CAUSE NO. D-1-GV-04-001288

STATE OF TEXAS ex rel. ALLEN JONES, Plaintiffs, 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' MOTION FOR LEAVE TO FILE FOURTH AMENDED PETITION

TO THE HONORABLE JOHN K. DEITZ:

Plaintiffs, State of Texas and Relator, Allen Jones, by counsel, respectfully request the Court to allow them to file their proposed Fourth Amended Petition, attached hereto as Exhibit A.

Plaintiffs seek to amend their petition in order to narrow significantly the number of causes of action to be tried, as well as to update and clarify their allegations. Aside from this narrowing and clarification, the proposed amendments will not affect the substance of Plaintiffs' claims. Furthermore, this amendment will not result in surprise or prejudice to the Defendants.

Respectfully Submitted,

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**ATTORNEYS FOR RELATOR,
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CERTIFICATE OF CONFERENCE

I certify that counsel for the State of Texas conferred with counsel for Defendants via phone and electronic mail in an attempt to file this as an agreed motion for leave to amend, but the parties failed to reach such an agreement.

Patrick Sweeten

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing *Plaintiffs' Motion for Leave to File Fourth Amended Petition* was sent by via electronic mail to all counsel of record on April 8, 2011.

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EXHIBIT A

CAUSE NO. D-1GV-04-001288

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

PLAINTIFFS' FOURTH 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 Fourth 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] Janssen Research Foundation was a division of Janssen Pharmaceutica at times pertinent to this litigation. Janssen Pharmaceutica Inc. is liable for the acts committed by its division, Janssen Research Foundation during the time period relevant to this litigation.

6. Defendant ORTHO-MCNEIL PHARMACEUTICAL, LLC ("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

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

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., f/k/a Janssen Pharmaceutical 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, LLC, Janssen, L.P., and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. assumed all assets and liabilities of Johnson & Johnson Pharmaceutical Research & Development, L.L.C. and is liable for the acts committed by Johnson & Johnson Pharmaceutical Research & Development, L.L.C. during the time period relevant to this litigation. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. conducts business in Texas.

10. 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.[2] Johnson & Johnson conducts business in Texas. All Defendants have answered and appeared for all purposes in this case.

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[2] Johnson & Johnson, Janssen, L.P., Janssen Pharmaceutica, Ortho-McNeil, McNeil Consumer & Specialty, Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Ortho are collectively referred to herein as the "Defendants."

III. JURISDICTION AND VENUE

11. 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

12. 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.

13. 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

A. Risperdal

14. 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.[3] The previous generation of antipsychotics drugs, such as haloperidol and perphenazine, are known as typical or conventional antipsychotics (the "conventionals").[4] Throughout the period covered by this litigation, the new atypical antipsychotics were vastly more expensive than similarly safe and effective conventional antipsychotics.

15. 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 which may require mastectomy; medically serious weight gain; hyperglycemia and diabetes mellitus; increased risk of stroke and transient ischemic attacks; excessive sedation; metabolic

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

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

syndrome; hyperlipidemia (elevations in cholesterol, triglycerides); increased risk of pituitary tumors and death.

B. Risperdal's FDA-Approved Indications

16. 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 advised Defendants that they would be required to revise the Risperdal label to clarify that its FDA approval was for use in schizophrenic adults only. Thus, in early March 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 time Risperdal received its first FDA-approved indication in December 1993 until October 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 adolescents (age 13-17) and for manic or mixed episodes of Bipolar I in children and adolescents (age 10-17).
- Risperdal has never received an FDA indication for use specifically in the elderly population or for diseases commonly associated with the elderly population, such as dementia and psychosis in Alzheimer's disease. Risperdal

received a black box warning in August 2005 for increased mortality in elderly patients with dementia-related psychosis.

C. Defendants Recognized Challenges to Gaining Widespread Acceptance, Use and Reimbursement of Their Costly Drug, Risperdal

17. Schizophrenic adults represent less than one percent (1%) of the population. Moreover, schizophrenic adults are more likely to be uninsured, unemployed, impoverished and, therefore, unable to afford Risperdal. Consequently, prior to launch, Defendants anticipated that up to 85% of Risperdal revenue would be derived from 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 safe and 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

18. 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. The Medical Assistance Program in Texas, commonly referred to as Texas Medicaid, was created to provide medical assistance for low-income individuals and families in Texas.

19. The Texas Medicaid Program, which includes Texas decision makers as well as Texas Medicaid providers, is a system that provides medical products and services to persons

qualified as recipients. Texas Medicaid reimburses eligible providers for the approved pharmaceuticals they provide to Medicaid recipients. The program is funded jointly by the State of Texas and the federal government. The Texas Health and Human Services Commission ("HHSC")[5] administers the Texas Medicaid program and has authority to promulgate rules and other methods of administration governing the program.

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

20. The Vendor Drug Program ("VDP") within HHSC was established to oversee the outpatient prescription drug portion of the Texas Medicaid program, and was in operation at all times relevant to this case.

21. Providers can obtain reimbursement through VDP only for products approved for use and reimbursement under this program. Texas Medicaid, like all state Medicaid programs, is authorized to reimburse for "covered outpatient drugs" and is not authorized to reimburse for drugs that are used for an indication which is not "medically accepted." An indication or use is not "medically accepted" unless it is approved by the FDA or supported by one of three compendia enumerated under the Federal Medicaid Act. *See* 42 U.S.C. § 1396r-8(k)(3), (6); 42 U.S.C. § 1396r-8(g)(1)(B)(i).

22. To have its particular pharmaceutical products listed on the VDP formulary, a drug company or manufacturer must file an application with VDP. Included in the application is a detailed 16-point questionnaire that, pursuant to HHSC regulations, must be completed and filed. Texas Medicaid expects that the information provided to it by pharmaceutical manufacturers as part of the VDP application process will be complete, truthful, and up-to-date.

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

23. VDP applications require drug manufacturers 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 VDP applications also require manufacturers to certify that all the information provided with their application is correct and that their drug is in not violation of either state or federal law. The applications further require manufacturers, on a going forward basis, to submit notification of any changes pertaining to their product's status within fifteen (15) days of such changes occurring.

24. In approving VDP applications, HHSC expressly provides that manufacturers 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. Accordingly, manufacturers owe a continuing duty to Texas Medicaid to supplement information provided with their VDP application after its initial submission to the VDP, including materials provided to physicians. Moreover, a new VDP application must be submitted each time a drug first becomes available in a new formulation, such as in an oral, "melt-in-your mouth" or injectable form, or in different dosages.

25. Pharmaceutical manufacturers' interaction with Texas Medicaid, and Texas Medicaid's review of drugs placed on its formulary, do not stop with submission of the initial VDP application. Texas Medicaid has an on-going obligation 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 obligation, Texas Medicaid created the DUR Program in 1990 to promote optimal and cost-effective pharmaceutical therapy in the Texas Medicaid VDP.

26. Specifically, the drug utilization review program exists to ensure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical results.

Moreover, the program is designed to educate pharmacists and physicians to identify and reduce the frequency of patterns of fraud, abuse, gross overuse or inappropriate or medically unnecessary care among providers and patients, or associated with specific drugs or groups of drugs. The DUR Board has a number of tools available to it to achieve these goals, including prior authorization, educational letters expressing therapeutic concerns to Texas Medicaid providers, DUR alerts and clinical edits. If necessary, the DUR process initiates recommendations that certain drugs be made subject to prior authorization or to restrictions concerning the types of patients (*e.g.*, children, elderly persons, etc.) or the types of conditions for which Medicaid reimbursement is obtainable.

27. As part of this program, the DUR Board monitors and analyzes provider-level activity. Additionally, drug manufacturers, including Defendants, provide the DUR Program with information concerning their drugs. The DUR program expects all such provided information to be complete and accurate.

28. In February 2004, Texas Medicaid implemented yet another means through which Texas Medicaid could manage its expenditures for pharmaceuticals— the Texas Medicaid Preferred Drug List (the "PDL"). In making recommendations for the preferred drug list, the Texas Medicaid Pharmacy and Therapeutics Committee (the "P&T Committee") considers the clinical efficacy, safety, and cost-effectiveness of each drug reviewed. As part of this PDL process, the P&T Committee receives information from drug manufacturers, including Defendants, concerning their drugs, which the P&T Committee expects to be complete and accurate. 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 and the existence of a supplemental

rebate agreement and/or other program benefits. Drugs that are reviewed but not selected for the PDL require prior authorization. Defendants sought and achieved the placement of Risperdal on the PDL without prior authorization, including by making presentations to the P&T committee and submitting written information to the State and/or State contractors concerning Risperdal.

3. The Texas Medicaid Program

29. As discussed above, Texas Medicaid includes not just the Medicaid decision makers such as the VDP, DUR, and P&T committee members, but also 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

30. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 29 of this Petition.

31. 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 the person knows affects the initial or continued right of the person to a benefit or payment under the Medicaid program and to permit 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).

32. 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 31 or this Paragraph 32 applied, and was done in ways and through means that satisfy all the required elements of at least one applicable statutory provision.

33. Under Texas law it is illegal for persons to actively encourage, induce 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 33.

VII. DEFENDANTS' UNLAWFUL ACTS

A. Defendants Knowingly Made or Caused to Be Made False and/or Misleading Statements of Material Fact to Texas Decision Makers and Providers

1. Defendants' Knowledge of the Truth about Risperdal

34. Defendants knew that Risperdal was no safer and no more effective than other marketed antipsychotic drugs, including the generic conventionals, prior to receiving the first approved indication for the use of Risperdal in 1993. For example, a 1990 study conducted by Defendants comparing Risperdal to perphenazine, a medium-potency conventional antipsychotic, showed Defendants that Risperdal was not only no more effective or safer than perphenazine, but, in fact, was worse than perphenazine in causing side effects such as weight gain.

35. Further, 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 Risperdal 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.

36. As discussed further below, however, from the time they launched Risperdal, Defendants completely disregarded this FDA mandate, despite the knowledge that doing so would be false and misleading.

37. In February of 1994, the FDA made further admonishments to Defendants based on its review of Defendants' proposed introductory campaign for Risperdal tablets. The FDA asked Defendants to delete and/or revise certain statements from the promotional materials it had submitted, explaining:

- "All comparisons to haloperidol are unacceptable."
- The claim "Low incidence of EPS (at doses $\leq$10 mg/day)" is misleading. The word 'low' is not consistent with a 17% incidence."
- The phrase "Well tolerated in clinical trials worldwide" is misleading because the "phrase 'well-tolerated' is not consistent with the treatment-emergent adverse experience incidence."
- "Excellent safety profile" and "an outstanding safety profile that offers excellent potential for compliance" are misleading because the "adverse event rates of Risperidone are not consistent with claims for an outstanding or excellent safety profile." and
- "A page discussing the Warnings and Precautions section of the approved product labeling should be added to all promotional material. There are many serious warnings, such as . . . tardive dyskinesia . . . which should be disclosed."

Thus, the bounds of what kinds of claims about Risperdal were permissible were made clear to Defendants at the time of Risperdal's launch.

38. In January of 1999, following its review of a number of Defendants' Risperdal promotional materials, the FDA again admonished Defendants for making claims about Risperdal 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." 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."

39. 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.

2. Defendants Specifically Targeted Texas Medicaid Decision Makers and Providers with False and/or Misleading Statements of Material Fact

40. As described above, the Texas Medicaid Program attempted to control and manage the utilization of and reimbursements for drugs through a number of means, including the VDP, DUR and PDL processes, to: (1) ensure the safe and effective usage of prescription medications

in appropriate patient populations and (2) to maximize state resources for patients receiving government medical assistance. Because the Texas Medicaid Program is necessarily concerned with efficiently managing its budget, it has historically preferred the prescription of generic drugs whenever possible. Defendants knew this. Defendants also knew that Risperdal was expensive, especially when compared to generic older antipsychotics.

41. To overcome the barriers to Risperdal's profit potential presented by both the Texas Medicaid Program's management tools and Risperdal's high price, Defendants targeted every level of the Texas Medicaid Program with misrepresentations about the safety, superiority, efficacy, appropriate uses and cost effectiveness of Risperdal, including by conveying the impression that Risperdal is superior to haloperidol or other marketed antipsychotic drug products with regard to safety or effectiveness. This marketing message was in direct contravention to the FDA's 1993, 1994, and 1999 letters discussed above. Additionally, the Defendants prevented the Texas Medicaid Program from receiving truthful information about the safety, efficacy, appropriate uses and cost effectiveness of Risperdal.

42. Defendants created a distinct business unit, the Reimbursement or Public Health Systems and Reimbursement Department ("PHS&R"), specifically 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. Defendants, through Janssen's PHS&R and Johnson & Johnson's State and Government Affairs ("SGA") representatives, specifically 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.

43. Defendants' false and misleading messages aimed at the Texas Medicaid program and government payors nationwide include, but are not limited to:

- claims that Risperdal is safer than the conventionals or competitor atypical antipsychotics;
- claims that Risperdal is more effective than the conventionals or competitor atypical antipsychotics;
- claims that Risperdal has fewer and/or less severe side-effects than the conventionals or competitor atypical antipsychotics (including claims that Risperdal has "low EPS"; no risk or a low risk of Tardive Dyskinesia ("TD"); no risk or a low risk of movement disorders; no risk or a low risk of diabetes, weight gain or other related metabolic issues; or a low risk of EPS, TD, movement disorders, diabetes, weight gain or other related metabolic issues as compared to other antipsychotic drugs);
- claims that Risperdal reduces non-drug health care costs or total health care costs as compared to conventional antipsychotic drugs;
- claims that Risperdal is appropriate and safe to treat a broad range of symptoms in populations and disease states for which it had no FDA approved indication, including, among other things, in the child and adolescent population, and that there was substantial scientific evidence to support those claims at the time they were made.

44. Defendants made these misrepresentations directly to Texas Medicaid decision-makers and providers. Defendants also caused these misrepresentations to be made by others to Texas Medicaid decision-makers and providers. Many of the individuals who Defendants caused to make misrepresentations to Texas Medicaid were co-opted or otherwise influenced by Defendants, as discussed further below.

45. Such conduct began in or around 1993 with Risperdal's launch and continued through all relevant time periods to this case. Such conduct constitutes statutory fraud.

46. 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 before 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. Defendants, therefore, knowingly and/or intentionally made, sought, induced and/or caused others to make the above misrepresentations of material fact or omissions to disclose information, all of which conduct constitutes statutory fraud.

3. 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

47. An integral tool in the Defendants' fraudulent scheme was the use of mental health medication guidelines and algorithms, which Defendants knew would provide mechanisms to prevent limitations on usage of Risperdal in public health systems, including the Texas Medicaid Program. Defendants funded and influenced the creation of the Tri-University Guidelines as a treatment model that favorably positioned Risperdal and that could be adopted in Texas. Under Defendants' influence, the State of Texas adopted the Tri-University Guidelines "whole-cloth" in the form of the the schizophrenia module of the Texas Medication Algorithm Project ("TMAP"), placing Risperdal in a first-line position, and then at the urging of Texas officials over whom Defendants exercised undue influence, further modified said module to place Risperdal in an

even more favored position that falsely represented that Risperdal was superior to all conventional antipsychotics. 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.

48. 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").

49. 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 that misrepresented Risperdal's superiority over conventional antipsychotics, contrary to what Defendants knew to be true based on their own studies.

50. The Defendants further improperly influenced one or more key mental health decision-makers to champion these algorithm projects both state-wide and nationally, without disclosing Defendants' influence over the algorithm projects or Defendants' influence over the key opinion leaders themselves.

51. Defendants invested their substantial resources in TMAP to obtain the Texas seal of approval to Defendants' false and 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 significant scientific evidence showed that Risperdal was safe and effective for children and adolescents, despite the fact that Risperdal's label expressly stated that safety and efficacy had not been established for use in this population.

52. As a result of Defendants' manipulation of, and influence over TMAP, CMAP and key Texas Mental Health decision-makers, TMAP became a key vehicle for Defendants' misrepresentations. The Texas mental health community, including Texas Medicaid, looked to TMAP as the standard of care and a vehicle for accountability in Texas, thereby leading to an over-inflated perception of the value of Risperdal and a lack of reimbursement restrictions. As a result of this manipulation, 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.

53. As set forth more fully below, to the extent one or more of the individuals referenced in Paragraphs 47 through 52 were 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 knowingly encouraging, substantially assisting, aiding or abetting breach of fiduciary duty.

54. Although Defendants were aware of state and federal laws, rules, and regulations governing payments to government employees, Defendants 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.

55. In violation of the laws of the State of Texas set out in Paragraph 33, Defendants, therefore, knowingly 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.

56. By engaging in the conduct set forth in the preceding Paragraphs 47 through 55, Defendants, further, disseminated or caused to be disseminated false and/or misleading claims and or misrepresentations and/or failed to disclose information about Risperdal to the Texas Medicaid community, and, in so doing, engaged in conduct constituting statutory fraud and, as referenced in Paragraph 55, knowingly encouraging, substantially assisting, aiding or abetting breach of fiduciary duty.

4. Defendants Caused Others to Disseminate, False and/or Misleading Statements of Material Fact to Texas Mental Health and Medicaid Providers and Decision-Makers

57. Defendants employed other tactics and strategies to disseminate their false and misleading messages about Risperdal to Texas Medicaid decision makers and providers. Defendants' strategies included manipulation of and control over speeches and publications of "thought leaders," "key opinion leaders," "advisors" "consultants" and/or "experts" touting Defendants' false and misleading message of Risperdal's superiority to peers and colleagues, as well as undue influence over and control of advocacy groups' position statements and initiatives. Defendants compromised the objectivity of these individuals and organizations 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 above, one or more of the individuals referenced in this Paragraph 57 were persons who owed a fiduciary duty to the State of Texas, and in those instances the conduct of Defendants also constitutes aiding or abetting breach of fiduciary duty.

58. 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, both directly to Texas Medicaid decision-makers and providers and indirectly through Defendants' key opinion leaders, advisors and experts, who then took those misrepresentations back to their colleagues in their respective communities, including the Texas Medicaid community. Further, these forums provided Defendants with an opportunity to provide the previously described inducements to "key opinion leaders," "advisors," "experts," and attendees.

59. Defendants manipulated and/or concealed the results of key Risperdal studies, including without limitation studies known internally by Janssen as RIS-INT-35 and RIS-USA-79.

60. Defendants also, 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.

61. By employing the above strategies, 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. By disseminating false and misleading information favorable to Risperdal, and by concealing truthful information unfavorable to Risperdal, Defendants' misrepresentations and omissions contaminated the entire field of medical knowledge, thereby preventing the Texas Medicaid Program from making fully informed decision regarding the safe and appropriate use of Risperdal.

62. By engaging in the conduct set forth in the preceding Paragraphs 57 through 61, Defendants, further, disseminated or caused to be disseminated false and/or misleading claims and or misrepresentations and/or failed to disclose information about Risperdal to the Texas Medicaid community, and, in so doing, engaged in conduct constituting statutory fraud and, as referenced in Paragraph 57, aiding or abetting breach of fiduciary duty.

63. The conduct of Defendants as described in Paragraphs 57 through 61 above also constitutes a continuing pattern and practice of disseminating false and misleading material

information and failing to disclose 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.

5. Defendants Submitted False VDP Applications for Risperdal to Texas Medicaid to Obtain the Benefit of Inclusion on the VDP Formulary

64. Defendants sought and gained the benefit of Risperdal's inclusion on the VDP formulary by filling out and submitting an initial application and seven subsequent applications for new dosages, package sizes, and formulations to VDP from 1994 to 2007. In each application, Defendants certified that all the information provided was correct and that Risperdal was "not now in violation of Federal or State Law." The applications further required Defendants to submit notification of any changes pertaining to the product status within fifteen (15) days of such changes occurring. Accordingly, Defendants owed, and continue to owe, a continuing duty to Texas Medicaid to supplement information provided about Risperdal after initial submission to the VDP.

65. If a company makes false or misleading statements regarding a drug or promotes a drug "off-label," *i.e.*, for a use not included within the labeling approved by the FDA, then the drug is "misbranded" and/or an "unapproved new drug" in violation of both federal and Texas law. Therefore, Defendants' misrepresentations concerning the safety, efficacy, appropriate use and cost of Risperdal outlined in detail above, as well as their misrepresentations concerning TMAP, caused Risperdal to be "misbranded" and/or an "unapproved new drug" in violation of both federal and Texas law. As a result, each of Defendants' certifications on their VDP applications that Risperdal was not in violation of federal or state law was false at the time of submission, or was rendered false by Defendants' subsequent conduct described above.

66. Defendants, therefore, knowingly and/or intentionally sought, induced and/or caused others to make the above misrepresentations of material fact or omissions to disclose information, all of which conduct constitutes statutory fraud.

B. Defendants Knowingly Concealed Information From Texas Mental Health and Medicaid Providers and Decision-Makers Who Were Unaware of Defendant's Unlawful Conduct

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

68. 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. As just one example, 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, including in the child and adolescent population, Defendants sent an inaccurate and misleading "Dear Healthcare Provider Letter" refuting the substance of the required label change to thousands of physicians around the country, including Texas Medicaid providers and decision makers. 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 the Defendants for failing to recommend glucose monitoring, and for sending the misleading message that Risperdal was safer than other atypical antipsychotics. Despite this grave warning, it was not until July of 2004 that Defendants sent a "Dear Healthcare Provider Letter" that was acceptable to the FDA. This is just one example of Defendant's systematic attempts to conceal or

misrepresent the seriousness and severity of Risperdal's side effects. The making of such false or misleading statements or deceptive omissions in promotional materials like the Dear Healthcare Provider letter of November 10, 2003, was a violation of federal and state law and rendered Risperdal misbranded, in further contradiction to the certification made by Defendants in connection with their various VDP applications relating to Risperdal.

69. Further, Defendants failed to supplement their VDP applications to notify Texas Medicaid of this change in product status concerning hyperglycemia and diabetes. Similarly. Defendants failed to disclose either the substance or existence of the January 1999 FDA Notice of Violation or the April 2004 FDA warning letter to the Texas Medicaid Program.

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

71. 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 became proponents of Risperdal in a wide variety of patient populations throughout Texas and who participated in the widespread dissemination of Defendants' false and misleading messages.

72. Defendants further failed to disclose and/or concealed the extent to which they exercised control over the creations, development, funding, adoption, revision, promotion and implementation of medication guidelines and algorithms, including the TMAP and CMAP algorithms, which the Defendants used as tools for marketing Risperdal and spreading their misrepresentations to the Texas Medicaid Program. Defendants further failed to disclose the extent to which they paid honoraria and otherwise exercised undue influence over the TMAP and CMAP decision makers.

73. Defendants failed to disclose and/or concealed their influence over and payments to government employees by funneling funding through and controlling or manipulating the activities of third-party vendors, advocacy groups, governmental entities and charitable organizations, including the Robert Wood Johnson Foundation. In this way, Defendants 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.

74. 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.

75. 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 populations and for diagnoses and symptoms beyond Risperdal's FDA-approved indications, including for use in the child and adolescent population at a time when there was no FDA approval for such use, thereby creating the false impression that valid and well-supported scientific evidence supported such use.

76. Additionally, Defendants failed to disclose and/or concealed from the State of Texas that an investigation by the Pennsylvania Office of the Inspector General, triggered by Defendants' improper payments related to treatment algorithms in Pennsylvania (PennMap), in which Defendants participated, revealed, suspected Medicaid fraud and kick-backs involving the Defendants, Texas state officials, TMAP and PennMAP.

77. 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.

C. Defendants' Conduct Resulted in Harm to The State of Texas

78. Defendants' fraudulent and sophisticated marketing scheme targeting the Texas Medicaid Program based upon misrepresentations and omissions about Risperdal resulted in excessive reimbursements for Risperdal by the Texas Medicaid Program. Specifically, as a result of Defendants' conduct, the perceived value of Risperdal throughout the Texas Medicaid Program was falsely inflated and the Texas Medicaid Program was prevented from making fully-informed and appropriate policy decisions, and from utilizing the tools and safeguards available to the Program, including the VDP, DUR and PDL processes, to appropriately manage the reimbursement if Risperdal prescriptions.

VIII. DEFENDANTS' VIOLATIONS OF THE TEXAS MEDICAID FRAUD PREVENTION ACT[6]

79. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 78 of this Petition.

A. Defendants' Violations of the TMFPA That Resulted in Harm to The State of Texas, and for Which Plaintiffs Seek Restitution and Civil Penalties

80. 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

[6] In August of 2005, applicable provisions of the TMFPA were amended as set forth in ¶¶ 31 through 32 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.

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).

81. 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).

82. 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).

83. 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).

84. As a result of Defendants' conduct, the perceived value of Risperdal throughout the Texas Medicaid Program was falsely inflated and the Texas Medicaid Program was prevented from making fully-informed and appropriate policy decisions, and from utilizing the tools and safeguards available to the Program, including the VDP, DUR and PDL processes, to appropriately manage the reimbursement if Risperdal prescriptions. Defendants' illegal conduct,

therefore, resulted in millions of dollars in excessive reimbursements for Risperdal by the State of Texas.

85. 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 in this matter. TEX. HUM. RES. CODE §§ 36.052, 36.007, 36.110(c).

86. 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.

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

88. 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. <u>Defendants' Violations of the TMFPA for Which Plaintiffs Seek Civil Penalties</u>

89. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 88 of this Petition.

90. 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.

91. 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 costs effectiveness, was that Defendants' false and misleading messages were disseminated repeatedly to thousands of Texas Medicaid providers and decision-makers. 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 or decision-maker 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).

92. Defendants' November 10, 2003, false and misleading "Dear Healthcare Provider Letter" described in detail in Paragraph 68 above, provides just one of numerous examples of such unlawful acts. Defendants' letter, which was characterized by the FDA as false and misleading, and which omitted material information and minimized the risk of hyperglycemia and diabetes associated with Risperdal, was sent by Defendants to thousands of Texas Medicaid providers and decision-makers. Moreover, 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.

93. 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 means.

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

95. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 94 of this Petition.

96. 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.

97. Defendants knowingly 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 conflicted with their duties to the State. Defendants also knowingly provided inducements to the Texas state mental health decision maker(s), including honoraria, payment for meals, accommodations, and travel expenses, contributions to said decision-makers' favored charitable organizations, agencies or institutions, and other financial inducements. 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.

98. 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.

99. 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) and are entitled to recovery in an amount to be determined at trial exclusive of interest and costs.

X. JURY DEMAND

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

XI. PRAYER

101. 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.

102. The State of Texas asks that it recover from Defendants under all applicable Texas common law principles:

A. its reasonable damages as they may appear at trial;

B. punitive or exemplary damages;

C. forfeiture of Defendants' revenues from Risperdal sales in Texas in connection with Risperdal use in the Texas Medicaid population;

D. prejudgment interest and interest on the judgment; and

E. such other and further relief to which it may show itself entitled, either at law or in equity, exclusive of interest and costs.

103. 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. 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;

D. prejudgment interest;

E. expenses, costs and attorneys' fees; and

F. post-judgment interest at the legal rate.

104. The Relator asks that he be awarded:

A. his expenses, costs and attorneys' fees;

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

C. such other and further relief to which Relator may show himself entitled, either at law or in equity.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing document has been served, upon all counsel of record, as identified below, on April 8, 2011:

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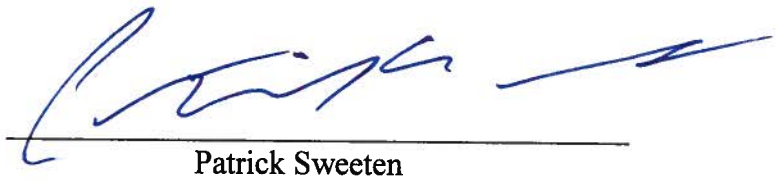

Patrick Sweeten

CAUSE NO. D-1-GV-04-001288

STATE OF TEXAS ex rel. ALLEN JONES, Plaintiffs, 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

ORDER

On the date signed below, came on for submission *Plaintiffs' Motion for Leave to File Fourth Amended Petition.* After reviewing the Motion, the Court is of the opinion that the Motion should be GRANTED.

SIGNED this _____ day of _____, 2011.

_____

JUDGE PRESIDING