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, INC.,** **Defendants**	**IN THE DISTRICT COURT** **250th JUDICIAL DISTRICT** **TRAVIS COUNTY, TEXAS**

PLAINTIFFS' SECOND 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 cause of 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 Second Amended Petition (the "Petition") and would respectfully show the Court as follows:

I. DISCOVERY CONTROL PLAN

1.1 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. PRELIMINARY STATEMENT AND NATURE OF THIS ACTION

2.1 This is a law enforcement action to recover taxpayer dollars spent as a result of Defendants' fraudulent conduct. Specifically, Defendants targeted Texas Medicaid with their sophisticated and fraudulent marketing scheme for their powerful, atypical antipsychotic drug, Risperdal--a scheme that was built upon their misrepresentations about the drug's safety,

superiority, efficacy, appropriate use and cost effectiveness. Additionally, Defendants concealed and failed to disclose to Texas Medicaid truthful information about Risperdal, including the long-term health effects resulting from its use. Further, as part of their marketing plan to generate blockbuster sales for Risperdal, Defendants unduly influenced and improperly utilized Texas officials and decision makers to facilitate Defendants' misrepresentations about Risperdal. This illegal conduct by Defendants caused millions of dollars in excessive expenditures for Risperdal by the Texas Medicaid program. Plaintiffs bring this action under the TMFPA, common law, and other applicable Texas statutes and case law.

III. THE PARTIES

3.1 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").

3.2 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.

3.3 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.

3.4 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]

3.5 Defendant ORTHO-MCNEIL PHARMACEUTICAL, INC. ("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.

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

3.6 Defendant MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS ("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.

3.7 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.

3.8 Defendant JOHNSON & 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, and Janssen Ortho.[2] Johnson & Johnson conducts business in Texas. All Defendants have answered and appeared for all purposes in this case.

IV. JURISDICTION AND VENUE

4.1 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.

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

V. DEFENDANTS' COORDINATED CONDUCT

5.1 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.

5.2 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 thus are mutually, jointly and severally, directly and/or vicariously liable under the legal theory of respondeat superior. 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 entity at law and equity. 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 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.

VI. BACKGROUND: THE HISTORY OF RISPERDAL

6.1 Beginning in the early 1990s and through the present day, drug companies developed new schizophrenia drugs known as atypical antipsychotics ("atypicals"). These drugs are also known as second generation, non-conventional or new generation antipsychotics. They are also sometimes referred to as atypical neuroleptics. For example, the prescription antipsychotics Risperdal, Zyprexa, Abilify, and Seroquel, are atypicals. The cost of these atypical antipsychotics far exceeds the cost of the older generation of antipsychotic drugs which have been available in generic form for decades. The older generation antipsychotic drugs first appearing in the 1960s are known as typical antipsychotics ("typicals"). They are also known as conventional or first generation antipsychotics, or traditional neuroleptics.

6.2 On December 29, 1993, Risperdal received United States Food and Drug Administration ("FDA") approval, and in January 1994, Defendants launched the atypical antipsychotic, Risperdal, entering a market which was dominated by a single atypical, Clozaril. When the product was launched, the FDA had approved Risperdal for use only in adults for the management of the manifestations of psychotic disorders. In 2000, the FDA revised the language to be used in manufacturer labeling to describe the approved use for atypical antipsychotics from "the management of the manifestations of psychotic disorders" to "treatment of schizophrenia." In early 2002, Janssen complied with the FDA requirement by revising the Risperdal label to clarify that its FDA approval was for use in schizophrenic adults only. In October 2003, Janssen launched a long-acting injectable form of Risperdal ("Risperdal Consta"), which received the same limited FDA approval for use in schizophrenic adults. In December 2003, the FDA approved Risperdal for short term treatment of adults with Bipolar I disorder. 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 narrow indication for use in the limited population of children and adolescents (age 5-17) for irritability associated with a diagnosis of autism. Additional 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).

6.3 At launch, Risperdal was a drug for use in the treatment of schizophrenia. However, studies indicate that the incidence of schizophrenia in the United States population ranges from 0.55% to 1%. This was a miniscule market segment compared to what Defendants needed to make Risperdal a blockbuster drug. Even in 2003, when the FDA approved the expanded use of Risperdal to treat patients suffering from Bipolar I, the market was still small. The National Institute of Mental Health reports that manic bipolar disorder affects approximately 2.6% of the United States population. Knowing this limitation on the market, Defendants engaged in their sophisticated marketing plan to establish Risperdal as a first line, preferred drug with a broad use position beyond its FDA approved indication.

VII. BACKGROUND: MEDICAID REIMBURSEMENT FOR RISPERDAL

7.1 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, 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")[3] administers the Texas Medicaid program and has authority to promulgate

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

rules and other methods of administration governing the program. Texas Medicaid reimburses eligible providers for the approved pharmaceuticals they provide to Medicaid recipients. 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 not later than the date such revisions are scheduled to occur. Defendants voluntarily sought and gained inclusion of the pharmaceutical product, Risperdal, on the Texas Medicaid formulary, by submitting an initial application and subsequent applications for new dosages, package sizes, and formulations to VDP. In one or more of those applications, Defendants asserted affirmatively that the drug was safe and effective.

VIII. BACKGROUND: DEFENDANTS TARGET TEXAS WITH MISREPRESENTATIONS

8.1 Defendants' pre-launch marketing plans anticipated that up to 85% of Risperdal sales would be to public sector payors, like Texas Medicaid. However, government agencies are

charged with efficiently managing the monies they have budgeted, and have historically exhibited a preference for generic drugs. The older prescription antipsychotics, typicals, have been available in generic form for many years, since before the atypicals came on to the market. The availability of the typicals in generic form means that patients and state health programs pay pennies per pill rather than the dollars per pill incurred for the purchase of newer, patented atypicals. Defendants viewed government fiscal responsibility as a barrier to the overall success and tremendous profit potential of Risperdal. To overcome this barrier, Defendants sought to distinguish their product, Risperdal, by improperly claiming that it was safer, more effective and more economical based upon improved patient outcomes. However, this was in direct contravention of the FDA's warning to Janssen in December 1993 that the FDA would consider any advertisement or promotional labeling for Risperdal false, misleading, or lacking fair balance if there is a presentation of data that conveys the impression that Risperidone was superior to haloperidol or any other marketed antipsychotic drug product with regard to safety or effectiveness. Despite the narrow FDA-approved indication and this very early warning from the FDA, Defendants developed and executed a marketing plan based on misrepresentations and concealment of material facts to tout the superiority, cost-effectiveness, appropriate use, safety and efficacy of Risperdal and to promote the drug to a wider patient population.

IX. DEFENDANTS' MARKETING PLAN TO DISSEMINATE THEIR MISREPRESENTATIONS

9.1 Since the launch of Risperdal, Defendants have, through the use of a variety of marketing tools disguised as medical education, scientific research and patient advocacy literature, targeted public sector payors in states with substantial populations of Medicaid patients with mental illness by promoting its product as appropriate for a broad range of mental illnesses, symptoms and disorders. Defendants targeted state and federal government public

health systems, including Texas Medicaid, with their marketing plan designed to promote Risperdal via these marketing tools. In fact, Defendants misrepresented the safety, superiority, appropriate use, efficacy, and cost effectiveness of Risperdal to Texas Medicaid prescribers and decision-makers. Additionally, Defendants prevented Texas Medicaid prescribers and decision-makers from receiving truthful information about Risperdal by concealing and failing to disclose information about the safety of and long-term health effects resulting from Risperdal use. Defendant's conduct resulted in excessive expenditures for Risperdal by the Texas Medicaid program.

9.2 Defendants used sophisticated strategies and tactics to disseminate misrepresentations about Risperdal to Texas Medicaid prescribers and decision-makers about Risperdal's safety, superiority, appropriate use, efficacy and cost effectiveness. These strategies included control over speeches and publications by individuals deemed by Defendants to be "key opinion leaders" and advocacy group messages. Defendants used tactics such as initiating, controlling, and producing scientifically-insignificant studies (small-scale clinical trials, investigator-initiated research, and pilot studies), ghostwritten publications, and/or letters to editors of professional journals, and seemingly independent articles related to non-FDA approved indications, some of which were ghostwritten, for marketing and public relations purposes. Defendants engaged in such tactics to "seed the literature" and increase the "noise level" in the public and healthcare communities about Risperdal, thereby priming the market and influencing Texas doctors to prescribe Risperdal to vulnerable populations for which Risperdal had no FDA-approved indication. Also, Defendants compromised the objectivity of researchers, prescribers and public mental health decision-makers by deeming them to be "key opinion leaders," "advisors," and "experts" and providing inducements including research funding,

consulting fees, extravagant meals and travel accommodations, honoraria and enhanced professional reputation. This compromised objectivity led to the publication of biased research in favor of Risperdal, which was disseminated by the Defendants' sales force, medical science liaisons and public sector marketing representatives when they called on Texas prescribers and decision makers.

9.3 Defendants recruited these "key opinion leaders," "advisors," and "experts" to participate in continuing medical education programs ("CMEs"), speaker bureaus, advisory boards, home office visits, symposia, and round-table discussions that Defendants sponsored, organized, and funded to accomplish a two-fold purpose. First, the forums provided Defendants with a 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. Second, they created an opportunity for Defendants to earn and maintain their loyalty by providing the previously described inducements. Defendants concealed and failed to disclose the improper influence they exercised over state mental health decision-makers and key opinion leaders who spoke at and attended these forums as proponents of Risperdal use in a wide variety of patient populations.

9.4 Defendants masked their undue influence and fraudulent scheme by using third party vendors and advocacy organizations as a conduit for funneling their funding and control. For example, additional marketing tools employed by Defendants included publications and presentations targeting medical professionals and state mental health decision makers disseminated by third-party contractors which gave the impression that the information received was from an independent source. Similarly, they deployed and funded advocacy groups to

influence legislation and state policy for the benefit of their product. Central to all of these marketing vehicles were Defendants' claims that Risperdal was a broad-use, safer, more cost effective and efficacious medication which the mental health community should choose not only over the older, cheaper typical generic medications, but also over other available atypicals. The FDA notice(s) and warning(s) cited Defendants for making unsubstantiated comparative claims such as these.

X. DEFENDANTS' MISREPRESENTATIONS OF APPROPRIATE USE OF RISPERDAL

10.1 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, including, but not limited to, tardive dyskinesia; increased risk of stroke and transient ischemic attacks; hyperglycemia; diabetes mellitus; metabolic syndrome; hyperlipidemia (elevations in cholesterol, triglycerides); excessive weight gain; hyperprolactinemia; and increased risk of pituitary tumors.

10.2 Defendants did not limit their claims of safety and efficacy to the treatment of the very small adult population believed to suffer from schizophrenia and bipolar disorder. Rather, Defendants used each of the marketing tools described above to promote Risperdal as a medication that could be safely prescribed for a variety of symptoms and disorders in the child and adolescent and other vulnerable populations. Their promotional message was delivered through a concerted campaign of CMEs, speaker's bureaus, advisory boards, purchased clinical research and other publications and presentations as discussed above. Defendants targeted individual Texas Medicaid prescribers and state mental health decision makers to penetrate the child and adolescent market. Defendants concealed and misrepresented the risk of serious side effects and long-term health consequences of Risperdal use in all patient populations, including children and adolescents.

XI. DEFENDANTS DOWNPLAY AND NEUTRALIZE CONCERNS ABOUT SIDE EFFECTS

11.1 Defendants downplayed and neutralized the risk of a number of serious side effects, including the risk of diabetes and hyperglycemia. In September of 2003, the FDA advised Defendants of what they had known for years: that epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with atypical antipsychotics. The FDA's conclusions were based on its review of data available for patients treated with atypical antipsychotics over a number of years. The FDA concluded that Risperdal created a risk of hyperglycemia, in spite of Defendants' repeated claims that the incidence of diabetes associated with Risperdal was due to background incidence inherent in the schizophrenic population.

11.2 On September 11, 2003, the FDA formally notified Defendants of the requirement to add language concerning the risk of hyperglycemia and diabetes to the warning section of the product labeling for Risperdal. In November of 2003, Defendants sent to prescribing physicians an inaccurate and misleading "Dear Healthcare Provider Letter" about the label change that had been required by the FDA. This letter was received by thousands of physicians all over the country, including significant numbers of Texas Medicaid prescribers and decision makers.

11.3 In April 2004, the FDA sent Defendants a warning letter regarding Defendants' "Dear Healthcare Provider Letter," characterizing the message as false and misleading, omitting material information, and minimizing the risk of hyperglycemia and diabetes. The FDA also noted Defendants had failed to recommend regular glucose monitoring and made misleading claims that Risperdal was safer than other atypical antipsychotics. The FDA further chastised Defendants for misrepresenting the pertinent scientific evidence and failing to accurately

describe the results of the scientific studies cited in their letter. Consistent with their previous marketing messages, Defendants' "Dear Healthcare Provider Letter" downplayed or concealed the risk of hyperglycemia and diabetes by differentiating Risperdal from its atypical competitors as less likely to cause this side effect. Accordingly, the FDA demanded that Defendants immediately cease the dissemination of promotional materials for Risperdal containing claims similar to those the FDA cited and that Defendants provide a plan of action to correct the effects of its false and misleading letter. It was not until July 2004 that Defendants finally sent a "Dear Healthcare Provider Letter" that was acceptable to the FDA, containing the new warnings.

11.4 Defendants' misconduct described above is just one of many examples of how they attempted to neutralize safety concerns and downplay side effects to Texas Medicaid prescribers and decision makers. Their sales messages and marketing scheme systematically concealed or misrepresented, *inter alia*, the existence and severity of the side effects of Risperdal.

XII. MEDICATION ALGORITHMS AS A MARKETING TOOL

12.1 An integral part of Defendants' Risperdal pre-launch and subsequent marketing scheme was the concept of mental health medication guidelines and algorithms, which Defendants viewed as a mechanism to prevent or overcome limitations on expenditures for Risperdal in public health systems, including Texas Medicaid. Further, Defendants recognized that these guidelines and algorithms could be utilized for primary placement for Risperdal, thereby increasing Defendants' tremendous profit potential and advancing their misrepresentations about the safety, superiority, efficacy, appropriate use and cost effectiveness of this drug. Further, the guidelines and algorithms had the potential for use as a marketing tool to expand utilization of Risperdal beyond the FDA-approved indication.

12.2 In late 1995, Risperdal's second year on the market, the State of Texas began developing a set of medication protocols or "algorithms"[4] to standardize the treatment of patients in public mental health programs with certain psychiatric disorders. These efforts resulted in the creation and implementation of the "Texas Medication Algorithm Project" or TMAP. After TMAP's initial adoption by Texas mental health program decision-makers, a project was developed to facilitate the implementation of TMAP throughout the Texas public mental health system, also known as the Texas Implementation of Medication Algorithms ("TIMA").

12.3 Defendants recognized that TMAP could be used as a marketing tool for Risperdal. Defendants viewed TMAP as a mechanism to overcome the lack of scientific evidence to support widespread prescription of the newer atypicals, and the economic advantage of generic typicals.

12.4 To enhance their marketing capability, Defendants provided substantial financial contributions to and improperly influenced the evolution of TMAP algorithms. Published reports indicate that funding for TMAP exceeded 6 million dollars, including contributions from Defendants and other pharmaceutical manufacturers. The largest contributors to this fund were Defendants and the Robert Wood Johnson Foundation. The Robert Wood Johnson Foundation was founded by Robert Wood Johnson, former Johnson and Johnson Chairman from 1932 to 1963 and a member of the company's founding family. Throughout the years, the Robert Wood Johnson Foundation and Johnson and Johnson have had board members in common and the vast majority of the Robert Wood Johnson Foundation investments have been in Johnson and Johnson stock. Donations from the Robert Wood Johnson Foundation and Defendants facilitated

[4] Medication algorithms are flow charts that illustrate step-by-step movements in a process. The proposed algorithms, together with text guidelines, were to guide a clinician in prescribing medications to patients and in changing or adjusting medications. Each medication algorithm lists the required medications from which the

the development and promotion of the Texas algorithms which preferred Janssen's profit-center drug, Risperdal, over the older typicals.

12.5 Schizophrenia, bipolar disorder, and major depressive disorder were addressed by TMAP, which required the prescription of specific medications for the treatment of these mental illnesses. Defendants' product, Risperdal, has always been a first-line drug in the TMAP schizophrenia algorithm. Initial versions of the TMAP schizophrenia algorithm gave doctors a first-line choice between typical and atypical antipsychotics. Once TMAP became infused with funding from Defendants and other manufacturers of atypical antipsychotics, the algorithms transformed to require doctors to first treat their patients with the newest, most expensive drugs, the atypicals. Based upon the revised algorithms, providers could choose which atypical to use first, but could not choose to use less expensive, equally effective generic drugs first, without clearing the hurdle of providing written justification for exercising their professional judgment.

12.6 In Texas, Defendants unduly influenced one or more mental health program decision-maker to become a chief proponent of Risperdal by virtue of its placement in the TMAP protocol. As a result, Defendants' antipsychotic Risperdal enjoyed preferred status on the TMAP algorithms and in Texas public mental health policy.

12.7 In 1997-98, efforts began on the Texas Children's Medication Algorithm Project ("CMAP"). As a result of Defendants' continuing misconduct, Defendants' product, Risperdal, received a preferential recommendation as a medication of choice on the CMAP algorithms for the treatment of attention deficit and hyperactivity disorder (ADHD), that would be used to treat children and adolescents. Defendants' product appeared on CMAP algorithms for eight years without FDA approval for use in children and adolescents. The CMAP algorithms in which

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prescriber may choose. A clinician may not stray from the algorithm to prescribe a different drug for the patient without written justification.

Risperdal appeared created an appearance of the existence of substantial scientific evidence to support the use of Risperdal in children and adolescents at a time when no FDA indication existed for any usage of Risperdal in the child and adolescent population.

12.8 Defendants misused TMAP and CMAP as key marketing tools for Risperdal. Further, Defendants concealed and failed to disclose the improper influence they exercised through aspects of the funding, adoption, revision, promotion, dissemination and implementation of these medication guidelines and algorithms.

12.9 Defendants' substantial investment in the Texas algorithm projects proved wise, since after the adoption of these algorithm projects in Texas, Defendants reaped the benefits of increased Risperdal prescriptions, sales and profits throughout the state and country. As Defendants anticipated, TMAP and CMAP proved to be powerful drivers for Risperdal.

12.10 Defendants provided substantial funding of the algorithm projects through a series of donations to state agencies and universities. Indeed, one primary reason Defendants made a significant investment in the Texas algorithms was so they could develop the algorithm models and then export them across the country. Defendants' rationale was to develop this approach in Texas, find out the most effective way to roll it out, and then other states could replicate the algorithms with minimal investment. Defendants did this by utilizing experts who served on the consensus panels that developed TMAP and CMAP as their paid consultants. Defendants then used those consultants to export the Texas algorithms to other states. In doing so, Defendants used one highly effective sales strategy known as "peer to peer" marketing. As a direct result of Defendants' marketing scheme, numerous states, including Texas, have implemented algorithms patterned after TMAP and CMAP. As part of Defendants' nationwide exportation of the Texas algorithms, Defendants' utilized Texas state mental health program decision-makers as

pitchmen, providing them with trips, perks, travel expenses, honoraria and other payments. Defendants also entered into consulting and other agreements with Texas state mental health decision makers that created conflicts of interest for these public servants. TMAP became the standard-bearer for Defendants' Risperdal marketing plan and they benefited from increased sales in the states that adopted TMAP and CMAP algorithms.

12.11 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 they ignore those laws, they violated their own healthcare compliance requirements which were designed to ensure their companies' conduct was lawful. Defendants concealed their improper conduct by funneling funding to the state employees through third-party vendors, charitable organizations, advocacy groups, and governmental entities.

12.12 One of the earliest states targeted by Defendants was Pennsylvania, where Defendants engaged in an aggressive marketing effort to persuade Pennsylvania officials to adopt the Texas algorithm project. Defendants were successful, resulting in the PennMAP project. Defendants' improper payments related to the PennMAP effort triggered an investigation by the Pennsylvania OIG. Relator was the investigator initially assigned to this investigation in the course of his employment with the Pennsylvania OIG. Relator began investigating allegations of impropriety in the course of PennMAP's adoption and implementation. In the course of his investigation of PennMAP, Relator traveled to Janssen headquarters in Titusville, NJ, to conduct interviews of Defendants' attorneys, agents and employees about payments made to state agencies and employees. During those interviews, one or more of Defendants' attorneys, agents or employees revealed payments made to one or more

Texas state mental health program decision-maker. These interviews and Pennsylvania's investigation alerted Defendants, through their attorneys, agents or employees, of the existence of suspected Medicaid fraud and potential violations of the Texas anti-kickback statutes. Despite this knowledge, Defendants failed to report this suspected Medicaid fraud and possible violation of the Texas anti-kickback statute to the State of Texas. Defendants concealed and failed to disclose to the State of Texas that the Pennsylvania investigation, in which Defendants participated, revealed suspected Medicaid fraud and kick-backs involving Defendants, Texas state officials, TMAP, and PennMAP.

XIII. DEFENDANTS' MARKETING MESSAGE IS REFUTED BY FDA AND UNBIASED RESEARCH

13.1 In September 2005, the results of the first phase of the Clinical Antipsychotic Trials of Intervention Effectiveness ("CATIE") were published in the New England Journal of Medicine. The CATIE study was initiated by the National Institute of Mental Health ("NIMH") to compare the relative safety and efficacy of atypical antipsychotics to typicals. CATIE studied 1,400 participants over an 18 month period at multiple clinical sites across the United States. In addition, drug companies had no input into the study's design, implementation, data analysis or manuscript publication. The CATIE study is one of the largest, longest, and most comprehensive independent trial ever done to examine existing therapies for schizophrenia.

13.2 The CATIE study was a double-blind comparison between the typical antipsychotic Perphenazine and newer atypicals including Risperdal. The study found that the older antipsychotic, Perphenazine, was as effective in treating schizophrenia and as well tolerated as the atypical antipsychotics including Risperdal. The study further found that the atypical antipsychotics have no substantial advantage over the older, less expensive medication used in the study.

13.3 The CATIE Study was consistent with what Defendants already knew since launching Risperdal – that Risperdal was no more effective in treating schizophrenia, and no safer, than first generation antispychotics. Nonetheless, Defendants responded to such unbiased research by propagating a misleading interpretation of the implications of this study in an attempt to minimize the impact on their profits. For example, in response to the CATIE study, Defendants immediately responded by criticizing the primary measure of the study group – length of time to drug discontinuation, and claimed that the study did not demonstrate the full efficacy of Risperdal because many received doses Defendants claimed were too low. Defendants targeted healthcare providers with a message intended to discount the significance of the results of the research, thus encouraging the continued preference for Risperdal without regard to the tremendous savings of taxpayer dollars that could be had. Consequently, Texas Medicaid prescribers and decision makers continue to hear Defendants' misleading message.

13.4 Additional independent studies have followed CATIE with similar findings. The Cost Utility of the Latest Antipsychotic Drugs in Schizophrenia Study (CUtLASS 1) was published in October 2006. The CUtLASS 1 study was also a noncommercially funded study, multisite randomized controlled trial of antipsychotic drug classes, conducted within the English National Health Service. This study found that in people with schizophrenia whose medication is changed for clinical reasons, there is no disadvantage across one year in terms of quality of life, symptoms, or associated costs of care in using typical, or conventional antipsychotics, as opposed to nonclozapine atypicals. In September 2008, a six-year multisite National Institute of Mental Health (NIMH) study was published in the American Journal of Psychiatry. According to this study, Risperdal was no more effective in treating children and adolescents than older drugs, and may lead to more metabolic side effects.

XIV. DEFENDANTS' UNLAWFUL ACTS UNDER THE TEXAS MEDICAID FRAUD PREVENTION ACT

14.1 Plaintiffs re-allege and incorporate the allegations in paragraphs 1 – 13.4 as if fully set forth herein.

14.2 At various times in the past, and continuing through the present date, Defendants knowingly or intentionally made false statements or misrepresentations to the Texas Medicaid Program regarding their drug, Risperdal. Further, Defendants knew and concealed or failed to disclose events, information, or material facts concerning their drug Risperdal.

14.3 The commission of these unlawful acts commenced in or around the early 1990s. Before September 1, 2005, Defendants committed unlawful acts by:

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).

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).

14.4 After August 31, 2005, Defendants committed unlawful acts by:

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. Except as authorized under the Medicaid program, knowingly paying, charging, soliciting, accepting, or receiving, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program. TEX. HUM. RES. CODE ANN. § 36.002(5).

E. Knowingly 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 ANN. § 36.002(9).

XV. CIVIL REMEDIES UNDER THE TMFPA

15.1 Defendants' misconduct caused harm to and entitles Plaintiffs to remedies under the TMFPA. 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).

15.2 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. Plaintiffs will seek an amount as civil penalties that will be justified and appropriate under the facts and the law.

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

15.4 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).

15.5 Defendants' unlawful acts have cost the State of Texas millions of dollars over the years. 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.

XVI. STATUTORY INJUNCTION UNDER § 36.051 OF THE ACT

16.1 There is good reason for the Attorney General to believe Defendants are committing, have committed, or are about to commit unlawful acts as defined by the TMFPA.

16.2 Defendants continue to violate Texas law by continuing to target the Texas public mental health system including Texas Medicaid with misrepresentations about the safety, superiority, appropriate use, efficacy, appropriate use and cost effectiveness of Risperdal. These illegal acts may be enjoined under § 36.051 of the Act, and under TEX. GOV'T. CODE § 2001.202.

XVII. COMMON LAW FRAUD

17.1 Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1-16.2 of this Petition.

17.2 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.

17.3 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 prescribers and 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 prescribers and 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.

17.4 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.

XVIII. CONSPIRACY TO BREACH FIDUCIARY DUTY

18.1 Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 – 17.4 of this Petition.

18.2 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.

18.3 Defendants knew that one or more Texas state mental health decision makers owned fiduciary duty(ies) to the State, yet entered into contracts or other arrangements with them and received services from them. Defendants also provided inducements to the Texas state mental health decision maker(s), including honoraria. Defendants reasonably knew or should have known that in rendering services required under these contracts and other arrangements, the Texas state mental health decision maker(s) breached the fiduciary duty(ies) to the State. 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.

18.4 Defendants 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 of Texas. Defendants' conspiracy included the execution of consulting or other contracts that required services and imposed conditions that were at odds with and at times mutually exclusive to the duties owed to the State. 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. 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

on the object or course of their action, and committed an unlawful, overt act in furtherance of the object or course of their action.

18.5 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).

XIX. NEGLIGENT MISREPRESENTATION

19.1 Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 – 18.5 of this Petition.

19.2 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.

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

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

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

XX. MONIES HAD AND RECEIVED

20.1 Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 – 19.5 of this Petition.

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

20.3 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.

20.4 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.

20.5 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.

20.6 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.

XXI. REMEDIES FOR COMMON LAW FRAUD, CONSPIRACY TO BREACH FIDUCIARY DUTY, NEGLIGENT MISREPRESENTATION, AND MONIES HAD AND RECEIVED

21.1 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.

XXII. JURY DEMAND

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

XIII. PRAYER

23.1 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.

23.2 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.

23.3 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.

23.4 The Relator asks that he be awarded;

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

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

23.5 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.

23.6 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' Second Amended Petition** was sent by facsimile and electronic mail to all counsel of record on December 12, 2008.

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At
Amalia Rodriguez-Mendoza, Clerk