CAUSE NO. D-1GV-04-001288

THE STATE OF TEXAS, ex rel. ALLEN JONES, Plaintiff, v. JANSSEN, L.P., JANSSEN PHARMACEUTICA, INC., ORTHO-MCNEIL PHARMACEUTICAL, INC., MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS, JANSSEN-ORTHO, LLC, and JOHNSON & JOHNSON, Defendants	IN THE DISTRICT COURT 250th JUDICIAL DISTRICT TRAVIS COUNTY, TEXAS

PLAINTIFFS' THIRD AMENDED PETITION

The State of Texas, by and through the Attorney General of Texas, Greg Abbott, ("the State") and Private Person Plaintiff/Relator Allen Jones ("Relator") bring this law enforcement action pursuant to the Texas Medicaid Fraud Prevention Act, ("the TMFPA"), TEX. HUM. RES. CODE ANN. Chapter 36, and common law. Plaintiffs, the State and Relator, file this Third Amended Petition (the "Petition") and would respectfully show the Court as follows:

I. DISCOVERY CONTROL PLAN

1. Discovery is to be conducted under Level 3 of Rule 190, Texas Rules of Civil Procedure and there is an agreed Scheduling Order in place.

II. THE PARTIES

2. The Plaintiffs are the State of Texas, by and through the Attorney General of Texas, Greg Abbott, ("the State") and Allen Jones, ("Relator") (collectively, "Plaintiffs").

3. Relator is a citizen of the United States and a resident of the State of Pennsylvania. From May 2002 until June 28, 2004, Relator was an employee of the Office of the

Inspector General ("OIG"), Bureau of Investigations of the Commonwealth of Pennsylvania. Relator originally provided information to the State of Texas which is the basis for this suit. Relator filed the Original Petition under seal, pursuant to the authority granted by Texas Human Resources Code § 36.101, alleging Defendants' false statements, misrepresentations and concealment of material information violated the Texas Medicaid Fraud Prevention Act ("TMFPA"), Texas Human Resources Code, §36.001 *et seq.* Plaintiff State elected to intervene and proceed with this action pursuant to §36.102 (c), Texas Human Resources Code. Relator's allegations in the Original Petition were based on his direct, independent, and personal knowledge and also on information and belief. Relator is an original source of the information underlying this Amended Petition and provided such information to the State of Texas in the Disclosure Statement served with Relator's Original Petition. Relator's Disclosure Statement presented substantially all material evidence and information he had in his possession at the time of the filing of the Original Petition pursuant to Texas Human Resources Code §36.102. Furthermore, Relator was an original source of information underlying media reports on Defendants' scheme.

4. Defendant JANSSEN, L.P. ("JANSSEN L.P.") is organized under the laws of New Jersey and has its principal place of business in New Jersey, at 1125 Trenton-Harbourton Rd., Titusville, NJ 08560. Janssen L.P. is a wholly-owned subsidiary of Johnson & Johnson. Janssen L.P. manufactured and marketed the drug risperidone in Texas known by the brand name Risperdal. Janssen L.P. conducts business in Texas.

5. Defendant JANSSEN PHARMACEUTICA, INC. ("JANSSEN PHARMACEUTICA") is incorporated in Pennsylvania and has its principal place of business in New Jersey, at 1125 Trenton Harbourton Rd., Titusville, NJ 08560. Janssen Pharmaceutica

manufactured and marketed the drug risperidone known by the brand name Risperdal. Janssen Pharmaceutica conducts business in Texas.[1]

6. Defendant ORTHO-MCNEIL PHARMACEUTICAL, INC.[2] ("ORTHO-MCNEIL") is incorporated in Delaware and has its principal place of business in New Jersey, at 1000 US Hwy. 202, Raritan, NJ 08869. Ortho-McNeil marketed the drug risperidone known by the brand name Risperdal. Ortho-McNeil is a wholly-owned subsidiary of Johnson & Johnson. Ortho-McNeil conducts business in Texas.

7. Defendant MCNEIL CONSUMER & SPECIALTY PHARMACEUTICAL, n/k/a MCNEIL CONSUMER HEALTHCARE DIVISION OF MCNEIL-PPC, INC. ("MCNEIL CONSUMER & SPECIALTY") is incorporated in New Jersey and has its principal place of business in Pennsylvania at 7050 Camp Hill Rd., Fort Washington, PA 19034. McNeil Consumer & Specialty is a wholly-owned subsidiary of Johnson & Johnson. McNeil Consumer & Specialty conducts business in Texas.

8. Defendant JANSSEN ORTHO LLC ("JANSSEN ORTHO") is incorporated in Delaware and has its principal place of business at One Johnson & Johnson Plaza, New Brunswick, NJ 08933. Janssen Ortho is a wholly owned subsidiary of Johnson & Johnson. Janssen Ortho conducts business in Texas.

9. Defendant ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. is organized under the laws of New Jersey and has its principal place of business in New Jersey,

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1 Janssen, L.P. and Janssen Pharmaceutica are collectively referred to herein as Janssen.

2 Defendants claim that this entity was "incorrectly named" in their Special Exceptions to Plaintiffs' Second Amended Petition; however, Defendants' Response to the State of Texas' Request for Disclosure, served on 2/27/07, lists "Ortho-McNeil Pharmaceutical, Inc." as the correct name for this defendant.

and is the successor entity of Ortho-McNeil Pharmaceutical, Inc, and Janssen Pharmaceutica, Inc. Defendant Ortho-McNeil- Janssen Pharmaceuticals, Inc. conducts business in Texas.

10. Defendant ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. is organized under the laws of Pennsylvania and has a main business address at 1125 Trenton – Harbourton Rd. Titusville, NJ 08560-0200. Ortho- McNeil-Janssen Pharmaceuticals, Inc. is the successor entity of Ortho-McNeil Pharmaceutical, Inc. and Janssen Pharmaceutica, Inc. Defendant Ortho-McNeil- Janssen Pharmaceuticals, Inc. conducts business in Texas.

11. Defendant JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C. is the successor entity of Defendant Janssen Research Foundation, Inc., a division of Janssen Pharmaceutica, Inc. Defendant Johnson & Johnson Pharmaceutical Research & Development, L.L.C. conducts business in Texas. Defendant Johnson & Johnson Pharmaceutical Research & Development, L.L.C. assumed all assets and liabilities of Janssen Research Foundation, Inc. and is liable for the acts committed by Janssen Research Foundation, Inc. during the time period relevant to this litigation.

12. Defendant JOHNSON & JOHNSON, INC. a/k/a JOHSON & JOHNSON ("JOHNSON & JOHNSON") is incorporated in New Jersey and has its principal place of business in New Jersey at One Johnson & Johnson Plaza, New Brunswick, NJ 08933. Johnson & Johnson is the parent company of Janssen, L.P, Janssen, Ortho-McNeil, McNeil Consumer & Specialty, Ortho- McNeil-Janssen Pharmaceuticals, Inc., Johnson & Johnson Pharmaceutical Research & Development, L.L.C. and Janssen Ortho.[3] Johnson & Johnson conducts business in Texas. All Defendants have answered and appeared for all purposes in this case.

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[3] Johnson & Johnson, Janssen, L.P, Janssen, Ortho-McNeil, McNeil Consumer & Specialty, Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Research Foundation, Inc., Johnson & Johnson Pharmaceutical Research & Development, L.L.C. and Janssen Ortho are collectively referred to herein as the "Defendants."

III. JURISDICTION AND VENUE

13. This Court has jurisdiction of this action pursuant to Texas Human Resources Code § 36.101. Venue is proper in Travis County and this judicial district pursuant to the Texas Human Resources Code § 36.052(d). Jurisdiction is further proper because the amounts sought from each Defendant are in excess of the minimum jurisdictional limits of this Court.

IV. DEFENDANTS' COORDINATED CONDUCT

14. Any and all acts alleged herein to have been committed by any of Defendants were committed by said Defendants' officers, directors, employees, representatives or agents who at all times acted on behalf of their respective Defendant(s) and within the scope of their employment.

15. The Defendant companies do not operate as separate entities, but rather integrate their resources to achieve the common business purpose of selling Risperdal. Through co-promotion, cross-training and shared services, Defendants acted in concert to defraud the State of Texas and engage in the unlawful acts that constitute each of the statutory and common law causes of action alleged herein. Defendants are related entities sharing common elements of management, finances, control, supervision, research and reporting and are engaged in a common enterprise. Further, the past, present and continuing relations and dealings by and between these related entities are so inextricably intertwined that for purposes of this suit some or all of them should be considered as a single business enterprise. Defendants have knowingly and jointly committed the unlawful acts that constitute each of the statutory and common law causes of action set forth herein, causing the State of Texas to pay excessive reimbursements under the Texas Medicaid program. In the interest of equity, each Defendant should be held liable for unlawful conduct of the common enterprise. In the alternative, Defendants herein have

conspired to commit and have knowingly committed the unlawful acts that constitute each of the statutory and common law causes of action set forth herein, causing the State of Texas to pay excessive reimbursements under the Texas Medicaid program.

V. BACKGROUND[4]

A. Risperdal

16. Beginning in the early 1990s and through the present day, drug companies developed a new generation of powerful schizophrenia drugs commonly referred to as atypical antipsychotics ("atypicals"). The prescription antipsychotics Risperdal, Zyprexa, Geodon, Abilify and Seroquel are known as atypicals.[5] The previous generation of antipsychotics drugs, such as haloperidol and perphenazine, are known as conventional antipsychotics (the "conventionals").[6] Throughout the period covered by this litigation, the cost of the new atypical antipsychotics exceeded the cost of similarly potent, conventional antipsychotics by as much as four thousand percent (4000%).

17. The use of Risperdal has given rise to serious safety concerns and has been shown to have a number of serious side effects and health risks, which may be especially pronounced in vulnerable populations such as children and the elderly. These side effects include, but are not limited to: extrapyramidal symptoms ("EPS"), including tremors, muscle spasms and rigidity; tardive dyskinesia (a potentially irreversible movement disorder); hyperprolactinemia (elevated prolactin levels), which can lead to the development of lactating breasts, even in males, and

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[4] The allegations in Plaintiffs' Petition ¶¶ 16 through 26 pertain to Defendants' violations of the TMFPA, including §§ 36.002(1)(A) &(B), 36.002(2), 36.002(4) and 36.002(9), set forth in ¶¶ 28 and 29. These allegations also pertain to Defendants' violations of common law set forth below.

[5] The atypicals are also known as second generation antipsychotics, non-conventional antipsychotics, new generation antipsychotics or atypical neuroleptics.

which may require mastectomy; extreme weight gain; hyperglycemia and diabetes mellitus; increased risk of stroke and transient ischemic attacks; excessive sedation; metabolic syndrome; hyperlipidemia (elevations in cholesterol, triglycerides); increased risk of pituitary tumors and death.

B. Risperdal's FDA-Approved Indications

18. The United States Food and Drug Administration ("FDA") has narrowly limited the approved uses of Risperdal to small groups of profoundly impaired individuals:

- On December 29, 1993, the FDA approved Risperdal oral tablets for the management of the manifestations of psychotic disorders in adults.
- On June 10, 1996, the FDA approved Risperdal Oral Solution for the management of the manifestations of psychotic disorders in adults.
- In 2000, the FDA required Defendants to revise the Risperdal label to clarify that its FDA approval was for use in schizophrenic adults only. Thus, in early 2002, the description of the approved use for Risperdal was changed from "management of the manifestations of psychotic disorders" to "treatment of schizophrenia.
- On April 2, 2003, the FDA approved Risperdal M-Tab (a melt-away form of Risperdal) for the treatment of schizophrenia in adults.
- On October 29, 2003, the FDA approved Risperdal Consta (a long-acting injectable form of Risperdal) for the treatment of schizophrenia in adults.
- On December 4, 2003, the FDA approved Risperdal oral tablets, Risperdal Oral solution and Risperdal M-Tab for the short-term treatment of acute manic or mixed episodes associated with Bipolar I disorder in adults.
- From the product launch in 1994 until late 2006, Risperdal had no FDA-approved indication for any use in the child and adolescent population. In October 2006, Risperdal received a very narrow indication for use in a limited population of children and adolescents (age 5-17) for irritability associated with a diagnosis of autism. Additional extremely narrow indications for Risperdal were approved by the FDA in August 2007, for Schizophrenia in

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[6] The conventionals are also known as first generation antipsychotics or traditional neuroleptics.

adolescents (age 13-17) and for manic or mixed episodes of Bipolar I in children and adolescents (age 10-17).

C. Defendants Recognized Challenges To Gaining Widespread Acceptance, Use And Reimbursement Of Their Costly Drug, Risperdal

19. Schizophrenic adults represent less than one percent (1%) of the population. Moreover, schizophrenic adults are more likely to be uninsured, unemployed, impoverished and, therefore, ill-able to afford Risperdal. Consequently, prior to launch, Defendants anticipated that up to 85% of Risperdal sales would be to public sector payors, like Texas Medicaid. Defendants thus faced the challenges of overcoming public payor resistance to the use of their expensive, patented drug over similarly effective generic conventionals, and circumventing state Medicaid safeguards and restrictions, such as prior authorization, meant to protect Texas Medicaid recipients and taxpayers. Understanding the need to obtain significant government buy-in to achieve their financial goals for Risperdal, Defendants set their sights on a state with one of the largest Medicaid populations in the country -- Texas.

D. Texas Medicaid

1. Overview

20. The state and federal governments fund health care for the poor and mentally ill through public health assistance programs. Government assistance programs incur the vast majority of the prescription drug costs associated with the treatment of mental illness in the United States.

21. The Medical Assistance Program in Texas, commonly referred to as Texas Medicaid, is jointly funded by the federal government and the State and was created to provide medical assistance for low-income individuals and families. The Texas Health and Human Services

Commission ("HHSC")[7] administers the Texas Medicaid program and has authority to promulgate rules and other methods of administration governing the program.

22. Texas Medicaid reimburses eligible providers for the approved pharmaceuticals they provide to Medicaid recipients.

2. Texas Medicaid Tools For Managing Appropriate And Cost-Effective Pharmaceutical Therapy

23. The Vendor Drug Program ("VDP") within HHSC was established to oversee the prescription drug portion of the Texas Medicaid program, and was in operation at all times relevant to this case. Providers can obtain reimbursement through VDP only for products approved for use and reimbursement under this program. To have its particular pharmaceutical products listed on the VDP formulary, a drug company or manufacturer must file an application with VDP. This application also requires the manufacturer to report, for each drug submitted, *inter alia,* the recommended daily dosages, formulation of the drug, FDA approval letters, and copies of the package inserts and materials for physicians. The application requires that a manufacturer certify that the information it has provided is correct and that it will provide specified corrected information within 15 days of such changes occurring. Further, in approving the application, HHSC expressly provides that the applicants are responsible for submitting notification of changes pertaining to the 16 points specified in the application no later than the date such revisions are scheduled to occur. Defendants sought and gained the inclusion of Risperdal on the Texas Medicaid formulary by submitting an initial application and subsequent applications for new dosages, package sizes, and formulations to VDP.

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[7] The Vendor Drug Program was transferred from the Texas Department of Health to the Texas Health and Human Services Commission in September 2001.

24. Texas Medicaid is obligated to manage its drug formulary through Drug Use Review ("DUR") in accordance with the Omnibus Budget Reconciliation Act of 1990 ("OBRA 90"). Pursuant to that federal law, Texas Medicaid created the DUR Program to promote optimal and cost-effective pharmaceutical therapy in the Texas Medicaid VDP. Prior authorization, educational letters expressing therapeutic concerns to Texas Medicaid providers, DUR alerts and edits are the tools available to Texas Medicaid to achieve optimal and cost-effective pharmaceutical therapy.

25. In February of 2004, Texas Medicaid implemented the Texas Medicaid Preferred Drug List (the "PDL") pursuant to legislation from the 78th Texas Legislature, Regular Session, 2003. The Preferred Drug List is yet another means through which Texas Medicaid managed their expenditures for pharmaceuticals. The Texas Medicaid Pharmacy and Therapeutics Committee (the "P&T Committee") considers the clinical efficacy, safety, and cost-effectiveness of each drug in making recommendations for the Preferred Drug List. HHSC then decides which drugs are placed on the PDL based on P&T Committee recommendations, the cost of competing drugs to the state, clinical considerations, written information offered by manufacturers about their products, the existence of a supplemental rebate agreement and/or other program benefits. Drugs not selected for the PDL require prior authorization. Defendants sought and achieved the placement of Risperdal on the PDL without prior authorization.

3. The Texas Medicaid Program

26. Texas Medicaid includes not just the Medicaid decision makers such as the VDP, DUR, and P&T committee members discussed above, but also includes Medicaid providers such as pharmacies and physicians who enter into agreements with Texas Medicaid in order to be covered providers. Together, the Texas Medicaid decision makers and providers constitute the

Texas Medicaid program. The Texas Medicaid Fraud Prevention Act seeks to protect against fraud at all levels of the Texas Medicaid program. *See* TEX. HUM. RES. CODE § 36.001 et. seq.

VI. APPLICABLE TEXAS STATUTORY AND COMMON LAW

27. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 26 of this Petition.

28. Prior to August 31, 2005, a person committed an unlawful act as defined under the Texas Medicaid Fraud Prevention Act by, among other things:

A. Knowingly or intentionally making or causing to be made a false statement or misrepresentation of material fact on an application for a contract, benefit, or payment under the Medicaid Program; or that is intended to be used to determine a person's eligibility for a benefit or payment under the Medicaid program. TEX. HUM. RES. CODE § 36.002(1)(A) & (B)

B. Knowingly or intentionally concealing or failing to disclose an event that permits a person to receive a benefit or payment that is not authorized, or that is greater than the benefit or payment that is authorized. TEX. HUM. RES. CODE § 36.002(2).

C. Knowingly or intentionally making, or causing to be made, inducing, or seeking to induce the making of a false statement or misrepresentation of a material fact concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid Program. TEX. HUM. RES. CODE § 36.002(4)(B).

D. Knowingly or intentionally entering into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another person in obtaining an unauthorized payment or benefit from the Medicaid program or a fiscal agent. TEX. HUM. RES. CODE § 36.002(9).

29. Since August 31, 2005, a person commits an unlawful act as defined under the Texas Medicaid Fraud Prevention Act by, among other things:

A. Knowingly making or causing to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized. TEX. HUM. RES. CODE ANN. § 36.002(1)(A) & (B).

B. Knowingly concealing or failing to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized. TEX. HUM. RES. CODE ANN. § 36.002(2).

C. Knowingly making, causing to be made, inducing, or seeking to induce the making of a false statement or misrepresentation of material fact concerning information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program. TEX. HUM. RES. CODE ANN. § 36.002(4)(B).

D. Knowingly enters into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another person in obtaining an unauthorized payment or benefit from the Medicaid program or a fiscal agent. TEX. HUM. RES. CODE ANN. § 36.002(9).

Hereinafter, references to conduct as constituting "statutory fraud" mean that the conduct being described was done by Defendants at times when one or more of the statutory provisions set forth in Paragraph 28 or this Paragraph 29 applied, and was done in ways and through means that satisfy all the required elements of at least one applicable statutory provision.

30. Under Texas common law, a person commits common law fraud by:

A. Making representations of material facts that are false, with knowledge that such representations are false, or by making misrepresentations recklessly, as a positive assertion, and without knowledge of their truth, with the intent that the victim act upon such representations; or by

B. Failing to disclose material facts within that person's knowledge, which he had a duty to disclose, knowing that the victim is not aware of the concealed facts and does not have an equal opportunity to discover the truth, with the intent to induce the victim to take action by failing to disclose those facts.

Hereinafter, references to "common law fraud" mean that the conduct being described was done by Defendants in ways and through means that satisfy all the required elements set forth in Subparagraphs A or B of this Paragraph 30.

31. Under Texas law it is illegal for persons to actively encourage or assist a fiduciary to breach his fiduciary duties, or to conspire among themselves to do so. Persons commit this unlawful act by:

A. Providing substantial assistance to and/or aiding, abetting, assisting, inducing, or encouraging a fiduciary to breach his fiduciary duties owed to the victim, if such wrongdoers knew, or reasonably should have known, that their conduct would cause the fiduciary to breach the fiduciary duties to the victim; or

B. Together or in combination with one or more other persons as joint tortfeasors or otherwise, having a meeting of the minds and conspiring among themselves to induce, actively encourage or assist a fiduciary to breach the fiduciary duties owed to the victim, and committing an unlawful, overt act in furtherance of the object or course of their action.

Hereinafter, references to "aiding or abetting breach of fiduciary duty" mean that the conduct being described was done by Defendants in ways and through means that satisfy all the required elements set forth in Subparagraphs A or B of this Paragraph 31.

32. Under Texas Law, a person commits the tort of negligent misrepresentation if, in the course of his business or transactions in which he had pecuniary interests, he supplies information that is false, for the guidance of others, and he fails to exercise reasonable care or competence in obtaining or communicating the information. Hereinafter, references to "negligent misrepresentation" mean that the conduct being described was done by Defendants in ways and through means that satisfy all the required elements set forth in this Paragraph 32.

33. Under Texas Law, if a victim, unaware of a wrongdoer's unlawful acts, pays money that would otherwise not have been paid, such that the wrongdoer holds money that in equity and good conscience belongs to the victim, the retention of those funds by the wrongdoer would be inequitable and unjust.

VII. DEFENDANTS' UNLAWFUL ACTS

A. Defendants Knowingly Made False And/ Or Misleading Statements Of Material Fact[8]

34. Defendants were aware that Risperdal was no safer and no more effective than any other marketed antipsychotic drug, including the generic conventionals, prior to receiving the first approved indication for the use of Risperdal in 1993. Based on its review of research that had been funded and conducted by Defendants, the FDA delivered the following admonishment to Defendants in a December 29, 1993 letter:

> At the present time, we would consider any advertisement or promotional labeling for Ripserdal false, misleading, or lacking fair balance . . . if there is presentation of data that conveys the impression that risperidone is superior to haloperidol or any other marketed antipsychotic drug product with regard to safety or effectiveness.

35. In violation of this warning from the FDA, Defendants knowingly made presentations of data conveying the impression that Risperdal is superior to haloperidol or other marketed antipsychotic drug products with regard to safety or effectiveness. Such conduct began in or around 1994 with the launch of Risperdal and continued through all time periods relevant to this case. Such conduct constitutes statutory fraud, common law fraud and negligent misrepresentation.

36. In January of 1999, following its review of a number of Defendants' Risperdal promotional materials that had already been disseminated nationwide, including to hundreds of Texas Medicaid providers, the FDA admonished Defendants for making claims about Risperdal

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[8] To be more specific, and without limiting these and other allegations of Defendants' unlawful conduct set forth herein, the allegations in Plaintiffs' Petition ¶¶ 34 through 41 pertain, at minimum, to Defendants' violations of the TMFPA, including, but not limited to, §§ 36.002(1)(A) &(B) and 36.002(4), set forth in ¶¶ 28 and 29.

that were "false, misleading, and/or lacking in fair balance." The FDA's January 5, 1999 letter to Defendants stated, among other things, that:

- "Materials that claim that Risperdal is indicated 'for psychotic symptoms associated with a broad range of disorders,' including schizophrenia, schizophreniform disorder, schizoaffective disorder, bipolar disorder, and elderly psychosis, are false or misleading because the adequate and well-controlled clinical studies for Risperdal were not designed to examine the efficacy of Risperdal in this broad range of disorders."

- "Materials that state or imply Risperdal has a low incidence of movement disorders are false or misleading."

- "Materials that state or imply Risperdal has a low incidence of excessive sedation are false or misleading."

- "Materials that state or imply that Risperdal has a low incidence of anticholinergic affects are false or misleading." and

- "Claims of low incidence of adverse events coupled with presentations of adverse events associated with discontinuation are false or misleading because it implies that the events associated with discontinuation were the extent of the adverse events experienced with Risperdal."

37. In violation of these continual warnings from the FDA, Defendants disseminated and/or caused to be disseminated materials in Texas and/or made or caused to be made claims in Texas about Risperdal that were specifically prohibited by the FDA and that constituted statutory fraud, common law fraud and negligent misrepresentation.

38. In 1994, Defendants launched a wide-ranging marketing effort targeting the Texas Medicaid program and government payors nationwide, with the central message that Risperdal was the only first choice antipsychotic agent due to its efficacy for a broad range of symptoms, and a safety and tolerability profile unmatched by any other antipsychotic. This marketing message was in direct contravention to the FDA's 1993 warning letter and 1999 letter of reprimand. In conducting this marketing effort in Texas, Defendants engaged in statutory fraud, common law fraud and negligent misrepresentation.

39. Defendants expanded on this theme by formulating a number of false and/or misleading marketing messages aimed at the Texas Medicaid program and government payors nationwide, that were intended to: 1) circumvent the FDA's narrow, approved indications for Risperdal and 2) overcome state Medicaid safeguards against over-spending taxpayer dollars for inordinately expensive medications when generic medications were equally as safe and effective. These false and misleading messages include, but are not limited to:

- claims that Risperdal is safer than the conventionals or other atypical antipsychotics;
- claims that Risperdal is more cost-effective than the conventionals or other atypical antipsychotics;
- claims that Risperdal is more effective than the conventionals or other atypical antipsychotics;
- claims that Risperdal has fewer and/or less severe side-effects than the conventionals or other atypical antipsychotics; and
- claims that Risperdal is appropriate and safe to treat a broad range of symptoms in the child and adolescent population, and for other uses that are beyond Risperdal's FDA-approved indications.

40. Subsequent independently-funded studies, including the Clinical Antipsychotic Trials of Intervention Effectiveness study ("CATIE") study and the Cost Utility of The Latest Antipsychotics in Severe Schizophrenia ("CUtLASS") study, confirmed what Defendants and the FDA already knew at Risperdal's launch: that Risperdal was no more effective in treating schizophrenia, and no safer, than conventional antipsychotics. Defendants have responded to such research by propagating misleading interpretations of those research results in an attempt to minimize the impact on their profits. In doing so, Defendants have continued their longstanding pattern and practice of making false and misleading misrepresentations to, among others, Texas

Medicaid decision-makers and providers. This conduct, too, constitutes statutory fraud, common law fraud and negligent misrepresentation.

41. Defendants, therefore, knowingly, intentionally, recklessly and/or negligently made, sought, induced and/or caused others to make the above misrepresentations of material fact or omissions to disclose material information, all of which conduct constitutes statutory fraud, common law fraud and/or negligent misrepresentation.

B. Defendants' Disseminated, Or Caused Others To Disseminate, False And/Or Misleading Statements Of Material Fact To Texas Mental Health And Medicaid Providers And Decision-Makers[9]

42. The conduct of Defendants as described in Paragraphs 43 through 48 below constitutes a continuing pattern and practice of disseminating false and misleading material information and failing to disclose material information about Risperdal in numerous ways and through a variety of means. Taken together and separately, they constitute further instances of Defendants engaging in statutory fraud, common law fraud and negligent misrepresentation.

43. Since the launch of Risperdal, Defendants have, through the use of a wide variety of marketing tools, disseminated the false and misleading messages outlined above. Defendants' marketing strategy, including both on-label and illegal, off-label promotion, specifically targeted government payors, including Texas Medicaid decision-makers and/or Texas Medicaid providers.

44. One strategy Defendants used to disseminate their false and misleading messages was to enlist health care professionals, including Texas health care professionals, to serve as seemingly independent researchers, "thought leaders," "key opinion leaders," "advisors" and/or

[9] To be more specific, and without limiting these and other allegations of Defendants' unlawful conduct set forth herein, the allegations in Plaintiffs' Petition ¶¶ 42 through 48 pertain, at minimum, to Defendants' violations of the TMFPA, including, but not limited to, §§ 36.002(1)(A) &(B), 36.002(4) and 36.002(9), set forth in ¶¶ 28 and 29.

"experts" touting Defendants' false and misleading message of Risperdal's superiority to peers and colleagues. Defendants compromised the objectivity of these individuals by providing them with inducements including consulting fees, extravagant meals and travel accommodations, research funding, enhanced professional reputation and honoraria (cash). Defendants then recruited these individuals to, among other things,

- participate in studies that were initiated, designed, funded and/or otherwise controlled by Defendants and conveyed false and misleading messages about Risperdal's safety, efficacy, cost-effectiveness or appropriate use;
- "author" and publish or present ghost-written, posters and publications that were approved, edited and/or otherwise controlled by Defendants and contained false or misleading information about the safety, efficacy, cost-effectiveness or appropriate use of Risperdal;
- give speeches that were approved and/or otherwise controlled by Defendants and conveyed false and misleading messages about Risperdal's safety, efficacy, cost-effectiveness or appropriate use; and
- participate in continuing medical education programs ("CMEs"), speaker bureaus, advisory boards, home office visits, symposia and round-table discussions that Defendants sponsored, organized, funded and/or otherwise controlled and conveyed false and misleading messages about Risperdal's safety, efficacy, cost-effectiveness or appropriate use.

As set forth more fully below, one or more of the individuals referenced in this Paragraph 44 were persons who owed a fiduciary duty to the State of Texas, and in those instances the conduct of Defendants set forth in this Paragraph 44 also constitutes aiding or abetting breach of fiduciary duty.

45. By employing this strategy, Defendants controlled information about Risperdal that was released to or concealed from the public, including Texas Medicaid providers and decision-makers. Defendants thus "seeded the literature" and increased the "noise level" in the Texas healthcare community, including the Texas Medicaid community, with their false and

misleading tale of Risperdal's superiority to other antipsychotics and suitability for off-label use on vulnerable populations.

46. CMEs, advisory boards, home office visits and other forums provided Defendants with additional means to disseminate misrepresentations about Risperdal's safety, superiority, appropriate use, efficacy and cost effectiveness to their key opinion leaders, advisors and experts, who then took those misrepresentations back to their colleagues in their respective communities, including the Texas Medicaid community.

47. Defendants further, through their sales force, medical science liaisons, public sector marketing and reimbursement representatives or other means, knowingly disseminated both oral and written communications or information containing false or misleading claims about Risperdal, including small-scale clinical trials, case reports, studies, publications, letters to the editor, reprints, sales aids or other marketing messages or paraphernalia, that were of limited to no scientific value, to Texas Medicaid providers and decision-makers.

48. In engaging in the conduct set forth in the preceding Paragraphs 42 through 47, Defendants, therefore, disseminated or caused to be disseminated false and/or misleading claims and or misrepresentations and/or failed to disclose material information about Risperdal to the Texas Medicaid community, and, in so doing, engaged in conduct constituting statutory fraud, common law fraud, negligent misrepresentation, and, as referenced in Paragraph 44, aiding or abetting breach of fiduciary duty.

C. Defendants Specifically Targeted Texas Medicaid Providers And Decision-Makers With False And/Or Misleading Statements Of Material Fact[10]

49. The conduct of Defendants as described in Paragraphs 50 through 61 below constitutes a continuing pattern and practice of disseminating false and misleading material information and failing to disclose material information about Risperdal in numerous ways and through a variety of means. Taken together and separately, they constitute further instances of Defendants engaging in statutory fraud, common law fraud and negligent misrepresentation.

1. Defendants' "Reimbursement" Unit

50. Defendants targeted Texas with their false and misleading claims that Risperdal was a broad-use drug, safe and appropriate for both on and off-label use, that was more cost-effective and efficacious than the other marketed antipsychotics.

51. Soon after the launch of Risperdal, Defendants created a distinct business unit, the Reimbursement or Public Health Systems and Reimbursement Department ("PHS&R"), dedicated to marketing Risperdal to public sector payors. The PHS&R unit focused its efforts on influencing legislation and Medicaid reimbursement policy in the state of Texas.

52. Specifically, Defendants, through their PHS&R and State and Government Affairs ("SGA") representatives, set out to prevent restrictions on reimbursements for Risperdal (such as required prior authorization), and to position Risperdal, in all of its formulations, as a preferred drug on the Texas Medicaid formulary by making, seeking, inducing or otherwise causing to be made misrepresentations about the safety, efficacy, cost-effectiveness and appropriate use of Risperdal to Texas Mental Health and Medicaid decision-makers.

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[10] To be more specific, and without limiting these and other allegations of Defendants' unlawful conduct set forth herein, the allegations in Plaintiffs' Petition ¶¶ 49 through 61 pertain, at minimum, to Defendants' violations of the TMFPA, including, but not limited to, §§ 36.002(1)(A) &(B), 36.002(4) and 36.002(9), set forth in ¶¶ 28 and 29.

2. Defendants' Manipulation And Co-Option Of The Texas Medication Algorithm Project ("TMAP") Achieved State-Sponsored Dissemination Of Defendants' False And/Or Misleading Statements Of Material Fact

53. Defendants identified medication guidelines and algorithms as mechanisms to prevent limitations on usage of Risperdal in public health systems, including Texas Medicaid. In 1995, the State of Texas began developing a set of medication protocols or "algorithms" to standardize the treatment of patients with certain psychiatric disorders within the public mental health system. These efforts resulted in the creation and implementation of the Texas Medication Algorithm Project ("TMAP"). Recognizing that TMAP could be used as a powerful marketing tool for Risperdal to embody their misrepresentations about the safety, efficacy, appropriate use and cost-effectiveness of Risperdal, Defendants exercised improper influence over the development and evolution of the TMAP algorithms by providing millions of dollars in contributions to the project, with a significant portion of that money going directly to key decision-makers involved with the project.

54. In 1997-98, Texas expanded the use of medical algorithms into the child and adolescent arena with the creation of the Texas Children's Medication Algorithm Project ("CMAP").

55. As a result of Defendants' substantial monetary contributions to the TMAP and CMAP projects and/or developers, and the Defendants' undue influence over one or more Texas Mental Health decision-makers involved with those projects, Risperdal achieved a preferred position on both the TMAP and CMAP algorithms when little or no scientific evidence existed to justify such placement.

56. Defendants invested their substantial resources in TMAP to obtain the Texas seal of approval to Defendants' false and/or misleading marketing message that Risperdal was

superior to the older, cheaper conventionals. Defendants' influence over the CMAP developers similarly lent the Texas imprimatur to Defendants' false and/or misleading message that Risperdal was safe and effective for children and adolescents in the absence of FDA approval.

57. As a result of Defendants' manipulation of, and influence over TMAP, CMAP and key Texas Mental Health decision-makers, Defendants achieved their goal of shaping Texas Medicaid policy to favor the wholly unrestricted reimbursement of Risperdal without regard to its extreme expense or medically-approved uses.

58. As set forth more fully below, to the extent one or more of the individuals referenced in Paragraphs 53 through 57were persons who owed a fiduciary duty to the State of Texas, in those instances the conduct of Defendants set forth in those Paragraphs also constitutes aiding or abetting breach of fiduciary duty.

59. The Defendants further improperly influenced one or more Texas Mental Health decision-makers and/or "key opinion leaders" to champion these algorithm projects both state-wide and nationally.

60. Although Defendants were aware of state and federal laws, rules, and regulations governing payments to government employees, they utilized state mental health program decision-makers as a part of their marketing scheme. Not only did Defendants ignore those laws, they also violated their own healthcare compliance requirements which were designed to ensure their companies' conduct was lawful. Defendants failed to disclose and/or concealed their improper conduct by funneling funding to the state employees through third-party vendors, charitable organizations, advocacy groups and governmental entities.

61. In violation of the laws of the State of Texas set out in Paragraph 31, Defendants, therefore, provided substantial assistance to and/or aided, abetted, assisted, induced, and/or

encouraged at least one fiduciary of the State of Texas to breach his or her fiduciary duties owed to the State of Texas, knowing that Defendants' conduct would cause the fiduciary to breach the fiduciary duties to the State of Texas.

D. Defendants Knowingly Concealed Information From Texas Mental Health And Medicaid Providers And Decision-Makers Who Were Unaware Of Defendant's Unlawful Conduct[11]

62. In addition to their other misconduct alleged above, Defendants knowingly failed to disclose to and/or concealed events and/or information including, but not limited to the following:

63. Defendants repeatedly failed to disclose, concealed and/or misleadingly downplayed the risk of Risperdal's serious side effects in all patient populations, including adolescents and children.

64. Defendants failed to disclose and/or concealed the results of research and/or study results that were deemed unfavorable to Risperdal.

65. Defendants failed to disclose and/or concealed the extent of the improper influence they exercised over certain doctors, including Texas Mental Health decision-makers and key opinion leaders, who participated in the widespread dissemination of Defendants' false and misleading messages. Defendants further failed to disclose and/or concealed the extent to which they influenced and/or manipulated the development of the TMAP and CMAP algorithms.

66. Defendants failed to disclose and/or concealed their undue influence and fraudulent scheme by using third party vendors and entities, including the Robert Wood Johnson Foundation, as conduits for funneling their funding and control. In this way, Defendants

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[11] To be more specific, and without limiting these and other allegations of Defendants' unlawful conduct set forth herein, the allegations in Plaintiffs' Petition ¶¶ 62 through 69 pertain, at minimum, to Defendants' violations of the TMFPA, including, but not limited to, § 36.002(2), set forth in ¶¶ 28 and 29.

intentionally left outsiders, including those Texas Mental Health and Medicaid decision-makers who were uninvolved in Defendants' fraudulent marketing scheme, with the impression that the information received through these third parties was from an independent source.

67. Defendants failed to disclose and/or concealed that they routinely deployed and funded advocacy groups to influence legislation and state policy for the benefit of Risperdal.

68. Defendants failed to disclose and/or concealed the truthful, complete and up-to-date information about Risperdal from Texas Medicaid decision-makers with regard to the VDP, the DUR process and the PDL, including that they were aggressively marketing Risperdal for use in the child and adolescent population at a time when there was no FDA approval for such use and there was a paucity of sound scientific evidence to support such use.

69. Defendants, therefore, knowingly or intentionally concealed or failed to disclose events that permitted them to receive benefits that were not authorized or were greater than the benefit or payment that was authorized; Defendants further failed to disclose material facts within their knowledge, which they had a duty to disclose, knowing that the State of Texas was not aware of the concealed facts and did not have an equal opportunity to discover the truth, with the intent to induce the State of Texas to take action by failing to disclose those facts.

VIII. DEFENDANTS' VIOLATIONS OF THE TEXAS MEDICAID FRAUD PREVENTION ACT[12]

70. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 69 of this Petition.

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[12] In August of 2005, applicable provisions of the TMFPA were amended as set forth in ¶¶ __ through __ above. Plaintiffs are seeking the appropriate remedies for Defendants' unlawful acts (which include Defendants' conduct both prior to and after August 2005 for purposes of this lawsuit) as defined in the TMFPA at the time such unlawful acts were committed.

A. Defendants' Violations Of The TMFPA That Resulted In Harm To The State Of Texas, And For Which Plaintiffs Seek Restitution And Civil Penalties

71. Defendants knowingly made or caused to be made false statements or misrepresentations of material facts in applying for Risperdal's inclusion in the Texas Medicaid VDP and PDL, and during the Texas Medicaid DUR process. Furthermore, Defendants' false statements and/or misrepresentations permitted Defendants to receive benefits under the Medicaid program, including, but not limited to, the unfettered reimbursement of Risperdal, in violation of Section 36.002(1)(A) & (B) of the TMFPA. TEX. HUM. RES. CODE ANN. § 36.002(1)(A) & (B).

72. Defendants knowingly concealed or failed to disclose events or information from Texas Medicaid in conjunction with the VDP, PDL, and DUR processes. This conduct permitted Defendants to receive benefits under the Medicaid program, including, but not limited to, the unfettered reimbursement of Risperdal, that were not authorized or that were greater than the benefits authorized in violation of Section 36.002(2) of the TMFPA. TEX. HUM. RES. CODE ANN. § 36.002(2).

73. Defendants knowingly or intentionally made, or caused to be made, induced, or sought to induce the making of a false statements or misrepresentations of a material facts concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid Program in violation of Section 36.002(4) of the TMFPA. TEX. HUM. RES. CODE § 36.002(4)(B).

74. Defendants knowingly entered into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another person in obtaining an unauthorized payment or benefit from the Medicaid program or a fiscal agent in violation of Section 36.002(9) of the TMFPA. TEX. HUM. RES. CODE ANN. § 36.002(9).

75. As a result of Defendants' conduct, Texas Medicaid was prevented from making fully-informed and appropriate policy decisions and from utilizing the tools and safeguards available to appropriately manage the reimbursement of Risperdal prescriptions.

76. Defendants' illegal conduct, therefore, resulted in millions of dollars in excessive reimbursements for Risperdal by the State of Texas. The State is unable, pending full discovery pursuant to the Texas Rules of Civil Procedure, to determine the total extent of the overpayments caused by Defendants' fraudulent conduct.

77. Under the TMFPA, each Defendant is liable to the State of Texas for the value of any payments or any monetary or in-kind benefits provided under the Medicaid program, directly or indirectly, as a result of its unlawful acts, two times the amount of those payments, plus pre-judgment interest on the value of those payments, and a civil penalty for each unlawful act committed, in addition to the fees, expenses, and costs of the Sate of Texas and the Relator in investigating and obtaining civil remedies and injunctive relief in this matter. TEX. HUM. RES. CODE §§ 36.052, 36.007, 36.110(c).

78. Plaintiffs invoke in the broadest sense all relief possible at law or in equity under TEX. HUM. RES. CODE § 36.052, whether specified in this pleading or not.

79. The amounts sought from each Defendant are in excess of the minimum jurisdictional limits of this Court.

80. The TMFPA is a statute of absolute liability. There are no statutory, equitable, or common law defenses for any violation of its provisions. Further, Texas jurisprudence provides that the defenses of estoppel, laches, and limitations are not available against the State of Texas, as a Sovereign. *State v. Durham,* 860 S.W.2d 63, 67 (Tex. 1993).

B. Defendants' Violations Of The TMFPA For Which Plaintiffs Seek Civil Penalties

81. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 80 of this Petition.

82. Under the TMFPA, Defendants are liable to the State of Texas for a civil penalty for each unlawful act committed by Defendants without regard to whether that violation resulted in harm. TEX. HUM. RES. CODE §§ 36.052.

83. The inevitable byproduct of Defendants deluging the Texas Mental Health community with their false and misleading messages about Risperdal's safety, superiority, appropriate use, efficacy and cost effectiveness, was that Defendants' false and misleading messages were disseminated repeatedly to thousands of Texas Medicaid providers. Each time that Defendants knowingly made, caused to be made, induced, or sought to induce the making of such false and misleading statements to a Texas Medicaid provider concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid Program, Defendants committed an unlawful act under the TMFPA. See, e.g., TEX. HUM. RES. CODE §§ 36.002(4).

84. As just one of numerous examples of such unlawful acts, On September 11, 2003, the FDA notified Defendants of the requirement to add a warning concerning the risk of hyperglycemia and diabetes to the Risperdal label. On November 10, 2003, despite having been aware of these risks for years, Defendants sent an inaccurate and misleading "Dear Healthcare Provider Letter" about the label change to thousands of physicians around the county, including Texas Medicaid prescribers and decision-makers. Defendants deliberately constructed the wording of this letter to circumvent the FDA's mandated warning and to mislead healthcare professionals who rely on this type of information when prescribing medication for their patients.

In April of 2004, the FDA sent Defendants a warning letter characterizing Defendants' "Dear Healthcare Provider Letter" message as false and misleading, omitting material information and minimizing the risk of hyperglycemia and diabetes. The FDA also chastised Defendants for failing to recommend glucose monitoring, and for sending the misleading message that Risperdal was safer than other atypical antipsychotics. Despite the FDA's grave warning, it was not until July 31, 2004 that Defendants sent a letter that was acceptable to the FDA. From November 10, 2003 to July 31, 2004, Defendants disseminated the false and misleading message of their November 10, 2003 "Dear Healthcare Provider Letter" during hundreds, if not thousands, of sales calls concerning Risperdal made to Texas Medicaid providers. Similar conduct by Defendants was identified by the FDA in their January 5, 1999 letter described in Paragraph 36 of this Petition.

85. Defendants also knowingly made, caused to be made, induced, or sought to induce the making of false and misleading statements in violation of the TMFPA to Texas Medicaid providers and decision-makers through journal publications, promotional materials, sales aids, advertisements, press releases, advisory boards, home office visits, CMEs, symposia, speeches, sales calls and other media.

86. Defendants, therefore, seek civil penalties under the TMFPA for each of Defendants' unlawful acts under the TMFPA. Plaintiffs will seek an amount as civil penalties that will be justified and appropriate under the facts and the law.

IX. COMMON LAW FRAUD

87. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 86 of this Petition.

88. Defendants made representations of material facts to the State of Texas that were false concerning the safety, efficacy, appropriate use and cost effectiveness of Risperdal. Defendants knew such representations were false or made the representations recklessly, as a positive assertion, and without knowledge of their truth with the intent that the State of Texas act upon such representations. The State of Texas justifiably relied upon such representations which caused injury and damages to the State of Texas.

89. Defendants also engaged in common law fraud by nondisclosure by failing to disclose material facts within their knowledge, which they had a duty to disclose, knowing that the Plaintiff State and Texas Medicaid decision-makers were not aware of the concealed facts and did not have an equal opportunity to discover the truth. Defendants intended to induce Plaintiff State and Texas Medicaid decision-makers to take action by failing to disclose those facts. Plaintiff State has suffered injury as the result of acting without the knowledge of the undisclosed facts.

90. As a result of Defendant's conduct, Plaintiffs suffered harm and are entitled to recovery under common law fraud, including actual damages and prejudgment interest. Plaintiffs invoke in the broadest sense all relief possible at common law, whether specified in this pleading or not.

X. DEFENDANTS ACTIVELY ENCOURAGED OR ASSISTED FIDUCIARY OF THE STATE TO BREACH FIDUCIARY DUTIES AND CONSPIRED AMONG THEMSELVES TO DO SO

91. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 90 of this Petition.

92. One or more Texas state mental health decision-makers owed one or more fiduciary duties to the State of Texas, such as the duty(ies) of good faith, fair dealing, loyalty, and fidelity to the State of Texas and its citizens.

93. Defendants provided substantial assistance to and/or aided, abetted, assisted, induced, or encouraged one or more Texas state mental health decision-makers to breach their fiduciary duties owed to the State of Texas. Defendants knew that one or more Texas state mental health decision-makers owned fiduciary duty(ies) to the State, yet Defendants executed consulting or other contracts that required services and imposed conditions upon those state employees that were at odds with and at times mutually exclusive to the duties owed to the State. Defendants also provided inducements to the Texas state mental health decision maker(s), including honoraria. The contracts, inducements, and other arrangements provided by the Defendants resulted in one or more Texas state mental health decision-makers giving advice and making decisions that advanced the Defendants' financial interests ahead of the State's interests. Further, Defendants knew, or reasonably should have known, that their conduct would cause the Texas state mental health decision maker(s) to breach the fiduciary duties to the State.

94. Furthermore, Defendants, together or in combination with one or more other persons as joint tortfeasors or otherwise, had a meeting of the minds and conspired among themselves to induce, actively encourage or assist one or more Texas state mental health decision-makers to breach fiduciary duties owed to the State, and the Defendants committed an unlawful, overt act in furtherance of the object or course of their action.

95. Plaintiff State of Texas, and the people and taxpayers of the State of Texas, suffered injury as a proximate result of Defendants' wrongful act(s).

XI. NEGLIGENT MISREPRESENTATION

96. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 95 of this Petition.

97. Defendants made misrepresentations to the Plaintiff State of Texas, by and through its Texas state mental health decision-makers and other officers and employees, in the course of the defendant's business or transactions in which Defendants had pecuniary interests.

98. Defendants supplied information that was false for the guidance of others, and failed to exercise reasonable care or competence in obtaining or communicating the information.

99. Plaintiff State, by and through its state mental health decision-makers, officers and employees, justifiably relied on the representations.

100. Defendants' negligent misrepresentations proximately caused Plaintiff State's injuries, including pecuniary loss.

XII. MONIES HAD AND RECEIVED

101. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 100 of this Petition.

102. Plaintiff State, unaware of Defendants' wrongdoing and unlawful acts, paid excessive Medicaid reimbursements that would otherwise not have been allowed.

103. Defendants hold money that in equity and good conscience belongs to the Plaintiff State, and retention of those funds by any of Defendants would be inequitable and unjust in this case.

104. Defendants should be required to disgorge to Plaintiff State the revenue wrongfully and unlawfully obtained from Risperdal sales ultimately reimbursed under the Texas Medicaid program.

105. The State demands that judgment be entered against Defendants in an undetermined amount for unjust enrichment, restitution of monies gained by the Defendants, interest and costs of suit, including attorney's fees and all such other relief at law and equity to which the State of Texas is entitled.

106. By reason of the overpayments described above, the State of Texas is entitled to damages in an amount to be determined at trial exclusive of interest and costs.

XIII. REMEDIES FOR COMMON LAW CAUSES OF ACTION

107. As a result of Defendant's conduct, to wit: common law fraud, negligent misrepresentation, and wrongfully receiving and retaining funds rightfully belonging to the Plaintiff State of Texas, Plaintiffs suffered harm as a proximate result of that conduct, and are entitled to recovery including actual damages, prejudgment interest, post-judgment interest, disgorgement, restitution for the value of all payments that the State has made for Risperdal prescriptions reimbursed under the Texas Medicaid program, and other legal and equitable relief as the court may determine appropriate. Plaintiffs invoke in the broadest sense all relief possible at common law, whether specified in this pleading or not.

XIV. JURY DEMAND

108. Plaintiffs respectfully request a trial by jury on all claims pursuant to Texas Rules of Civil Procedure 216.

XV. PRAYER

109. Plaintiffs ask that judgment be entered upon trial of this case in favor of the State and the Relator against Defendants to the maximum extent allowed by law.

110. The State of Texas asks that it recover from Defendants under the TMFPA:

A. restitution of the value of any payments or any monetary or in-kind benefits provided under the Texas Medicaid program, directly or indirectly, as a result of their unlawful acts;

B. two times the value of any payments or any monetary or in-kind benefits provided under the Medicaid program, directly or indirectly, as a result of their unlawful acts;

C. prejudgment interest;

D. civil penalties in an amount not less than $1,000.00 or more than $10,000.00 for each unlawful act committed by Defendants before May 4, 2007; and in an amount not less than $5,000.00 or more than $10,000.00 for each unlawful act committed by Defendants on or after May 4, 2007;

E. expenses, costs and attorneys' fees; and

F. post-judgment interest at the legal rate.

111. The State of Texas asks that it recover from Defendants under common law:

A. all out of pocket damages, including full restitution of all payments which the State has made for Risperdal prescriptions under the Texas Medicaid program;

B. disgorgement of all revenue improperly received and retained;

C. disgorgement of revenue received by Defendants for Risperdal sales ultimately reimbursed under the Texas Medicaid program as a result of Defendants' conduct in actively encouraging or assisting fiduciaries in the

breach of said fiduciaries' duties to the State, and Defendants' conduct in conspiring among themselves to do so;

D. prejudgment interest;

E. expenses, costs and attorneys' fees; and

F. post-judgment interest at the legal rate.

112. The Relator asks that he be awarded;

A. his expenses, costs and attorneys' fees; and

B. Relator's share as provided by the TMFPA.

113. The State asks the Court to grant an injunction, ordering Defendants to do the following:

A. make publicly available through the Internet an annual listing of all payments made directly or indirectly by any of Defendants to or for the benefit of individuals located or primarily employed in Texas who are physicians, researchers, public health officials, public officials, or employees of any public university or public health agency including the individual's name, the amount of the payment, the date of the payment and a description of the service rendered;

B. provide a list on an annual basis, to the State of Texas, Office of the Attorney General, Civil Medicaid Fraud Division, of all individuals employed by any entity or agency of the State of Texas upon whom Defendants called on, regardless of whether the call or contact was by e-mail, in person, by other written instrument, or by telephone or facsimile;

C. provide to the to the State of Texas, Office of the Attorney General, Civil Medicaid Fraud Division, the right to access and review without limitation and with three

business days' notice, Defendants' business records pertaining to the calls set out in Section 23.5.B.;

D. review their sales, marketing, and medical affairs activities on an annual basis and provide to the to the State of Texas, Office of the Attorney General, Civil Medicaid Fraud Division, a certification stating whether Defendants' conduct and business practices comply with applicable state and federal law relating to pharmaceutical marketing and Medicaid Fraud; and

E. requiring Defendants to pay an amount, to be determined by the Court, for each violation of the Judgment or other Order entered by this Court in this matter.

114. Plaintiffs pray for such other and further relief to which they may show themselves entitled, either at law or in equity.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **Plaintiffs' Third Amended Petition** was sent by facsimile and electronic mail to all counsel of record on May 15, 2009.

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