IN THE CIRCUIT COURT OF
MONTGOMERY COUNTY, ALABAMA

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| STATE OF ALABAMA,<br><br>Plaintiff,<br><br>v.<br><br>JANSSEN PHARMACEUTICA INC.;<br>JANSSEN, L.P.; and<br>JOHNSON & JOHNSON,<br><br>Defendants. | ) | COMPLAINT<br><br>Jury Trial Demanded |

**COMPLAINT**

COMES NOW the State of Alabama ("the State"), by and through its Attorney General, to bring this action for itself and its Medicaid program. The State seeks restitution, other monetary relief, civil penalties, and injunctive relief against Defendants Janssen Pharmaceutica Inc., Janssen, L.P., and Johnson & Johnson ("Defendants").

PARTIES

1. The plaintiff is the State of Alabama, represented by its Attorney General. The Attorney General is statutorily authorized to initiate and maintain this action, and does so.

2. Defendant Janssen Pharmaceutica Inc. ("JPI") is a Pennsylvania corporation. JPI can be served at its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

3. JPI is the general partner of Janssen, L.P. ("JLP"). JLP is a New Jersey limited partnership which can be served at its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

4. Johnson & Johnson is a New Jersey corporation which can be served at its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Johnson & Johnson is the parent company of JPI and JLP and is legally responsible for the actions of JPI and JLP.

5. The acts alleged to have been done by Defendants were authorized, ordered done and/or ratified by Defendants' officers, directors, agents, employees or representatives while engaged in the management, direction, control or transaction of Defendants' business affairs.

JURISDICTION & VENUE

6. This Court has personal jurisdiction over Defendants because Defendants do business in Alabama and in Montgomery County, and they have the requisite minimum contacts with the State to constitutionally permit the Court to exercise personal jurisdiction over them.

7. Defendants did, individually or in conjunction with others, research, develop manufacture, create, design, test, label, sterilize, package, distribute, supply, market, sell, promote, advertise, and otherwise distribute the prescription medicine

Risperdal throughout Alabama and specifically in Montgomery County.

INTRODUCTION

8. This is an action to recover funds expended by the State in providing medical treatment to Medicaid participants. The funds at issue were expended to purchase Risperdal for unapproved uses. The State's Medicaid program is an injured purchaser and/or reimburser of Risperdal.

9. This is an action pursuant to the Alabama Deceptive Trade Practices Act, or "ADTPA," Code of Alabama §§ 8-19-1, et seq., to punish and deter the deceptive promotion and sale of Risperdal.

10. The State seeks reimbursement of funds expended by Alabama pursuant to the Medicaid program, as it is operated pursuant to statute and regulation.

11. The State seeks to recover Medicaid funds paid to pharmacies, hospitals, and other medical providers for unapproved/unauthorized Risperdal prescriptions.

12. The claims asserted by the State arise under laws of the State. No federal claims are asserted and to the extent that any claim or factual assertion set forth may be construed to state a claim under federal law, such claim is expressly and undeniably disavowed and disclaimed by the State.

## ALLEGATIONS OF FACT

13. The State participates in and operates the Medicaid program to promote the general welfare of its citizens and to furnish adequate and high-quality health care to those Alabama citizens who cannot afford it.

14. The Medicaid program includes individualized provisions, by statute and regulation, concerning reimbursement for prescription drugs. Defendants are providers of prescription drugs within the meaning of the Medicaid program.

15. The State, as is true of many states, cannot ensure beforehand that each prescription for every drug paid for by the Medicaid program constitutes a medically necessary use of that drug. The Defendants, recognizing that circumstance, illegally promoted the use of Risperdal for non-medically accepted indications and non-medically necessary uses. They did so to bilk the Medicaid program, and specifically to violate the rule established by statute and regulation that drug prescriptions for non-medically accepted indications and non-medically necessary uses fall outside the coverage of the Medicaid program.

16. In promoting and selling Risperdal, Defendants falsely represented to the State, to the public in general, and to physicians and other providers that Risperdal is safer and more effective than less expensive, first generation antipsychotics.

17. In promoting and selling Risperdal, Defendants exaggerated the drug's efficacy and understated or concealed its risk of adverse health side effects.

18. In promoting and selling Risperdal, Defendants misrepresented it as effective and approved for conditions for which it is not effective and approved. For example, Defendants promoted Risperdal in the State of Alabama for many conditions for which the FDA had not approved its use. Defendants promoted Risperdal as a safe and effective treatment for use in children, depression, anxiety, ADD, ADHD, sleep disorders, anger management, mood enhancement, mood stabilization, as well as other conditions - none of which were approved by the FDA. As a result of the illegal off-label promotion, millions of dollars have been paid by the Alabama Medicaid Department to pay for Risperdal use in treating conditions for which the drug was not approved by the FDA to treat.

19. Since approximately 1994, Defendants have manufactured and sold Risperdal and have promoted the drug to physicians in Alabama through their representatives.

20. Risperdal is a prescription antipsychotic drug belonging to the atypical antipsychotic class. Defendants obtained approval from the U.S. Food and Drug Administration (hereinafter the "FDA") to market Risperdal oral tablets for the management of manifestations of psychotic disorders in adults on December 29,

1993.

21. On June 10, 1996, the FDA approved Risperdal oral solution for the management of manifestations of psychotic disorders in adults.

22. On March 3, 2002, the approved indication for Risperdal was changed by the FDA to "treatment of schizophrenia" in adults.

23. On April 2, 2003, the FDA approved Risperdal M-Tab for the treatment of adults with schizophrenia. On October 29, 2003, the FDA approved Risperdal Consta for the treatment of schizophrenia in adults.

24. On December 4, 2003, the FDA approved Risperdal oral tablets, Risperdal oral solution and Risperdal M-Tab as monotherapy for the short-term treatment of acute manic or mixed episodes associated with Bipolar I Disorder, and as combination therapy, with lithium or vaiproate, for the short-term treatment of acute manic or mixed episodes associated with Bipolar I Disorder.

25. The United States Pharmacopeia-Drug Information and the DRUGDEX Information System support the use of Risperdal for the indications approved by the FDA. The American Hospital Formulary Service Drug Information ("AHFS") supports the use of Risperdal for the indications approved by the FDA and, in 2003, initiated support for the use of Risperdal to treat behavioral problems in children 5-17 years old with autistic disorder, The AHFS noted that it did not support the use

of Risperdal to treat the core symptoms of autism, but only manifestations of moderate to severe behavioral problems associated with autistic disorder. Prior to 2003, the compendia supported only the uses of Risperdal approved by the FDA. The uses supported by these three compendia and the FDA-approved labeling are collectively defined as medically-accepted indications.

26. Neither the compendia cited above nor the FDA-approved labeling support any use of Risperdal by children or adults with depression, anxiety, ADD, ADHD, sleep disorders, anger management, mood enhancement or mood stabilization.

27. The traditional or "typical" antipsychotics include chlorpromazine (Thorazine), fluphenzine (Proxilin), haloperidol (Haldol), loxapine (Loxitane), molindone (Moban), mesoridazine (Serentil), perphenazine (Trilafon), thioridazine (Mellaril), thiothixene (Navane), and trifluoperazine (Stelazine). Until the early 1990's, the typical antipsychotics were the common drug therapy for schizophrenia.

28. Although there are many traditional antipsychotics, the efficacy of these drugs is similar because all the drugs have similar mechanisms of action. A troubling side effect of typical antipsychotics is that the blockage of dopaminergic neurotransmission in the basal ganglia caused extrapyramidal syndromes (BPS) such as Parkinsonian effects. A long-lasting movement disorder, tardive dyskinesia,

also occurred with prolonged treatment.

29. During the 1990's pharmaceutical companies, acting on the "atypical" hypothesis, introduced newer drugs attempting to capture the enhanced therapeutic effect of clozapine without its toxicity and without the increased BPS caused by traditional antipsychotics. Before 1993, the only atypical antipsychotic in the United States market was clozapine, and due to its toxicity it had very little market share. Ten years later, atypical antipsychotics such as Risperdal would account for about 90% of all antipsychotic drugs prescribed for all psychiatric purposes, regardless of whether they were approved for those indications.

30. The atypical antipsychotics include clozapine (Clozaril), olanzapine (Zyprexa), quetiapine (Seroquel), Risperdal, aripiprazole (Abilify), and ziprasidone (Geodon), and are considered the second-generation antipsychotics (SGA).

31. The Defendants achieved, through a series of unlawful acts and practices, the largest United States market share for atypical antipsychotics, both for FDA-approved purposes and for unapproved purposes.

32. In late 1993, Risperdal became the second atypical antipsychotic to receive FDA approval. In early 1994, Janssen, a subsidiary of Johnson & Johnson, began marketing and selling Risperdal. During the next several years, Janssen heavily marketed and promoted Risperdal for its approved indication, management

of the manifestation of psychotic disorders, and for multiple non-approved purposes of the drug, for example, attention deficit-hyperactivity disorder (ADHD), depression, anxiety, mood disorder, bipolar disorder, and aggression associated with late-onset dementia. By late 1996, Janssen had significant market share for United States antipsychotic drug use, and demonstrated the sales potential of marketing atypical antipsychotic usage for non-approved indications.

33. Medical literature dating as far back as the 1950s, and Defendants' own pre-clinical studies of Risperdal, demonstrate that Risperdal, like older antipsychotic medications, had the potential to cause diabetes, diabetes-related injuries (e.g. weight gain and hyperglycemia), cardiovascular and cerebrovascular complications, and other severe adverse effects. By the time Risperdal was first marketed, the neurochemical bases for the efficacy and side-effects were generally known to Defendants, i.e., effects on dopamine, serotonin, and histamine systems in the brain. Therefore, prior to marketing Risperdal, Defendants knew or should have known that Risperdal causes neurological problems, weight gain, diabetes, pancreatitis, hyperglycemia, cardiovascular complications, and metabolic syndrome.

34. Despite having been on notice, for years, of the potential for deadly diabetes-related side effects, Defendants opted for the bare minima of clinical trials, of limited duration, such that no side effects were likely to be revealed.

35. Defendants had actual knowledge that Risperdal causes weight gain, which significantly increases a patient's risk of contracting diabetes. Despite such knowledge, Defendants failed to include a Warning of the potential for weight gain and the possible development of diabetes as a result of the use of Risperdal in its U.S. labeling for years. In fact, Defendants concealed the true safety profile of Risperdal from patients from 1993 until 2004. Even then, Defendants did not warn citizens of the State of the risk of diabetes associated with Risperdal.

36. In 1999, the FDA caught Janssen promoting Risperdal for the non-medically accepted treatment of the elderly. In a letter from the FDA to Todd McIntyre, Director of Janssen's Regulatory Affairs department, the agency strongly disagreed with certain promotional materials that it had received as part of its monitoring and surveillance program. According to the FDA, Janssen engaged in a false and misleading campaign to promote Risperdal to geriatric patients. Among the items found by the FDA to be false and misleading were:

- Janssen's claims in its promotions that Risperdal was safe and effective for elderly patients, despite little or no data to support such claims;
- 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;
- Janssen's claims that Risperdal is safer or more effective than other antipsychotics;
- Janssen's claims that Risperdal "enhances daily living" or that it offers "quality control of symptoms for daily living;"
- Janssen's claims that Risperdal can "control health-related quality of life;"
- 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;
- Janssen's marketing Risperdal outside its education by representing that Risperdal is a safe and effective treatment for hostility in the elderly; and
- Janssen's claims that Risperdal is a safe and effective treatment for "psychotic symptoms associated with a broad range of disorders," including schizophrenia, schizophreniform disorder, schizoaffective disorder, bipolar

disorder and elderly psychosis.

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

- The risk 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," thus lacking the "prominence and readability that is reasonably comparable to the presentation of efficacy information"; and
- It minimized important information related to tardive dyskinesia and extrapyramidal symptoms.

38. Upon information and belief, despite studies and data that confirm the lack of efficacy and significant health and safety risks associated with the promotion of Risperdal for the elderly, Defendants continued this practice.

39. Prior to Risperdal's FDA approval, Defendants had a well-developed strategy to expand the use of Risperdal beyond patients with schizophrenia. Upon information and belief, Defendants sought ghost written research and paid "key opinion leaders" to support Defendants' marketing aims. These "key opinion leaders" were nothing more than third-party consultants and researchers who were put on Defendants' payroll to support and lend credibility to Defendants' scientific and marketing goals.

40. Among these goals were plans to create a series of studies designed to illustrate Risperdal's superior profile to both (a) a placebo and (b) a representative conventional antipsychotic while providing funding to engage key opinion leaders in publication worthy trials.

41. Throughout these years, Janssen never provided a prominent warning about the increased risk of diabetes and hyperglycemia and of the need to provide baseline diabetes screening and glucose monitoring. A warning did not appear until it was forced by the FDA in mid-September of 2003.

42. On September 11, 2003, the FDA informed all manufacturers of atypical antipsychotic drugs, including Defendants, that due to an increasing prevalence of diabetes related illnesses associated with this class of drugs, that all labeling must bear the following language in the Warnings section: Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. 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, studies suggest an increased risk of emergent hyperglycemia-related adverse events in patients treated with atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events 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. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

43. Despite the FDA's mandate that Defendants immediately warn of the dangers described above, Defendants waited two more months, until November of 2003, to send prescribing physicians a "Dear Doctor Letter" advising of the new

warnings.

44. On April 19, 2004, that November letter was rebuked by the FDA for being brazenly "false" and "misleading."

45. According to the FDA, Janssen's November letter misled doctors by failing to disclose information relating to hyperglycemia and diabetes mellitus, minimizing the risks of potentially fatal hyperglycemia-related adverse events, failing to recommend regular glucose control monitoring to identify diabetes mellitus and misleadingly claiming that Risperdal is safer than other atypical antipsychotics.

46. The FDA demanded that Janssen immediately cease the dissemination of promotional materials for Risperdal containing claims similar to the foregoing and provide a plan of action to correct the effects of its false and misleading letter.

47. Finally, the FDA admonished Janssen that the violations detailed above did not constitute an exhaustive list, and that it was continuing to "evaluate other aspects" of Janssen's promotional campaign for Risperdal. The FDA reserved the right to determine that "additional measures" would be necessary to "fully correct the false or misleading messages resulting from your [Janssen's] violative conduct."

48. Months later, in July of 2004, Janssen finally sent a dear healthcare provider letter, that was acceptable to the FDA, containing the new warnings.

49. Risperdal is the most widely used atypical antipsychotic in the world. Risperdal has gone from annual sales of zero on 1/1/94 to over $3,500,000,000 in 2005. Crucial to this blockbuster success was Defendants' aggressive marketing of Risperdal, which consisted chiefly of overstating the drug's efficacy, while concealing its life-threatening side effects. As a direct result of Defendants' inflated pricing and illegal marketing efforts, the State has been billed, charged, and as a result overpaid millions of dollars for non-medically accepted (non-FDA approved) indications of Risperdal.

50. There is no valid scientific evidence to support Defendants' contention that Risperdal is safe and effective for treatment of any non-medically accepted indication, including any use in children. There is no valid scientific evidence concerning the therapeutic equivalence of Risperdal for any non-medically accepted indication, including any use in children.

51. Further, even in cases where treatment with an antipsychotic was appropriate, Risperdal prescriptions should not have been submitted to the State, as Risperdal is no safer or more effective than less expensive first generation antipsychotics.

52. Defendants did business in the State of Alabama; made contracts to be performed in whole or in part in Alabama and/or manufactured, tested, sold,

offered for sale, supplied or placed in the stream of commerce, or in the course of business materially participated with others in so doing, Risperdal, which Defendants knew to be defective, unreasonably dangerous and hazardous, and which Defendants knew would be substantially certain to cause injury to the State and to persons within the State thereby negligently and intentionally causing injury to persons within Alabama and to the State, and as described herein, committed and continue to commit tortious and other unlawful acts in the State of Alabama.

53. From the 1993 product launch of Risperdal to the present, Defendants engaged in widespread fraudulent statements and conduct, and pervasive false and misleading marketing, advertising and promotion of Risperdal. Defendants deceived physicians, consumers, the State, and others regarding the comparative efficacy of Risperdal to other traditional and atypical antipsychotics. Defendants failed to warn – and affirmatively misled – physicians, consumers, the State, and others in the medical community regarding Risperdal's association with diabetes, diabetes-related conditions and other adverse effects. And even though Risperdal is an antipsychotic drug and thereby limited to its FDA-approved indications, Defendants actively marketed and promoted Risperdal for unapproved uses in several populations where the efficacy and safety of the drug had yet to be established – marketing Risperdal for the treatment of various conditions or

symptoms in children, marketing Risperdal for treatment in the elderly for dementia, and marketing Risperdal for treatment of patients who experience depressive or other physiological conditions as previously described herein.

54. After achieving FDA approval of Risperdal, Defendants plotted and schemed to increase the sales of Risperdal while avoiding the substantial expense and delay of petitioning the FDA for approval of expanded or additional uses of Risperdal. The scheme consisted of elaborate and clandestine promotion of non-medically accepted indications and non-medically necessary uses of Risperdal.

55. Upon information and belief, this scheme was carried out by: employing the illegal direct solicitation of physicians to prescribe Risperdal for non-medically accepted indications and non-medically necessary uses; the making of false statements to physicians and pharmacists concerning the efficacy and safety of Risperdal for non-medically accepted indications and non-medically necessary uses; the use of active concealment to avoid the utilization policies of Medicaid, which are intended to refuse payment for uses of drugs which are not medically accepted and medically unnecessary; and the active training of Defendants' employees in methods of avoiding detection of their activities by the FDA.

56. The State spends millions of dollars each year to provide or pay for health care and other necessary facilities and services on behalf of indigents and

other eligible citizens whose said health care costs are directly caused by Risperdal-induced diabetes, stroke, pancreatitis, seizures and other diseases.

57. Defendants, through their funding and control of certain studies concerning the effects of Risperdal on human health, their control over trade publications, promoting, marketing, and/or through other agreements, understandings and joint undertakings and enterprises, conspired with, cooperated with and/or assisted in the wrongful suppression, active concealment and/or misrepresentation of the true relationship between Risperdal and various diseases, all to the detriment of the public health, safety and welfare and thereby causing harm to the State.

58. Defendants individually, and through their representatives, fraudulently misled the public and physicians treating Medicaid participants regarding the efficacy and health risks of Risperdal, all for the purpose of increasing Defendants' profits from the sale of Risperdal.

59. Specifically, and in addition to the allegations above, Defendants knew of the hazards associated with Risperdal. Defendants nevertheless affirmatively and actively concealed information which clearly demonstrated the dangers of Risperdal and affirmatively misled the public and physicians treating Medicaid participants with regard to the material and clear risks of Risperdal. Defendants did so with the

intent that physicians treating Medicaid participants would continue to prescribe Risperdal, burdening Alabama's Medicaid program with that cost.

60. Defendants knew that prescribing physicians would not be in a position to discover the true risks of Risperdal and would rely upon the misleading information that Defendants promulgated. Defendants further knew that physicians treating Medicaid participants would write Risperdal prescriptions that would be paid for by the State's Medicaid program.

61. Upon information and belief, the statements, representations and promotional schemes of Defendants were deceptive, false, incomplete, misleading and untrue. Defendants knew, or should have known, that their statements, representations and advertisements were deceptive, false, incomplete, misleading and untrue at the time of making such statements. Defendants had an economic interest in making such statements. Neither the State nor the physicians in Alabama who prescribed Risperdal had knowledge of the falsity or untruth of Defendants' statements, representations and advertisements when Medicaid claims for Risperdal prescriptions were submitted.

62. As a result of Defendants' misrepresentations, and in an effort to spare their patients from experiencing adverse effects, Alabama doctors treating Medicaid participants widely prescribed Risperdal instead of less expensive first generation

antipsychotics.

63. Each of the Defendants' statements, representations and advertisements concerning Risperdal were material to the State's purchase of Risperdal. The State would not have reimbursed for or purchased Risperdal if it had known that Defendants' statements, representations and advertisements related to Risperdal were deceptive, false, incomplete, misleading and untrue.

COUNT I

MEDICAID FRAUD

64. The State incorporates by reference the foregoing allegations as if set forth at length herein.

65. Medicaid recipients in the State who have used Risperdal have their prescription costs paid in whole or in part by Alabama Medicaid.

66. Defendants' aggressive, off-label promotion of Risperdal, which induced the expenditure of the State's Medicaid funds, constitutes a pattern of fraudulent conduct which has burdened the State unjustly and illegally. Defendants' conduct constitutes Medicaid fraud within the meaning of controlling Alabama statutes and rules, including but not limited to Ala. Admin. Code Chapter 560-X-4 through 560-X-33.

67. Defendants' aggressive, off-label promotion of Risperdal which induced

the expenditure of the State's Medicaid funds constitutes Medicaid fraud, insofar as the conduct is or was intentional deception or intentional misrepresentation made with the knowledge that the deception could result in an unauthorized benefit.

68. Defendants, as alleged, concealed from the State their promotion of Risperdal for non-FDA approved and therefore non-medically accepted indications and non-medically necessary uses. Said active concealment was motivated by the desire to, and had the effect of, preserving and increasing the flow of State funds to reimburse Risperdal prescriptions for non-medically accepted indications and non-medically necessary uses. Said concealment and results constitute Medicaid fraud.

69. Defendants knowingly caused false claims for payment to the State's Medicaid program by intentionally promoting Risperdal by deceptive means and for non-medically accepted indications and non-medically necessary uses. They did so to receive greater compensation than that to which they are legally entitled, with the costs ultimately being borne, in whole or in part, by the State through its Medicaid reimbursement payments. The prescriptions constitute false claims because it is unlawful to procure Medicaid reimbursement by deceptive means and/or for non-medically accepted indications and non-medically necessary uses of a drug.

70. Accordingly, the State is due to be reimbursed in full by Defendants for all costs of the foregoing misconduct.

COUNT II

DECEPTIVE TRADE PRACTICES

71. The State incorporates by reference the foregoing allegations as if set forth at length herein.

72. The foregoing alleged actions of Defendants constitute trade or commerce affecting the people of the State within the meaning of Code of Alabama § 8-19-3, and the actions are proscribed by the ADTPA, Code of Alabama §§ 8-19-1 et seq.

73. The foregoing alleged actions of Defendants constitute unlawful trade practices under Code of Alabama § 8-19-5, insofar as:

- Defendants fraudulently represented and sold Risperdal as a safer and more effective medicine than less expensive, first generation antipsychotics;
- Defendants represented, portrayed, promoted, and sold Risperdal as an approved therapy for conditions for which it is not an FDA-approved therapy;
- Defendants caused Risperdal to be widely prescribed to Medicaid participants in Alabama on the basis of deceptive claims about its

effectiveness and its improvement over other, existing drugs;

- Contrary to Defendants' representations, Risperdal is no more effective (or is less effective) than other medicines which are much less expensive, and it causes profoundly adverse side effects that Defendants knew of and did not warn about;
- Defendants minimized and suppressed data that disproved their claims of Risperdal's improved effectiveness, and they did so to increase and ensure sales of the drug at prices they otherwise could not have charged had the truth about the drug reached the community of prescribing doctors;
- Defendants knowingly caused false claims to be submitted to the Medicaid Program by fraudulently representing that Risperdal is safer and more effective than less expensive, first generation antipsychotics. The increased incremental cost of Risperdal, relative to available first generation antipsychotics, was borne by the State and resulted in excessive payment to Defendants.
- Defendants made false and misleading misrepresentations of fact regarding Risperdal's risk profile, including but not limited to misrepresenting the likelihood and severity of the side effects associated with Risperdal, including diabetes, stroke, high blood pressure, weight gain and other serious and

potentially life-threatening conditions;

- Defendants misrepresented and concealed material facts and/or failed to inform and educate Alabama physicians as to the risks and dangers associated with Risperdal use when such facts were well known to or readily ascertainable by Defendants;
- Defendants misrepresented and concealed material facts which were known to them, but unknown to Alabama physicians, when promoting the drug to the physicians;
- Defendants knew that Alabama physicians would rely on their representations when deciding whether to prescribe Risperdal to their patients;
- Defendants misrepresented Risperdal as being of a particular standard, quality or grade when it is not;
- Defendants intentionally created a false impression or a likelihood of confusion or misunderstanding in the minds of Alabama physicians as to whether Risperdal is safe and medically necessary, and/or FDA-indicated, for patients, including Medicaid participants; and
- Defendants made, and continue to make, orally and in writing, false, misleading or deceptive representations in advertisements, promotions and

statements, and otherwise disseminated, and continue to disseminate, false, misleading or deceptive information to the public, including Alabama citizens, physicians and the State regarding non-medically necessary and non-medically accepted uses of Risperdal and the health risks and benefits associated with using Risperdal.

74. The foregoing deceptive trade practices have caused substantial financial harm to the State and its Medicaid program.

75. To penalize and deter the foregoing deceptive trade practices, Defendants should be ordered to pay the State statutory penalties of not less than $2,000.00 for each and every occurrence of an unlawful trade practice, namely for each Risperdal prescription caused or procured by any one or more of the deceptive acts or practices alleged. The State hereby pleads and petitions for such penalties.

PRAYER FOR RELIEF

WHEREFORE, the State prays that this Honorable Court enter judgment in its favor and against Defendants, for this relief specifically:

(a) restitution, interest, and monetary penalties to the utmost amounts allowed by law for all expenditures made for non-medically accepted or non-medically necessary prescriptions of Risperdal;

(b) monetary penalties to the utmost amount for each occurrence of a

Risperdal prescription caused or procured by any one or more of the deceptive acts or practices alleged;

(c) an injunction against the offending conduct; and

(d) other relief that is just.

DEMAND FOR JURY TRIAL

The State demands that all issues presented by its above Complaint be tried to a jury, except any issue that, by law, must be decided by the Court.

s/ Roger L. Bates
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