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IN THE THIRD JUDICIAL DISTRICT COURT OF SALT LAKE COUNTY,
WEST JORDAN DEPT., STATE OF UTAH

MARK L. SHURTLEFF, ATTORNEY GENERAL OF THE STATE OF UTAH, ex rel. THE STATE OF UTAH, Plaintiff, v. JANSSEN ORTHO LLC, ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., and ASTRAZENECA PHARMACEUTICALS, LP, Defendants.	**COMPLAINT** Case No. 100409573 Judge: Keith Kelly

The State of Utah, by and through the Attorney General of the State of Utah, Mark L. Shurtleff, makes the following claims against Defendants:

INTRODUCTION

1. This is a civil action for damages, civil penalties and injunctive relief for violations of the Utah False Claims Act and other state common law and statutory causes of action stated herein brought by the Utah Attorney General in the exercise of his constitutional, common law, and statutory powers against Janssen Ortho LLC, Ortho-McNeil-Janssen Pharmaceuticals, 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 marketing, sale and promotion of the atypical antipsychotics risperidone (known as Risperdal®) and quetiapine (known as Seroquel®).

2. Janssen and AstraZeneca (hereinafter "Defendants") knew or should have known but failed to warn—and affirmatively misled—the United States Food and Drug Administration ("FDA"), the State of Utah, physicians, and consumers regarding Risperdal's and Seroquel's association with the development of diabetes, diabetes-related conditions, including weight gain, and other serious, even life threatening medical conditions.

3. Prior to October 20, 2006, Risperdal's FDA-approved indications were limited to treatment of adults for schizophrenia (December 1993) and to short-term treatment of adults for acute manic or mixed episodes associated with bipolar I disorder (December 2003). Prior to October 20, 2006, Seroquel's FDA-approved indications were limited to treatment of adults for schizophrenia (September 1997) and to short-term treatment of adults for acute manic episodes associated with bipolar I disorder (January 2004). These indications, along with any not approved by the FDA (so-called "off-label" uses) that might be supported in at least one of three drug compendia—American Hospital Formulary System Drug Information ("AHFS"), United States Pharmacopeia-Drug Information ("USP-DI"), or DRUGDEX Information System ("DRUGDEX")—are the only indications that were "medically accepted" for Risperdal and Seroquel before October 20, 2006. The Utah Medicaid Program statutorily is required only to provide reimbursement for prescriptions that are FDA-approved or supported as being effective in at least one of the three statutorily approved compendia, that is, those prescriptions that are for "medically accepted" indications.

4. Since Janssen launched Risperdal in 1994 and AstraZeneca launched Seroquel in 1997, the companies have engaged in false and misleading marketing, advertising and sales campaigns to promote these drugs for indications that are not approved by the FDA. Defendants

successfully deceived the FDA, the State of Utah, physicians, and consumers regarding the comparative safety, efficacy and superiority of Risperdal and Seroquel over traditional or other atypical antipsychotics in order to achieve a 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.

5. Janssen and AstraZeneca aggressively marketed and promoted Risperdal and Seroquel for indications that are not approved by the FDA and for which the efficacy and safety of the drugs have 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.

6. 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 indications that are not medically accepted, 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 indications are not medically accepted but have been

expressly promoted by Janssen or have resulted from Janssen's deceptive marketing campaign.

7. 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, with $4.2 billion in sales for 2006 and $4.7 billion in sales for 2007.

8. 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. Seroquel profits continued to rise, with sales of $4.9 billion in 2009.

9. Only about 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.

10. As a result of Janssen's and AstraZeneca's improper, false, and misleading marketing of these atypical antipsychotic drugs, the State of Utah, through its Medicaid program, has been injured as a result of Defendants' actions, actions which caused the submission of False Claims to Utah Medicaid. Those injuries include the costs of Risperdal and Seroquel prescriptions that should not have been reimbursed, as well as consequential damages to the Utah Medicaid population that have been and will be incurred as a result of the ingestion of Defendants' drugs. The injuries suffered include disability and death. Defendants knew, deliberately ignored or acted in reckless disregard in subjecting the Utah Medicaid population to disability or death through the ingestion of Risperdal and Seroquel. Defendants also knew or

should have known that they were causing the submission of False Claims in that they promoted their drugs for uses not reimbursable by Utah Medicaid because they knew or should have known they were promoting the drugs for indications that were not medically accepted.

11. As a result of the above and foregoing actions by Defendants Janssen and AstraZeneca, Plaintiff seeks damages for injuries caused by statutorily prohibited prescriptions of Risperdal and Seroquel being submitted to Utah Medicaid, including costs of care already incurred and consequential care to be rendered in the future, as well as the costs of the drugs.

12. Further, Plaintiff seeks injunctive relief, including but not limited to, a Court Order: (i) prohibiting Defendants from making any oral or written claims that are false, misleading or deceptive with respect to Risperdal and Seroquel, including false, misleading or deceptive claims regarding the safety and efficacy of Risperdal and Seroquel for indications that are not FDA-approved; (ii) prohibiting Defendants from affirmatively seeking the inclusion of Risperdal and Seroquel in hospital protocols or standing orders for indications that are not FDA-approved; (iii) requiring Defendants to distribute improved educational materials for patients and primary care physicians that clearly identify the risks and benefits of Risperdal and Seroquel, including precautions when Risperdal and Seroquel are prescribed for indications that are not FDA-approved; and (iv) requiring Defendants to develop programs that include small group meetings with Risperdal and Seroquel prescribers, particularly primary care physicians, to inform the health care providers of the drugs' appropriate uses, risks, benefits, and reasonable therapeutic alternatives.

PARTIES

Plaintiff

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

Defendants

14. 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 Utah.

15. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Ortho-McNeil-Janssen") is incorporated in Pennsylvania, with a principal place of business located at 1125 Trenton-Harbourton Road, Titusville, NJ 08560. Ortho-McNeil-Janssen is a wholly-owned subsidiary of Johnson & Johnson. Ortho-McNeil-Janssen manufactured and marketed the drug risperidone under the brand name Risperdal® throughout the entire United States, including Utah.

16. 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 Utah.

JURISDICTION AND VENUE

17. This is a civil action for damages and civil penalties for violations of the Utah False Claims Act, Utah Code Ann. § 26-20-1, et seq. and other state common law and statutory provisions.

18. The Attorney General brings this action on behalf of the State of Utah pursuant to his authority under Utah Code Ann. § 67-5-1(18).

19. This Court has subject matter jurisdiction pursuant to Utah Code Annotated § 26-20-1, et seq., which provides remedies to redress Defendants' actions under the Utah False Claims Act.

20. Personal jurisdiction over Defendants is proper under the Utah Long Arm Statute as codified in § 78-27-24 of the Utah Code Annotated.

21. Venue is proper in the Third Judicial District and Salt Lake County pursuant to Utah Code Annotated § 78-13-7, in that many of the unlawful acts committed by Defendants were committed in Salt Lake County, including the making of false statements.

22. 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 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. Indeed, 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 Utah. Likewise, the instant, well-pleaded Complaint exclusively seeks the recovery of damages solely for the State of Utah, 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.

THE MEDICAID PROGRAM

23. The Utah Medicaid program provides medical assistance to low income state residents. The primary purpose of the Medicaid program is to enable the State to furnish medical assistance on behalf of families with dependent children and of aged, blind or disabled individuals whose income and resources are insufficient to meet the costs of necessary medical services. Utah enjoys a broad measure of flexibility in tailoring the scope and coverage of its Medicaid plan. By state law, Utah is required to recover Medicaid funds which have been improperly provided to participants and suppliers.

24. Utah's Medicaid plan includes an optional prescription drug program. Pursuant to Utah Code Annotated § 26-18-2.4(1)(a), this plan provides care, including prescription drugs, that must be based upon clinical and cost-related factors, including "medical necessity."

25. The Utah Medicaid program restricts its coverage of drugs to only the medically

accepted indications that are FDA-approved or supported by an officially recognized compendia, AHFS, USP-DI or DRUGDEX. A drug prescribed for any indication that is not medically accepted is **not** a Medicaid benefit. Utah Medicaid Provider Manual, July 2006, pp. 9-11.

26. Risperdal and Seroquel have been prescribed by Utah physicians to many Medicaid recipients for indications that are not medically accepted. These prescriptions are not reimbursable under Utah Medicaid. As a result of ingesting these drugs, Utah Medicaid patients have suffered serious adverse health effects, which have required and continue to require further and more extensive medical treatment and healthcare services. The State of Utah is the financially responsible party for these services. The State has thus suffered and will continue to suffer additional financial loss in the care of those Medicaid recipients who consumed prescriptions for indications that are not medically accepted.

FDA-APPROVED INDICATIONS

27. A company wishing to market a new drug must seek the approval of the 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

28. 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 in adults, which combined afflict less than 2% of the U.S. population. Thus, 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.

29. 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.

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

31. Even with the additional indications for which Risperdal was approved in October 2006 and August 2007, only a small portion of the U.S. population suffers from the conditions Risperdal is FDA-approved to treat. However, despite the extraordinarily small population of individuals who use Risperdal for the treatment of medically accepted indications, annual sales of Risperdal in 2006 were $4.2 billion.

Seroquel

32. AstraZeneca obtained approval from the FDA to market Seroquel for treatment of adults with schizophrenia in September 1997. On January 12, 2004, the FDA approved Seroquel 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 were approved for treatment of adults with major depressive episodes associated with bipolar disorder.

33. Despite the additional indication for which Seroquel was approved in October 2006, only a minute portion of the U.S. population suffers from the conditions for which Seroquel is FDA-indicated. However, despite the extraordinarily small population of individuals who use Seroquel for the treatment of medically accepted indications, annual sales of Seroquel in 2006 were $3.4 billion.

FRAUDULENT AND UNLAWFUL MARKETING ACTIVITIES

34. The Defendants illegally marketed and promoted Risperdal and Seroquel for indications that are not FDA-approved 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.

As a result of Defendants' unlawful sales activities, Risperdal and Seroquel have been prescribed by Utah physicians to many Medicaid recipients for indications that are not medically accepted and, therefore, not reimbursable under Utah Medicaid.

35. Defendants represented 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. Actually, Defendant sought no such approval from the FDA and there is, in fact, insufficient medical evidence to warrant approval for these indications.

36. To implement this deceptive, fraudulent and unlawful marketing campaign, Janssen and AstraZeneca used their marketing department, sales managers and field sales force to: (i) fund clinical research studies, publications, and authors; (ii) advertise directly to physicians; and (iii) promote Risperdal and Seroquel to treat general symptoms of mood and behavioral disorders.

COMPANY-FUNDED CLINICAL RESEARCH STUDIES, PUBLICATIONS AND AUTHORS

37. 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 process 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.

38. 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.

39. 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 indications that are not medically accepted.

40. 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 morbidity and potentially fatal side-effects of Risperdal and Seroquel, and endorsed the drugs for dangerous indications that are not medically accepted.

41. Janssen and AstraZeneca also constructed a portfolio of articles for the medical community that promoted Risperdal and Seroquel. These articles were primarily written by a medical writing or education agency. Academic authors were then approached to become the named "authors" of Defendants' 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 articles 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 Defendants' drugs.

DIRECT TO PHYSICIAN ADVERTISING

42. 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.

43. 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 indications that are not medically accepted.

44. 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 indications that are not FDA-approved, and to recommend such use of Risperdal and Seroquel to other physicians.

45. 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.

46. 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' conclusions that ostensibly underscored the references were misleading, biased, invalid and inconsistent with the data.

47. 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

48. 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.

49. 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, Defendants have capitalized on this by creating a market for Risperdal and Seroquel in areas where atypical antipsychotics formerly were 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.

50. By and through these types of deceptive conduct, Janssen and AstraZeneca caused the State of Utah and consumers to unnecessarily pay large sums of money for Risperdal

and Seroquel that were improperly prescribed as a result of Defendants' fraudulent marketing scheme.

FRAUDULENT AND UNLAWFUL ACTS REGARDING SAFETY AND EFFICACY

51. In executing their marketing scheme, Defendants also misrepresented the safety and efficacy of Risperdal and Seroquel for indications that are not FDA-approved as described in paragraph 34 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, but are not necessarily limited to, 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;

(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.

52. A 2000 position paper penned by AstraZeneca's global safety physician, Dr. Wayne Geller, found that there was a "fairly sizable" number of reports linking Seroquel with impaired blood glucose regulation, and concluded there was "reasonable evidence to suggest that Seroquel therapy can cause impaired glucose regulation including diabetes mellitus in certain individuals." *See* Erin Marie Daly, *Docs Show AstraZeneca Knew of Seroquel Risks*, Law 360, March 2, 2009.

53. In an August 15, 2005 transcribed voicemail message to company salespeople, AstraZeneca employee Christine Ney stated, "Our objective is to neutralize customer objections to Seroquel's weight and diabetes profile." Ms. Ney then instructed the sales representatives to "refocus the call" away from diabetes to the drug's tolerability. *See* Wang and Johnson, *AstraZeneca Papers Raise Seroquel Issues*, The Wall Street Journal, February 27, 2009, B3.

54. In a 2006 e-mail, the company's medical science director for Seroquel, Dr. Martin Brecher, wrote to a patient safety director about the company's position on glucose and lipids. "I don't know how you can spin that," Brecher said in the e-mail provided in the released documents. "Hope team can settle on positioning glucose metabolism that will largely deemphasize weight gain." *See* Cronin and Feeley, *AstraZeneca Planned Off-Label Drug Sales in 2000* (Update6), Bloomberg.com, May 20, 2009.

55. Further, Defendants knew or recklessly disregarded the fact that Risperdal's and Seroquel's lack of efficacy and serious acute and chronic side effects made the drugs totally unsuitable as a drug therapy for the unapproved uses described in paragraph 34, especially when compared to other drugs that had been approved by the FDA for those uses.

56. 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 while continuing to aggressively market the drugs as safe and effective.

57. Among other things, Defendants failed to disclose Risperdal's and Seroquel's known side effects in the drugs' package inserts 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

58. 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:

(a) Janssen's claims that Risperdal has a low incidence of movement disorders;

(b) Janssen's claims that Risperdal has a low incidence of sedation;

(c) Janssen's claims that Risperdal has a low incidence of anticholinergic effects (variety of movement disorder);

(d) 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

(e) 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.

59. 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) Janssen minimized important information related to TD and EPS.

60. 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.

61. 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.

62. 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.

63. 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 not only prevented, but further perpetuated, misunderstanding among physicians and patients regarding the severe risks associated with Risperdal.

64. 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."

65. 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 or similar claims, and warned that the FDA was continuing to evaluate all aspects of the promotional campaign for Risperdal.

66. 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.

67. In January 2010, the United States Department of Justice ("DOJ") filed suit against Johnson & Johnson ("J&J") and two of its subsidiaries, Johnson & Johnson Health Care Systems, Inc. and Defendant Ortho-McNeil-Janssen, alleging that J&J paid millions of dollars in kickbacks to Omnicare, Inc., the nation's largest pharmacy specializing in dispensing drugs to nursing home patients. The Complaint can be found at:

http://www.justice.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/JJ/J&J%20complaint%20--%20filed.pdf.

The press release can be found at:

http://www.justice.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Jan2010/JohnsonandJohnsonPR.html.

68. According to the DOJ, J&J was aware that Omnicare's pharmacists reviewed nursing home patients' charts on a monthly basis and gave recommendations to doctors for what drugs to prescribe to patients. The DOJ further alleges that J&J viewed such pharmacists as an "extension of [J&J's] sales force."

69. The government complaint details several ways in which J&J disguised its kickbacks to Omnicare, including payments for "data," "grants," and "educational funding." In response to these kickbacks, the DOJ alleges that Omnicare undertook various intervention programs for J&J drugs. For example, Omnicare instituted a "Risperdal Initiative" whose purpose, as J&J understood it, was to "persuade physicians to write Risperdal in the areas of Behavioral Disturbances associated with Dementia." After physicians began to prescribe Risperdal for these indications that are not FDA-approved, the FDA mandated that the label for Risperdal carry a "black box" warning that "Elderly Patients with dementia-related psychosis treated with atypical antipsychotic drugs [including Risperdal] are at an increased risk of death compared to placebo."

70. In July 1997, Omnicare purchased the Superior Care Pharmacy, which is a long-term care pharmacy and one of the highest dollar volume Medicaid pharmacy providers in the State of Utah.

71. In November 2009, Omnicare, the United States and several individual states entered into a $98 million settlement agreement, a portion of which resolved Omnicare's civil liability under the False Claims Act for taking kickbacks from J&J.

ASTRAZENECA'S FRAUD AND DECEPTION REGARDING THE DANGERS OF SEROQUEL

72. AstraZeneca deliberately concealed the harmful side effects of Seroquel to further its unlawful and misleading marketing campaign. In fact, in a company communication, officials of AstraZeneca's U.S. unit noted that slides prepared in connection with a study involving indications that are not medically accepted of Seroquel were "financed outside of commercial for obvious legal reasons." *See* Cronin and Feeley, *AstraZeneca Planned Off-Label Drug Sales in 2000* (Update6), Bloomberg.com, May 20, 2009.

FDA Action

73. 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.

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

(a) AstraZeneca's claims that Seroquel is safe and effective in a broad range of conditions, including [illegible] disorder;

(b) AstraZeneca's claims as to how Seroquel helps schizophrenics [illegible]; and

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

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

76. The FDA's 1999 letter did not deter AstraZeneca. In October of 2006, the FDA again admonished AstraZeneca for making 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 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 advise doctors of the irreversibility of TD 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 risks of seizures, orthostatic hypotension and cataract development associated with Seroquel usage.

77. 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.

78. 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.

79. As a result of improper marketing practices, since 2003 AstraZeneca 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.

80. 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:

> Hyperglycemia, 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.

81. By sending this letter, AstraZeneca not only prevented, but further perpetuated misunderstanding among physicians and patients regarding the severe risks associated with Seroquel.

82. 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.

83. 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.

84. 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 reveal that the conditions may be fatal 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 risks associated with Seroquel usage.

85. 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.

Study 15

86. In 1997, AstraZeneca conducted a long-term trial of Seroquel designated "Study 15," that cast doubt on the commonly held belief within the psychiatric community that newer drugs were far superior to older drugs.

87. The results of Study 15 were never published or shared with doctors, and not until eight years later was this information rediscovered in a different study. In fact, research has found that the newer antipsychotic drugs such as Seroquel and Risperdal are 10 times more expensive and offer little advantage over older medications, like Haldol.

88. Details from Study 15 showed that patients taking Seroquel gained an average of 11 pounds in a year, a fact that was troubling to company scientists and marketing executives. Internal AstraZeneca documents show that company officials were concerned by what AstraZeneca physician Lisa Arvantitis termed "clinically significant" weight gain.

89. In an email dated August 13, 1997, Arvantitis reported that regardless of how the numbers were crunched, patients taking Seroquel gained weight: "I'm not sure there is yet any type of competitive opportunity no matter how weak."

90. In separate correspondence, company strategist Richard Lawrence praised AstaZeneca's efforts to put a "positive spin" on "this cursed study" and said of Arvantitis: "Lisa

has done a great 'smoke and mirrors' job!"

91. Two years after those exchanges, the documents show that the company presented different data at an American Psychiatric Association conference and at a 1999 European meeting. The conclusion: Seroquel helped psychotic patients lose weight.

92. Study 15 was not the only one AstraZeneca hid from the public. On December 6, 1999, another AstraZeneca employee wrote: "Thus far, we have buried Trials 15, 31, 56 and are now considering COSTAR."

FRAUDULENT AND UNLAWFUL ACTS REGARDING PROMOTIONS FOR INDICATIONS THAT ARE NOT MEDICALLY ACCEPTED FOR ELDERLY PATIENTS

93. From the time their 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.

94. Defendants' decision to target the elderly, and in particular Utah's elderly, had two results: (1) claims for indications that are not medically accepted for Risperdal and Seroquel were submitted to Medicaid for reimbursement; and (2) the drugs caused adverse health consequences for geriatric patients.

95. A 2002 AstraZeneca marketing document from Seroquel's brand manager contained handwritten notes suggesting the company "grease the skids for dementia" and market Seroquel for the elderly. *See* Cronin and Feeley, *AstraZeneca Planned Off-Label Drug Sales in 2000* (Update6), Bloomberg.com, May 20, 2009.

96. 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.

97. In January 2009, new study results were released indicating that Alzheimer's patients who take antipsychotics such as Risperdal may face a doubled risk of death. The study authors concluded, "[e]stimates of mortality for the whole study periods showed a significantly increased risk of mortality for patients who were allocated to continue anti-psychotic treatment compared with those allocated to placebo." *See* Erin Marie Daly, *Alzheimer's Patients Could Die From Risperdal: Study*, Law360, Jan. 9, 2009.

98. 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.

99. 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 Utah. In October of 2005, a study appearing in the Journal of the American Medical Association concluded that:

> [D]rugs 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.

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

101. 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.

102. 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."

103. 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.

104. Following May 13, 2004, AstraZeneca conceded its inappropriate promotion of Seroquel. A management decision was made to have the company's Long-Term Care sales force end its misleading 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 indications that are not medically accepted.

105. 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 INDICATIONS THAT ARE NOT MEDICALLY ACCEPTED FOR PEDIATRIC

PATIENTS

106. 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.

107. Although these uses were never approved by the FDA nor supported by any of the drug compendia, this lack of approval did not deter Defendants from marketing their respective drugs for treatment of children and adolescents for indications that are not medically accepted.

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

109. A 2001 public relations plan for Seroquel indicated the company should focus on achieving "aggressive market penetration" among adolescents, the elderly and patients with bipolar disorder to protect the drug's market share against rival antipsychotics such as Eli Lilly & Co.'s Zyprexa or Risperdal. *See* Cronin and Feeley, *AstraZeneca Planned Off-Label Drug Sales in 2000* (Update6), Bloomberg.com, May 20, 2009.

110. Upon information and belief, Dr. Melissa DelBello has been retained by AstraZeneca to help in its promotion of Seroquel to pediatric patients. In fact, in calendar year 2003, Dr. DelBello was paid $134,000 by AstraZeneca to assist in the marketing of Seroquel to pediatric patients.

111. In addition to paying Dr. DelBello directly, AstraZeneca supports her in other ways. An 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.

112. 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. DelBello's' study claims an 87% response rate versus 53% in an FDA approved adult study.

113. 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.

114. 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.

115. 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.

116. 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 TD, cataracts and neuroleptic malignant syndrome.

117. 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.

118. 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.

119. Upon information and belief, Dr. Rimal Bera is yet another physician retained by AstraZeneca to promote the use of Seroquel for indications that are not medically accepted. Dr. Bera received approximately $175,000 from AstraZeneca in honoraria for CME lectures in 2003. Dr. Bera received an additional $55,000 from AstraZeneca for 41 presentations he made in 2004.

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

FIRST CLAIM FOR RELIEF
(Utah False Claims Act, § 26-20-7)

121. Plaintiff incorporates the preceding paragraphs as if fully set forth herein, and further alleges as follows:

122. Pursuant to the Utah False Claims Act, Utah Code Annotated § 26-20-7(1)(e), it

is illegal to make a claim for Medicaid reimbursement of an outpatient drug prescription that is not for a medically accepted indication. Similarly, causing such a claim to be made, or aiding and abetting such a claim, is also prohibited.

123. In representing Risperdal and Seroquel to be safe and effective for indications that are not medically accepted, Janssen and AstraZeneca either caused claims to be made by physicians and consumers, or aided and abetted such claims for indications that are not medically accepted.

124. Claims for "medically accepted indications" are limited to uses approved by the FDA or uses which are supported by officially recognized compendia, AHFS, USP-DI or DRUGDEX.

125. The FDA has approved Seroquel only for treatment of adults with schizophrenia, bipolar I disorder, acute mania associated with bipolar I disorder and major depressive episodes associated with bipolar disorder.

126. Neither the compendia cited above nor the FDA support the use of Seroquel by infants, children or adolescents for any indication, or by adults with bipolar II disorder, dementia, depression, ADD, ADHD, sleep disorders, anger management, mood enhancement, mood stabilization, or any other use not listed in paragraph 125.

127. Risperdal was initially approved by the FDA for the treatment of adult schizophrenia and for the adult treatment of acute manic or mixed episodes of bipolar I disorder. Not until October 2006, was Risperdal approved by the FDA for the treatment of children and adolescents with irritability associated with autism, and not until August 2007, was Risperdal approved for the treatment of schizophrenia in adolescents ages 13 to 17 and the short-term

treatment of manic or mixed episodes of bipolar I disorder in children and adolescents ages 10 to 17.

128. Neither the compendia cited above nor the FDA support the use of Risperdal by infants for any indication, or by adults with bipolar II disorder, dementia, depression, ADD, ADHD, sleep disorders, anger management, mood enhancement, mood stabilization, or any other use not listed in paragraph 127.

129. As a result of unlawful marketing of Risperdal and Seroquel for indications that are not medically accepted, the State of Utah has paid millions of dollars for inappropriate prescriptions of Risperdal and Seroquel. In addition, Utah Medicaid patients have suffered serious adverse health effects that have required and continue to require further and more extensive medical treatment and healthcare services.

130. As a result, Janssen and AstraZeneca have been illegally enriched at the expense of the State of Utah. The State has also paid for False Claims resulting from the unlawful promotion to physicians of uses not supported by the approved FDA label. Further, the State has been required and will be required to pay the costs of treatment, including medical monitoring, for state residents actively harmed by Janssen's and AstraZeneca's illegal actions.

131. In making representations that Risperdal and Seroquel were appropriate for indications that are not medically accepted, Janssen and AstraZeneca acted with actual knowledge of the falsity of their representations or acted in either deliberate ignorance or reckless disregard of the truth or falsity of the information.

132. Accordingly, under the Utah False Claims Act, the State is entitled to restitution for prescriptions for indications that were not FDA-approved or supported by officially

recognized compendia, AHFS, USP-DI or DRUGDEX, for the resulting cost of care, and a civil penalty of three times the restitution and not less than $5,000 or more than $10,000 for each such prescription. In addition, the State seeks the costs of enforcement, including the cost of investigators, attorneys and other state employees.

SECOND CLAIM FOR RELIEF
(Utah False Claims Act, § 26-20-4)

133. Plaintiff incorporates the preceding paragraphs as if fully set forth herein, and further alleges as follows:

134. Pursuant to the Utah False Claims Act, Utah Code Annotated § 26-20-4(2), it is illegal to solicit, offer, pay or receive a kickback or bribe in return for the purchase of any good for which payment is or may be made in whole or in part pursuant to a medical benefit program.

135. Defendants Janssen Ortho and Ortho-McNeil-Janssen are wholly-owned subsidiaries of Johnson & Johnson, a company that paid millions of dollars to Omnicare for "data," "grants," and "educational funding" that, according to the United States Department of Justice, were actually kickbacks designed to induce their pharmacists to recommend prescriptions of Risperdal to nursing home patients, many or most of which were for indications that were not medically accepted.

136. Defendants Janssen Ortho and Ortho-McNeil-Janssen knew or should have known that Utah Medicaid would be responsible for paying for many of the Risperdal prescriptions given to the nursing home residents that resulted from the illegal kickbacks.

137. In July 1997, Omnicare purchased the Superior Care Pharmacy, which is a long-term care pharmacy and one of the highest dollar volume Medicaid pharmacy providers in the

State of Utah.

138. Accordingly, under the Utah False Claims Act, the State is entitled to restitution for prescriptions that resulted from the illegal kickbacks for the resulting cost of care, and a civil penalty of three times the restitution and not less than $5,000 or more than $10,000 for each such prescription. In addition, the State seeks the costs of enforcement, including the cost of investigators, attorneys and other state employees.

THIRD CLAIM FOR RELIEF
(Strict Products Liability — Failure to Warn)

139. Plaintiff incorporates the preceding paragraphs as if fully set forth herein, and further alleges as follows:

140. Defendants Janssen and AstraZeneca are the manufacturers and/or suppliers of Risperdal and Seroquel.

141. The Risperdal and Seroquel manufactured and/or supplied by Defendants Janssen and AstraZeneca were and are unaccompanied by proper warnings or packaging regarding all possible side effects associated with the drugs. Janssen and AstraZeneca failed to warn of the comparative severity, incidence and duration of such adverse effects. The warnings given to the FDA, the State of Utah, physicians, and consumers, including Medicaid recipients, did not accurately reflect the signs, symptoms, incidents or severity of the side effects of Risperdal and Seroquel. Further, the warnings did not accurately reflect the necessity of medical monitoring and blood tests to determine the users' elevated risk of hyperglycemia, diabetes, and other conditions.

142. Janssen and AstraZeneca failed to adequately test Risperdal and Seroquel. Such

testing would have shown that Risperdal and Seroquel possessed serious potential side effects, of which full and proper warnings should have been made.

143. The Risperdal and Seroquel manufactured or supplied by Janssen and AstraZeneca were defective due to inadequate post-marketing warnings, packaging or instructions. After the manufacturers knew or should have known of the risks of injury from Risperdal and Seroquel, they failed to provide adequate warnings to the FDA, the State of Utah, physicians, and consumers. Further, Janssen and AstraZeneca continued to aggressively market Risperdal and Seroquel for both FDA-approved indications and indications that are not FDA-approved, in spite of these known defects and risks.

144. On information and belief, Janssen and AstraZeneca actually knew of the defective nature of Risperdal and Seroquel, but continued to market and sell them without proper warning, so as to maximize sales and profits in conscious disregard for the foreseeable harm caused by the drugs.

145. As a proximate cause and legal result of Janssen's and AstraZeneca's failure to warn of known and reasonably knowable dangers associated with the use of Risperdal and Seroquel, the State of Utah has suffered and will continue to suffer damages and is entitled to recover for those damages.

FOURTH CLAIM FOR RELIEF
(Fraud and Negligent Misrepresentation)

146. Plaintiff incorporates the preceding paragraphs as if fully set forth herein, and further alleges as follows:

147. Janssen's and AstraZeneca's warnings of Risperdal's and Seroquel's side effects

contained false representations and/or failed to accurately represent the material facts of the full range and severity of the risks and adverse reactions associated with their products.

148. Janssen's and AstraZeneca's Risperdal- and Seroquel-related claims and assertions to the FDA, the State of Utah, physicians, and consumers, including Medicaid recipients contained false representations regarding the safety of Risperdal and Seroquel and their defective design. Further, Janssen's and AstraZeneca's claims concerning uses for indications that are not medically accepted were false and fraudulent.

149. Janssen and AstraZeneca were negligent in not making accurate representations regarding the side effects and adverse medical conditions associated with the use of Risperdal and Seroquel.

150. Janssen and AstraZeneca knew or reasonably should have known through adequate testing that the claims made to the FDA, the State of Utah, physicians, and consumers, including Medicaid recipients, with regard to the safety and efficacy of Risperdal and Seroquel were false or incomplete and misrepresented the material facts of the drugs' unsafe and defective conditions.

151. Janssen's and AstraZeneca's misrepresentations in this regard were done with the intention of inducing the State to allow the distribution of Risperdal and Seroquel to participants in the Utah Medicaid Program and profiting from that distribution.

152. As a proximate and legal result of Janssen's and AstraZeneca's fraudulent misrepresentations, the State of Utah has suffered and will continue to suffer damages and is therefore entitled to recover for those damages.

FIFTH CLAIM FOR RELIEF
(Negligence)

153. Plaintiff incorporates the preceding paragraphs as if fully set forth herein, and further alleges as follows:

154. Janssen and AstraZeneca owed a duty to exercise reasonable care in the testing, marketing, manufacture, sale, labeling and/or distribution of Risperdal and Seroquel, including a duty to ensure that users would not suffer from unreasonable, dangerous, undisclosed or misrepresented side effects. Janssen and AstraZeneca owed this duty to the State of Utah as the State funded the distribution of Risperdal and Seroquel to Utah Medicaid recipients.

155. Janssen and AstraZeneca breached this duty, as they were negligent in the testing, marketing, manufacture, sale, labeling and distribution of Risperdal and Seroquel.

156. As a direct and proximate result of Defendant Janssen's and AstraZeneca's negligence, the State of Utah has suffered and will continue to suffer the damages and is therefore entitled to recover for those damages.

SIXTH CLAIM FOR RELIEF
(Pattern of Unlawful Activity Utah Statute Annotated §76-10-1601, et seq.)

157. Plaintiff incorporates the preceding paragraphs as if fully set forth herein, and further alleges as follows:

158. Janssen and AstraZeneca each constitute an "enterprise" within the meaning of Utah Code Annotated § 76-10-1602(1).

159. Janssen and AstraZeneca have engaged in a pattern of illegal activity in their respective advertising, sales, marketing, and distribution as described above. Defendants' actions meet the definition of "Pattern of Unlawful Activity" set out in Utah Code Annotated §§

76-10-1602(2) and 76-10-1602(4)(d).

160. Janssen and AstraZeneca have committed unlawful acts under Utah Code Annotated § 76-10-1603 in that they have received proceeds derived from a pattern of unlawful activity.

161. The State, as an injured party, may sue in District Court and recover twice the damages sustained as a result of Janssen's and AstraZeneca's unlawful acts.

162. Further, the State, as an injured party, is entitled to an award of reasonable attorney's fees incurred in enforcing its rights.

PRAYER FOR RELIEF

WHEREFORE, the State of Utah, by and through Attorney General Mark L. Shurtleff, prays as follows:

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

B. That the Court adjudge and decree that Defendants violated Utah Code Ann. § 26-20-7 and that the State of Utah was damaged thereby for which Defendants must pay.

C. That the Court, pursuant to Utah Code Ann. § 26-20-9.5 assess civil penalties of not less than $5,000 or more than $10,000 for each violation of Utah Code Ann. § 26-20-7 and § 26-20-4.

D. That the Court, pursuant to Utah Code Ann. § 26-20-9.5 award treble damages as a civil penalty for violation of the False Claims Act.

E. That the Court, pursuant to Utah Code Ann. §§ 70A-2-714 and 70A-2-715, assess

civil damages for breach of warranties as complained of herein.

F. That the Court, pursuant to Utah Code Ann. § 76-10-1605 assess damages for violating Utah Code Ann. § 76-10-1603 as complained of herein.

G. That the Court order Defendants to pay restitution which would restore the State of Utah to the financial position that it would have enjoyed absent Defendants' false representations and promotion of Risperdal and Seroquel.

H. That the Court award the State of Utah its costs of enforcement, including attorneys fees and other investigatory expenses pursuant to the Utah False Claims Act.

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

J. That the Court award injunctive relief, including but not limited to: (i) prohibiting Defendants from making any oral or written claims that are false, misleading or deceptive with respect to Risperdal and Seroquel, including false, misleading or deceptive claims regarding the safety and efficacy of Risperdal and Seroquel for indications that are not FDA-approved; (ii) prohibiting Defendants from affirmatively seeking the inclusion of Risperdal and Seroquel in hospital protocols or standing orders for indications that are not FDA-approved; (iii) requiring Defendants to distribute improved educational materials for patients and primary care physicians that clearly identify the risks and benefits of Risperdal and Seroquel, including precautions when Risperdal and Seroquel are prescribed for indications that are not FDA-approved; and (iv) requiring Defendants to develop programs that include small group meetings with Risperdal and Seroquel prescribers, particularly primary care physicians, to inform the health care providers of the drugs' appropriate uses, risks, benefits, and reasonable therapeutic

alternatives.

DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury on all issues so triable.

Respectfully SUBMITTED and DATED this ____ day of May, 2010.

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