 25, especially when compared to other drugs that had been approved by the FDA for those uses.

44. Defendants gained knowledge of Risperdal's and Seroquel's link to many serious

side effects through the FDA adverse event reporting system and self-funded studies they deliberately withheld from the public eye while continuing to aggressively market the drugs as safe and effective.

45. Among other things, Defendants failed to disclose Risperdal's and Seroquel's known side effects in the drugs' package insert and promotional materials. Instead, Defendants trained and encouraged their pharmaceutical sales representatives to make false statements to healthcare providers concerning the efficacy of Risperdal and Seroquel, and to minimize the above-described side effects.

JANSSEN'S FRAUD AND DECEPTION REGARDING THE DANGERS OF RISPERDAL

46. Janssen was admonished by the FDA in 1999 for disseminating false and misleading information regarding the adverse events associated with Risperdal use. Among the items found by the FDA to be false and misleading were:

- Janssen's claims that Risperdal has a low incidence of movement disorders;
- Janssen's claims that Risperdal has a low incidence of sedation;
- Janssen's claims that Risperdal has a low incidence of anticholinergic effects (variety of movement disorder);
- Janssen's claims that Risperdal treatment is associated with a low incidence of adverse events, coupled with presentations of adverse events associated with Risperdal's discontinuation because such presentations imply that the only adverse events associated with Risperdal result from a patient being taken off the drug; and
- Janssen's failure to warn that the use of Risperdal by healthy, elderly patients created a greater potential for hepatic and renal dysfunction and cardiovascular

sensitivity.

47. The FDA further found that Janssen's promotion of Risperdal lacked fair balance because:

(a) The risk of information in its promotional literature "appears in pale and tiny font at the bottom or back of a journal ad or other presentation, or after the closing of a letter;" and

(b) It minimized important information related to TD and EPS.

48. Janssen continued to deny Risperdal's side effects, but in September 2003, the FDA forced the Company to disclose the link between Risperdal and diabetes and other related side effects by requiring Janssen and the other makers of atypical antipsychotics to add to their labels a warning that the drugs can cause hyperglycemia, diabetes and even death.

49. Immediately following the September 2003 FDA mandate, Janssen launched a campaign to "blame the disease" for the causation of these serious, potentially fatal, side effects. Specifically, Janssen began advancing the misleading explanation – allegedly supported by their fraudulent science – that individuals who suffer from mental illnesses such as schizophrenia and bipolar disorder are predisposed, i.e., have a heightened incidence of diabetes, metabolic syndrome, cardiovascular disease, and premature mortality, compared to the general population.

50. On November 6, 2003, Janssen submitted supplemental New Drug Applications covering the addition of information to the Warnings section of the product labeling for Risperdal. The FDA approved the supplements and requested that Janssen issue a "Dear Health Care Provider" letter communicating the important new risk information. Additionally, the FDA asked Defendants to submit a copy of the letter to the FDA and to the MedWatch program.

51. On November 10, 2003, Janssen sent a "Dear Health Care Provider" letter that

continued to misrepresent Risperdal's risks. The letter stated in pertinent part:

> Hyperglycemia-related adverse events have infrequently been reported in patients receiving RISPERDAL. Although confirmatory research is still needed, a body of evidence from published peer-reviewed epidemiology research suggests that RISPERDAL is not associated with an increased risk of diabetes when compared to untreated patients or patients treated with conventional antipsychotics. Evidence also suggests that RISPERDAL is associated with a lower risk of diabetes than some other studied atypical antipsychotics.

By sending this letter, Janssen prevented physicians and patients from adequately understanding the severe risks associated with Risperdal.

52. On April 19, 2004, the FDA reprimanded Janssen for sending the November 10, 2003 Dear Health Care Provider letter, describing the transmission as "false" and "misleading."

53. In a separate Warning Letter issued to Janssen Chief Executive Officer Ajit Shetty, the FDA determined that the November 10, 2003 Dear Health Care Provider letter omitted material information, minimized risks, and claimed superior safety to other drugs in its class without "adequate substantiation." Additionally, Janssen failed to comply with the FDA requirements regarding post-marketing reporting by sending the letter. As a result, the FDA requested that Janssen immediately cease dissemination of promotional materials for Risperdal containing the same claims, or similar claims and warned that the FDA was continuing to evaluate all aspects of the promotional campaign for Risperdal.

54. In response to the FDA's Warning Letter, Janssen mailed another Dear Health Care Provider letter months later, on July 21, 2004, admitting that the previous letter omitted material information about Risperdal, minimized potentially fatal risks, and made misleading claims suggesting superior safety in comparison to other atypical antipsychotics without adequate substantiation.

ASTRAZENECA'S FRAUD AND DECEPTION REGARDING

THE DANGERS OF SEROQUEL

55. The FDA reprimanded AstraZeneca for making false statements in its promotion of Seroquel immediately after launch. In a May 1999 letter from the FDA to Anthony Rogers, Director of Marketed Products Group, the agency referenced its November 24, 1998 Warning Letter requesting information about statements that the FDA found to be false and misleading.

56. Among the statements contained in AstraZeneca's promotion of Seroquel found to be false and misleading were:

(a) AstraZeneca's claims that Seroquel is effective in a broader range of mental conditions, including bipolar disorder and schizoaffective disorder;

(b) AstraZeneca's claims as to how Seroquel "works" (the mechanism of antipsychotic drugs is unknown); and

(c) AstraZeneca's claims that Seroquel had been proven safer and more effective than first generation antipsychotics.

57. Further, the FDA found that AstraZeneca's promotion of Seroquel lacked fair balance because it failed to disclose risks and important warnings regarding NMD, TD, orthostatic hypotension, and seizures.

58. The FDA's 1999 letter did not deter AstraZeneca. In October of 2006, the FDA again admonished AstraZeneca for essentially identical false and misleading acts. The FDA found that AstraZeneca had again made presentations in its promotions related to Seroquel's risk profile that were false and misleading. According to the FDA, AstraZeneca's marketing of Seroquel "raises significant public health and safety concerns through its minimization of the risks associated with Seroquel." Among AstraZeneca's false and misleading actions regarding Seroquel's safety were the following:

(a) Failing to warn doctors of the increased risk of treatment-emergent

hyperglycemia-related adverse events in patients treated with Seroquel, thus undermining the FDA-approved labeling;

(b) Misrepresenting the incidence of diabetes in post-marketing adverse event reports;

(c) Failing to include relevant risk information about Seroquel;

(d) Failing to warn doctors of the irreversibility of TD as treatment continues and the fact that the condition may abate if treatment is interrupted;

(e) Failing to reveal that NMS is a potentially fatal symptom complex associated with Seroquel;

(f) Failing to inform doctors of the symptoms of NMS and that treatment with Seroquel should be immediately ceased upon the observance of such symptoms;

(g) Failing to reveal material facts about the risk of seizures, orthostatic hypotension and cataract development associated with Seroquel usage.

59. AstraZeneca continued to deny Seroquel's side effects, but in September 2003, the FDA forced the Company to disclose the link between Seroquel and diabetes and other related side effects by requiring AstraZeneca and the other makers of atypical antipsychotics to add to their labels a warning that the drugs can cause hyperglycemia, diabetes and even death.

60. Immediately following the September 2003 FDA mandate, AstraZeneca, like Janssen, launched a campaign to "blame the disease" for the causation of these serious, potentially fatal, side effects. Specifically, Defendant began advancing the misleading explanation – supported with fraudulent science – that individuals who suffer from mental illnesses such as schizophrenia and bipolar disorder are predisposed, i.e., have a heightened incidence of diabetes, metabolic syndrome, cardiovascular disease, and premature mortality,

compared to the general population.

61. As a result of improper marketing practices, since 2003 AztraZeneca has been operating under special federal scrutiny pursuant to a Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services.

62. On January 30, 2004, AstraZeneca sent a Dear Health Care Provider letter that continued to misrepresent Seroquel's risks. The letter stated in pertinent part:

> Hyperglygemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics, including Seroquel. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse event in patients treated with atypical antipsychotics are not available. Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control.

63. By sending this letter, AstraZeneca prevented physicians and patients from adequately understanding the severe risks associated with Seroquel.

64. On April 22, 2004, AstraZeneca was forced to send out a revised Dear Health Care Provider letter because the January 2004 letter was misleading and downplayed the need to continually monitor a patient's blood sugar level while taking Seroquel.

65. In January 2006, AstraZeneca was notified that the U.S. Attorney's office in Los Angeles, California had commenced an investigation of AstraZeneca's field promotional activities related to its products.

66. In a November 2006 letter from the FDA to James L. Gaskill, PharmD Director of Promotional Regulatory Affairs at AstraZeneca, the FDA found that AstraZeneca had again made representations in its promotions related to Seroquel's risk profile that were false and misleading. According to the FDA, AstraZeneca's marketing of Seroquel "raises significant public health and safety concerns through its minimization of the risks associated with Seroquel." Among AstraZeneca's false and misleading statements regarding Seroquel's safety were the following:

(a) Failing to warn doctors of the increased risk of treatment-emergent hyperglycemia-related adverse effects in patients treated with Seroquel in its promotions thus undermining the FDA-approved labeling;

(b) Misrepresenting the incidence of diabetes in post-marketing adverse event reports;

(c) Failing to include relevant risk information about Seroquel;

(d) Failing to warn doctors of the irreversibility of TD as treatment continues and the fact that the condition may abate if treatment is interrupted;

(e) Failing to reveal that NMS is a potentially fatal symptom complex associated with Seroquel;

(f) Failing to inform doctors of the symptoms of NMS and that treatment with Seroquel should be immediately ceased upon the observance of such symptoms; and

(g) Failing to reveal material facts about the risk of seizure, orthostatic hypotension and cataract development associated with Seroquel usage.

67. Despite receiving this reprimand, AstraZeneca failed to take action to correct the

defect with the Seroquel product labeling for several months. During this period, AstraZeneca failed to pass on information to physicians regarding the diabetes mellitus risk or issue new labeling containing specific warnings.

FRAUDULENT AND UNLAWFUL ACTS REGARDING PROMOTIONS FOR NON-MEDICALLY ACCEPTED ELDERLY USAGE

68. From the time these products were introduced on the market, Defendants' respective marketing campaigns included promotion for use in the elderly for both dementia symptoms and Alzheimer's disease.

69. Defendants' decision to target the elderly, and in particular Montana's elderly, had two results: (1) non-medically accepted and medically unnecessary claims for Risperdal and Seroquel were submitted to Medicaid for reimbursement, and (2) the drugs caused adverse health consequences for geriatric patients.

70. In April of 2005, the FDA determined that the treatment of behavioral disorders in elderly patients with dementia through atypical antipsychotic drugs is associated with increased mortality. In a total of seventeen placebo-controlled trials performed with Risperdal and Seroquel in elderly demented patients with behavioral disorders, fifteen trials revealed an increase in mortality in the drug-treated group compared to the placebo-treated patients. Examination of specific causes of death revealed that most were due to either heart-related events such as heart failure, or infections such as pneumonia.

71. Although the atypical antipsychotics are FDA-approved for the treatment of schizophrenia, none has been approved for the treatment of behavioral disorders in patients with dementia. As a result of the findings, the FDA required Defendants to include a Boxed Warning or "black box warning" in their respective labeling describing this risk and emphasizing that Risperdal and Seroquel are not approved for this indication.

72. Upon information and belief, despite the foregoing, Defendants continue to promote their respective drugs as safe and effective treatment for dementia in elderly patients, specifically the elderly in Montana. In October of 2005, a study appearing in the Journal of the American Medical Association concluded that:

> ...drugs often used to treat elderly patients with dementia-related aggression and delusions can raise their risk of death, according to a study that reinforces new warning labels required on medications. The researchers pooled results of 15 previous studies on drugs known as atypical anti-psychotics and sold under the brand names Zyprexa, Risperdal, Seroquel and Abilify. Among more than 5,000 elderly dementia patients, those taking any of the drugs faced a 54 percent increased risk of dying within 12 weeks of starting the medication, compared with patients taking dummy pills. There were 118 deaths among the 3,353 drug users versus 40 in the 1,757-patient placebo group, or 3.5 percent compared with 2.3 percent. The risks were similar for each of the drugs...

Schneider LS, Dagerman KS, Insel MS. Risk of Death With Atypical Antipsychotic Drug Treatment for Dementia. *JAMA*. 2005; 294:1934-1943.

73. The Omnibus Budget Reconciliation Act of 1987 ("OBRA"), 42 C.F.R. §483.25, called for the promulgation of regulations to guard against unnecessary prescription of psychotropic medication to nursing home residents.

74. However, AstraZeneca regularly publicizes effective selling methods in monthly newsletters as what the company describes as "Best Practices." By definition, persons residing in assisting living accommodations are higher functioning individuals capable of living on their own with minimal help and supervision. Portions of the June 2002 "Best Practices" describe how AstraZeneca sales representatives might bypass nursing home OBRA regulations in promoting the prescription of Seroquel to persons residing in assisted living accommodations:

> As nursing home care represents sicker patients on increasing "short term" stays (currently an average of 6-10 months vs. 2-3 years 5 years ago), **assisted living plays a much greater role. This is an important consideration since**

> **assisted living is not regulated to the same extent as nursing homes.** By keeping in mind the distinctive needs of the Long-term Care providers and the challenges they face, it is increasingly clear that Seroquel is the best choice for improving the quality of life in the elderly patients and offers clear advantages in the Long-term Care setting.

75. The June 2002 "Best Practices" also specifically contradicts FDA indications stating that: "The effectiveness of Seroquel in long-term use, that is, for more than 6 weeks, has not been systematically evaluated in controlled trials."

76. Until May 2004, AstraZeneca's heavy promotion for the prescription of Seroquel to long term health care patients failed to take into any account the relatively rare occurrence of either bipolar mania or schizophrenia in the elderly.

77. Following May 13, 2004, AstraZeneca conceded its inappropriate off-label promotion of Seroquel. A management decision was made to have the company's Long Term Care sales force end its off-label promotion of Seroquel in nursing homes. An explanatory internal voicemail stated the following:

> While the Long Term Sales force has been in place for five years and has generated huge Seroquel Dollar Volume, these representatives had little direction in the past and their discussions with physicians routinely centered on the use of Seroquel in treating agitation sleep and other off-label indications in nursing homes. (emphasis added)

The same voicemail announced the termination of physicians from the Long Term Sales force who were prescribing Seroquel for non-indicated use.

78. Upon information and belief, Defendants continue their practice of promotion to the elderly despite studies and data that confirm the lack of efficacy and significant health and safety risks associated with promoting these drugs for the elderly.

FRAUDULENT AND UNLAWFUL ACTS REGARDING PROMOTIONS FOR NON-MEDICALLY ACCEPTED PEDIATRIC USAGE

79. To generate additional sales, Defendants each undertook schemes to market and promote their respective drugs for use in the treatment of children suffering from disorders such as depression, anxiety, Attention Deficit Disorder (ADD), Attention Deficit Hyperactivity Disorder (ADHD), sleep disorders and generally as a mood stabilizer.

80. Although these uses were never approved by the FDA or any Montana agency, this lack of approval did not deter Defendants from marketing their respective drugs for treatment of children and adolescents.

81. As a result of Defendants' marketing, children in Montana, and particularly those participating in Medicaid in Montana were, and continue to be, exposed to medication which, at best, is ineffective and, at worst, can and does cause life-threatening illnesses such as movement disorders, diabetes and diabetes-related complications.

82. Upon information and belief, Dr. Melissa DelBello has been retained by AstraZeneca to help in its promotion of Seroquel to pediatric patients. In calendar year 2003, Dr. DelBello was paid $134,000 by AstraZeneca to assist in the marketing of Seroquel to pediatric patients. As of March, 2004, she had been paid $32,000 for 16 programs.

83. In addition to paying Dr. DelBello directly, AstraZeneca supports her in other ways. AstraZeneca sales representative's "call notes" states that Dr. DelBello is very pleased that AstraZeneca is using her husband's catering business to do the off-label Seroquel lunches.

84. Dr. DelBello's single study concerns the use of Seroquel in combination with depakote for the treatment of mania in bipolar adolescent children. Dr. DelBello's study was funded by AstraZeneca. The scientific value of the study is questionable for the following reasons: 1) the sample on which the study is based includes only 30 patients; and 2) the response rate is much higher than that of a larger study of 191 patients. Dr. DelBellos' study

claims an 87% response rate versus 53% in an FDA approved adult study.

85. The printed materials that accompany Dr. DelBello's presentations feature young children. One is entitled "Treatment of Bipolar Disorder Across the Life Span." These materials de-emphasize the health risks attendant to long term exposure to atypical antipsychotics.

86. The Seroquel package insert specifically warns:

> The effectiveness of SEROQUEL in long term use, that is, for more than 6 weeks has not been systematically evaluated in controlled trials. Therefore, the physician who elects to use Seroquel for extended periods should periodically re-evaluate the long term usefulness of the drug for the individual patient.

87. AstraZeneca management directed the AstraZeneca sales force to make copies of the slides presented by Dr. DelBello at a March 31, 2004 presentation. The slides were to be distributed to all participating physicians.

88. The presentations made by Dr. DelBello do little to alert the physician/health care provider audience to the possible long term side effects linked to Seroquel use in children, such as tardive dyskenesia, cataracts and neuroleptic malignant syndrome.

89. Dr. DelBello makes presentations throughout the United States. A presentation made in Pittsburgh, Pennsylvania was with AstraZeneca's assistance linked to 30 separate satellite locations.

90. Dr. DelBello speaks to groups of health care professionals with authority to prescribe or suggest the prescription of Seroquel to children. For example, on March 17, 2003, she made a Seroquel sales promotion at Saint Joseph's Orphanage in Cincinnati, Ohio for which she was paid $1,500.00.

91. Upon information and belief, Dr. Rimal Bera is another physician retained by AstraZeneca to promote off-label use of Seroquel. Dr. Bera received approximately $175,000

from AstraZeneca in honoraria for CME lectures in 2003. He has received $55,000 for 41 presentations in 2004.

92. On May 20, 2004, Dr. Bera made a slide presentation in Chico, California promoting the use of atypical antipsychotic drugs. One slide in his presentation discussed use of these drugs in children for "conduct disorders."

COUNT I

STRICT PRODUCTS LIABILITY-DESIGN DEFECT

93. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

94. Pursuant to MCA § 27-1-719, at the time Risperdal and Seroquel left the hands of Defendants they were in defective condition, unreasonably dangerous in their design, manufacture, testing, and marketing, and were so at the time they were prescribed by physicians in Montana, including those participating in the State of Montana's Medicaid program.

95. The unreasonably dangerous defects in Risperdal and Seroquel were known to Janssen and AstraZeneca at the time they began to market and sell their respective drugs. Any disclosure by Defendants was inaccurate, incomplete, misleading, and fraudulent.

96. Janssen and AstraZeneca knew Risperdal and Seroquel would be used by the ordinary citizen-users without knowledge of the dangerous condition and that the State, physicians, and medicinal users of Risperdal and Seroquel were reasonably relying upon Defendants' representations that the product was safe and appropriate for the particular uses for which it had been promoted.

97. Adequate pre-approval and post-approval testing and post marketing studies would have revealed the further extent of the dangers of ingesting Risperdal and Seroquel, and would have shown that the use of the drugs could cause extensive medical complications and

additional costs for injuries relating to its use.

98. As a proximate cause and legal result of the dangerous, defective condition, the State of Montana and its citizens, corporations, and business entities have been injured and suffered direct and consequential damages and are, therefore, entitled to all the damages and remedies provided by law.

COUNT II

THE MONTANA FOOD, DRUG, AND COSMETIC ACT: FALSE AND MISLEADING ADVERTISING

99. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

100. Since 1947, the sale of drugs within Montana has been regulated by the Montana Food, Drug, and Cosmetic Act (Montana FDCA), Mont. Code Ann. §50-31-101, *et seq.*

101. The Montana FDCA prohibits false or misleading advertising of drugs within the state. Mont. Code Ann. §50-31-501(1, 5). A drug advertisement is "deemed to be false if it is false or misleading in any particular." Mont. Code Ann. §50-31-107(1). A drug advertisement is also deemed to be misleading if it fails to reveal material facts about the consequences which may result from using the drug in the manner in which the advertisement suggests that it be used. Mont. Code Ann. §50-31-107(2).

102. The Montana Legislature has charged the Attorney General with the duty to bring appropriate proceedings in court to remedy violations of the Montana FDCA. Mont. Code Ann. §50-31-505.

103. As described above, Defendants' advertisements made false and misleading claims about the proper and approved uses of and effectiveness of Risperdal and Seroquel to doctors and the public in Montana in violation of the Montana FDCA. In particular, Defendants

have violated the Montana Unfair Trade Practices and Consumer Protection Act by, *inter alia*: (i) representing that Risperdal and Seroquel have approval, characteristics, ingredients, uses and/or benefits which they do not in fact have; (ii) representing that Risperdal and Seroquel are of a particular standard, quality, or grade which they are in fact not; (iii) advertising Risperdal and Seroquel with the intent not to sell as advertised; and (iv) engaging in conduct that created a likelihood of confusion or misunderstanding, and which misled or damaged buyers of Risperdal and Seroquel, including the State of Montana.

104. As a result of Defendants' violation of the FDCA, the State and its citizens, corporations and other business entities have been damaged and are entitled to all the remedies and damages provided by law.

COUNT III

DECEIT

105. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

106. In Defendants' advertising and promotional materials, in its marketing tactics in face-to-face meetings with doctors, in its press releases, and in its public advertisements Defendants made suggestions of fact that Defendants knew were not true. Such conduct constitutes deceit under Mont. Code Ann. §27-1-712.

107. Defendants, in face-to-face meetings with doctors, in its press releases and public advertisements suppressed facts about the dangers of Risperdal and Seroquel and promoted usage for non-medically appropriate conditions such that Montana doctors and the public were misled about its dangers, and unknowingly utilized these drugs for inappropriate conditions. Such conduct constitutes deceit under §27-1-712, Mont. Code Ann.

108. As a result of Defendants' violation of §27-1-712, the State and its citizens,

corporations and other business entities have been damaged and are entitled to all the remedies and damages provided by law.

COUNT IV

UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION ACT

109. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

110. In the course of business, Defendants misrepresented and/or omitted material facts about the safety and effectiveness of Risperdal and Seroquel. Defendants misleadingly claimed that Risperdal and Seroquel were safe and as/more effective than traditional antipsychotics and that they did not cause or contribute to any adverse consequences greater than other similar medications. Defendants also promoted the use of Risperdal and Seroquel for patients with conditions for which they had not been approved or proven safe and effective.

111. Defendants systematically suppressed and concealed material information they developed or otherwise knew about the adverse effects of Risperdal and Seroquel and engaged in a miss-information and dis-information campaign to conceal the truth.

112. Defendants systematically sought to discredit or cast doubt upon scientific studies and reports and the work of scientists which concluded that Risperdal and Seroquel caused or contributed to adverse effects.

113. Defendants systematically engaged in a false and misleading marketing and advertising campaign to over-promote the use of Risperdal and Seroquel.

114. Defendants' conduct as described above constitutes unfair and deceptive practices in violation of Mont. Code Ann. § 30-14-103.

115. As consequence of Defendants' violation of §30-14-103, the State, its citizens, corporations and business entities have been injured and suffered damages and are therefore

entitled to all the damages and remedies provided by law.

COUNT V

MONTANA FALSE CLAIMS ACT

116. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

117. By actively promoting the sale of Risperdal and Seroquel for non-medically accepted indications excluded from payment under the provisions of the Montana Medicaid prescription drug program, Defendants did knowingly make or cause to be made false statements or misrepresentations of material fact for use in determining rights to Medicaid benefits, in violation of the Montana False Claims Act, Mont. Code Ann. §17-8-403.

118. By actively promoting the sale of Risperdal and Seroquel for non-medically accepted indications excluded from payment under the provisions of the Montana False Claims Act, Defendants did knowingly enter into an agreement, combination or conspiracy to defraud the State of Montana by obtaining or aiding another to obtain the payment or allowance of a false, fictitious or fraudulent claim for Medicaid benefits in violation of the Montana False Claims Act, Mont. Code Ann. §17-8-403.

119. By affirmatively and consistently misrepresenting to healthcare providers and the citizen-users of Montana the serious side-effects caused by Risperdal and Seroquel, including considerable weight gain in patients and a resultant increased risk of diabetes, Defendants did knowingly make or cause to be made false statements or misrepresentations of material fact for use in determining rights to Medicaid benefits, in violation of the Montana False Claims Act, Mont. Code Ann. §17-8-403.

120. By affirmatively and consistently misrepresenting to healthcare providers and the

citizen-users of Montana the serious side-effects caused by Risperdal and Seroquel, including considerable weight gain in patients and a resultant increased risk of diabetes, Defendants did knowingly enter into an agreement, combination or conspiracy to defraud the State of Montana by obtaining or aiding another to obtain the payment or allowance of false, fictitious or fraudulent claims for Medicaid benefits in violation of the Montana False Claims Act, Mont. Code Ann. §17-8-403.

121. By affirmatively and consistently failing to warn healthcare providers and citizen-users of the State of Montana of the serious side-effects caused by Risperdal and Seroquel, including considerable weight gain in patients and a resultant increased risk of diabetes, Defendants did knowingly make or cause to be made false statements or misrepresentations of material fact for use in determining rights to Medicaid benefits, in violation of the Montana False Claims Act, Mont. Code Ann. §17-8-403.

122. As a direct and proximate result of the conduct of Defendants in committing the above and foregoing violations of the Montana False Claims Act, Defendants are directly liable to Plaintiff.

COUNT VI

UNJUST ENRICHMENT AND RESTITUTION

123. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

124. Defendants engaged in a systematic campaign to unlawfully promote the use of Risperdal and Seroquel, claiming it was safe from any adverse effects and as or more effective than traditional antipsychotics that were significantly less expensive than Risperdal and Seroquel.

125. Defendants knew that Risperdal and Seroquel cause or contribute to serious

adverse consequences and are no more effective than much cheaper and safer drugs.

126. Defendants had a duty to the State and to the citizens of the State to disclose all material facts about their products and to refrain from over-promoting or falsely promoting their products as safe and more effective than traditional antipsychotics when they knew that was not true.

127. As a result of Defendants' breaches of this duty and the misleading suppression of the truth, Defendants have sold millions of dollars of Risperdal and Seroquel to the State and citizens of the State of Montana which was not necessary and, in fact, likely caused adverse effects on the citizens of the State of Montana.

128. Defendants have been unjustly enriched by their false, deceitful, and misleading conduct to the extent that the citizens of the State of Montana and the State of Montana have unknowingly paid excessive costs for Risperdal and Seroquel, when they could have purchased significantly less expensive traditional pharmaceuticals that would have been equally effective and without the severe risks.

129. As a result of Defendants' conduct, the State of Montana and its citizens have suffered substantial economic damages and are entitled to damages and all other available remedies.

COUNT VII

MONTANA COMMON LAW FRAUD

130. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

131. By actively promoting the sale of Risperdal and Seroquel for non-medically accepted indications excluded from payment under the provisions of the Montana Medicaid prescription drug program, Defendants have committed acts of Montana common law fraud.

132. Specifically, Defendants knowingly made material false misrepresentations and/or failed to accurately represent the material facts of the full range and severity of side effects and adverse reactions associated with the product. Further, Janssen and AstraZeneca misrepresented the appropriateness of the suitability of Risperdal and Seroquel for unapproved uses.

133. Defendants' claims and assertions to the State of Montana, physicians, and the ordinary citizen-user of Montana, contained false representations as to the safety of Risperdal and Seroquel and their defective design. Further, Defendants' claims concerning unapproved use were false and fraudulent.

134. It is further alleged upon information and belief that Defendants committed acts constituting Montana common law fraud by specifically:

(a) Creating and implementing a marketing plan for Risperdal and Seroquel which included evaluation of sales opportunities for the drug based upon unapproved uses, including use by children/adolescents;

(b) Training and instructing its primary care sales force to attempt to expand Risperdal's and Seroquel's market by convincing primary care physicians to prescribe the drug for mood, thought and behavioral disturbances;

(c) Establishing a consistent sales message to primary care physicians based on patients' symptoms and behaviors, rather than on their confirmed diagnoses;

(d) Presenting hypothetical patient profiles to primary care physicians, which included patients complaining of symptoms such as anxiousness, irritability, mood swings and disturbed sleep, and submitting to said physicians that such hypothetical patients would be medically indicated for treatment with Risperdal and Seroquel; and

(e) Providing primary care physicians with copies of medical journal articles discussing unapproved uses of Risperdal and Seroquel.

135. Defendants knew or reasonably should have known through adequate testing that the claims made to the State of Montana with regard to the safety and efficacy of Risperdal and Seroquel were false or incomplete, and misrepresented the material facts of Risperdal's and Seroquel's unsafe and defective condition.

136. It is further alleged upon information and belief that Defendants deliberately concealed the side effects and adverse medical conditions caused by the use of Risperdal and Seroquel by specifically:

(a) Acknowledging within the company that weight change related to Risperdal and Seroquel was a significant issue and that Defendants needed to provide physicians with more information on same;

(b) Consistently suppressing attempts to make public the association between Risperdal- and Seroquel-induced weight gain and hyperglycemia; and

(c) Training and instructing its primary care sales forces not to introduce the issue of olanzapine-induced weight gain and hyperglycemia with primary care physicians, but rather discuss it only if introduced by the physician.

137. Defendants' fraudulent misrepresentations in this regard were done with the intention of inducing the State to approve the distribution of Risperdal and Seroquel to participants in the Montana Medicaid Program and the ordinary citizen-users of Montana for both approved and unapproved uses.

138. As a consequence of Defendants' fraudulent misrepresentations, the State of Montana and its citizens, corporations, and business entities have been injured and suffered

damages and are, therefore, entitled to all the damages and remedies provided by law.

PUNITIVE AND/OR EXEMPLARY DAMAGES

139. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

140. At all times mentioned herein, Defendants knew of the defective, unreasonably dangerous conditions of Risperdal and Seroquel. Defendants knew of their duties and obligations to consumers to provide safe products to them and to warn such consumers of all known dangers and defective conditions. Despite Defendants' knowledge of the dangers and defective conditions inherent in their products, Defendants callously, recklessly, willfully and wantonly failed to take appropriate steps to remedy the defects in Risperdal and Seroquel or to warn users of said dangers, and in fact misrepresented the condition of the drugs. The failures of Defendants to remedy defects and to warn consumers were the result of their desires for financial gain.

141. Defendants mass produced, marketed and sold Risperdal and Seroquel knowing of the dangerous, defective condition. Despite their knowledge of defects, and despite the extremely high risk of injury to users of Risperdal and Seroquel, Defendants callously, recklessly, willfully and wantonly disregarded the state of knowledge regarding the safety of the drug. The refusal of Defendants to remedy defects was based on their pursuit of financial gain.

142. The aforesaid acts of Defendants constituted actual malice and fraud in that they knew and intentionally disregarded the condition of Risperdal and Seroquel which created a high probability of injury to consumers and deliberately proceeded to act in conscious or intentional disregard or indifference to the high probability of injury and misrepresented the condition of the vehicle to the general public.

143. Therefore, pursuant to Montana law, Plaintiff is entitled to exemplary and

punitive damages in an amount sufficient so that an example will be made of Defendants to promote safety and to provide an incentive for Defendants and others so situated to engage in safer design, testing, production and marketing practices.

PRAYER FOR RELIEF

WHEREFORE, the State of Montana, by and through Attorney General Mike McGrath, prays as follows:

1. That the Court adjudge and decree that Defendants have engaged in the conduct alleged herein.

2. That the Court adjudge and decree that Risperdal and Seroquel were in defective condition, unreasonably dangerous pursuant to Mont. Code Ann. §27-1-719 and that Montana and its citizens and other entities were caused damage.

3. That the Court adjudge and decree that Defendants' advertising and promotion of Risperdal and Seroquel was false and misleading in violation of the Montana FDCA.

4. That the Court adjudge and decree that Defendants violated Mont. Code Ann. § 27-1-712 and that the State of Montana and its citizens were damaged thereby for which Defendants must pay.

5. That the Court adjudge and decree that Defendants' conduct is unlawful and in violation of Mont. Code Ann. §30-14-103.

6. That the Court, pursuant to Mont. Code Ann. §30-14-142, assess civil penalties of $10,000.00 against Defendants for each violation of Mont. Code Ann. §30-14-103 and §17-8-403, *et seq.* complained of herein.

7. That the Court, pursuant to Mont. Code Ann. §30-14-131, enter an order restoring to the State and to the citizens of the State all monies acquired by Defendants by means of their unlawful practices.

8. That the Court order Defendants to pay restitution which would restore the State of Montana and the citizens of the State of Montana to the financial position that they would have enjoyed absent Defendants' false representations and promotion of Risperdal and Seroquel.

9. That the Court award the State of Montana treble damages pursuant to Mont. Code. Ann. §17-8-403, *et seq*.

10. That the Court award the State of Montana its attorneys fees and costs.

11. That the Court award the State of Montana punitive and exemplary damages in an amount the Court deems just, necessary, and appropriate.

12. That pursuant to Montana Code Annotated § 27-19-101, *et seq*, the Court enjoin Defendants from their unlawful conduct.

13. That the Court order such other and further relief as the Court deems just, necessary, and appropriate.

Dated this 20th day of February, 2008.

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DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury on all issues so triable.

Dated this 20th day of February, 2008.

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