

IN THE CIRCUIT COURT OF PULASKI COUNTY, ARKANSAS
6th DIVISION

STATE OF ARKANSAS ex rel.

DUSTIN MCDANIEL, ATTORNEY GENERAL

PLAINTIFF

vs.

CASE NO. 07-15345

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Pat O'Brien Pulaski Circuit Clerk

JANSSEN PHARMACEUTICA, INC.,
JANSSEN, LP and
JOHNSON & JOHNSON, INC.

DEFENDANTS

COMPLAINT

Plaintiff, State of Arkansas ex rel. Dustin McDaniel, Attorney General, for its Complaint against the Defendants, states and alleges as follows:

The State brings this action on behalf of the Divisions of Behavioral Health Services ("DBHS") and Medical Services ("Medicaid") of the Arkansas Department of Human Services ("DHS"), and the Arkansas Department of Finance and Administration ("DFA"), specifically its Employee Benefits Division ("DFAEBD"), as injured purchasers and/or reimbursers of prescription drugs, and as representative of, and as *parens patriae* on behalf of the citizens of Arkansas. Under the Arkansas Constitution and other positive law of the State, including Arkansas's common law and including, among other laws, Ark. Code Ann. §§ 25-16-702, *et seq.*, 4-88-104, 4-88-201 *et seq.*, and 20-77-901, *et seq.*, the State is responsible for, and has a duty to protect, the health, safety and welfare of its citizens.

The State seeks to obtain compensatory, punitive and other damages, restitution, civil penalties, injunctive and other equitable relief against Defendants Janssen Pharmaceutica, Inc., Janssen, LP and Johnson & Johnson, Inc. ("Defendants"), as more fully set forth below and, in support thereof, avers as follows:

I. PARTIES

1. The Plaintiff is the State of Arkansas, with this suit being brought by its Attorney General, Dustin McDaniel, in the State's capacity as sovereign and in its proprietary capacity on behalf of the DHS, DFA and as representative of, and as *parens patriae* on behalf of, Arkansas citizens.

2. Defendant Janssen Pharmaceutica, Inc. ("JPI") is a Pennsylvania corporation. JPI can be served by serving its president, Marvin Woodall at 500 Iolab Dr., Claremont, Pennsylvania 91711. Janssen Pharmaceutica, Inc. is the general partner of Janssen, LP ("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. Johnson & Johnson, Inc. 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, Inc. is the parent company of both JPI and JLP and is responsible as respondent superior for the actions of its subsidiaries (all defendants referred to collectively herein as "Defendants").

3. The acts alleged to have been done by Defendants in Arkansas herein 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.

II. JURISDICTION & VENUE

4. This Court has jurisdiction over this matter pursuant to Ark. Code Ann. § 4-88-104, § 20-77-908, § 16-4-101 and the common law of the State of Arkansas. Venue is proper pursuant to Ark. Code Ann. § 16-106-101, § 16-106-102, § 16-60-103, § 20-77-908, § 4-88-104,

§ 4-88-112, and the common law of the State of Arkansas. The Defendants have transacted business in the State of Arkansas.

5. Defendants did, individually or in conjunction with others, research, develop, manufacture, create, design, test, label, sterilize, package, distribute, supply, market, sell, promote, advertise, warn and otherwise distribute Risperidone (“Risperdal”) in Arkansas and specifically in Pulaski County.

III. INTRODUCTION

6. This is an action to recover funds expended by the State in providing medical treatment to Medicaid, DBHS and DFAEBD participants suffering from Risperdal-related illnesses and to recover funds expended in purchasing Risperdal or the reimbursement of Risperdal prescriptions for uses that were not medically necessary. Many of the details and critical facts related to Defendants’ scheme are exclusively known by Defendants.

7. The State seeks to recover damages to the DFAEBD. The DFAEBD is a State-sponsored program that administers prescription drug benefits for the State’s active and retired employees. The DFA oversees the DFAEBD. The DFAEBD reimburses pharmacies, doctors and hospitals for prescriptions written for and dispensed to participants in the State’s employee health insurance program.

8. The State seeks to recover damages to the DBHS. The DBHS is a State-sponsored program that purchases Risperdal or reimburses participating pharmacies for Risperdal prescriptions for the State’s mental hospitals, clinics and centers, joint State and community sponsored mental health clinics and centers and facilities for the treatment and care of alcohol and drug addicts. The DBHS is a direct purchaser of Risperdal for patients under its care.

9. The State has discovered that Defendants have engaged in a protracted and willful course of corporate misconduct and misrepresentation in violating numerous State laws, and in actionable breach of the duties owed to the State and its citizens. Defendants have concealed their wrongdoing from the State.

10. The State brings this action exclusively under the common law and statutes of the State of Arkansas. No federal claims are being asserted and to the extent that any claim or factual assertion set forth herein may be construed to have stated any claim under federal law, such claim is expressly and undeniably disavowed and disclaimed by the State.

11. The claims asserted herein are brought solely by the State, and result from the damages incurred by the State itself and are wholly independent of any claims that individual users of Risperdal may have against Defendants.

12. Defendants manufacture Risperdal and promote the drug to physicians in Arkansas through their representatives. For years, the State has incurred significant expenses associated with the provision of necessary health care and other assistance necessary under its Medicaid, DBHS and DFAEBD programs to citizens who suffer, or who have suffered, from Risperdal-related injuries, diseases or sickness.

13. The State of Arkansas, as is true of many states, lacks a practical means of ensuring that each prescription for every drug constitutes a medically necessary use of that drug. The State thus relies on persons receiving payment and benefits to turn square corners in their dealings with the Medicaid, DBHS and DFAEBD Programs. Nevertheless, this lack of practical ability represents a loophole in the scheme of the Medicaid, DBHS and DFAEBD Programs.

14. Defendants have recognized and aggressively exploited this loophole in two ways. First Defendants have engaged in a direct, illegal, nationwide program of promotion of

the use of Risperdal for non-medically necessary uses. Defendants have conducted this program of promotion knowing that prescriptions for Risperdal are generally reimbursed by the State Medicaid, DBHS and DFAEBD programs even though such prescriptions may be written for non-medically necessary uses of Risperdal.

15. Second, since the inception of their promotion of Risperdal, Defendants have falsely represented to the State, and to the public in general, that Risperdal is safer and more effective than less expensive, first generation antipsychotics.

16. Finally, Defendants' failure to provide an adequate warning of the risks of using Risperdal has compromised the general health and welfare of Arkansas citizens. The State, in its common law duty to act as *parens patriae*, thus has standing to recover its necessary costs of treatment of Arkansas citizens resulting from Risperdal-related injuries for which Defendants are liable.

RISPERDAL'S CLINICAL PROFILE

17. Risperdal is a prescription antipsychotic drug belonging to the "atypical" antipsychotic class. Defendants obtained approval from the U.S. Food and Drug Administration (hereinafter "FDA") to market Risperdal oral tablets for the management of schizophrenia in adults on December 29, 1993. On June 10, 1996, FDA approved Risperdal oral solution for the treatment of schizophrenia in adults. On April 2, 2003, 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. 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 valproate, for the short-term treatment of acute manic or mixed episodes associated with Bipolar I Disorder.

18. 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.

19. Although there are many traditional antipsychotics, the efficacy of these drugs is similar because they all have similar mechanisms of action. A troubling side effect of antipsychotics is that the blockage of dopaminergic neurotransmission in the basal ganglia causes extrapyramidal syndromes (EPS), such as parkinsonian effects. A long-lasting movement disorder, tardive dyskinesia, also occurs with prolonged treatment.

RISPERDAL’S SAFETY PROFILE

20. During the 1990’s pharmaceutical companies, acting on the “atypical” hypothesis, introduced newer drugs attempting to capture the therapeutic effect of older drugs without the increased EPS. Before 1993, the only atypical antipsychotic in the United States market was clozapine, and due to its toxicity it had very little market share. Today, atypical antipsychotics such as Risperdal account for over 90% of all antipsychotic drugs prescribed for all psychiatric purposes.

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

22. In part, this lawsuit describes how Defendants achieved, through a series of unlawful acts and practices, the largest United States market share for atypical antipsychotics, driven largely by their marketing of Risperdal for non-medically necessary uses.

23. In late 1993, Risperdal became the second atypical antipsychotic to receive FDA approval. During the next several years, Janssen heavily marketed and promoted Risperdal for its approved indication, treatment of adults with schizophrenia, and for multiple non-medically necessary uses 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, Defendants had significant market share for United States antipsychotic drug use, and demonstrated the sales potential of marketing atypical antipsychotic drugs for non-medically necessary uses.

24. Medical literature dating as far back as the 1950s, and Defendants' own pre-clinical studies of Risperdal, demonstrated 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.

25. 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 should have been concerned about Risperdal causing neurological problems, weight gain, diabetes, pancreatitis, hyperglycemia, cardiovascular complications, and metabolic syndrome. And yet Risperdal's original label, and all label changes since, have not adequately warned of these adverse effects.

26. 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.

27. Further, Risperdal's pre-marketing clinical trials did not support an assertion that it is less likely to cause EPS than traditional antipsychotics. Upon information and belief, Defendants' trials were designed to produce similar rates of EPS in patients sorted into placebo groups and those taking Risperdal. In order to produce their desired result, Defendants selected patients for the placebo groups that were already in the course of treatment with high doses of typical antipsychotics.

28. The manifestation of EPS in a patient taking antipsychotic drugs is largely dose-dependent. In other words, the larger the dose, the more likely EPS becomes. Further, patients that develop EPS generally continue to experience EPS for months, even after discontinuing antipsychotic drug treatment. Because of this, patients in Defendants' placebo groups continued to experience EPS at the rate at which they had experienced EPS while on antipsychotic drug treatment before participating in the trials. Meanwhile, patients in the Risperdal group predictably developed EPS at the normal rate in a population taking antipsychotic drugs, a rate which essentially matched the placebo group.

29. Based on the similar levels of EPS in the placebo and Risperdal groups, Defendants claimed, in their marketing, that patients taking Risperdal were as likely to develop EPS as patients taking nothing and thus less likely to develop EPS than patients taking traditional antipsychotics.

30. Nevertheless, because the mechanism of action for Risperdal is fundamentally the same as other antipsychotics, the FDA required warnings for Risperdal that included neuroleptic malignant syndrome (NMS) and tardive dyskinesia (TD).

31. 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 adequately warn citizens of the State of the risk of diabetes associated with Risperdal.

32. In 1999, the FDA found Janssen promoting Risperdal for non-medically necessary treatment of the elderly. In a letter from the FDA to Todd McIntyre, Director of Defendants' 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 FDA, Defendants 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:

- a) Defendants' claims in its promotions that Risperdal was safe and effective for elderly patients, despite little or no data to support such claims;
- b) Defendants' claims that Risperdal has a low incidence of movement disorders;
- c) Defendants' claims that Risperdal has a low incidence of sedation;
- d) Defendants' claims that Risperdal has a low incidence of anticholinergic effects (variety of movement disorder);
- e) Defendants' 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;

- f) Defendants' claims that Risperdal is safer or more effective than other antipsychotics;
- g) Defendants' claims that Risperdal "enhances daily living" or that it offers "quality control of symptoms for daily living";
- h) Defendants' claims that Risperdal can "control health-related quality of life";
- i) Defendants' failure to warn that the use of Risperdal by healthy elderly patients created a greater potential for hepatic and renal dysfunction and cardiovascular sensitivity;
- j) Defendants' marketing Risperdal outside its education by representing that Risperdal is a safe and effective treatment for hostility in the elderly; and
- k) Defendants' 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.

33. FDA further found that Defendants' promotion of Risperdal lacked fair balance

because:

- a) **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**
- b) **It minimized important information related to tardive dyskinesia and extrapyramidal symptoms.**

34. 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 continue this practice.

35. Prior to Risperdal's FDA approval, Defendants had a well-developed strategy to expand the market for Risperdal beyond adult 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’ specious scientific and marketing representations.

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

37. Defendants failed to provide a prominent warning of the increased risk of diabetes and hyperglycemia and the need to provide patients with baseline diabetes screening and glucose monitoring. A warning, though still inadequate, did not appear until it was forced by the FDA in mid-September of 2003.

38. 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, 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, epidemiologic studies suggest an increased risk of treatment 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.

39. Despite 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.

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

41. According to FDA, Defendants' 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.

42. FDA demanded that Defendants 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.

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

44. 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 is Defendants' aggressive marketing, which consists chiefly of overstating the drug's efficacy, while concealing its life-threatening side effects. As a direct result of Defendants' marketing efforts, the State has paid millions of dollars for non-medically necessary uses of Risperdal.

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

46. 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 generic forms of less expensive, first generation antipsychotics.

IV. ALLEGATIONS

47. Defendants did business in the State of Arkansas; made contracts to be performed in whole or in part in Arkansas 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 Arkansas and to the State, and as described herein, committed and continue to commit tortious and other unlawful acts in the State of Arkansas.

48. 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, EPS and other adverse effects.

49. Defendants actively marketed and promoted Risperdal for use 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.

50. 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 necessary uses of Risperdal.

51. Upon information and belief, this scheme was carried out by: employing the illegal direct solicitation of physicians to prescribe Risperdal for non-medically necessary uses; the making of false statements to physicians and pharmacists concerning the efficacy and safety of Risperdal for non-medically necessary uses; and the use of active concealment to avoid the

utilization policies of Medicaid, DBHS and DFAEBD, which are intended to ensure reimbursement or purchase for medically necessary uses only.

52. 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 health care costs are directly caused by Risperdal-induced diabetes, stroke, pancreatitis, seizures and other diseases.

53. Defendants collectively sold or aided and abetted in the sale of Risperdal which was and is defective and unreasonably dangerous.

54. Upon information and belief, at all pertinent times, Defendants knew, or should have known, that Risperdal was and is unreasonably hazardous to human health.

55. 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 through other agreements, understandings and joint undertakings and enterprises, conspired with, cooperated with and assisted in the wrongful suppression, active concealment and 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.

56. **Risperdal is inherently, abnormally, and unreasonably dangerous.** The health risks and costs of Risperdal to the citizens of the State and to the State greatly outweigh any claimed utility of Risperdal. Defendants knew or should have known of the dangers inherent in the use of Risperdal, and that the public and the State would be harmed by Defendants' intended and foreseeable use of Risperdal.

57. As a direct and proximate result of the deceptive marketing practices of Defendants, Risperdal was and is defective and unreasonably dangerous.

58. Risperdal reached the users and consumers thereof in substantially the same condition which it was in when originally manufactured, distributed and sold by Defendants. At the time Risperdal was sold or placed on the market, it was in a defective condition and unreasonably dangerous to users and consumers.

59. The defective condition of Risperdal directly and proximately caused Arkansas residents to suffer various Risperdal-induced diseases, injuries and sicknesses, and directly and proximately caused the State to expend millions of dollars in order to provide necessary health care to these citizens through its Medicaid, DBHS and DFAEBD programs, thereby directly damaging the State.

60. At all pertinent times, it was foreseeable by Defendants that certain of the Arkansas Medicaid, DBHS and DFAEBD participants who used Risperdal would become ill and suffer injury, disease and sickness as a result of using Risperdal as Defendants intended, and it was further foreseeable by Defendants that the State would be required to expend millions of dollars each year in order to provide necessary medical treatment and facilities to those citizens.

61. Defendants individually, and through their representatives, fraudulently misled the public, physicians treating Medicaid, DBHS and DFAEBD participants and the State, with regard to the health risks of Risperdal, all for the purpose of increasing Defendants' profits from the sale of Risperdal.

62. 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, DBHS and DFAEBD participants with regard to the material and clear risks of Risperdal. Defendants did so with the intent that physicians treating

Medicaid, DBHS and DFAEBD participants would continue to prescribe Risperdal. However, 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, DBHS and DFAEBD participants would write Risperdal prescriptions that would be paid for by the State's Medicaid, DBHS and DFAEBD programs.

63. At all pertinent times, Defendants purposefully and intentionally engaged in these activities, and continue to do so, knowing that when the State's Medicaid, DBHS and DFAEBD participants use Risperdal as it was and is intended to be used, that the State's Medicaid, DBHS and DFAEBD participants would be substantially certain to suffer disease, injury and sickness, including diabetes, stroke, pancreatitis, seizures and other illnesses, and that the State would be directly injured thereby, all as described above.

64. Also at all pertinent times, Defendants purposefully and intentionally engaged in these activities, and continue to do so, knowing that the State, in the absence of any such efforts by Defendants, would be obligated to, and would, provide health care and other necessary facilities and services for certain of the State's Medicaid, DBHS and DFAEBD participants harmed by the intended use of Risperdal, and that the State itself would thereby be directly harmed.

65. Upon information and belief, the statements, representations and promotional schemes publicized by 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 Arkansas who prescribed Risperdal had knowledge of the falsity or untruth of Defendants' statements, representations and advertisements when Medicaid, DBHS and DFAEBD claims for Risperdal were submitted; moreover, the State had a right to rely on Defendants to act honestly when dealing with the State. Each of the Defendants' statements, representations and advertisements were material to the State's purchase or reimbursement of Risperdal in that the State does not intentionally cover drugs for non-medically necessary uses.

66. The State has a right to rely upon the representations of Defendants and was directly and proximately injured by such reliance, all as described above.

67. Upon information and belief, a significant percentage of Arkansas Medicaid, DBHS and DFAEBD participants, believed to number in the hundreds, if not thousands, suffered serious diseases and/or potentially life-threatening medical conditions after taking Risperdal. Such risks of use were known, or should have been known, to Defendants who failed to warn Arkansas physicians treating Medicaid, DBHS and DFAEBD participants of those risks.

V. CAUSES OF ACTION

COUNT I

VIOLATION OF THE ARKANSAS MEDICAID FRAUD FALSE CLAIMS ACT

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

69. A significant percentage of patients who use or have used Risperdal are persons whose prescriptions are paid for in whole or in part by Medicaid.

70. As entities providing goods to providers under the Arkansas Medicaid Program, Defendants are persons within the meaning of Ark. Code Ann. § 20-77-901(6).

71. Submission of Risperdal prescriptions to Medicaid for reimbursement constitute claims within the meaning of Ark. Code Ann. § 20-77-901(2).

72. Defendants' purposeful false statements and representations regarding the safety and efficacy of Risperdal for non-medically necessary uses violate the Medicaid Fraud False Claims Act. Defendants' purposeful false statements and representations regarding Risperdal caused the submission of claims for Risperdal to Medicaid for reimbursement. Defendants' conduct constitutes Medicaid fraud within the meaning of Ark. Code Ann. § 20-77-902(1)-(3), (10).

73. Defendants' have purposely offered to pay remuneration, including kickbacks, bribes and rebates, both directly and indirectly, in cash and in kind, to physicians and pharmacists participating in the Medicaid program. These payments were in exchange for the recipients' submission to Medicaid of non-medically necessary claims for Risperdal. Defendants' conduct constitutes Medicaid fraud within the meaning of Ark. Code Ann. § 20-77-902(7)(A)(i)-(ii).

WHEREFORE, pursuant to Ark. Code Ann. § 20-77-903, the State respectfully requests that this Honorable Court enter judgment in its favor and against Defendants and that the State be awarded reimbursement for all expenditures made for non-medically necessary prescriptions of Risperdal, three (3) times the amount Defendants knowingly caused to be submitted for wrongful reimbursement of Risperdal, ten thousand dollars per false claim, the State's reasonable expenses in enforcing the Medicaid Fraud Act and such other relief as justice and equity may require.

COUNT II

VIOLATIONS OF THE ARKANSAS MEDICAID FRAUD FALSE CLAIMS ACT

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

75. A significant percentage of patients who use or have used Risperdal are persons whose prescriptions are paid for in whole or in part by Medicaid.

76. As entities providing goods to providers under the Arkansas Medicaid Program, Defendants are persons within the meaning of Ark. Code Ann. § 20-77-901(6).

77. Submission of Risperdal prescriptions to Medicaid for reimbursement constitute claims within the meaning of Ark. Code Ann. § 20-77-901(2).

78. Since the inception of their marketing of Risperdal, Defendants knowingly misrepresented that Risperdal is more effective in the treatment of the negative symptoms of schizophrenia and less likely to produce certain adverse events involving involuntary movement disorders, which are commonly associated with antipsychotics. Defendants knew these representations were unsubstantiated and false at the time they were made and that Risperdal is no more effective than appropriate doses of first generation antipsychotic drugs and no less likely to produce these adverse events. Defendants touted Risperdal's added efficacy dimension and the reduction of these adverse events as justification for its higher cost. As a result of these representations, and in an effort to spare their patients from experiencing these adverse effects, Arkansas doctors treating Medicaid participants opted for Risperdal instead of less expensive first generation antipsychotics.

79. Defendants' purposeful false statements and representations regarding the safety and efficacy of Risperdal relative to other antipsychotics violate the Medicaid Fraud False

Claims Act. Defendants' purposeful false statements and representations regarding Risperdal caused the submission of claims for Risperdal to Medicaid for reimbursement. Defendants' conduct constitutes Medicaid fraud within the meaning of Ark. Code Ann. § 20-77-902 (1)-(3), (10).

80. Defendants have purposely offered to pay remuneration, including kickbacks, bribes and rebates, both directly and indirectly, in cash and in kind, to physicians and pharmacists participating in the Medicaid program. These payments were in exchange for the recipients' submission to Medicaid of claims for Risperdal instead of claims for less expensive antipsychotics. Defendants' conduct constitutes Medicaid fraud within the meaning of Ark. Code Ann. § 20-77-902 (7)(A)(i)-(ii).

WHEREFORE, pursuant to Ark. Code Ann. § 20-77-903, the State respectfully requests that this Honorable Court enter judgment in its favor and against Defendants and that the State be awarded reimbursement for the amount of the incremental cost of reimbursement for Risperdal instead of available first generation antipsychotics, three (3) times the amount Defendants knowingly caused to be submitted for wrongful reimbursement of Risperdal, ten thousand dollars per false claim, the State's reasonable expenses in enforcing the Medicaid Fraud Act and such other relief as justice and equity may require.

COUNT III

RECOVERY OF THE COST OF TREATMENT FOR INJURIES CAUSED BY RISPERDAL

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

82. The method by which Risperdal was marketed in Arkansas rendered it defective and unreasonably dangerous.

83. The design and/or manufacture of Risperdal rendered it a dangerously defective drug in that its use causes dangerous, and potentially life-threatening, medical conditions when taken as recommended by Defendants and such risks were not generally known by Arkansas physicians, the State and/or Arkansas Medicaid, DBHS and DFAEBD participants.

84. Risperdal was a dangerously defective drug in that Defendants failed to conduct adequate pre-marketing testing, notwithstanding the known side effects associated with Risperdal and anti-psychotic medications generally.

85. Risperdal was dangerously defective because it lacked a sufficient warning of the risks associated with its use and also because:

- (a) the lack of an adequate warning caused Arkansas physicians treating Medicaid, DBHS and DFAEBD participants to prescribe Risperdal in inappropriate circumstances and on inappropriate classes of patients;
- (b) Defendants had a duty to warn Arkansas physicians treating Medicaid, DBHS and DFAEBD participants of the risks and potentially life-threatening side effects associated with Risperdal use and failed to do so; and
- (c) the warning and/or labeling provided by Defendants for Risperdal failed to include the risks and or potentially life-threatening side effects associated with Risperdal use that were known to, or readily ascertainable by, Defendants and such risks were concealed from Arkansas physicians treating Medicaid, DBHS and DFAEBD participants.

86. Risperdal is abnormally and unreasonably dangerous as marketed in that the health risks and costs associated with Risperdal greatly outweigh any claimed utility of Risperdal to the State and its Medicaid, DBHS and DFAEBD participants.

87. Risperdal reached the users and consumers thereof in substantially the same condition that it was when originally manufactured, distributed and sold by Defendants. At the time Risperdal was sold or placed on the market, it was in a defective condition and unreasonably dangerous to Arkansas Medicaid, DBHS and DFAEBD participants.

88. Arkansas Medicaid, DBHS and DFAEBD participants, and their physicians, used Risperdal in the manner in which it was intended to be used, without any substantive alteration or change in the product.

89. As a result of Risperdal's defective nature, certain Arkansans whose care is provided by Medicaid, DBHS and DFAEBD were injured.

90. The State was forced to expend significant sums of money, through its Medicaid, DBHS and DFAEBD programs, to treat Medicaid, DBHS and DFAEBD participants who sustained Risperdal-related injuries.

91. The State is entitled to recover the costs of such treatment as *parens patriae*.

WHEREFORE, the State respectfully requests that this Honorable Court enter judgment in its favor and against Defendants and award the State compensatory damages and any other relief as justice may require.

COUNT IV

VIOLATION OF THE ARKANSAS DECEPTIVE TRADE PRACTICES ACT

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

93. By labeling, distributing, marketing, promoting and selling Risperdal through Arkansas physicians and pharmacies to the State, and Arkansas consumers, Defendants are engaging in trade or commerce directly, or indirectly, affecting the people of the State.

94. Pursuant to the Arkansas Deceptive Trade Practices Act ("DTPA"), Ark. Code Ann. § 4-88-113, the Arkansas Attorney General has the authority to seek restitution and penalties for violations thereof.

95. Defendants have repeatedly and willfully engaged in the following conduct which constitutes a deceptive trade practice and a violation of the DTPA:

- (a) Misrepresenting that Risperdal is safe and effective for indications for which safety and efficacy had not been demonstrated which caused Arkansas physicians treating Medicaid, DBHS and DFAEBD participants to prescribe Risperdal in inappropriate, non-medically necessary circumstances;
- (b) Making 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;
- (c) Misrepresenting and concealing material facts and/or failing to inform and educate Arkansas physicians as to the risks and dangers associated with Risperdal use when such facts were well known to, or readily ascertainable by, Defendants;
- (d) Misrepresenting and concealing material facts which were known to Defendants, and unknown to Arkansas physicians, when Defendants knew that Arkansas physicians rely on such facts when deciding whether to prescribe Risperdal to their patients;
- (e) Misrepresenting that Risperdal is safer and more effective than less expensive first generation antipsychotics;
- (f) Misrepresenting Risperdal as being of a particular standard, quality or grade when it is not; and
- (g) Intentionally creating a likelihood of confusion or misunderstanding in the minds of Arkansas physicians as to whether Risperdal was safe or medically necessary for Medicaid, DBHS and DFAEBD participants.

96. Due to the secrecy of the foregoing conduct, the State has only recently been made aware of its actionable nature.

97. 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 Arkansas citizens, physicians and the State regarding non-medically necessary uses of Risperdal and the health risks and benefits associated with using Risperdal.

98. Moreover, as detailed above, Defendants have violated Arkansas Code Ann. § 4-88-201 *et seq.* in that Defendants have targeted “elder or disabled persons,” as such persons are defined in the statute, through Defendants’ violations of the DTPA described above, and have actually committed such DTPA violations against such elder or disabled persons. Defendants knew or should have known that their conduct was directed to elder or disabled persons, such conduct was in disregard of the rights of the elder or disabled persons, the elder or disabled persons were more vulnerable to the Defendants’ conduct because of age, poor health, infirmity, impaired understanding, restricted mobility, and/or disability than other persons, and the elder or disabled persons actually suffered substantial physical, emotional, or economic damage resulting from the Defendants’ conduct. In addition to any civil penalty otherwise set forth or imposed by the Court, the Court should impose an additional civil penalty of ten thousand dollars (\$10,000) for each violation, or such other amount as the Court finds just and appropriate not to exceed ten thousand dollars (\$10,000).

99. Defendants acted knowingly in committing the violations of the DTPA described herein.

100. Each Risperdal prescription written without an adequate warning, for a non-medically necessary use or where a first generation antipsychotic was available constitutes a separate and distinct violation of the DTPA.

101. As a consequence of Defendants’ illegal and deceptive sales and marketing practices, the State made monetary expenditures on behalf of Arkansas Medicaid, DBHS and DFAEBD participants who were prescribed Risperdal for conditions which were not medically

necessary and/or where a first generation antipsychotic was as safe and effective and less expensive.

102. As a consequence of Defendants' illegal and deceptive sales and marketing practices, Arkansas consumers who were prescribed Risperdal expended money for conditions which were not medically necessary and/or where a first generation antipsychotic was as safe and effective and less expensive.

103. As a further consequence of Defendants' illegal and deceptive sales and marketing practices, many Arkansas Medicaid, DBHS and DFAEBD participants, including children and elderly, were prescribed Risperdal by their physicians and sustained serious and potentially life-threatening side effects.

104. The State was forced to expend significant sums of money for the treatment of those Arkansas Medicaid, DBHS and DFAEBD participants who sustained serious and potentially life-threatening side injuries as a result of using Risperdal.

105. The Attorney General has determined that the imposition of an injunction against Defendants prohibiting the conduct set forth herein is in the public interest.

106. The State seeks the entry of a permanent injunction prohibiting Defendants' unlawful and deceptive conduct and the imposition of all appropriate remedies available under the DTPA.

107. The State seeks restitution for all expenditures incurred by it resulting from non-medically necessary or non-medically accepted uses of Risperdal caused by Defendants' unlawful and deceptive sales and marketing practices and the difference in cost between the State's expenses for Risperdal and what the State would have spent on first generation antipsychotics, absent Defendants' violations of the DTPA.

108. The State seeks compensatory damages for all State expenditures resulting from the treatment of those Arkansas Medicaid, DBHS and DFAEBD participants who sustained injuries, side effects and/or adverse medical events after using Risperdal.

WHEREFORE, the State respectfully requests that this Honorable Court enter judgment in its favor and against Defendants and also seeks;

- (a) a permanent injunction preventing Defendants from deceptively marketing and/or promoting Risperdal as appropriate for non-medically necessary uses;
- (b) restitution of all State expenditures for prescriptions caused by Defendants' deceptive marketing and/or promotion of Risperdal;
- (c) compensatory damages for all expenditures made by the State on behalf of Arkansas Medicaid, DBHS and DFAEBD participants who sustained injuries associated with Risperdal use;
- (d) imposition of \$10,000 civil penalty for each method, act or practice deemed to violate the Act;
- (e) imposition of an additional \$10,000 civil penalty for each DTPA violation committed against an elder or disabled person;
- (f) the State's reasonable expenses in prosecuting the Act; and
- (g) such other relief as justice and equity may require.

COUNT V

NEGLIGENCE

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

110. Defendants owed the State a duty to use reasonable care in the design, manufacture and marketing of its product, Risperdal.

111. Defendants negligently, carelessly, recklessly, willfully and/or intentionally engaged in the following conduct:

- (a) Marketing and/or promoting Risperdal for non-medically necessary uses;

- (b) Failing to adhere to all applicable laws and regulations pertaining to the marketing, promotion and/or labeling of pharmaceutical products, such as Risperdal;
- (c) Marketing and/or promoting Risperdal as appropriate for children;
- (d) Failing to adequately train their sales force so that when Arkansas physicians treating Medicaid, DBHS and DFAEBD participants raised safety concerns regarding Risperdal important safety information was withheld;
- (e) Supplying a product that they knew, or should have known, contained inadequate warnings of side effects and risks that were known to, or based on facts available to Defendants;
- (f) Supplying a product lacking sufficient warnings and/or instructions when they knew, or should have known, the side effects associated with Risperdal were not generally known by Arkansas physicians treating Medicaid, DBHS and DFAEBD participants;
- (g) Representing that Risperdal was safer than less expensive, first generation antipsychotics;
- (h) Continuing to promote, market and/or sell Risperdal after they knew, or should have known, of the serious side effects and risks associated with Risperdal use;
- (i) Allowing Risperdal to be used indiscriminately for uses which are not medically appropriate; and
- (j) Not disclosing data pertaining to such use.

112. Defendants' negligent, careless, reckless, willful and/or intentional conduct was the proximate cause of injuries and damages sustained by the State.

113. At all relevant times, Defendants knew, or should have known, that Risperdal was, and is, hazardous to human health.

114. Risperdal is abnormally and unreasonably dangerous as marketed in that the health risks and costs associated with Risperdal greatly outweigh any claimed utility of Risperdal to Medicaid, DBHS and DFAEBD participants.

115. As a direct result of the unreasonable marketing practices of Defendants, Risperdal was, and is, defective and unreasonably dangerous.

116. Risperdal reached the users and consumers thereof in substantially the same condition as when originally manufactured, distributed and sold by Defendants. At the time Risperdal was sold or placed on the market, it was in a defective condition and unreasonably dangerous to Medicaid, DBHS and DFAEBD participants.

117. Arkansas Medicaid, DBHS and DFAEBD participants used Risperdal in the manner in which it was intended to be used, without any substantive alteration or change in the product.

118. Due to the negligent, careless, reckless, willful and/or intentional conduct of Defendants, as set forth above, the State expended millions of dollars of Medicaid, DBHS and DFAEBD funds in purchasing Risperdal prescriptions and was also forced to expend significant sums of money for the care and treatment of Arkansas Medicaid, DBHS and DFAEBD participants injured by Risperdal, all of which was foreseeable to Defendants.

119. The reprehensible nature of Defendants' conduct entitles the State to an award of punitive damages.

WHEREFORE, the State respectfully requests that this Honorable Court enter judgment in its favor and against Defendants and award the State compensatory and punitive damages and any other relief as justice may require.

COUNT VI

BREACH OF WARRANTY

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

121. Through their sales and marketing practices to Arkansas physicians treating Medicaid, DBHS and DFAEBD participants, Defendants warranted that Risperdal was fit and appropriate for patients suffering from conditions for which it was not proven safe and effective.

122. Through their sales and marketing practices to Arkansas physicians treating Medicaid, DBHS and DFAEBD participants, Defendants warranted that Risperdal had no significant risks or side effects that were not identified on its labeling. Defendants further warranted that Risperdal was safer than less expensive, first generation antipsychotics.

123. Arkansas physicians treating Medicaid, DBHS and DFAEBD participants relied on the warranties made by Defendants regarding the appropriate uses and safety profile for Risperdal.

124. Defendants breached the express and implied warranties they made to the State, through Arkansas physicians treating Medicaid, DBHS and DFAEBD participants, since the product was not appropriate for many of the uses for which it was promoted. Also, Risperdal is far less safe than warranted by Defendants.

125. The State expended millions of dollars in Medicaid, DBHS and DFAEBD expenditures for non-medically necessary uses of Risperdal and in purchasing Risperdal when a less expensive, first generation antipsychotic was available. The State also spent significant sums of money, through its Medicaid, DBHS and DFAEBD programs, for medical treatment for those Arkansas citizens who developed serious side effects and/or adverse reactions after using Risperdal. The State's expenses were caused by Defendants' express and implied warranties.

WHEREFORE, the State respectfully requests that this Honorable Court enter judgment in its favor and against Defendants and award the State compensatory damages and any other relief as justice may require.

COUNT VII

FRAUD & MISREPRESENTATION

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

127. As part of their promotion of Risperdal, Defendants, through their sales representatives and other advertising and promotion, willfully, knowingly and deceptively communicated to Arkansas physicians treating Medicaid, DBHS and DFAEBD participants that Risperdal was safe and effective for non-medically necessary uses and that it was safer and more effective than less expensive first generation antipsychotics, all of which were knowingly false.

128. Defendants had a duty to disclose the conditions for which Risperdal was arguably proven safe and effective, and not to go beyond those uses in their sales and marketing to Arkansas physicians, the intermediary between Defendants and the State.

129. Defendants intended to induce Arkansas physicians treating Medicaid, DBHS and DFAEBD participants to prescribe Risperdal for Arkansas Medicaid, DBHS and DFAEBD participants for whom Risperdal was not medically necessary.

130. Arkansas physicians treating Medicaid, DBHS and DFAEBD participants as well as the State, were justified in relying on Defendants to educate the physicians as to the appropriate uses and risks of Risperdal.

131. The State, through its Medicaid, DBHS and DFAEBD programs, was forced to expend significant amounts of money for non-medically necessary Risperdal prescriptions which were directly caused by the fraudulent and misleading statements of Defendants.

132. Defendants willfully, knowingly and deceptively withheld material facts regarding the risks and side effects associated with Risperdal use from Arkansas physicians treating Medicaid, DBHS and DFAEBD participants.

133. Defendants had a duty to disclose known risks and side effects associated with Risperdal use, particularly, but not solely, when specifically asked about those risks by Arkansas physicians.

134. Defendants intentionally withheld information regarding the safety risks and side effects associated with Risperdal use with the intention of inducing Arkansas physicians to prescribe Risperdal for Arkansas Medicaid, DBHS and DFAEBD participants in greater quantities than they otherwise would have, or was otherwise appropriate.

135. Arkansas physicians treating Medicaid, DBHS and DFAEBD participants, as well as the State, were justified in their reliance on Defendants to educate them as to the risks and dangerous and potentially life-threatening side effects associated with Risperdal use.

136. Defendants knew that the State and Arkansas Medicaid, DBHS and DFAEBD participants would not be in a position to discover and understand the true risks of using Risperdal, and the public relied upon the misleading information that Defendants promulgated to Arkansas physicians to the detriment of the State.

137. Defendants knew that the representations that were relied upon by Arkansas physicians treating Medicaid, DBHS and DFAEBD participants were false or were made recklessly without any knowledge of the truth.

138. Each of Defendants' misleading and deceptive statements, representations and advertisements related to non-medically necessary and other inappropriate uses of Risperdal were material to the State's purchase of Risperdal in that the State would not have been required

to reimburse pharmacies for many non-medically necessary uses of Risperdal if Defendants had marketed Risperdal legally.

139. The State, through its Medicaid, DBHS and DFAEBD programs, was forced to expend significant amounts of money to treat Arkansas citizens who contracted serious and potentially life-threatening medical conditions resulting from Defendants' deceptive withholding of adequate safety information regarding Risperdal use and/or misrepresenting Risperdal's safety profile.

WHEREFORE, the State respectfully requests that this Honorable Court enter judgment in its favor and against Defendants and award the State compensatory and punitive damages and any other relief as justice may require.

COUNT VIII

UNJUST ENRICHMENT

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

141. Defendants knowingly, willfully and intentionally marketed and promoted Risperdal for conditions and illnesses for which it was not medically necessary.

142. Defendants knowingly, willfully and intentionally withheld information from Arkansas physicians treating Medicaid, DBHS and DFAEBD participants regarding the risks associated with Risperdal use.

143. As a result of the deceptive marketing practices of Defendants, Arkansas physicians treating Medicaid, DBHS and DFAEBD participants prescribed Risperdal in far greater numbers than would have been generated absent Defendants' deceptive and illegal

conduct. The inflated levels of Risperdal reimbursement for Medicaid, DBHS and DFAEBD participants resulted in a financial windfall for Defendants.

144. The State paid, reimbursed and/or otherwise conferred a benefit upon Defendants to the extent of the inflated numbers of Risperdal prescriptions that directly resulted from Defendants' fraudulent marketing practices relative to Arkansas Medicaid, DBHS and DFAEBD participants who were not suffering from illnesses for which Risperdal is the medically necessary treatment.

145. Further, Defendants have been unjustly enriched as a result of their false representations that Risperdal is safer and more effective than less expensive, first generation antipsychotics. The State would have purchased far less Risperdal in the absence of Defendants' fraudulent representations.

146. Defendants have been unjustly enriched to the extent of the increased revenue received by Defendants from Risperdal prescriptions that were ultimately reimbursed by the State and resulted from Defendants' deceptive and illegal marketing program and disgorgement of those profits is appropriate.

WHEREFORE, the State respectfully requests that this Honorable Court enter judgment in its favor and against Defendants and that Defendants be required to make restitution to the State for all expenditures made for non-medically necessary prescriptions of Risperdal as well as the incremental cost of reimbursing for Risperdal instead of less expensive first generation antipsychotics and such other relief as justice and equity may require.

REQUEST FOR JURY TRIAL

The State respectfully requests that all issues presented by its above Complaint be tried before a jury, with the exception of those issues that, by law, must be tried before the court.

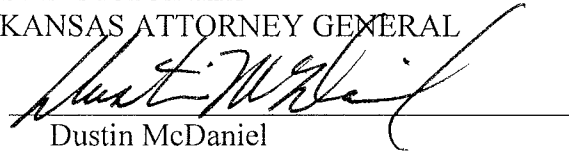
Respectfully submitted,

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By:

A handwritten signature in black ink, appearing to read "Dustin McDaniel", is written over a horizontal line.

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