IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA; and
THE STATES OF CALIFORNIA, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, WISCONSIN, THE COMMONWEALTHS OF MASSACHUSETTS and VIRGINIA, and THE DISTRICT OF COLUMBIA,

ex rel. HELEN GE, M.D.

PLAINTIFFS AND RELATOR,

v.

TAKEDA PHARMACEUTICAL COMPANY LIMITED; and
TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.

DEFENDANTS

CIVIL ACTION NO.

1:10-CV-11043-FDS

JURY TRIAL DEMANDED

SECOND AMENDED FALSE CLAIMS ACT COMPLAINT

TABLE OF CONTENTS

I. INTRODUCTION

1. Helen Ge, M.D. ("Relator"), through her attorneys, Baum, Hedlund, Aristei & Goldman, P.C., The Ashcroft Group, LLC, and Roddy, Klein & Ryan, brings this action on behalf of the United States of America ("United States") for treble damages and civil penalties arising from Defendants Takeda Pharmaceutical Company Limited's and Takeda Pharmaceuticals North America, Inc's. (collectively referred to as "Takeda" or "Defendants") conduct in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA"). The violations arise out of false claims for payment made to Medicare, Medicaid, Tricare and other federally funded government healthcare programs (hereinafter, collectively the "Government Healthcare Programs"). Relator is an "original source" of the information upon which this complaint is based, as that term is used in the False Claims Act. As a former employee at Takeda, Relator has direct and independent knowledge of the information on which her allegations are based, and through her attorneys she voluntarily provided this information to the Government, including but not limited to the United States Attorneys' Office in Boston, before filing her qui tam action.

2. This action is also brought under the respective *qui tam* provisions of False Claims Acts (or similarly named) on behalf of the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, the District of Columbia, Virginia, and Wisconsin. These states, together with the United States, are hereafter collectively referred to as the Government.

3. This is an action to recover damages and civil penalties on behalf of the Government arising from false and fraudulent records, statements, and claims made, used and caused to be made, used or presented by Defendants and/or their agents, employees and co-

conspirators in violation of the Federal Civil False Claims Act, 31 U.S.C. §3729 et. seq., as amended ("the FCA" or "the Act").

4. As set forth below, Defendants' acts also constitute violations of the California False Claims Act, Cal. Govt Code §12650 *et seq*.; the Delaware False Claims and False Reporting Act, 6 Del. C. §1201 *et seq*.; the Florida False Claims Act, Fla. Stat. §68.081 *et seq*.; the Georgia False Medicaid Claims Act, Ga. Code Ann. §49-4-168 *et seq*.; the Hawaii False Claims Act, Haw. Rev. Stat. §661-21 *et seq*.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §17511-8; the Indiana False Claims and Whistleblower Protection Act, Ind. Code Ann. §5-11-5.5-1 *et seq*.; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §437.1 *et seq*.; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §5 *et seq*.; the Minnesota False Claims Act, Minn.Stat. §§ 15C.01 *et seq*.; the Montana False Claims Act, Mont. Code Ann. §17-8-401 *et seq*.; the Nevada False Claims Act, Nev. Rev. Stat. Ann. §§357.010 *et seq*.; the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. §167.61 *et seq*; the New Jersey False Claims Act, N.J. Stat. §2A:32C-l *et seq*.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §27-2F-l *et seq*.; the New York False Claims Act, N.Y. State Fin. §187 *et seq*.; the North Carolina False Claims Act, N.C.G.S., §1-605 *et seq*.; the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 §5053 *et seq*.; the Rhode Island False Claims Act, R.I. Gen. Laws §9-1.1 *et seq*.; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-181 *et seq*.; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§36.001 *et seq*.; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§8.01-216.1 *et seq*.; the Wisconsin False Claims Act for Medical Assistance, Wis. Stat. §20.931 *et seq*.; and the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §§1-1188.13 *et seq*.

5. As alleged herein, Takeda has caused thousands, if not millions, of false claims to be made on federal and state health care programs.

II. SUMMARY OF CLAIMS

6. This is a whistleblower case brought by a former medical reviewer in Takeda's pharmacovigilance division, Dr. Helen Ge. Her claims involve Takeda's failure to report bladder cancer, Congestive Heart Failure (CHF) and other adverse events for the diabetes drug Actos (the only drug in the same class and competing with GlaxoSmithKline's Avandia).

7. Dr. Ge, a medical doctor and former safety consultant to Takeda Pharmaceuticals, was hired by Takeda to work in the company's pharmacovigilance department to review adverse events and to identify and evaluate potential safety signals for Actos (amongst other drugs).

8. Dr. Ge had direct knowledge of the Actos bladder cancer risk and encountered resistance from her superiors when she tried to report bladder cancer as related to Actos. Dr. Ge claims her supervisors directed her to change her "related" assessment to unrelated. According to her recollection of reviewing Takeda's adverse event database for Actos, there were more than 100 bladder cancers reported to the company, but only 72 reported to the FDA, which she alleges is a serious discrepancy. Dr. Ge also alleges that carcinogenesis from Actos was discovered during the initial Actos animal studies.

9. According to Dr. Ge, Takeda failed to properly report each Actos-related CHF adverse event to the FDA. Specifically, Takeda instructed its medical reviewers not to report hundreds of non-hospitalized or non-fatal CHF cases as "serious" adverse events and thus avoided its responsibility of accurately analyzing and reporting these hundreds of serious adverse events to the FDA. Dr. Ge estimates that Takeda failed to report several hundred CHF events as "serious" between late 2007 and 2010. To illustrate the magnitude of this failure, between 1999 and 2009, the manufacturer of Avandia reported a cumulative total of 2,628 Congestive Heart Failure adverse events during that 10 year period.

10. When Dr. Ge complained to her superiors that her medical assessments were being downgraded from "serious" to "non-serious" and that, as a result of this, the CHF events were being under-reported to the FDA, her contract with Takeda was terminated.

11. "Actos" is Takeda's trade name for its multi-billion dollar blockbuster drug "pioglitazone." Actos (pioglitazone) is a prescription drug within a class of drugs known as thiazolidinediones ("TZDs"), which are prescribed for the treatment of Type II diabetes. Today, the two primary TZDs marketed in the United States are Actos (manufactured by Takeda) and Avandia (rosiglitazone), which is manufactured and distributed by GlaxoSmithKline LLC ("GSK").

12. Takeda submitted its New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") on January 15, 1999. Six months later, on July 15, 1999 the U.S. Food and Drug Administration approved Actos' New Drug Application ("NDA") (NDA No. 21-073). The FDA approved Actos for use to improve glycemic control in patients with Type II Diabetes (non-insulin-dependent diabetes mellitus).

13. Actos developed into Takeda's most profitable drug with $3.1 billion annual sales in 2008 and $3.4 billion annual sales in 2009, according to an April 6, 2010 IMS Health report. At its peak, Actos alone was responsible for more than half of the total revenue of Takeda Pharmaceuticals North America. Takeda was able to capture a majority of the Diabetes drug market by falsely portraying Actos as safer than it actually was.

14. Actos, however, is not as safe as Takeda has led the FDA, healthcare professionals and the general public to believe. Rather, the FDA and the public were led to believe that Actos is safer because Takeda failed to properly report all of the Actos-related adverse events to the FDA.

15. Upon information and belief, Takeda's motivation to fraudulently report and under report the serious adverse events was driven by an economic desire to falsely enhance Actos' safety profile and to increase sales. Vice President of Takeda's Pharmacovigilance Department, Dr. Maria Paris, informed her employees, including Relator, that "As a company, reporting adverse events is one thing, but we must make sure that the company has to be profitable first."

16. Takeda's failure to properly and accurately report hundreds of serious adverse events caused the FDA to falsely view Actos as safer than it really was. In an October 7, 2008 report, Dr. David J. Graham, the Associate Director for Science and Medicine, Office of Surveillance and Epidemiology at the FDA commented that "there was strong evidence that rosiglitazone [Avandia] confers an increased risk of AMI and heart failure compared to pioglitazone [Actos]." Further, in a May 2010 observational study Dr. Graham and colleagues conducted comparing Avandia to Actos, in the absence of accurate adverse event amounts for Actos CHF events due to Takeda's mis-categorizations, the authors projected excess "serious cardiovascular harm or death as a result of using Avandia instead of Actos." Had Takeda not submitted false reports or records to the FDA, the FDA and the public would not have been misled regarding the safety of Actos, which, at minimum, would have resulted in far fewer submissions of claims for Actos to Government Healthcare Programs.

17. On July 13 and 14, 2010, a joint meeting of the Endocrinologic and Metabolic Drugs and the Drug Safety and Risk Management advisory committees reviewed results from the Rosiglitazone Evaluated for Cardiac Outcome and Regulation of Glycemia in Diabetes (RECORD) trial, as well as observational data, health-claims data, and a meta-analysis of controlled clinical trials. The FDA also presented its meta-analysis of several trials of

pioglitazone (Actos) to help panel members understand the relative risk and benefits of the two market-approved thiazolidinediones.

18. But for Takeda's fraud, Government health care programs would have paid for substantially fewer Actos claims. But for the fraud, physicians would have prescribed Actos less frequently than they did, and patients would have used Actos less than they did. Upon information and belief, Takeda's fraud has caused tens of thousands of false claims to be made on federal and state health care programs causing the Government to have suffered hundreds of millions of dollars of damages.

III. FEDERAL JURISDICTION AND VENUE

19. The acts proscribed by 31 U.S.C. § 3729 *et seq*. and complained of herein occurred in the District of Massachusetts and elsewhere, as Defendants do business in the District of Massachusetts and throughout the United States. Therefore, this Court has jurisdiction over this case pursuant to 31 U.S.C. § 3732 (a), as well as under 28 U.S.C. §§ 1331 and 1345. This Court has supplemental jurisdiction over this case for the claims brought on behalf of the states (referenced in paragraph 2) pursuant to 31 U.S.C. §3732(b) and/or 28 U.S.C. § 1367, inasmuch as recovery is sought on behalf of said states which arises from the same transactions and occurrences as the claims brought on behalf of the United States.

20. This court has personal jurisdiction over defendants Takeda Pharmaceutical Company Limited and Takeda Pharmaceuticals North America, Inc. pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because defendants have minimum contacts with the United States. Moreover, the defendants can be found in, reside, or transact or have transacted business in this District.

21. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), and 28 U.S.C. §1391 because Defendants transact business in this District, and one or more of the acts

proscribed by section 31 U.S.C. §3729 occurred in this District. At all times relevant to this Complaint, Defendants regularly conducted substantial business within this District, maintained employees and offices in this District, and made significant sales within this District.

22. The facts and circumstances alleged in this Complaint have not been publicly disclosed in a criminal, civil or administrative hearing, nor in any congressional, administrative, or government accounting office report, hearing, audit investigation, or in the news media.

23. Relator is an "original source" of the information upon which this complaint is based, as that term is used in the False Claims Act.

IV. PARTIES

24. The United States funds the provision of medical care, including pharmaceutical products, for eligible citizens through Government Healthcare Programs such as Medicare, Medicaid, TRICARE and other agencies and programs, acting through the Centers for Medicare & Medicaid Services ("CMS") within the U.S. Department of Health and Human Services ("HHS"), the Department of Defense, and other federal agencies.

25. Relator Helen Ge, M.D. is a resident of North Reading, Massachusetts. Dr. Ge is a graduate of the First Medical University of Shanghai and conducted her residency and post-doctorate education at the Postgraduate Medical School of PLA in Beijing, China. During the 1980s and 1990s, she was a Clinical Research Fellow at the University of Pittsburgh School of Medicine and later became an Associate Medical Director at Harvard Clinical Research Institute, which is affiliated with Harvard Medical School.

26. From 1998 through to the present, Dr. Ge has worked as an independent consultant and contractor for various major pharmaceutical companies in the United States. Her work has specialized in assisting pharmaceutical companies with, among other things, preparing FDA mandated safety reports, reviewing and evaluating clinical trial data, performing medical

review for spontaneous and clinical study adverse event reports and making side-effect causality assessments associated with a manufacturer's pharmaceutical products.

27. In September 2008, Dr. Ge accepted an assignment to consult as a Contract Physician of Drug Safety with Takeda Pharmaceuticals North America. The consulting agreement had an initial term of one year with an end date of October 6, 2009.

28. Dr. Ge was contracted to, among other things, perform medical review of spontaneous and clinical trial adverse events and serious adverse event reports; to confirm the seriousness of the adverse events; to make causality assessments; and to assist with risk management by identifying and evaluating potential safety signals and providing analysis of product safety. As part of her assignments, she was assigned to medically review all adverse events associated with the drug Actos.

29. Because of her excellent performance at Takeda, Dr. Ge's initial consulting contract was extended another six months, with a new end date of March 31, 2010. She was continuously a contractor for Takeda Pharmaceuticals North America at its Lake Forest, Illinois facility from October 2008 until her contract was prematurely and wrongfully terminated on January 15, 2010.

30. Takeda Pharmaceutical Company Limited ("TPC") is a Japanese corporation having its corporate headquarters and principle place of business in Osaka, Japan. TPC is the largest pharmaceutical company in Japan. According to its 2009 annual reports, TPC's annual sales exceeded $15 billion.

31. Takeda Pharmaceuticals North America, Inc. ("TPNA") is a wholly owned U.S. subsidiary of TPC. TPNA is organized under the laws of Delaware and has its principal place of business in Deerfield, Illinois. TPNA is one of the 15 largest pharmaceutical companies in the United States. According to its annual report, TPNA's 2008 annual sales were reported to be in

excess of $5 billion. More than half of its annual sales were attributable to its prescription drug Actos – whose 2008 annual sales exceeded $2.9 billion. In the following year (2009), Actos' annual sales were reported to be $4.2 billion.

32. In 2008, TPNA merged with TAP Pharmaceutical Products, Inc. ("TAP"), which was another TPC subsidiary. TAP had a history of dealing dishonestly with the federal government. In 2001, TAP pled guilty to various charges arising out of their "fraudulent drug pricing and marketing conduct" with regard to Lupron, a Takeda drug used to treat prostate cancer. To avoid prosecution, TAP pled guilty to conspiracy to violate the Prescription Drug Marketing Act and paid a $290,000,000 criminal fine (which at the time was the largest criminal fine ever in a health care fraud prosecution). In addition, as part of the plea agreement, TAP agreed to settle its federal civil False Claims Act liabilities and to pay the U.S. Government $559,483,560 for filing false and fraudulent claims with the Medicare and Medicaid programs as a result of TAP's fraudulent drug pricing schemes and sales and marketing misconduct. TAP also agreed to comply with the terms of a sweeping Corporate Integrity Agreement, which, among other things, required it to deal honestly with the United States and the Medicare and Medicaid programs.

33. TPC and TPNA will be collectively referred to as "Takeda" or "Defendants."

34. Takeda is engaged in the business of research, developing, manufacturing and marketing of a broad spectrum of pharmaceutical products, including Actos (pioglitazone).

35. Takeda is currently transacting business in the District of Massachusetts, at least by maintaining offices and employees in this District, marketing and shipping into this District, or by using, offering to sell, or selling or by causing others to use, offer to sell or sell, pharmaceutical products, including Actos in this District. Takeda derives substantial revenue

from interstate and or international commerce, including substantial revenue from goods used or consumed or services rendered in the State of Massachusetts and this Judicial District.

V. THE FALSE CLAIMS ACT

36. The False Claims Act (hereinafter referred to as "FCA" or "the Act"), 31 USC § 3729, was originally enacted in 1863, and was substantially amended in 1986 by the False Claims Amendments Act, Pub.L. 99-562, 100 Stat. 3153. Congress enacted the 1986 amendments to enhance and modernize the government's tools for recovering losses sustained by frauds against it after finding that federal program fraud was pervasive. The amendments were intended to create incentives for individuals with knowledge of Government fraud to disclose the information without fear of reprisal or government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the Government's behalf. The FCA was further amended in May 2009 by the Fraud Enforcement and Recovery Act of 2009 ("FERA") and again in March 2010 by the Patient Protection and Affordable Care Act ("PPACA"). Both FERA and PPACA made a number of procedural and substantive changes to the FCA in an attempt to ease the government and private Relators' burdens in investigating and prosecuting *qui tam* suits under the FCA.

37. The FCA provides that any person who knowingly presents, or causes to be presented, false or fraudulent claims for payment or approval to the United States Government, or knowingly makes, uses, or causes to be made or used false record or statement material to a false or fraudulent claim is liable for a civil penalty ranging from $5,000 up to $10,000 (and adjusted upward for inflation) for each such claim, plus three times the amount of the damages sustained by the federal government.

38. The FCA allows any person having information about false or fraudulent claims to bring an action for himself and the Government, and to share in any recovery. The FCA

requires that the complaint be filed under seal for a minimum of 60 days (without service on the Defendants during that time). Based on these provisions, *qui tam* plaintiff/relator seeks through this action to recover all available damages, civil penalties, and other relief for state and federal violations alleged herein.

VI. FEDERAL HEALTH CARE PROGRAMS

39. In 1965, Congress enacted Title XVIII of the Social Security Act (known as "Medicare" or the "Medicare Program") to pay for the cost of certain medical services and care. Entitlement to Medicare is based on age, disability or affliction with certain diseases. See 42 U.S.C. §1395 to 1395ccc. Outpatient prescription drugs are covered under Parts A-D of the Medicare Program.

40. In 1965, the federal government also enacted the Medicaid program. It is a cooperative undertaking between the federal and state governments to help the states provide health care to low-income individuals. The Medicaid program pays for services pursuant to plans developed by the states and approved by the U.S. Department of Health and Human Services ("HHS") Secretary through CMS. 42 U.S.C. §§ 1396a(a)-(b). States pay doctors, hospitals, pharmacies, and other providers and suppliers of medical items and services according to established rates. 42 U.S.C. §§1396b(a)(1), 1903(a)(1). The federal government then pays each state a statutorily established share of "the total amount expended ... as medical assistance under the State plan." See 42 U.S.C. §1396b(a)(1). This federal-to-state payment is known as Federal Financial Participation ("FFP"). Outpatient prescription drugs are covered under the Medicaid Program as long as they meet the definition of a "Covered Outpatient Drug."

41. TRICARE Management Activity, formerly known as CHAMPUS, is a program of the Department of Defense that helps pay for covered civilian health care obtained by military beneficiaries, including retirees, their dependents, and dependents of active-duty personnel. 10

U.S.C. §§ 1079, 1086; 32 C.F.R. Part 199. TRICARE contracts with fiscal intermediaries and managed care contractors to review and pay claims, including claims submitted for outpatient prescription drugs.

42. Pharmaceutical drugs are also used on an inpatient basis, purchased by nursing homes, hospitals, and other facilities for inpatients. Generally, in such settings, the provider does not separately bill the Government Healthcare Programs for the drug -- rather, the provider is reimbursed based upon a composite rate, a daily rate, the actual cost, or a combination. Even so, federally funded Government Healthcare Programs such as Medicare Part A, Medicaid inpatient, and TRICARE inpatient benefit are damaged when they pay for pharmaceuticals that have been paid for in violation of the FCA.

43. Under the Medicare Act, 42 U.S.C. § 1395y(a)(1)(A), there is an express fundamental condition of payment: "no payment may be made [under the Medicare statute] for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury." This condition links each Medicare payment to the requirement that the particular item or service be "reasonable and necessary." Medicaid, TRICARE and other federally funded programs restrict coverage under the same principle.

44. Hospitals and other inpatient facilities participating in the Medicare, Medicaid and other federally funded Government Healthcare programs are required to file annual cost reports with the appropriate agencies. When a provider submits a Medicaid cost report which includes requests for payment for pharmaceuticals that were not reasonable and necessary, the claims for those expenses are legally false.

VII. THE FOOD, DRUG AND COSMETIC ACT AND ITS POST MARKETING SAFETY REPORTING REGULATIONS

45. The Food and Drug Administration ("FDA") is the agency responsible for protecting the health and safety of the American public by ensuring, among other things, that pharmaceuticals designed for use in humans are safe and effective for their intended uses and are labeled accurately and in compliance with the law. Toward this end, FDA, pursuant to its statutory mandate, regulates and monitors the approval, manufacture, processing, packing, labeling, and shipment in interstate commerce of pharmaceuticals.

46. To ensure that consumers are receiving safe and effective drugs, Congress through various amendments enacted the Food, Drug, and Cosmetic Act, which requires that a drug manufacturer secure approval of a New Drug Application from the FDA before it may commercially market the drug. 21 U.S.C. §355(a). To obtain such approval, the manufacturer must undertake to conduct and submit the results of investigations in animals and humans that demonstrate that the drug is safe and effective for its intended uses and other information pertinent to an evaluation of the safety and effectiveness of the drug. 21 U.S.C. §355; see also 21 C.F.R. §314.50 (detailing contents of NDA). According to the statutory scheme, the FDA evaluates the safety and effectiveness of the drug and approves the directions for use and cautionary information in the labeling for the drug on the basis of the information supplied to it by the manufacturer. The FDA does not conduct its own tests of the drug. It relies on the manufacturer to inform it of adverse reaction reports. Thus, the FDA's ability to·evaluate a drug's safety and efficacy and to protect the public adequately depends on the manufacturer's reports of timely, accurate and complete data to the FDA.

47. After the drug has been approved for commercial marketing, the FDCA and applicable regulations require the manufacturer to establish and maintain such records and make

such reports as will enable the FDA to continue to evaluate the safety and effectiveness of the drug and, when appropriate, withdraw the New Drug Application or change the labeling. 21 U.S.C. §355(k).

48. To implement Congress' mandate, the FDA promulgated 21 C.F.R. §314.80 and 314.81, which require expedited and accurate reports of postmarketing adverse drug experiences ("ADE") by drug manufacturers. The manufacturer must report information pertinent to the safety and effectiveness of the drug, from any source, including unpublished reports of clinical experience not previously submitted to the FDA. The regulations require the manufacturer to report within 15 days any unexpected side effects and injuries associated with the drug. The manufacturer must report all other adverse reactions to the FDA in quarterly periodic reports during the first three years following approval, and then thereafter at annual intervals. 21 C.F.R. §314.80(c)(2).

49. These FDA regulations provide that drug manufacturers "shall promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigation, postmarketing epidemiological/surveillance studies, reports in the scientific literature and unpublished scientific papers." 21 C.F.R. §314.80(b). The regulations go on to provide that "any person subject to the reporting requirements . . . shall also develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA." 21 C.F.R. §314.80(b).

50. An "adverse experience" is defined as "any undesirable event that is associated with the use of a drug or biological product in humans whether or not considered product-related by the [manufacturer]." A serious adverse event is defined by the FDA and Takeda's own Standard Operating Procedure (SOP) as: … any untoward medical occurrence that at any dose:

> 1) results in death.
> 2) is life-threatening,
> Note: The term "life-threatening" in the definition of "serious" refers to an event in which the patient was at risk of **death** at the time of the event; it does not refer to an event which hypothetically **might** have caused death if it were more severe.
> 3) requires inpatient hospitalization or prolongation of present hospitalization,
> 4) results in persistent or significant disability/incapacity,
> 5) leads to a congenital anomaly/birth defect;
> 6) may require intervention to prevent one of *1-5* above or may expose the patient to danger, even though the event is not immediately life-threatening or fatal or does not result in hospitalisation, and includes any event or synonym described in the Takeda Medically Significant List… (Refer to Attachment 2.)"
> Note: The term "severe" is often used to describe the intensity (severity) of a specific event (as in mild, moderate or severe myocardial infarction); the event itself however, may be of relatively minor medical significance (such as severe headache). It is not the same as "serious," which is based on patient/event outcome or action criteria usually associated with events that pose a threat to a patient's life or functioning. Seriousness (not severity) serves as a guide for defining regulatory reporting obligations.

51. Per Takeda's and the FDA's definitions above, events that require medical intervention to prevent death, hospitalization, disability or incapacity are considered serious. CHF requires medical intervention, whether mild, moderate or severe, to prevent the condition from progressing to death or its being life threatening or requiring hospitalization, therefore it is a serious adverse event. This makes sense—the heart is a vital organ and its untreated failure rapidly progresses through its becoming life threatening, requiring hospitalization and eventually death. "Clinical Guidelines for the Management of CHF" by The American College of Cardiology/American Heart Association Task Force on Practice Guidelines directs physicians to "intervene" with Angiotensin Converting Enzyme (ACE) inhibitors and Angiotensin Receptor Blockers (ARB) for all forms of CHF, even the mildest versions. Likewise, "Drug Therapy Recommendations from the 2005 ACC/AHA Guidelines for Treatment of Chronic Heart Failure," by Patricia A. Howard, et al., 10/06/2006, The Annals of Pharmacotherapy, 2006; 40(9):1607-1617, at Table 1, lists the medical therapies, including ACE inhibitors and ARBs, for treating all stages of heart failure development.

52. As discussed in the "Note" section from Takeda's SOP in paragraph 48 above, conflating the regulatory definition of "serious" and "severe" can lead to confusion. Despite what its own SOP says, Takeda has taken advantage of that confusion by deeming "non-hospitalized" CHF (i.e., may not in end stage of CHF) as "not serious," when in fact CHF requires treatment, whether hospitalized or not, to reduce death, hospitalization, disability or incapacity even if not hospitalized. Any harm to the heart "poses a threat to a patient's life or functioning," hence any severity level of CHF is serious.

53. The FDA in its regulations (21 C.F.R. §314.80(b)) and in its Guidance Documents has classified four types of adverse experiences which trigger different reporting requirements. The four categories include:

- **Serious and Unexpected**: these include serious adverse experiences which are not provided for in the label. Serious adverse events include death, life threatening adverse experiences, hospitalization, significant persistent disability/ incapacity, and important medical events based upon appropriate medical judgment that may jeopardize the patient and may require medical or surgical intervention. Such events must be reported to the FDA within 15 days of initial receipt of the adverse event. 21 C.F.R. §314.80(b)(1).
- **Serious and Expected**: these include serious adverse experiences that are listed in the current label. For example, if the warning section of the label warns that the drug can cause suicide and a patient commits suicide, this would be classified as a serious and expected adverse experience which must be reported to the FDA in the manufacturer's quarterly and/or annual safety reports.
- **Non-serious and Unexpected**: these include non-serious adverse experiences that are not provided for in the label. For example, if a patient suffers from dry-mouth

as a result of taking a drug, and the label of the drug does not warn about the risk of dry-mouth, then this would constitute a non-serious and unexpected adverse experience which must be reported to the FDA in the manufacturer's quarterly and/or annual safety reports.

- **Non-serious and Expected**: these include non-serious adverse experiences that are already in the label. For example, if a patient develops dry-mouth after taking the drug and the label of the drug warns of the risk of dry mouth, then this would constitute a non-serious and expected adverse event. While non-serious and expected adverse events are to be reported to the FDA in the manufacturer's quarterly and/or annual safety reports, they are *not* listed out in detail in the periodic reports and, in fact, the FDA encourages manufacturers to obtain waivers from having to submit the individual case safety reports for non-serious expected adverse experiences.

54. A manufacturer's failure to comply with the FDCA reporting obligation constitutes a "prohibited act" under the FDCA which subjects the manufacturer to various civil and criminal penalties, including but not limited to withdrawal of the approval of the NDA (i.e., prohibiting the continued marketing of the drug), injunctive orders, monetary fines and up to one year imprisonment. *See* 21 U.S.C § 331(e); 21 U.S.C § 332(a); 21 U.S.C § 333(a)(1); 21 U.S.C. §355(e); and 21 C.F.R.§314.80(j).

VIII. SUBSTANTIVE ALLEGATIONS

55. There are serious health risks associated with prescription drugs whose sponsors fail to abide by the FDA's ADE reporting requirements. This risk becomes even more poignant when taking into account the fact that approximately eighty percent of drug spending in

Government Healthcare Programs is for elderly and disabled enrollees, who have extensive health care needs.

56. In addition, any patient who has taken an unsafe and/or ineffective drug is likely to require additional laboratory tests and physician visits, thereby causing additional unnecessary increased costs to Government Healthcare Programs.

57. In order to dominate the diabetes drug market, to increase the sales of Actos and to facilitate the continued reimbursement from Government Healthcare Programs for claims made by providers for Actos, Takeda misrepresented and/or concealed material facts regarding adverse events attributable to Actos.

58. Takeda disregarded its duty to deal honestly with the Government and with knowledge that its concealment and intentional misrepresentations would result in hundreds of millions, and perhaps billions of dollars in damage to Government Healthcare Programs.

59. On May 21, 2007, the *New England Journal of Medicine* published an online study which found a 43% increase in risk of acute myocardial infarction (AMI) and a 64% increase in risk of cardiovascular death with patients who had been prescribed Avandia (a diabetes drug manufactured by GSK that is in the same class as Actos). See Steven E. Nissen, *Effects of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes*, 356 N. ENG. J. MED. 2457-71 (2007) ("Nissen Study").

60. On May 23, 2007, following publication of the Nissen Study, the FDA ordered all TZD manufacturers, including GSK (for Avandia related products) and Takeda (for Actos related products) to add a stronger warning about the risk of Congestive Heart Failure, a condition that occurs when the heart does not adequately pump blood. The new warnings were included in the form of a "boxed" warning — FDA's strongest form of a warning. 21 C.F.R.

§201.57(c)(1). The upgraded warning emphasized that the drugs may cause or worsen heart failure in certain patients. Specifically, the 2007 Boxed Warning Provides:

WARNING: CONGESTIVE HEART FAILURE

- Thiazolidinediones, including ACTOS, cause or exacerbate congestive heart failure in some patients (see WARNINGS). After initiation of ACTOS, and after dose increases, observe patients carefully for signs and symptoms of heart failure (including excessive, rapid weight gain, dyspnea, and/or edema). If these signs and symptoms develop, the heart failure should be managed according to the current standards of care. Furthermore, discontinuation or dose reduction of ACTOS must be considered.

- ACTOS is not recommended in patients with symptomatic heart failure. Initiation of ACTOS in patients with established NYHA Class III or IV heart failure is contraindicated (see CONTRAINDICATIONS and WARNINGS).

61. In an August 2007 Press Release regarding the Black Box Warning, the FDA stated that it had asked the drugs' manufacturers, GlaxoSmithKline and Takeda, to address the safety concerns related to heart failure. In the same press release, FDA directors also noted that "Under FDA's postmarketing surveillance program, we carefully monitor new safety information for marketed drugs and take appropriate action when necessary to inform patients and health care providers of new information."

62. Because the majority of the risk data, including the Nissen Study, focused on Avandia, the FDA began to work with GSK, the manufacturer of Avandia, to conduct further studies to examine cardiovascular risks.

63. The cardiovascular safety concerns raised about Avandia, including the implementation of the class wide Congestive Heart Failure Boxed warning, prompted Takeda to position its drug, Actos, as the safer alternative to Avandia and try to capture a larger share of the diabetes drug market. Notably, after the implementation of the FDA's 2007 class-wide Congestive Heart Failure black-box warning as well as the negative publicity surrounding Avandia, Takeda implemented a nationwide advertising campaign to promote the purported

safety of Actos. In November 2007, Takeda began to run print advertising in 82 major market newspapers and national publications such as Time and Newsweek, advising readers with type 2 diabetes that "Actos has been shown to lower blood sugar without increasing your risk of having a heart attack or stroke."

64. Upon information and belief, Takeda stated that it wanted to inform patients afraid of treatment due to the cloud over Avandia, that not all oral diabetes drugs are alike when it comes to heart risks. Shay Weisbrich, a general manager at Takeda, publicly stated: "A lot of patients on oral anti-diabetes drugs seemingly left the market over the last six months... The confusion goes way beyond TZDs to all classes of drugs. This is a very unusual step for us, but we felt compelled to reach out to patients directly with a message of clarity and get them to talk to their physicians." In addition, Takeda also supplied physicians with sales aids in an attempt to advertise Actos as being safe and free of any cardiovascular risks.

65. To make Actos appear as the safer alternative, Takeda instigated a policy where it instructed its employees to classify most Congestive Heart Failure adverse events as non-serious. Takeda knew reporting non-hospitalized Congestive Heart Failure events as serious would trigger more prominent reporting requirements and would have caused the events to be listed in the FDA's safety database (AERS). Instead, Takeda instructed its employees to *only* report Congestive Heart Failure cases involving *hospitalization or fatality* as a serious adverse event.

66. Notably, prior to the implementation of the Boxed Warning, Takeda was reporting all Congestive Heart Failure events (including hospitalized and non-hospitalized cases) as serious events. However, following the implementation of the Boxed Warning and realizing the negative publicity surrounding the cardiovascular risks associated with Avandia, Takeda made a decision to report only hospitalized or fatal Congestive Heart Failure events as serious events, thus substantially reducing the number of serious Congestive Heart Failure events

reported for Actos. Furthermore, by not reporting all Congestive Heart Failure cases as serious events, Actos avoided the additional responsibility of highlighting these adverse events in its FDA reports and further avoided the responsibility of having to analyze the frequency and reporting rate of these adverse events. Moreover, because the FDA's public safety database (AERS) only captures "serious" adverse events, these non-reported serious Congestive Heart Failure events were never entered into the FDA's public safety database. Simply put, by fraudulently classifying the Congestive Heart Failure cases as non-serious, Takeda was able to reduce and eliminate its reporting and analysis obligation and was able to publicly make Actos appear much safer than it really was. Unlike Takeda, GSK, the manufacturer of Avandia, has been reporting non-hospitalized cases of Congestive Heart Failure as "serious" adverse events.

67. Congestive Heart Failure is listed as a Boxed Warning in the Actos label. Pursuant to FDA Regulations, a Boxed Warning is reserved for the most serious of adverse events. Specifically, the regulations provide that "[c]ertain contraindications or serious warnings, particularly those that may lead to death or serious injury, may be required by the FDA to be presented in a box." By requiring a boxed warning for Congestive Heart Failure, the FDA had made a determination that all Congestive Heart Failure cases are "serious" adverse events and Takeda had a corresponding duty to report all Congestive Heart Failure events as serious events.

68. In addition, the U.S. National Library of Medicine and the National Institutes of Health define Congestive Heart Failure as serious:

> Heart failure, also called congestive heart failure, is a condition in which the heart can no longer pump enough blood to the rest of the body...Heart failure is a *serious* disorder. It is usually a chronic illness, which may get worse with infection or other physical stress.
> (http://www.nlm.nih.gov/medlineplus/ency/article/000158.htm)
> (emphasis added)

69. Moreover, respected national and international medical organizations, including the Council for International Organizations of Medical Sciences (CIOMS), which publishes pharmacovigilance guidelines to which numerous pharmaceutical companies adhere, has concluded that Congestive Heart Failure should "always be considered 'serious'" and should be reported as a serious adverse event in periodic reports. *See* 2001 Report of CIOMS Working Group V at 191-194.

70. Many other consumer sources on which doctors rely define Congestive Heart Failure as either "serious" or "severe":

> Drugs.com: Seek medical attention right away if any of these SEVERE side effects occur when using Actos: ...symptoms of *[congestive] heart failure* (eg, shortness of breath; sudden unexplained weight gain;
> (http://www.drugs.com/sfx/actos-side-effects.html)
>
> WebMD.com: [Congestive] Heart Failure listed as "Severe" side effect.
> (http://www.webmd.com/drugs/drug-17410-actos.aspx?drugid=17410&drugname=actos&source=1&pagenumber=6)

71. In addition, Takeda North America has consistently defined Congestive Heart Failure, in public forums, as a serious event:

> Takeda Pharmaceuticals North America, Inc. (TPNA) today announced that the company will revise warnings related to congestive heart failure (CHF) in the prescribing label of its type 2 diabetes medication ACTOS(R) (pioglitazone HCl). Takeda is working in conjunction with a request from the U.S. Food and Drug Administration (FDA) that a Boxed Warning be added to the label. The new Boxed Warning will heighten awareness of the risk of CHF.
>
> "By giving the CHF guidance more prominence in the ACTOS label, we hope to ensure that this information is being attended to by treating physicians to optimize patient care," said Robert Spanheimer, M.D., senior medical director, Diabetes and Metabolism, Takeda Pharmaceuticals North America. "Takeda remains confident in the safety and efficacy of ACTOS when used according to its label, and with this revision, we can heighten

> patient and physician awareness of an already known, but *serious* side effect." (June 2007) (emphasis added). (http://www.medicalnewstoday.com/articles/73375.php)

Takeda's failure to accurately report its Congestive Heart Failure adverse events as serious adverse events was a violation of its obligations under the FDCA and FDA regulations. 21 C.F.R. §314.80 and 21 U.S.C. §355(k).

72. Relator Dr. Ge was assigned the task of reviewing post-marketing adverse event reports for Actos. During her review of adverse events, she classified Congestive Heart Failure cases as "serious" adverse events. Her Takeda colleagues and manager at Takeda, including Mike Zabrinas, R.N., Miche Hisada, M.D., Maria Paris, M.D. and Michelle Peralta, R.N., however, instructed her to alter her classification because, according to them, Takeda had a blanket policy of not classifying non-hospitalized Congestive Heart Failure cases as serious.

73. Such a blanket policy of not counting non-hospitalization cases as "serious" events violates a manufacturer's pharmacovigilance obligations and further violates FDA regulations, which specifically provide that: "[i]mportant medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in the definition." 21 C.F.R. §314.80(a) (definition of serious adverse drug experience).

74. During the first week of January 2009, Relator triaged a Congestive Heart Failure case reported from Actos as serious and labeled. A few hours later, Mike Zabinas, a specialist, came to her office and stated that Takeda had an internal policy to assess Congestive Heart Failure as a non-serious and labeled event. Relator replied, in effect "Are you kidding me? Congestive Heart Failure is in the black boxed warning section, how could Takeda assess this event as non-serious?" Mr. Zabinas thereafter said that he knew that Relator was correct but it was Takeda's policy to assess Congestive Heart Failure as non-serious.

75. A couple of hours later, Michie Hisada, MD, a Medical Director at Takeda, went to Relator's office and stated that Relator's assessment for the Congestive Heart Failure adverse event report was changed from serious to non-serious because Takeda's internal policy is to label Congestive Heart Failure events as non-serious unless the patient is hospitalized.

76. Upon learning of Takeda's blanket policy to report all Congestive Heart Failure adverse events as non-serious unless hospitalized, Relator, on January 9, 2009, sent an email to Janet Johnston, R.N., and Neila Smith, M.D, stating Relator's opinion that Takeda was under-reporting Congestive Heart Failure as a serious event. In the email, Relator stressed the importance of properly reporting Congestive Heart Failure adverse events to the FDA so that the government could monitor the frequency of the reporting rate of such events, especially given Actos' boxed warning. Neila Smith, M.D., a Senior Medical Director, responded by assuring Relator that her concerns would be discussed at the next staff meeting; however, contrary to Dr. Smith's assurances, these issues were never addressed at the staff meeting. Nurse Johnston, the Associate Director of Operations, responded by assuring Relator that all the Congestive Heart Failure cases would be reported to the FDA in the next periodic report. Relator never saw any evidence that these events were reported in subsequent periodic reports and, upon information and belief, alleges that Takeda continued to conceal these reports from the FDA and continues to improperly classify them as "non-serious" events.

77. While at Takeda, Relator reviewed all of the Congestive Heart Failure events listed in Takeda's safety database (known as ARISg). Prior to the 2007 implementation of the black-box warning, Takeda had classified virtually all Congestive Heart Failure adverse events as serious; however, after the implementation of the black-box warning, the majority of the Congestive Heart Failure adverse events were being classified as non-serious. Since 2007,

Takeda has falsely classified several hundred Congestive Heart Failure cases as "non-serious" -- when they should have been classified and reported as "serious."

78. During the Summer of 2009, Relator received several Congestive Heart Failure adverse event reports that were reported as "life threatening." Takeda had initially assessed these "life threatening" CHF cases as serious and *labeled/expected* events. Relator had refused to sign off on these assessments after her medical review of the cases. She returned the cases to the Takeda specialist and requested the upgraded classification of serious and *unlabeled/ unexpected*, and triggering a 15 day report to the FDA. Shortly thereafter, Elizabeth Fletcher, a manager of specialist group, complained to Relator's boss, Neila Smith, M.D., about the assessments. Dr. Smith then asked Relator to bring these cases to her office for further review.

79. Dr. Smith asked why Relator considered these cases to be unlabeled events and Relator explained to her that, per FDA's guidance, if the severity of an event was not written in the package insert, then it should be reported as an unlabeled event. See 21 C.F.R. §314.80(a) (definition of "Unexpected adverse drug experience"). Relator further stated that, because "life threatening" and "death" were not written in the package insert for Actos, both types of events should be assessed and reported as *unlabeled/unexpected*. Dr. Smith replied that it is Takeda's rule not to report life-threatening events as unlabeled, but rather, only death is reported as unlabeled, so no 15-day reports to the FDA would be allowed to be generated concerning these types of cases. In order to protect herself from any future audits, Relator inserted a note in the ARISg database (Takeda's safety database) that she was instructed by Dr. Smith to assess these *life threatening* CHF events as labeled/expected events.

80. On January 12, 2010, the Vice President of Takeda's Pharmacovigilance Department, Dr. Paris, informed Takeda employees that an FDA auditor had informed Takeda that they could report non-hospitalized Congestive Heart Failure as Non-serious adverse events.

Dr. Paris went on to remark: "As a company, reporting adverse event is one thing, but we must make sure that the company has to be profitable first."

81. Following a diligent search, and upon information and belief, there is no publicly available evidence supporting Takeda's contention that an FDA auditor had permitted Takeda to report Congestive Heart Failure events as non-serious nor would such a remark by an FDA auditor be consistent with the FDA's goals and policies of ensuring patient safety and its policy of adequately monitoring serious safety risks (i.e., risks serious enough to have a boxed warning). Upon information and belief, Relator alleges that an FDA auditor lacks the authority to make such a policy decision and does not have the authority to alter FDA Regulations. Moreover, during the two-week period that the FDA auditor was at Takeda, Relator observed that the auditor ate lavish meals, lunches, drinks and desserts that Takeda had provided for him. With the exception of the FDA auditor at Takeda, during her entire professional career, Relator had never before seen an FDA auditor accept any meals while conducting an audit.

82. Unlike Takeda, GSK, the manufacturer of Avandia, has been reporting non-hospitalized cases of Congestive Heart Failure as "serious" adverse events. Per GSK's Periodic Adverse Event Reports and other governmental submissions, not only has GSK been reporting all Congestive Heart Failure cases as serious (including non-hospitalized cases), GSK has also been reporting all non-hospitalized Congestive Heart Failure symptom related events, including all fluid retention related events such as macular edema, macular degeneration, cardiomyopathy, pulmonary edema, pleural effusion, and pulmonary hypertension as "serious" events. Unlike GSK, Takeda has been classifying similar events as "non serious."

83. On January 14, 2010, there were three Congestive Heart Failure cases reported from one doctor's office in Texas. In the pharmacovigilance area, this is a strong signal of the drug's risk and is commonly referred to as a "cluster report." Cluster reports provide a warning

to the drug company and immediate action is required according to industry pharmacovigilance guidelines. Takeda instructed its employees to assess these three events as non-serious in order to downplay the risks reported to the FDA. Dr. Ge returned these cases back to the Takeda specialists and requested that the events be upgraded to serious after her medical review of the events was performed. Shortly thereafter, Michelle Peralta, a Takeda manager, visited Dr. Ge's office and stated to her that the top management of the company had an emergency meeting on this issue, and that Takeda North America was fighting with the European Medicines Agency ("EMEA") (Europe's equivalent of the FDA) to down-grade CHF as non-serious. She also stated to Dr. Ge, that Dr. Ge gets paid to sign off on Actos' adverse events and if Dr. Ge did not feel comfortable with signing off on these adverse events, then she would ask another Takeda employee, Anton T. to sign off on them.

84. Relator complained to her superiors, including Gregory Fusco, M.D., Janet Johnston, R.N., Niela Smith, M.D. and Maria Paris, M.D., that her medical assessments were being downgraded from "serious" to "non serious" and that, as a result of this, the Congestive Heart Failure events were being under reported to the FDA. After raising these safety issues with her superiors, Relator's contract was summarily terminated by Takeda on January 15, 2010 and she was instructed to return her office key and badge to the company.

IX. VIOLATIONS OF THE ADVERSE EVENT REPORTING REQUIREMENTS

85. Takeda has submitted false statements and records in connection with the Adverse Events reporting requirements for its drug Actos. These false statements and records were made by Takeda to the FDA and caused false claims to be made to Government Healthcare Programs.

86. Takeda suppressed knowledge of, and failed to submit full and complete Periodic Adverse Drug Experience Reports to the FDA, which would have shown that there were increased risks from Actos associated with Congestive Heart Failure. Such conduct by Takeda

deviated from the duties and conduct of a responsible pharmaceutical manufacturer and demonstrated a failure to ensure its own minimal compliance with requirements of the Federal Food Drug and Cosmetic Act.

87. During the previous three years, it is unknown how many patients suffered from Congestive Heart Failure after receiving Actos. Multiple Congestive Heart Failure adverse events, however, were purposefully not properly reported to the FDA.

88. Takeda was required to submit "Periodic Adverse Drug Experience Reports." It was required to submit each adverse drug experience not reported under paragraph (c)(1)(I) of section 314.80 at quarterly intervals, for three years from the date of approval of the Actos NDA, and then at annual intervals.

89. Takeda submitted false "Periodic Adverse Drug Experience Reports" to the FDA. Takeda did so because it failed to include numerous Congestive Heart Failure adverse events as serious adverse events. Takeda used these false "Periodic Adverse Drug Experience Reports" to get false claims paid in violation of the False Claims Act, to wit, claims for Takeda submitted to Government Healthcare Programs which would otherwise not have been paid or approved.

X. TAKEDA'S FRAUD CAUSED THE GOVERNMENT TO PAY FOR MORE ACTOS PRESCRIPTIONS THAN IT OTHERWISE WOULD HAVE

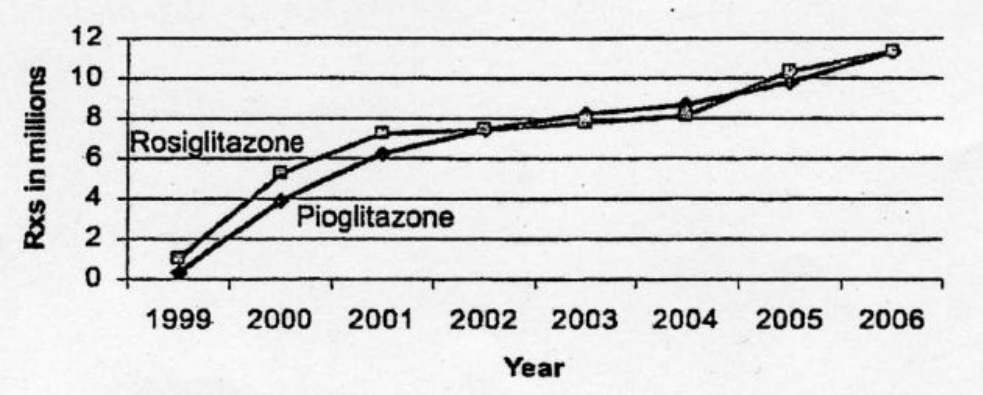
90. Takeda, by suppressing and fraudulently concealing the above described adverse events, and also by disseminating false information to physicians and the public about the safety and efficacy of Actos, caused physicians and other health care providers to prescribe Actos and submit claims for Actos in violation of the False Claims Act, when they otherwise would not have prescribed Actos for their patients.

91. Applicable laws and regulations, including §314.80(j), provide that, if an applicant such as Takeda "fails to establish and maintain records and make reports required

under this section, FDA may withdraw approval of the application and, thus, prohibit continued marketing of the drug product that is the subject of the application." Takeda failed to submit accurate and truthful reports as required by the FDA regulations. Had Takeda not submitted false reports or records to the FDA, the FDA would have either withdrawn approval of Actos, or would not have recommended Actos as the safer alternative to Avandia, which at minimum, would have resulted in far fewer submissions of claims for Actos to Government Healthcare Programs.

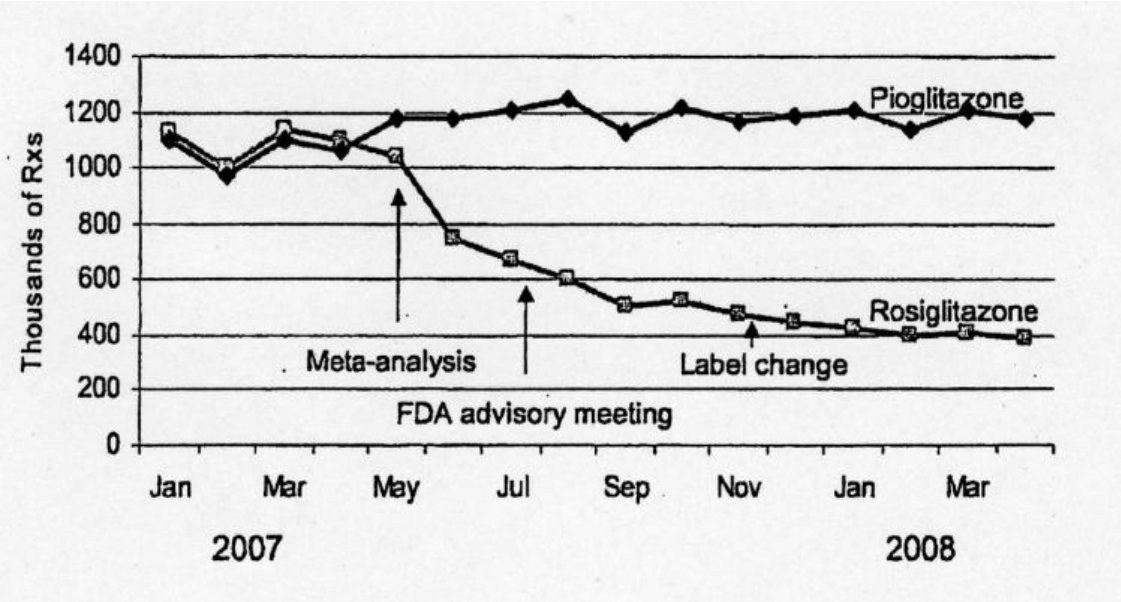
92. But for Takeda's fraud, Government health care programs would have paid far fewer Actos claims. But for the fraud on the FDA, physicians would have prescribed Actos substantially less than they did, and patients would have used Actos substantially less than they did, if at all.

93. Both Actos and Avandia were marketed in the United States beginning in 1999. Between the start of marketing and 2006, annual prescription use of each was very similar, as indicated in the chart below:



94. In 2007, prescriptions for Avandia began to fall following publication of a meta-analysis of Avandia clinical trials by Nissen, et al. in May 2007. Since May 2007 through April 2008, use of Avandia has declined approximately 65% while use of Actos has remained steady due to Takeda's failure to label and report Congestive Heart Failure adverse events as serious.

During this time, Takeda was billed as the "safer alternative" to Avandia by the FDA and, thereafter, prescribing doctors. See David J. Graham, *Benefit-risk Assessment of Rosiglitazone vs. Pioglitazone*, Report to FDA, Division of Metabolism and Endocrinology Products (October 2008) ("Graham Report").



95. Takeda continues to paint a favorable picture of Actos by falsifying post-marketing submissions to the FDA concerning Congestive Heart Failure adverse events while Avandia's post marketing adverse event reports are being closely monitored. As expected, Actos sales have soared as the pressure to take Avandia off the market has increased. In January 2010, the United States Senate Finance Committee released its Staff Report On GlaxosmithKline And The Diabetes Drug Avandia ("Senate Finance Report"). The Senate Finance Report concluded that GSK "focused on strategies to minimize findings that Avandia may increase cardiovascular risk" and that "[s]uch an environment requires diligent oversight by the FDA to protect the citizens of this country and to ensure the safety of American medicine." Senate Finance Report, p.15.

96. The overwhelming negative press coupled with the false information on Actos, is fraudulently causing even more doctors, who have been actively deprived of the truth concerning the frequency of Congestive Heart Failure associated with Actos' use, to be misled and prescribe Actos as the "safer alternative" to Avandia.

XI. TAKEDA'S CULTURE OF FRAUD

97. Upon information and belief, Relator alleges that the corporate culture at Takeda is riddled with systemic fraud and deceit with motivation to falsely report and under report not only serious Congestive Heart Failure events, but other serious side effects experienced by people taking Actos, driven by an economic desire to falsely enhance Actos' safety profile and to increase sales. For example:

- **Bladder and Other Actos Related Cancers**

98. Dr. Ge has direct knowledge by observation and experience of Takeda's publicly denying the causal relationship between the Bladder cancer and Actos even though Takeda knew otherwise as far back as the 90's when Actos was tested in animals and bladder cancer was detected. While working at Takeda, Dr. Ge had reviewed at least 10 bladder cancer cases reported from Yale University where the Actos Post Marketing Commitment bladder cancer study had been ongoing. The Yale study had enrolled more than 40 patients who were diagnosed with bladder cancer while taking Actos. She reviewed each bladder cancer case in Takeda's ARISg database and saw that they were all reported as related to Actos by the Yale clinical investigator, including one patient who was on Actos for 6-7 weeks that was the subject of a dispute which arose when Dr. Ge attempted to report it as an Actos related adverse event, but her superiors and Takeda-Japan resisted and directed her to change her assessment. To support her contention that the bladder cancer was related, Dr. Ge investigated the Actos NDA and Takeda's ARISg database. Per her recollection, there were more than 100 bladder cancers reported in

Takeda's ARISg database, but only 72 found in AERS—that is a serious discrepancy, likely the result of bladder cancer events getting classified as "not-related" by Takeda personnel other than by Dr.Ge. The Actos bladder cancer issue did get some limited FDA attention in late 2005 and early 2006 after the PROactive study result was published in both EU and US. Upon information and belief, Takeda executives and personnel had many internal discussions on how to defend Actos' market share against the impact of the bladder cancer findings, an outcome of which may have been to deflect attention to Avandia's cardiovascular problems.

99. Dr. Ge analyzed the FDA's Adverse Event Reporting System (AERS) for adverse event reported by patients taking Actos and Avandia. From 1999 up to the most current 2010 data, there were 1,813 Actos-related cancers reported to AERS. Of the 1,813 cancers reported to AERS, 161 were Pancreatic Cancers, 72 Bladder Cancers, 102 Breast Cancers, 61 Biliary Cancers, 70 GI Cancers, 104 Hematologic Cancers (47 leukemia, 57 Multiple Myeloma), 94 Lung cancers, 107 Lymphomas, 110 Renal Cancers, and the remaining cancers were reported from every organ system with cluster patterns in all kinds of cancers. Besides these 1,813 cancers, there were 31 Aplastic Anemias and 32 Myelodysplastic Syndromes also reported in cluster patterns. Most of these cancers were reported within one year after taking Actos, especially those hematologic cancers and neoplasms from every body system organ.

100. Takeda has been publicly denying that Actos is causally related to those cancers and has not been updating or revising the Actos label to warn the public pursuant its obligations under 21 CFR 201.57(c)(6)(i) since Actos was marketed in 1999.

101. Carcinogenesis from Actos was discovered during the initial Actos animal studies. As the Actos NDA package indicates, Pharmacology Review, there was a special discussion on neoplastic lesions: "Various tissues of control and treated groups had usual types of mouse tumors. Peto analysis of neoplastic lesions present in this study revealed 2 tumor types

that were significant ($P < 0.05$)." "In mouse lymphoma assays, metabolite M-I produced a positive response in the presence of metabolic activation and an equivocal response…" After Actos was marketed for human use, thousands of cancers/neoplasms were reported regarding every organ system in a cluster pattern with patients who took Actos. The hundreds of lymphomas of all types reported by patients showed a pattern similar to that shown in the Actos mouse studies.

102. A January 2003 Southern Medical Journal article entitled "Thiazolidinediones: A Review of Their Benefits and Risks" by Fernando Ovalle, MD, J. Fernando Ovalle-Berúmen, MD also observed, as a class risk, neoplastic potential based on animal studies that showed "TZDs may induce the formation of lipomas, benign and/or malignant urinary bladder (transitional cell) tumors, vascular tumors…and the growth of uterine leiomyomas."

103. These carcinogenesis findings were further confirmed in humans during the phase III clinical trials. According to the Actos NDA Medical Review section, there were three patients reported having cancers from Japanese and European trials while taking Actos. One died from Gall Bladder Carcinoma, one died from hepatic duct carcinoma, and another discontinued the study due to Pancreatic Carcinoma. There was one additional patient reported with bladder cancer and fourteen patients reported to have category C3 cytology in their urine from US trials. (Cytology is a study of cells to diagnose cancer. C3 is probably benign with suspicion of malignancy, and C4 is malignancy. Some authors believe that C3 and C4 should be categorized in the same group).

The Pharmacology Review in Actos' NDA states:

> Currently, the relevance of these tumors in male rats to humans is unclear. The label is modified to reflect this. Note: the committee's summary of tumor findings was as follows:
>
> Mice: no significant tumor findings
> Rats: benign/and/or malignant transitional tumors in the urinary bladder in <u>all dose-</u>

groups of the males except the lower dose. These were statistically significant by the trend tests.

104. These animal findings clearly indicated the causal relationship between Actos and bladder cancer. However, in order to reduce the number of bladder cancers reported from the Actos clinical trials and thereby enable the company to create a better safety profile for regulatory approval, Takeda amended the patient enrollment criteria in the middle of the phase III trials and added the urine cytology test as an exclusion criteria. Urine cytology tests were not amongst the exclusion criteria for the earlier Study PNFP 001. In later trials, if a patient had a positive urine cytology test, then that patient would be excluded from entering the clinical study. However, once Takeda received Actos marketing approval in July 1999, recommending urine cytology tests was never included in the package insert to warn patients of the risk of getting bladder cancer while on Actos in the absence of such testing.

105. After the FDA approved Actos for marketing in the US, Takeda received an average of more than 180 cancer reports each year (1,813 over 10 years) from spontaneous sources, but Takeda never included these cancer reports in the label, and never issued a Dear Doctor's letter in the last 10 years as required by 21 CFR 200.5 to warn the medical community of the risk of getting cancer while taking Actos. Most notably, during the first three quarters of 2010, Takeda received 21 reports of multiple myeloma, alone, among other cancers reported from domestic sources, but Takeda did not change the Actos label to address these cancers. Pursuant to 21 CFR 201.57(c)(7)(B), prescription drug labeling requirements, postmarketing experience, "This section of the labeling must list the adverse reactions, as defined in paragraph (c) (7) of this section, that are identified from domestic and foreign spontaneous reports. This list must be separate from the listing of adverse reactions identified in clinical trials."

106. In late 2005, Takeda presented results from its first post-marketing study, the PROactive trial, at the European Endocrinology Annual Meeting. In the PROactive trial, there

were 16 bladder cancers reported from patients given Actos, which was four times higher than those who received other drugs. Consequently, in 2006, Takeda was required by the FDA to include bladder cancers reported from the PROactive study in the Actos label. The FDA directed that, if Takeda were to issue a Dear Doctor Letter to warn medical professionals of the bladder cancer risk, a copy of the letter ought to be sent to the NDA. Takeda never issued a Dear Doctor Letter to the medical community regarding the risk of bladder cancer and only added a clause to the label that 16 bladder cancers were reported from the PROactive study, while denying the causality associated with administration of Actos. In the most recent January 2011 label revision, Takeda continued to deny causality between bladder cancer and Actos using the same wording that was in the original label published in 1999: "Drug-induced tumors were not observed in any organ except for the urinary bladder. Benign and/or malignant transitional cell neoplasm were observed in male rats at 4 mg/kg/day and above (approximately equal to the maximum recommended human dose based on mg/m^2)." At the time of this latest label revision, Takeda had received more than 1,800 cancer/neoplasm reports from patients who had been taking Actos.

107. Recently, Diabetes Care (April 22, 2011) published an analysis of the FDA's AERS and found that one fifth of the 138 bladder cancer reports for all drugs submitted between 2004 and 2009 were regarding patients taking Actos. According to the study author, Dr. Elisabeta Poluzzi, this indicates a disproportionate risk of bladder cancer for patients taking Actos, warranting additional investigation. This corroborates Dr. Ge's own analysis of the AERS and her attempts to get Takeda to properly report bladder cancer adverse events as Actos-related.

108. "Disproportionate risk" analysis, as discussed in the Poluzzi study, is used as a method to detect signals for causality assessments regarding spontaneous reports. ALL of the

cancers reported from Actos in the AERS as Dr. Ge has detailed herein were disproportionally higher than the background rate to a very substantial degree. The key issue on these spontaneously reported Actos cancers is that, because cancer was reported in both Actos animal studies and human clinical trials, Takeda has had the legal obligation to update its Actos label ever since it received the first post-marketing spontaneous cancer report in 1999. (See 21 CFR 201.57(c)(7)(B).) Also, having used cytology testing during their Phase III clinical trials to exclude persons at risk for developing bladder cancer following exposure to Actos, Takeda was obligated to include cytology testing as a pre-requisite for prescribing Actos to prospective patients. All persons placed on Actos since 1999 that were not given cytology screening have been unnecessarily exposed to the risk of developing bladder cancer which could have been avoided, but for Takeda's efforts to deceitfully suppress the appearance of bladder cancers during the Actos NDA clinical trials by excluding persons with positive cytology testing results.

109. At the very least, Takeda should have discussed this with the FDA when submitting its first Actos labeling change in order to warn the public. Instead, Takeda chose to keep quiet and later deny any causal link between Actos and cancer. Moreover, when directed by the FDA to conduct a PMC study regarding Actos and bladder cancer, Takeda delayed initiating such a trial until 2003 at Yale University. It was constructed as a 10 year trial, so the results of the study were intentionally arranged to become available after Takeda's exclusive Actos patent had expired, after exposing Actos patients to 13 years of non-cytology screened exposure to Actos. Thus, Takeda will get the benefit of tens of billions of dollars in Actos sales while awaiting the bladder cancer results which ought to have been labeled and warned of to begin with.

110. However, the rules, laws and regulations regarding causality assessments have always been that spontaneous reports are deemed drug-related. (See ICH E2A, p. 4: "For

purposes of reporting, adverse event reports associated with marketed drugs (spontaneous reports) usually imply causality.") The ICH guidelines have been in place in the United States since the latter 90's.

111. The majority of hematologic cancers such as Acute Myeloid Leukaemia, Leukaemia, Myltiple Myeloma and Lymphoma were reported between six months to one year after patients taking Actos. A similar short onset period was also reported for Endometrial cancer, Pancreatic cancer and all types of neoplasms from every organ system. Most significantly, the majority of malignant neoplasm progressions and tumor lyses syndromes were also reported within six months after patients began taking Actos.

112. Dr. Ge applied the Bradford Hill cancer causality criteria relative to Actos and Avandia. (See criteria listed in Table 11-4 of Cancer, Principles & Practice of Oncology/6th edition.) Dr. Ge found that Actos patients' cancers fulfilled several of those criteria, including: 1) Temporality/Does exposure precede effect? Yes; 2) Biologic gradient/Is there a dose-response relation? Yes; 3) Plausibility/Is the effect predictable? Yes, it was observed in Actos animal studies when high doses were given to mice. 4) Analogy/Do other similar agents act similarly? Yes, Avandia has the same issue, but because the treatment dose of Avandia is 4-8 mg/daily, the cancer rate is much lower, whereas effective Actos treatment requires a much higher dose of 30-45 mg/daily, therefore, the cancer rate for Actos is much higher than Avandia.

113. A possible biological mechanism for TZDs' carcinogenesis might be the presence of benzene in Avandia's and Actos' molecular structure. One of the classic and well known causes of hematologic cancers is benzene toxins, which, like alkylating chemotherapy for treating previous malignancies, show a short onset period within months after receiving such chemotherapy. The short onset period for cancers reported by Actos patients is very similar to the onset period for patients who receive chemotherapy.

114. It is Dr. Ge's opinion that carcinogenesis is a class effect among the TZD's, just as water retention that causes CHF is a TZD class effect. However, compared to Avandia, Actos patients exhibit a cancer reporting rate in the AERS four times higher than Avandia patients. A possible explanation is that Actos is a salt-based chemical preparation with benzenesulfonate involved in the salt's crystal formation, and its post-decomposition chemical particles are not totally biodegradable, resulting in excess benzene exposure, i.e. non-biodegraded toxic chemicals such as benzene remain in circulated blood and suppressed bone marrow and immune cells leading to cancer formations. On the other hand, Avandia is an ester-based chemical preparation, with most of its chemical ingredients largely biodegraded and excreted during decomposetion/metabolism, resulting in a lesser exposure to benzene. Since Avandia cancers/neoplasms appear to be reported at a lower rate than those reported for Actos, it is possible that carcinogenesis is one of the TZDs' class effects depending on how the chemical compound was structured and formulated.

- **Suicidal Ideation**

115. In May 2009, Relator reported an Actos suicidal ideation event as a 15-day serious event, as required by FDA regulations. Suicidal ideation is a serious unlabelled event, which, under the FDA regulations (21 C.F.R. §314.80), should have triggered a mandatory 15-day report. Janet Johnston, R.N., the Associate Director of Operations, stated that she did not agree with Relator's assessment of serious. Relator replied that "serious" was the proper label for this event according to the regulations and that this was the classification Relator had always reported to other drug companies she worked for concerning this type of event, and that no other drug company had ever disagreed. Ms. Johnston replied that she was not interested in what other drug companies were reporting and instructed Relator to never again report suicidal ideation as a serious event.

116. Relator then consulted the FDA's Adverse Event Reporting System (AERS) and prepared a data sheet for ALL the suicidal ideations reported to AERS for the 3rd quarter of 2008. One of Relator's colleagues at Takeda helped her download the suicidal ideations reported to the AERS and analyzed them. The 1st column on this sheet lists all 72 pharmaceuti-cal companies that reported suicidal ideation to AERS. The 2nd column under EXP lists the number of expedited 15 day reports for "suicidal ideation" by each company, i.e. the number of suicidal ideation events deemed "serious" and "unexpected/unlabeled." The 3rd column under PER lists the number of "suicidal ideations" classified as "serious" and "expected/labeled" and thus submitted for the companies; periodic reports. At this point in 2008, the AERS received 725 reports of "suicidal ideation," 663 of which were submitted in expedited reports and 62 were submitted as serious events in the companies' periodic reports. Thus, 91.4 % of the suicidal ideations were reported as 15 day (serious and unlabeled) by ALL the pharmaceutical companies, and 8.6% were reported from Periodic report (serious and labeled). For those reported as serious and labeled, 10 cases were reported from Lilly, 18 reported from Shire, and 16 reported from Wyeth, because these 3 companies had anti-depressant drugs which had labeling changes to add suicidal ideation as a labeled event. None of the suicidal ideations were reported as non-serious across the entire industry. This is very powerful evidence that Takeda had been violating adverse event reporting rules contrary to what even this much maligned industry was reporting—Takeda's ethics level relative to reporting adverse events is worse than this entire ethically challenged industry.

117. Shortly after this event, Relator was also approached by Niela Smith, Takeda Senior Medical Director, who stated to Relator that if Relator wanted to continue working for Takeda, she would be required to compromise.

- **Renal Failure**

118. Throughout 2009, Relator received multiple adverse event reports where the patient suffered renal failure while on Actos. Renal failure is an *unlabeled* event for Actos, which should have been categorized as a "serious" and unexpected event and triggered a 15 day report to the FDA. When Takeda found out that Relator was going to categorize this event as serious and unlabeled, triggering a 15 day report, the project manager, Michelle Peralta, R.N., instructed her to report it as non-serious. Relator was also informed that Takeda had a blanket policy of classifying renal failure as a non-serious event. Contrary to Takeda's refusal to report renal failure as a serious adverse event, GSK, the manufacturer of Avandia, reported renal failure events as serious and unlabeled and issued 15-day reports.

- **Pancreatic Cancer**

119. In the Summer of 2009, Relator was informed of an adverse event where an Actos patient suffered pancreatic cancer following the use of Actos. Upon information and belief, this case subsequently resulted in litigation in Illinois. Per FDA guidelines, spontaneous reports like this one are to be presumed associated events. Relator reviewed the case and assessed that it was related to Actos use. People within Takeda, including the legal department, became upset, contacted Relator, and encouraged her to change her assessment. When Relator refused to do so, Takeda resubmitted the case to Anton T., another reviewer, wherein he changed Relator's assessment from related to unrelated.

- **Cardiomyopathy**

120. In the Summer of 2009, Relator assessed a cardiomyopathy adverse event as serious and unlabelled and requested that it be reported to the FDA as a 15-day report pursuant to 21 C.F.R. §314.80. Relator's superiors, including Dr. Maria Paris, the Vice President of Pharmacovigilance, and Gregory Fusco, the Director of Pharmacoepidemiology, instructed

Relator to change the assessment to "non-serious" so as to avoid the 15-day reporting obligation. Relator reluctantly changed her assessment to comply with her superiors' mandates. Upon information and belief, GSK, the manufacturer of Avandia reported cardiomyopathy events as serious and unlabeled and issued 15-day reports.

121. To support her contention that this Actos patient's cardiomyopathy should be assessed as serious-unlabeled and therefore subject to a 15 day report, Dr. Ge saved a screen shot of an ARISg search she did for "cardiomyopathy." The screen shot was used to show Drs. Fusco and Paris that prior to 2007, Takeda had been reporting "cardiomyopathy" as serious, which is what Dr. Ge was recommending. Notwithstanding, Paris had Fusco direct Dr. Ge to change her report to "not serious."

122. Dr. Ge found an old email she had sent to herself in August 2009 while she was debating with Takeda's Dr. Gregory Fusco and Dr. Maria Paris over whether "cardiomyopathy" should be reported as serious and unlabelled.

123. Dr. Ge had emailed to herself the email string with her colleagues over this debate and the ARISg screenshot in case she might need them in the future. She also made a copy of the Medwatch form for this event.

124. The ARISg screen shot reveals a number of things:

125. First, the search accidentally captured some pre-2007 Actos CHF/heart failure events, each of which were then classified as "serious."

126. Second, two pre-2007 cardiomyopathy cases were classified "not serious"—Dr. Ge believes these were non-hospitalized cardiomyopathies, so Takeda had them assessed as "not-serious." In 2009, Dr. Ge was told by Fusco, Paris and Johnston that Takeda wanted to classify non-hospitalized adverse events, like CHF, cardiomyopathy, renal failure, suicidal ideation and bone marrow failure to be "not-serious." The third "not serious" cardiomyopathy

event at the bottom of the page is the one Fusco and Paris had Ge change from "serious" to "not serious." The friction over what Dr. Ge thought was improper failure to report serious, but not hospitalized, events led to Dr. Ge's dismissal.

- **Rhabdomyolysis**

127. In January 2011, the FDA released its quarterly list of investigations including one concerning rhabdomyolysis suffered by patients taking Actos. Takeda had immediately told the media that they had only received 67 reports of rhabdomyolysis and most of them were reported from Japan. Dr. Ge checked the AERS for Actos rhabdomyolsis events at eHealthme and found that there were 191 reported to AERS by the end of 2010. This further illustrates Takeda's pattern of concealing safety information from the public for marketing advantages. Takeda should have updated this problem in the Actos label long time ago since the AERS had been receiving an average of 18 rhabdomyolysis reports per year regarding patients taking Actos since 2000, but Takeda chose to keep quiet, as they did with the cancer reports.

XII. AERS AND CLINICAL TRIAL DATA SHOW THAT ACTOS' SAFETY PROFILE IS WORSE THAN AVANDIA, CONTRARY TO TAKEDA'S MARKETING AND OPINION LEADER PUBLICATIONS

128. In addition to the cancer adverse events, Dr. Ge reviewed the FDA's Adverse Event Reporting System (AERS) for numbers and reporting rates of heart attacks, congestive heart failure, stroke, bone marrow toxicity, psychiatric toxicity, epilepsy and efficacy related events (failure to safely control glucose levels leading loss of consciousness and falls, etc.). Dr. Ge analyzed the number and rates for each of these effects for both Actos and Avandia. The following subsections explain Dr. Ge's analysis of each adverse event comparison.

A. Myocardial infarction (Heart Attack)

129. Both Actos and Avandia are "glitazone" oral antidiabetic medications (TZDs). The market cycle peak for the glitazone class (both Actos and Avandia) was from 2003 to 2005.

(Exh. 7.) According to IMS dispensing data for the glitazone class, the market share for Avandia /Avandamet was 51.4%, 55.1%, and 55.8% respectively; and Actos was 48.6%, 45% and 44.2% respectively during that period. The total myocardial infarction events spontaneously reported from Avandia/Avandamet for that period was 229, with an average of 76/patient year; and the total for the same events reported for Actos was 243 events with an average 81/patient year. (Exh. 8.) Based on the reporting rate/frequency calculated from the IMS dispensing data, the myocardial infarction events reported from Actos was 6.5% higher than Avandia on average patient/year between 2003 and 2005 -- Avandia: 229/3 = 76/y; Actos: 243/3 = 81/y. The number of myocardial infarction events reported in the Dr. Wertz' WellPoint study for the same time period was 96 events for patients taking Avandia, and 121 events for patients taking Actos, which showed even greater excess Actos myocardial infarction events compared to Avandia, i.e., 20% more for Actos.

130. After Nissen published his Avandia meta-analysis in June 2007, myocardial infarction became a well-publicized safety issue for Avandia. Thereafter, myocardial infarction reports for Avandia rose four times higher than the prior years' average, 20 times higher in 2008, 53 times higher in 2009 and 26 times higher in 2010. These increases are likely products of the publicity and litigation that ensued, particularly in light of the fact that the dispensed prescriptions for Avandia had decreased 63% in 2007, and further decreased 85% in the following years, yet, the number of Myocardial Infarction, Congestive Cardiac Failure, Cardiac Failure and Stroke events reported since 2007 was 20-53 times higher for Avandia. Declining prescriptions should result in lower reported adverse event numbers, not substantially higher ones.

131. Dr. Ge also reviewed the WHO criteria for diagnosis of myocardial infarction to search for adverse events reported under MedDRA preferred terms "ECG ST Segment

Abnormal," "ECG ST Segment Depression" and "Creatine Phosphokinase MB increased" to see if these reported abnormal tests were supportive or proportional to the myocardial infarction reported on both drugs. Dr. Ge found that the event numbers reported under the medical terms "ECG ST Segment Abnormal" and "ECG ST Segment Depression" were four times higher for Actos than Avandia, and the event number under the medical term of "Creatine Phosphokinase MB increased" was 10 times higher for Actos than Avandia. These data suggest that the media and the public were not aware of "ECG ST Segment Abnormal and/or Depression" being used for diagnosis of myocardial infarction. As a result, the reported numbers under these terms were a fraction of myocardial infarction. Dr. Ge believes the numbers of these events show less myocardial infarction for Avandia than Actos. This further demonstrates that the majority of the reports under the MedDRA preferred term "myocardial infarction (Heart Attack)" regarding Avandia after July 2007 were likely influenced by Nissen's publication and the media, and that those reports are not reliable.

B. Cardiac Failure Congestive/Cardiac Failure/Heart Failure

132. From 1999 to 2006, before publication of Nissen's 2007 Avandia meta-analysis, the total Actos events reported under the MedDRA preferred term "Cardiac Failure" was 332 and, under "Cardiac Failure Congestive," 708. Of note, there were 125 Cardiac Failures reported in 2001, and it dropped to only 20 in 2002 when Actos sales actually increased. A similar pattern is seen with the reporting rate of Actos-related "Cardiac Failure Congestive."

133. While Dr. Ge worked in Takeda's phamacovigilance department in 2009, 179 "Cardiac Failure Congestive" were reported to AERS, which was the highest reporting rate since 1999. This was likely a function of Dr. Ge's responsibility during that period to medically review the Actos post-marketing reports and she assessed every spontaneously reported "Cardiac Failure Congestive" as serious labeled pursuant to product insert. As a result, each of those

"Cardiac Failure Congestive" events was entered into the AERS. On the other hand, during the first quarter of 2009, while Actos was assigned to a new physician who was inexperienced in pharmacovigilance, 40-50 "Cardiac Failure Congestive" cases were misclassified as non-serious labeled events and were, thus, not entered into AERS. Based on Dr. Ge's experience at Takeda, she estimates the annual reporting rate for "Cardiac Failure Congestive" was between 150-180 cases before 2007 and increased to 220-230 after 2007 when Actos sales rose dramatically.

134. Dr. Ge also compared these numbers with GSK's Avandia Periodic Safety Update Report ("PSUR") from 2007 to 2009. She noticed the total "Cardiac Failure Congestive" events reported for Avandia in 2009 was 131 because the prescriptions of Avandia had declined 70% compared to 2005. The total "Cardiac Failure Congestive" events reported for GSK's Avandia PSUR from 1999 to 2009 was 2,628. Based on her observations at Takeda, Dr. Ge believes the total "Congestive Cardiac Failure" reported for both Avandia and Actos from 1999 to 2009 should have been very close. If GSK reported a total of 2,628 for Avandia by the end of 2009, Takeda should have reported at least a similar total number for Actos, especially because Actos sales actually increased to 70% of the TZD market after 2007. However, there were less than 1,100 Actos "Cardiac Failure Congestive" reports found in AERS. These calculations demonstrate that Takeda had been substantially under-reporting this particular adverse event starting in 2002.

135. After Dr. Ge's contract was terminated by Takeda in January 2010 and she was no longer there to report each Actos "Cardiac Failure Congestive" as serious and labeled, the number of "Cardiac Failure Congestive" reported to AERS dropped to only 74 in 2010, which was one third of the number Dr. Ge had reported to AERS in 2009, even though Actos sales had actually further gone up in 2010, likely due to the additional restrictions placed on Avandia

prescriptions and the Takeda-created misperception that Actos had a safer cardiovascular profile than Avandia.

136. According to a review of AERS, the reporting pattern for Avandia under both "Cardiac Failure" and "Cardiac Failure Congestive" appears consistent and reliable through most of Avandia's market cycle -- there were 242 reports under the term "Cardiac Failure" between 1999 and 2006 and 1,045 reported under the term "Cardiac Failure Congestive" during the same seven-year time period. The sharply-increased reporting rate of Avandia "Cardiac Failure" and "Cardiac Failure Congestive" events started in 2007, mirroring the same pattern as "myocardial infarction" (Heart Attack) where the majority of those events were reported following nationally publicized litigation that accelerated after Nissen's June 14, 2007 publication. Hence, those reports are likely confounded and not reliable as reporting rates compared to the pre-2007 rates.

137. Dr. Ge analyzed the AERS data and noticed several interesting numbers: the "Cardiac Failure Acute" reported for Actos was nine times higher than Avandia: 43/23,532 (.18%) vs. 9/40,084 (.02%). This was probably because acute CHF must be hospitalized. Because hospitalized events were automatically classified as "serious" and cannot be over-written manually in the ARISg (the software program used by Takeda to generate MedWatch reports), which had to be reported to AERS, the manufacturer could not classify them as non-serious and non-reportable as they did with non-hospitalized CHF events. Also, the reporting rates for other medical terms that are associated with "Cardiac Failure Congestive," such as "Pulmonary Congestion" and "Acute Pulmonary Edema," were 23-26% higher in Actos than Avandia. Most significantly, "Pleural Effusion," a complication of "Cardiac Failure Congestive" was 28% higher in Actos than Avandia. These data further confirm Dr. Ge's observation that Takeda had under-reported Cardiac Failure/Cardiac Failure Congestive substantially since 2002 The FDA's meta-analysis of all post-marketing studies also confirmed that CHF was higher in

Actos than Avandia (CV death 0.4% in Actos vs. 0.2% in Avandia; MI 0.5% in Actos vs. 0.4% in Avandia; Serious Ischemic event 1.3% in Actos vs. 1.2% in Avandia; Total Ischemic event 2.3% in Actos vs. 2.2% in Avandia, CHF 1.2% in Actos vs. 0.9% in Avandia).

C. Stroke

138. The AERS reporting rate for "Stroke" revealed the same pattern as "Myocardial Infarction" and "Cardiac Failure/Cardiac Failure Congestive." From 1999 to 2007, the number of strokes reported by Avandia patients was 278 (9 years data) with an average of 31/patients year and from 2002 to 2007 (6 years data) by Actos patients with 38/patients year. After Nissen published his meta-analysis, the strokes reported for Avandia increased 7.3 times in 2008, 32 times in 2009, and 22 times in 2010, even though the sales of Avandia had plunged 85% compared to its peak between 2005 and 2006. On the other hand, the reporting rate under the MedDRA preferred term "Cerebral Infarction," which is the same medical concept as "Stroke," for the time period of 2000 to 2010 was 147 (.62%) from Actos vs. 65 (.16%) reported from Avandia; and with another related term "Cerebral Haemorrhage," the reporting rate was 36 (.15%) from Actos vs. 23 (.06%) from Avandia. Since both "Cerebral Infarction" and "Cerebral Haemorrage" were only used by medical professionals such as doctors and pharmacists, and were not commonly used by the media and litigators, the reporting rate under these two terms was only a fraction of the number of strokes that were more prominently reported. These data clearly demonstrate that, when the same adverse events were reported with different medical terms, then the term mentioned in Nissen's publication was significantly higher in Avandia; for those terms not mentioned in Nissen's publication, the reporting rate was significantly higher in Actos.

139. In conclusion, the estimated total serious adverse events reported to AERS regarding Actos under MedDRA preferred terms "Myocardial Infarction (Heart Attack),"

"Cardiac Failure Congestive" and "Stroke" help demonstrate that Takeda was under-reporting cardiovascular events for Actos. This is consistent with Dr. Ge's experience with Takeda's pharmacovigilance department executives and personnel who resisted or altered the reporting of CHF, renal failure and suicidal behavior events in patients taking Actos. This failure to report adverse events served Takeda's marketing plan to promote Actos' safety compared to Avandia, and thereby fraudulently secure the multi-billion dollar yearly TZD market. Nissen's June 2007 publication appears to have induced a media and litigation related accelerated reporting of Avandia adverse events which furthered the message that Actos is a safer alternative to Avandia. This inaccurate positioning misled physicians to prescribe Actos and exposed diabetes patients to hidden risks. Takeda has been enjoying this dramatic market advantage since Nissen's 2007 Avandia meta-analysis.

D. Bone marrow toxicity

140. Bone marrow toxicity events for Actos have been reported to AERS at a much higher rate than for Avandia, including single cell line (neutropenia and thrombocytopenia) to three cell line suppression (pancytopenia) as well as bone marrow failure. Autoimmune hemolytic anemia such as Aplasia Pure Red Cell and/or Red Cell Aplasia was higher in Actos than Avandia. The reporting rate of Aplastic Anaemia for Actos was four times higher than Avandia, and the majority of these were reported within six months to one year after taking Actos. Possible Bone Marrow Toxicity was identified as a TZD class risk in Thiazolidinediones: A Review of Their Risks and Benefits. (Exh. 17, supra, at pages 2 and 5.) Thus, Takeda had sufficient information to add clear warnings of this risk to the Actos label, but again, failed to do so.

141. The higher rate of reporting to AERS for severe bone marrow toxicity regarding patients taking Actos may be related to and explain the much higher rate of reporting cancer

regarding patients given Actos. See, e.g., Peroxidase-Dependent Metabolism of Benzene's Phenolic Metabolites and Its Potential Role in Benzene Toxicity and Carcinogenicity, Smith et al, Envir. Health Pers. 82: pp 23-29 which states: "Secondary activation of benzene's phenol metabolites in the bone marrow may therefore play an important role in benzene's myelotoxic and carcinogenic effects."

E. Psychiatric toxicity

142. Serious psychiatric events such as Completed Suicide, Delirium, Suicide Attempt, Suicidal Ideation, Homicidal Ideation, and Schizophrenia reported to AERS regarding Actos patients were three to four times higher than the rate those events were reported regarding Avandia patients. Such events often require emergency medical intervention. Strikingly, there were 11 Neuroleptic Malignant Syndrome cases reported regarding patients taking Actos, there were none reported for patients taking Avandia. Neuroleptic Malignant Syndrome is a very rare, serious, life threatening and toxic psychiatric emergency induced by an anti-psychotic drug; it not only requires emergency hospitalization, but also may require intensive care in the ICU. Even for the metoclopramide class of drugs, like Reglan, well recognized for being linked to tardive dyskinesia and NMS, by 2005, there had been only 45 metoclopramide related NMS cases even though Reglan had been generic since 1982, whereas Actos patients have been reported to have NMS 11 times already, suggesting it is a serious side effect linked to Actos use. (See Exh. 36, page 6, an FDA post-marketing safety memorandum on Myzan, a combination of metoclopramide and naproxen.)

143. In the Actos NDA Medical Review, psychiatric disorders occurred in 10% of the Actos patients and only 5% of the placebo patients in the Actos phase III US clinical trials, a doubling of the risk for Actos patients. This was one of the safety concerns raised by an FDA medical officer during the NDA review. According to 21 CFR 201.57 (g)(2), all adverse events

reported from clinical trials should be listed in the Adverse Event Section of the Package Insert in a descending order by frequency. Normally, every adverse event reported from clinical trials with a frequency greater than 5%, must be listed in the Adverse Event section of the Package Insert. Takeda did not include this group of highly frequent serious psychiatric events in the label, and has been concealing this important safety information from the public for many years.

F. Epilepsy, Seizure, Grand Mal Convulsion and other Rare Serious/Fatal Adverse Events

144. Epilepsy, Seizure and Grand Mal Convulsion are among the most serious adverse events induced by prescription drugs that poses immediate life threatening situations to patients. These adverse events often require sophisticated medical technology in emergency settings to save the patient's life. Takeda received a cluster of reports on each of these seizure-related events each year, but Takeda never included them in the Actos label.

145. Stevens Johnson Syndrome, a lethal skin eruption, has been reported in patients taking Actos at double the reporting rate for Avandia. Autoimmune diseases induced by drugs such as Scleroderma and Lupus that are rare and difficult to cure have also been reported at a rate two to three times more often for Actos compared to Avandia. These rare and serious adverse drug reactions suggest that Actos possesses much more toxicity than Avandia in its chemical formulation and preparation.

G. Actos exhibits poor glycemic control, resulting in expensive government-covered emergency and ICU medical care; Takeda underreported glycemic control related events prior to Dr. Ge's employment with Takeda

146. Cayman Chemical Company, a respected biochemical product manufacturing and research company specializing in chemical assay kits, posted a drug efficacy review on the Internet in which Cayman concluded that "Pioglitazone (Actos) is about one tenth as potent as Rosiglitazone (Avandia)." Duke University's Fuqua School of Business November 2003 (revised 11/2007) publication regarding TAP states: "Actos, which decreases the body's

tolerance to insulin and thereby reduces the need for insulin injections, was the result of a Takeda-Upjohn research partnership begun in 1980. **Upjohn took Actos to clinical trials, but found that the drug produced no effect.** Upjohn then tried to sell the rights to the drug, offering it first to TAP and then to Takeda Japan. Neither company was interested. However, Obayashi, now heading up TPA Research, saw the drug's potential and persuaded Takeda to allow him to develop it. Takeda America continued the trials and established that Actos was efficacious, but only after a period of at least one month and at a much higher dose." Thus, in order to have a detectable effect, if any, Actos had to be administered at high doses, which likely lead to the excess side effects compared to Avandia and other oral anti-diabetic treatments. Consistent with the Cayman Chemical and Duke analyses, participants in Actos' monotherapy NDA clinical trials (Studies 001, 012 and 026) showed a large drop out rate before finishing the trials, with the most reported reason being "Lack of Efficacy." These monotherapy results may have led to the European Union's only permitting Actos as a second-line treatment. Consequently, Dr. Ge categorized all of the efficacy related events revealed from eHealthMe/ AERS regarding Actos and Avandia, yielding a similar conclusion: Actos' glycemic control efficacy is inferior to Avandia's. This has resulted in large downstream hospitalization costs resulting from Actos' failure to adequately control glucose levels compared to other treatments.

147. For instance, under the event term "Blood Glucose Increased," the reporting frequency for Actos is double that of Avandia. Since Actos confers less glycemic control for diabetic patients than Avandia, some acute and serious complications, such as acute brain syndrome, acute respiratory failure, diabetic ketoacidosis, diabetic coma, and diabetic hyperosmolar coma were all reported two to three times more often for Actos patients than Avandia patients. Because Actos also showed much more fluctuation and less stable glycemic control, more patients were reported as having hypoglycaemia while taking Actos. This often

results in life threatening situations such as hypoglycaemic coma, hypoglycaemic seizure and/or hypoglycaemic encephalopathy as illustrated in the bar graphs which showed all of these serious consequences were reported at a several-times greater rate for Actos compared to Avandia. These types of events require expensive ambulance or emergency treatment to save the patient's life.

148. Reports of "Loss of Consciousness" or "Became Unconsciousness" due to hypoglycemia due to fluctuation in glycemic control were also received twice as often for Actos patients compared to Avandia patients. This often causes patients to fall, leading to head trauma and some serious complications such as Subdural Hematomas, which requires emergency hospitalizations and surgeries.

149. Before Dr. Ge started working for Takeda's pharmacovigilance department, Takeda reported all "Loss of Consciousness" due to hypoglycemia and subsequent falls resulting in head trauma, including subdural hematomas, as non-serious and labeled events, essentially resulting in these events not being specifically reported at all. Dr. Ge proposed a rule to report all of the hypoglycemia events as serious if the patient's glucose fell below 60 mg/dL and to report "Loss of Consciousness" as a 15-day report to the FDA. She wrote an email regarding this suggestion to Takeda's Janet Johnston in the summer of 2009. It is likely that a review of Takeda's ARISg database will show these events ceased being reported as "serious" after Dr. Ge was dismissed in January 2010.

H. Costs to government health care payers due to patients' worsening glycemic control while taking Actos

150. There have been two to three times as many patients on Actos reported as having acute and serious complications caused from worsening glycemic control evidenced by the reporting of events such as Metabolic Acidosis and Hypokalaemic Syndrome that require an emergency hospitalization for treatment. The reporting rate for chronic complications such as

diabetic nephropathy and gangrene for patients taking Actos were double that of patients taking Avandia. The cost of emergency hospitalization for treating these acute and life threatening complications due to poor glycemic control have been enormous to the government, which are often not counted when assessing impact of these adverse events.

151. There are additional, huge hidden costs to the government required to treat diabetic patients when their glycemic control treatment is less effective than expected. Each of the above mentioned acute and serious complications resulting from worsening glycemic control require hospitalization and/or emergency treatment in the ICU. The resulting costs could be from several thousand to tens of thousands of dollars per day. Likewise, reports of Actos causing renal failure due to poor glycemic control (30% greater than Avandia according to Dr. Ge's analysis), adds additional costs for dialysis, one of the most expensive expenditures covered by government sponsored healthcare plans averaging around $30,000 per year per patient.

152. The Actos label has been revised seven to eight times since Takeda received marketing approval in 1999. However, Takeda has not truthfully disclosed these serious adverse events from post marketing surveillance to the US government nor has it included them in the Actos label as required by the Food, Drug and Cosmetic Act. The Actos label has not truthfully and completely reflected Actos' actual safety and efficacy as mandated by the FDCA. This Act forbids "misbranding" and provides a range of civil and criminal enforcement mechanisms against inaccurate product labeling.

I. Financial connection between Takeda and Dr. Stephen Nissen

153. It is Dr. Ge's opinion that Takeda's financial connections with Dr. Nissen should be considered when analyzing Actos' risks compared to Avandia's. When Dr. Nissen published his meta-analysis of Rosiglitazone (Avandia) associated with a 43% increase of heart attacks in June 2007, he was the Principal Investigator of a phase III trial, PERISCOPE, sponsored by

Takeda for Actos Labeling expansion, started in 2004. PERISCOPE was one of the five major clinical trials that used Nissen's invention, Intravascular Ultrasound (IVUS) as an alternative imaging procedure to Coronary Angiography for assessment of Coronary Artery Disease. The cost per procedure was estimated to be $3,000-4,000, and each patient was required to have three to four IVUS procedures during 72 weeks of study. The payment Dr. Nissen received from Takeda through Cleveland Clinic Foundation was estimated to be $8-10 million for this study.

154. According to Dr. Ge's calculations, the total procedures/patient was four (one for screening, three after taking Actos at 24 weeks, 48 weeks and 72 weeks according to the study entry criteria posted on Clinicaltrial.gov). The estimated cost per patient was $16,000. According to Nissen's PERISCOPE trial publication, there were 568 patients enrolled in that study. Thus, the total amount for conducting the IVUS procedures on PERISCOPES' 568 patients was $9,080,000.00. In addition, there was the cost for conducting the IVUS on the excluded patients who failed the eligibility screening after the 1st procedure. The best screening failure ratio is three to one, which is very hard to achieve. Dr. Ge used the three to one ratio to add another $4,544,000.00 ($ 4,000 x 1136), which brings the total to $13,624,000.00.

155. According to Evan Stein's April 27, 2009 post on theheart.org regarding an article on conflicts of interest: "From the number of IVUS trials carried out over the last ten years at the Cleveland Clinic by Dr. Nissen it would not be surprising if the total amount was not well above $500,000,000. While a lot of this money is used to pay investigators and other direct costs (including directly or indirectly salary for Nissen and his coinvestigators) a substantial amount undoubtedly is 'profit' for the institution or department [he] runs." Dr. Malcolm Kendrick's published similar commentary making essentially the same point regarding influential income made from conducting major studies for a pharmaceutical company.

156. Dr. Nissen had previously criticized another of Actos' competitor drugs as well. In September 2005, Bristol-Myers Squibb received regulatory approval for its new generation TZD anti-diabetic drug, Muraglitazar, which created a new market competitor for Actos. The following month, Dr. Nissen published an article in the New England Journal of Medicine criticizing Muraglitazar for "excessive cardiovascular events." However, the FDA-approved dosage for Muraglitazar was 5 mg/daily, a dosage level that showed zero cardiovascular deaths and myocardial infarctions as a stand-alone treatment. Because of the "noise" made by Dr. Nissen, the FDA late-requested Bristol-Myers Squibb to conduct another study to further prove Muraglitazar's cardiovascular safety, following which Bristol-Myers Squibb withdrew the approved NDA for Muraglitazar, stating that, by the time the company completed the requested study, the new generation of anti-diabetic drugs would be available on the market.

157. In late 2005, a Takeda-sponsored post-marketing study, PROactive, revealed 115 more congestive heart failures and 16 more bladder cancers than the placebo group, and was criticized by endocrinologists in Europe and the US for overstating its results. In addition to these criticisms of PROactive's results, in late 2006, Takeda was required to include in Actos' US labeling the bladder cancers PROactive revealed. These negative factors placed Actos at risk for further loss of market share. On April 24, 2007, Dr. Nissen downloaded the data from GSK's 42 Avandia studies which had not been previously publicly available and, about a month later, on May 24, 2007, published his meta-analysis criticizing Avandia's cardiovascular safety in the New England Journal of Medicine. This was at a time when Dr. Nissen was also serving as the principal investigator for Takeda's PERISCOPE trial designed to show Actos lowers cholesterol.

158. In his statement at the June 6, 2007 Congressional Hearings, former FDA Commissioner, Dr. Andrew von Eschenbach also commented on Nissen's interaction with Congress, as well as the timing of Nissen's publication and told Congress that the FDA was not

aware of Dr. Nissen's study methods or findings until the date of the publication a couple of weeks earlier. In addition to Dr. von Eschenbach's admonitions concerning meta-analyses generally, there have been published criticisms of Dr. Nissen's Avandia meta-analysis. (See e.g., an article written by, amongst others, the former chairman of the American Heart Association, Dr. Sanjay Kaul, and a paper authored by Chaun Zhou, PhD, professor of biostatistics at Vanderbilt University, at pp. 4, 18 and 25.)

159. Additionally, as discussed above, the final statistical analysis performed by the FDA Bio-Statistical Department and presented by Dr. Bradley McEvoy at the July 13-14, 2010 FDA Advisory Committee meeting showed that meta-analysis for rates of Actos cardiovascular adverse events were actually higher than rates for Avandia.

160. Notwithstanding the fact that the AERS data and Dr. McEvoy's data summarized above shows Actos is *less* safe than Avandia, it is being touted as the safe alternative to Avandia. Takeda has not only taken advantage of Avandia's downfall to the detriment of patient safety and government funds, but Dr. Ge is convinced Takeda orchestrated this outcome. She strongly believes that, to allow this fraud and public perception to continue (not to mention government funds being expended on Actos, the "good" TZD while Avandia is singled out as the "bad" TZD) is unconscionable.

COUNT I
FALSE CLAIMS ACT
31 U.S.C. § 3729(a)(1)(A)

161. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

162. This is a claim by Relator, on behalf of the United States, for treble damages and penalties under the FCA, 31 U.S.C. §3729-3733 against Defendants for knowingly causing to be presented false claims to Government Healthcare Programs. From in or about 2007 through to

the present, Defendants have knowingly and willfully caused to be presented false claims as described in this Complaint.

163. By virtue of the acts described above, Defendants have knowingly caused physicians to prescribe Actos, and pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Actos, knowing that such false claims would be submitted to Government Healthcare Programs for reimbursement.

164. Defendants have also violated 31 U.S.C. §3729(a)(1)(A) by causing the states to submit false claims to the United States Government in Form CMS-64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program), which falsely certified that all drugs for which federal reimbursement was sought, including Actos, were paid for in compliance with federal law.

165. The government, unaware of the falsity of the claims made or caused to be made by defendants, paid and continues to pay claims that would not be paid but for defendants' omissions and misrepresentations.

166. By virtue of the false claims caused to be presented by Defendants, the United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,000.00 and not more than $10,000.00 (adjusted for inflation) for each false claim presented or caused to be presented.

COUNT II
FALSE CLAIMS ACT
31 U.S.C. §§ 3729(a)(1)(B)

167. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

168. Defendants have used a variety of false documents, including false submissions to the United States FDA, to cause the United States to continue to pay and approve claims for

reimbursement under the Government Healthcare Programs, which claims would not have been reimbursed had CMS known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos.

169. From, in or about 2007 to the present, Defendants' conduct violated the False Claims Act, 31 U.S.C. §§ 3729(a)(1)(B).

170. The United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,000.00 and not more than $10,000.00 (adjusted for inflation) for each false claim paid or approved.

COUNT III
CONSPIRACY TO SUBMIT FALSE CLAIMS
31 U.S.C. §3729(a)(1)(c)

171. Plaintiffs reallege and incorporate by reference paragraphs 1 through 87 as if fully set forth herein.

172. As detailed in the Complaint, Defendants TPC and TPNA, through their undisclosed agreement, conspired to defraud the government by suppressing and/or falsely reporting serious adverse events.

173. Defendants TPC and TPNA committed overt acts in furtherance of their conspiracy as alleged supra, including their decision not to report serious adverse events and their decision to intentionally mis-classify serious events as "non-serious."

174. This ultimately caused Actos to be promoted as the "safer" alternative to Avandia, caused the FDA to recommend Actos as being a safer alternative, caused physicians to prescribe Actos whereas they would not have but for Defendants' conspiracy to mask and conceal the serious adverse events.

175. Government Healthcare Programs, being unaware of these circumstances and therefore the falsity of the Actos claims, records and statements made and caused by Defendants,

and in reliance on the accuracy thereof, paid and may continue to pay for Actos claims in amounts far more than it otherwise would have.

176. From 2007 to the date of this Complaint, by reason of the conduct described above, the government has been damaged in an amount that is believed to exceed hundreds of millions of dollars.

WHEREFORE, as to Counts I-III, Relator respectfully requests that this Court enter judgment against Defendant(s), as follows:

(a) That the United States be awarded damages in the amount of three times the damages sustained by the U.S. because of the false claims alleged within this Complaint, as the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq*. provides;

(b) That statutory civil penalties of $10,000 (adjusted for inflation) be imposed for each and every false claim that Defendants caused to be presented to the Government Healthcare Programs under the Federal False Claims Act;

(c) That pre- and post-judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which the Relator necessarily incurred in bringing and pressing this case;

(d) That the Relator be awarded the maximum amount allowed pursuant to the Federal False Claims Act; and

(e) That the Court award such other and further relief as it deems proper.

COUNT IV
CALIFORNIA FALSE CLAIMS ACT

177. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

178. This is a *qui tam* action brought by Relator on behalf of the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § 12650 *et seq.*

179. Cal. Gov't Code § 12651(a) provides liability for any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof; a false claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
> (3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision;
> (4) is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

180. Defendants violated Cal. Gov't Code § 12651(a) and knowingly caused false claims to be made, used and presented to the State of California by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government funded healthcare programs.

181. The State of California, by and through the California Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

182. Compliance with applicable Medicare, Medi-Cal and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of California in connection with Defendants' conduct.

183. Had the State of California known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

184. As a result of Defendants' violations of Cal. Gov't Code § 12651(a), the State of California has been damaged in an amount far in excess of millions of dollars exclusive of interest.

185. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of herself and the State of California.

186. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of California:

(1) Three times the amount of actual damages which the State of California has sustained as a result of Defendants' conduct;
(2) A civil penalty of up to $10,000 for each false claim which Defendants presented or caused to be presented to the State of California;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT V
DELAWARE FALSE CLAIMS AND REPORTING ACT

187. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

188. This is a *qui tam* action brought by Relator on behalf of the State of Delaware to recover treble damages and civil penalties under the Delaware False Claims and Reporting Act, Title 6, Chapter 12 of the Delaware Code.

189. 6 Del. C. § 1201(a) provides liability for any person who:

> (1) knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved; or
> (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

190. Defendants violated 6 Del. C. § 1201(a) and knowingly caused false claims to be made, used and presented to the State of Delaware by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

191. The State of Delaware, by and through the Delaware Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

192. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Delaware in connection with Defendants' conduct.

193. Had the State of Delaware known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos,

it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

194. As a result of Defendants' violations of 6 Del. C. § 1201(a), the State of Delaware has been damaged in an amount far in excess of millions of dollars exclusive of interest.

195. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 6 Del. C. § 1203(b) on behalf of herself and the State of Delaware.

196. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Delaware in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Delaware:

(1) Three times the amount of actual damages which the State of Delaware has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Delaware;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 6 Del C. § 1205, and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT VI
FLORIDA FALSE CLAIMS ACT

197. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

198. This is a *qui tam* action brought by Relator on behalf of the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*

199. Fla. Stat. § 68.082(2) provides liability for any person who:

> (a) knowingly presents, or causes to be presented, to an officer or employee of an agency a false or fraudulent claim for payment or approval;
> (b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency;
> (c) conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid.

200. Defendants violated Fla. Stat. § 68.082(2) and knowingly caused false claims to be made, used and presented to the State of Florida by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

201. The State of Florida, by and through the Florida Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

202. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Florida in connection with Defendants' conduct.

203. Had the State of Florida known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

204. As a result of Defendants' violations of Fla. Stat. § 68.082(2), the State of Florida has been damaged in an amount far in excess of millions of dollars exclusive of interest.

205. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Fla. Stat. § 68.083(2) on behalf of herself and the State of Florida.

206. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Florida in the operation of its Medicaid program.

WHEREFORE, Relator respectfully request that this Court award the following damages to the following parties and against Defendants:

To the State of Florida:

(1) Three times the amount of actual damages which the State of Florida has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Florida;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Fla. Stat. § 68.085 and/or any other applicable provision of' law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action,
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT VII
GEORGIA FALSE MEDICAID CLAIMS ACT

207. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

208. This is a *qui tam* action brought by Relator on behalf of the State of Georgia to recover treble damages and civil penalties under the Georgia False Medicaid Claims Act, O.C.G.A. § 49-4-168 (2008) *et seq.*

209. O.C.G.A. § 49-4-168.1(a) provides liability for any person who:

> (1) knowingly presents, or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;
> (3) conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid.

210. Defendants violated O.C.G.A. § 49-4-168 *et seq.* by engaging in the conduct described herein.

211. The State of Georgia, by and through the Georgia Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

212. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Georgia in connection with Defendants' conduct.

213. Had the State of Georgia known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos,

it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

214. As a result of Defendants' violations of O.C.G.A. § 49-4-168, the State of Georgia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

215. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to O.C.G.A. § 49-4-168 on behalf of herself and the State of Georgia.

216. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Georgia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Georgia:

(1) Three times the amount of actual damages which the State of Georgia has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Georgia;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to O.C.G.A. § 49-4-168 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT VIII
HAWAII FALSE CLAIMS ACT

217. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

218. This is a *qui tam* action brought by Relator on behalf of the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq*.

219. Haw. Rev. Stat. § 661-21(a) provides liability for any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;
> (3) conspires to defraud the state by getting a false or fraudulent claim allowed or paid; or
> (8) is a beneficiary of an inadvertent submission of a false claim to the State, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the State within a reasonable time after discovery of the false claim.

220. Defendants violated Haw. Rev. Stat. §661-21(a) and knowingly caused false claims to be made, used and presented to the State of Hawaii by its deliberate and systematic violation of federal and *state* laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

221. The State of Hawaii, by and through the Hawaii Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

222. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express

condition of payment *of* claims submitted to the State of Hawaii in connection with Defendants' conduct.

223. Had the State of Hawaii *known* that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

224. As a result of Defendants' violations of Haw. Rev. Stat. § 661-21(a), the State of Hawaii has been damaged *in* an amount far in excess of millions of dollars exclusive of interest.

225. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who *has* brought this action pursuant to Haw. Rev. Stat. § 661-25(a) on behalf of herself and the State of Hawaii.

226. Relator requests *that* this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Hawaii in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Hawaii:

(1) Three times the amount of actual damages which the State of Hawaii has sustained as a result of Defendants' illegal conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Hawaii;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Haw. Rev. Stat. §661-27 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT IX
ILLINOIS WHISTLEBLOWER REWARD & PROTECTION ACT

227. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

228. This is a *qui tam* action brought by Relator on behalf of the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175 *et seq.*

229. 740 ILCS 175/3(a) provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the State of a member of the Guard a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

230. Defendants violated 740 ILCS 175/3(a) and knowingly caused false claims to be made, used and presented to the State of Illinois by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

231. The State of Illinois, by and through the Illinois Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

232. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express

condition of payment of claims submitted to the State of Illinois in connection with Defendants' conduct.

233. Had the State of Illinois known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

234. As a result of Defendants' violations of 740 ILCS 175/3(a), the State of Illinois has been damaged in an amount far in excess of millions of dollars exclusive of interest.

235. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 740 ILCS 175/3(b) on behalf of herself and the State of Illinois.

236. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Illinois in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Illinois:

(1) Three times the amount of actual damages which the State of Illinois has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Illinois;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 740 ILCS 175/4(d) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT X
INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

237. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

238. This is a *qui tam* action brought by Relator on behalf of the State of Indiana to recover treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Indiana Code 5-11-5.5 *et seq*. provides:

> Sec. 2.(b) A person who knowingly or intentionally:
>
> (1) presents a false claim to the state for payment or approval;
> (2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state;
> (3) with intent to defraud the state, delivers less money or property to the state than the amount recorded on the certificate or receipt the person receives from the state;
> (4) with intent to defraud the state, authorizes issuance of a receipt without knowing that the information on the receipt is true;
> (5) receives public property as a pledge of an obligation on a debt from an employee who is not lawfully authorized to sell or pledge the property;
> (6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;
> (7) conspires with another person to perform an act described in subdivisions (1) through (6); or
> (8) causes or induces another person to perform an act described in subdivisions (1) through (6)…

239. Defendants violated Indiana Code 5-11-5.5 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Indiana by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

240. The State of Indiana, by and through the Indiana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

241. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Indiana in connection with Defendants' conduct.

242. Had the State of Indiana known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

243. As a result of Defendants' violations of Indiana Code 5-11-5.5 *et seq.*, the State of Indiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

244. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Indiana Code 5-11-5.5 *et seq.* on behalf of herself and the State of Indiana.

245. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Indiana in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Indiana:

(1) Three times the amount of actual damages which the State of Indiana has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 for each false claim which Defendants caused to be presented to the State of Indiana;

(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Indiana Code 5-11-5.5 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XI
LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

246. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

247. This is a *qui tam* action brought by Relator on behalf of the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 437.1 *et seq.*

248. La. Rev. Stat. Ann. § 438.3 provides:

> (A) No person shall knowingly present or cause to be presented a false or fraudulent claim;
> (B) No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance program funds;
> (C) No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim;

249. Defendants violated La. Rev. Stat. Ann. §438.3 and knowingly caused false claims to be made, used and presented to the State of Louisiana by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

250. The State of Louisiana, by and through the Louisiana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

251. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Louisiana in connection with Defendants' conduct.

252. Had the State of Louisiana known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

253. As a result of Defendants' violations of La. Rev. Stat. Ann. § 438.3, the State of Louisiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

254. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to La. Rev. Stat. Ann. §439.1(A) on behalf of herself and the State of Louisiana.

255. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Louisiana in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Louisiana:

(1) Three times the amount of actual damages which the State of Louisiana has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Louisiana;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to La. Rev. Stat. § 439.4(A) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XII
MASSACHUSETTS FALSE CLAIMS ACT

256. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

257. This is a *qui tam* action brought by Relator on behalf of the Commonwealth of Massachusetts for treble damages and penalties under Massachusetts False Claims Act, Mass. Gen. Laws Ann. Chap. 12 § 5(A) *et seq*.

258. Mass. Gen. Laws Ann. Chap. 12 § 5B provides liability for any person who:

(1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or
(3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;
(9) is a beneficiary of an inadvertent submission of a false claim to the commonwealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim.

259. Defendants violated Mass. Gen. Laws Ann. Chap. 12 § 5B and knowingly caused false claims to be made, used and presented to the Commonwealth of Massachusetts by its

deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

260. The Commonwealth of Massachusetts, by and through the Massachusetts Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

261. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the Commonwealth of Massachusetts in connection with Defendants' conduct.

262. Had the Commonwealth of Massachusetts known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

263. As a result of Defendants' violations of Mass. Gen. Laws Ann. Chap. 12 § 5B, the Commonwealth of Massachusetts has been damaged in an amount far in excess of millions of dollars exclusive of interest.

264. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Mass. Gen. Laws Ann. Chap. 12 § 5(c)(2) on behalf of themselves and the Commonwealth of Massachusetts.

265. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Massachusetts in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the Commonwealth of Massachusetts:

(1) Three times the amount of actual damages which the Commonwealth of Massachusetts has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the Commonwealth of Massachusetts;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Mass. Gen. Laws Ann. Chap. 12, §5F and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XIII
MINNESOTA FALSE CLAIMS ACT

266. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

267. This is a *qui tam* action brought by Relator on behalf of the State of Minnesota to recover treble damages and civil penalties under the Minnesota False Claims Act, Minn Stat. § 15C.01 *et seq.*

268. Section 15C.01 provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof; a false claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
(3) knowingly conspires to either present a false or fraudulent claim to the state or a political subdivision for payment or approval or makes, uses, or causes to be made or used a

> false record or statement to obtain payment or approval of a false or fraudulent claim...

269. Defendants violated, Minn Stat. § 15C.01 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Minnesota by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

270. The State of Minnesota, by and through the Minnesota Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

271. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Minnesota in connection with Defendants' conduct.

272. Had the State of Minnesota known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

273. As a result of Defendants' violations of Minn Stat. § 15C.01 *et seq.*, the State of Minnesota has been damaged in an amount far in excess of millions of dollars exclusive of interest.

274. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Minn Stat. § 15C.01 *et seq.* on behalf of herself and the State of Minnesota.

275. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Minnesota in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Minnesota:

(1) Three times the amount of actual damages which the State of Minnesota has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Minnesota ;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Minn Stat. § 15C.13 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XIV
MONTANA FALSE CLAIMS ACT

276. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

277. This is a claim for treble damages and penalties under the Montana False Claims Act, M.C.A.§17-8-401 *et seq*.

278. Section 17-8-403 of the Montana False Claims Act provides liability for any person who:

(a) knowingly presents or causes to be presented to an officer or employee of the governmental entity a false or fraudulent claim for payment or approval;

> (b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the governmental entity;
> (c) conspires to defraud the governmental entity by getting a false or fraudulent claim allowed or paid by the governmental entity...

279. Defendants violated, M.C.A § 17-8-403 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Montana by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

280. Each prescription that was written as a result of Defendants' illegal conduct represents a false or fraudulent record or statement. And, each claim for reimbursement written for Actos submitted to Montana represents a false or fraudulent claim for payment.

281. The State of Montana, by and through the Montana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

282. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Montana in connection with Defendants' conduct.

283. Had the State of Montana known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

284. As a result of Defendants' violations of M.C.A.§ 17-8-401 *et seq.*, the State of Montana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

285. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to M.C.A.§ 17-8-406 *et seq.* on behalf of herself and the State of Montana.

286. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Montana in the operation of its Medicaid program.

287. WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Montana:

(1) Three times the amount of actual damages which the State of Montana has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Montana;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to M.C.A. § 17-8-410 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XV
NEVADA FALSE CLAIMS ACT

288. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

289. This is a *qui* tam action brought by Relator on behalf of the State of Nevada to recover treble damages and civil penalties under the Nevada False Claims Act, N.R.S. § 357.010, *et. seq.*

290. N.R.S. § 357.040(1) provides liability for any person who:

> (a) knowingly presents or causes to be presented a false claim for payment or approval;
> (b) knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim;
> (c) conspires to defraud by obtaining allowance or payment of a false claim;
> (h) is a beneficiary of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fails to disclose the falsity to the state or political subdivision within a reasonable time.

291. Defendants violated N.R.S. § 357.040(1) and knowingly caused false claims to be made, used and presented to the State of Nevada by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

292. The State of Nevada, by and through the Nevada Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

293. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Nevada in connection with Defendants' conduct.

294. Had the State of Nevada known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos,

it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

295. As a result of Defendants' violations of N.R.S. § 357.040(1), the State of Nevada has been damaged in an amount far in excess of millions of dollars exclusive of interest.

296. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.R.S. § 357.080(1) on behalf of herself and the State of Nevada.

297. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Nevada in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Nevada:

(1) Three times the amount of actual damages which the State of Nevada has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Nevada;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action..

To Relator:

(1) The maximum amount allowed pursuant to N.R.S. § 357.210 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XVI
THE NEW HAMPSHIRE HEALTH CARE FALSE CLAIMS LAW

298. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

299. This is a *qui tam* action brought by Relator on behalf of the State of New Hampshire to recover treble damages and civil penalties under the New Hampshire Health Care False Claims Law, N.H. Rev.Stat. Ann§167:61-b *et seq.,* which provides:

> 1. Any person shall be liable who:
>
> (a) knowingly presents, or causes to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval;
> (b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
> (c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

300. Defendants violated N.H. Rev.Stat. Ann. §167:61-b, and knowingly caused false claims to be made, used and presented to the State of New Hampshire by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

301. The State of New Hampshire, by and through the New Hampshire Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

302. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of New Hampshire in connection with Defendants' conduct.

303. Had the State of New Hampshire known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

304. As a result of Defendants' violations of N.H. Rev.Stat. Ann. §167:61-b, the State of New Hampshire has been damaged in an amount far in excess of millions of dollars exclusive of interest.

305. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.H. Rev.Stat. Ann. §167:61-b on behalf of herself and the State of New Hampshire.

306. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of New Hampshire in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of New Hampshire:

(1) Three times the amount of actual damages which the State of New Hampshire has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New Hampshire;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.H. Rev. Stat. Ann § 167:61-b and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XVII
NEW JERSEY FALSE CLAIMS ACT

307. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

308. This is a *qui tam* action brought by Relator on behalf of the State of New Jersey to recover treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 (2008) *et seq.*

309. N.J. Stat. § 2A:32C-1 provides liability for any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee, officer or agent of the State or to any contractor, grantee, or other recipient of State funds a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
> (3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

310. Defendants violated N.J. Stat. § 2A:32C-1 and knowingly caused false claims to be made, used and presented to the State of New Jersey by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

311. The State of New Jersey, by and through the New Jersey Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

312. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express

condition of payment of claims submitted to the State of New Jersey in connection with Defendants' conduct.

313. Had the State of New Jersey known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

314. As a result of Defendants' violations of N.J. Stat. § 2A:32C-1, the State of New Jersey has been damaged in an amount far in excess of millions of dollars exclusive of interest.

315. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.J. Stat. § 2A:32C-1 *et seq.* on behalf of herself and the State of New Jersey.

316. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of New Jersey in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of New Jersey:

(1) Three times the amount of actual damages which the State of New Jersey has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New Jersey;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.J. Stat. § 2A:32C-1 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XVIII
NEW MEXICO MEDICAID FALSE CLAIMS ACT

317. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

318. This is a *qui tam* action brought by Relator on behalf of the State of New Mexico to recover treble damages and civil penalties under the New Mexico Fraud Against Taxpayers Act N.M. Stat. Ann§§ 27-14-1 *et seq.*, which in pertinent part provides liability to any person who:

> (1) knowingly present, or cause to be presented, to an employee, officer or agent of the state or to a contractor, grantee, or other recipient of state funds a false or fraudulent claim for payment or approval;
> (2) knowingly make or use, or cause to be made or used, a false, misleading or fraudulent record or statement to obtain or support the approval of or the payment on a false or fraudulent claim;
> (3) conspire to defraud the state by obtaining approval or payment on a false or fraudulent claim...

319. Defendants violated, N.M. Stat. Ann§§ 27-14-1 *et seq.* and knowingly caused false claims to be made, used and presented to the State of New Mexico by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

320. The State of New Mexico, by and through the New Mexico Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

321. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of New Mexico in connection with Defendants' conduct.

322. Had the State of New Mexico known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

323. As a result of Defendants' violations of N.M. Stat. Ann§§ 27-14-1 *et seq.*, the State of New Mexico has been damaged in an amount far in excess of millions of dollars exclusive of interest.

324. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.M. Stat. Ann§§ 27-14-1 *et seq.* on behalf of herself and the State of New Mexico.

325. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of New Mexico in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of New Mexico:

(1) Three times the amount of actual damages which the State of New Mexico has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New Mexico;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.M. Stat. Ann §§ 27-14-1 *et seq*. and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XIX
NEW YORK FALSE CLAIMS ACT

326. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

327. This is a *qui tam* action brought by Relator on behalf of the State of New York to recover treble damages and civil penalties under the New York False Claims Act, 2007 N.Y. Laws 58, Section 39, Article XIII (Mickinney's State Finance Laws §187 *et seq.*). The New York False Claims Act provides liability for any person who:

> (a) knowingly presents, or causes to be presented, to any employee, officer or agent of the state or local government, a false or fraudulent claim for payment or approval;
> (b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or local government;
> (c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

328. Defendants violated the New York False Claims Act and knowingly caused false claims to be made, used and presented to the State of New York by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

329. The State of New York, by and through the New York Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

330. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of New York in connection with Defendants' conduct.

331. Had the State of New York known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

332. As a result of Defendants' violations of 2007 N.Y. Laws 58, Section 39, Article XIII, the State of New York has been damaged in an amount far in excess of millions of dollars exclusive of interest.

333. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 2007 N.Y. Laws 58, Section 39, Article XIII, on behalf of herself and the State of New York.

334. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of New York in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of New York:

(1) Three times the amount of actual damages which the State of New York has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $6,000 and not more than $12,000 for each false claim which Defendants caused to be presented to the State of New York;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 2007 N.Y. Laws 58, Section 39, Article XIII (Mickinney's State Finance Laws §190), and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XX
NORTH CAROLINA FALSE CLAIMS ACT

335. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

336. This is a *qui tam* action brought by Relator on behalf of the State of North Carolina to recover treble damages and civil penalties under the North Carolina False Claims Act, N.C.G.S § 1-605 *et seq.* Section 1-607 of this Act provides liability for any person who:

> (1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.
> (3) Conspires to commit a violation of subdivision (1), (2), ...of this section.

337. Defendants violated, N.C.G.S § 1-605 *et seq.* and knowingly caused false claims to be made, used and presented to the State of North Carolina by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

338. The State of North Carolina, by and through the North Carolina Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

339. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of North Carolina in connection with Defendants' conduct.

340. Had the State of North Carolina known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

341. As a result of Defendants' violations of N.C.G.S § 1-605 *et seq.*, the State of North Carolina has been damaged in an amount far in excess of millions of dollars exclusive of interest.

342. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.C.G.S § 1-608(b) on behalf of herself and the State of North Carolina .

343. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of North Carolina in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of North Carolina:

(1) Three times the amount of actual damages which the State of North Carolina has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of North Carolina;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.C.G.S § 1-610 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXI
OKLAHOMA MEDICAID FALSE CLAIMS ACT

344. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

345. This is a *qui tam* action brought by Relator on behalf of the State of Oklahoma to recover treble damages and civil penalties under the Oklahoma Medicaid False Claims Act 63 Okl. St. § 5053 (2008) *et seq.*

346. 63 Okl. St. § 5053.1 (2)(B) provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

347. Defendants violated 63 Okl. St. § 5053.1 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Oklahoma by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

348. The State of Oklahoma, by and through the Oklahoma Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

349. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Oklahoma in connection with Defendants' conduct.

350. Had the State of Oklahoma known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

351. As a result of Defendants' violations of 63 Okl. St. § 5053.1 *et seq.*, the State of Oklahoma has been damaged in an amount far in excess of millions of dollars exclusive of interest.

352. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 63 Okl. St. § 5053.1 *et seq.* on behalf of herself and the State of Oklahoma.

353. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Oklahoma in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Oklahoma:

(1) Three times the amount of actual damages which the State of Oklahoma has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Oklahoma;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 63 Okl. St. § 5053.1 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXII
RHODE ISLAND STATE FALSE CLAIMS ACT

354. Plaintiffs repeat and reallege each allegation contained in paragraphs 2-14, 21-22, and 27-76 above as if fully set forth herein.

355. This is a *qui tam* action brought by Relator on behalf of the State of Rhode Island to recover treble damages and civil penalties under the Rhode Island State False Claims Act R.I.Gen. Laws § 9-1.1-1 (2008) *et seq.*

356. R.I. Gen. Laws § 9-1.1-1 provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the State or a member of the Guard a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

357. Defendants furthermore violated R.I.Gen. Laws § 9-1.1-1 and knowingly caused false claims to be made, used and presented to the State of Rhode Island by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

358. The State of Rhode Island, by and through the Rhode Island Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

359. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Rhode Island in connection with Defendants' conduct.

360. Had the State of Rhode Island known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

361. As a result of Defendants' violations of R.I. Gen. Laws § 9-1.1-1, the State of Rhode Island has been damaged in an amount far in excess of millions of dollars exclusive of interest.

362. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to R.I. Gen. Laws § 9-1.1-1 *et seq.* on behalf of herself and the State of Rhode Island.

363. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Rhode Island in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Rhode Island:

(1) Three times the amount of actual damages which the State of Rhode Island has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Rhode Island;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to R.I. Gen. Laws § 9-1.1-1 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXIII
TENNESSEE FALSE CLAIMS ACT

364. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

365. This is a *qui tam* action brought by Relator on behalf of the State of Tennessee to recover treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*

366. § 71-5-182(a)(1) provides liability for any person who:

> (A) presents, or causes to be presented to the state, a claim for payment under the Medicaid program knowing such claim is false or fraudulent;
> (B) makes or uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;
> (C) conspires to defraud the State by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent.

367. Defendants violated Tenn. Code Ann. § 71-5-1 82(a)(1) and knowingly caused false claims to be made, used and presented to the State of Tennessee by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

368. The State of Tennessee, by and through the Tennessee Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

369. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Tennessee in connection with Defendants' conduct.

370. Had the State of Tennessee known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

371. As a result of Defendants' violations of Tenn. Code Ann. § 71-5-182(a)(1), the State of Tennessee has been damaged in an amount far in excess of millions of dollars exclusive of interest.

372. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tenn. Code Ann. § 71-5-183(a)(1) on behalf of herself and the State of Tennessee.

373. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Tennessee in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Tennessee:

(1) Three times the amount of actual damages which the State of Tennessee has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Tennessee;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Tenn. Code Ann. § 71-5-183(c) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXIV
TEXAS MEDICAID FRAUD PREVENTION LAW

374. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

375. This is a *qui tam* action brought by Relator on behalf of the State of Texas to recover double damages and civil penalties under V.T.C.A. Hum. Res. Code § 36.001 *et seq.*

376. V.T.C.A. Hum. Res. Code § 36.002 provides liability for any person who:

(1) knowingly or intentionally makes or causes to be made a false statement or misrepresentation of a material fact:
(a) on an application for a contract, benefit, or payment under the Medicaid program; or
(b) that is intended to be used to determine its eligibility for a benefit or payment under the Medicaid program.

(2) knowingly or intentionally concealing or failing to disclose an event:
(A) that the person knows affects the initial or continued right to a benefit or payment under the Medicaid program of
(i) the person, or
(ii) another person on whose behalf the person has applied for a benefit or payment or is receiving a benefit or payment; and
(B) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized;

> (4) knowingly or intentionally makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:
> (B) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program ...

377. Defendants violated V.T.C.A. Hum. Res. Code § 36.002 and knowingly caused false claims to be made, used and presented to the State of Texas by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

378. The State of Texas, by and through the Texas Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

379. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Texas in connection with Defendants' conduct.

380. Had the State of Texas known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

381. As a result of Defendants' violations of V.T.C.A. Hum. Res. Code § 36.002, the State of Texas has been damaged in an amount far in excess of millions of dollars exclusive of interest.

382. Defendants did not, within 30 days after it first obtained information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

383. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to V.T.C.A. Hum. Res. Code § 36.101 on behalf of herself and the State of Texas.

384. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Texas in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Texas:

(1) Two times the amount of actual damages which the State of Texas has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $15,000 pursuant to V.T.C.A. Hum. Res. Code § 36.052(a)(3) for each false claim which Defendants cause to be presented to the state of Texas;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to V.T.C.A. Hum. Res. Code § 36.110, and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXV
VIRGINIA FRAUD AGAINST TAXPAYERS ACT

385. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

386. This is a *qui tam* action brought by Relator on behalf of the Commonwealth of Virginia for treble damages and penalties under Virginia Fraud Against TaxPayers Act. Sec. 8.01-216.3a which provides liability for any person who:

> (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or
> (3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;

387. Defendants furthermore violated Virginia Fraud Against Tax Payers Act §8.01-216.3a and knowingly caused false claims to be made, used and presented to the Commonwealth of Virginia by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

388. The Commonwealth of Virginia, by and through the Virginia Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

389. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the Commonwealth of Virginia in connection with Defendants' conduct.

390. Had the Commonwealth of Virginia known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

391. As a result of Defendants' violations of Virginia Fraud Against Tax Payers Act §8.01-216.3a, the Commonwealth of Virginia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

392. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Virginia Fraud Against Tax Payers Act §8.01-216.3 on behalf of themselves and the Commonwealth of Virginia.

393. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Virginia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the Commonwealth of Virginia:

(1) Three times the amount of actual damages which the Commonwealth of Virginia has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the Commonwealth of Virginia;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to VA Code ANN § 32.1-315 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXVI
WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE LAW

394. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

395. This is a *qui tam* action brought by Relator on behalf of the State of Wisconsin to recover treble damages and civil penalties under the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931 *et seq.*

396. Wis. Stat. § 20.931(2) provides liability for any person who:

> (1) conspires to defraud this State by obtaining a false allowance or payment of claim for medical assistance, or by knowingly making or using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance Program;
> (2) knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, or decrease any obligation to pay or transmit money or property to the Medical Assistance Program.

397. Defendants violated Wis. Stat. § 20.931 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Wisconsin by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

398. The State of Wisconsin, by and through the Wisconsin Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

399. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express

condition of payment of claims submitted to the State of Wisconsin in connection with Defendants' conduct.

400. Had the State of Wisconsin known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

401. As a result of Defendants' violations of Wis. Stat. § 20.931 *et seq.*, the State of Wisconsin has been damaged in an amount far in excess of millions of dollars exclusive of interest.

402. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Wis. Stat. § 20.931 *et seq.* on behalf of herself and the State of Wisconsin.

403. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Wisconsin in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Wisconsin:

(1) Three times the amount of actual damages which the State of Wisconsin has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Wisconsin;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Wis. Stat. § 20.931 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXVII
DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

404. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

405. This is a *qui tam* action brought by Relator and the District of Columbia to recover treble damages and civil penalties under the District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.13 *et seq.*

406. D.C. Code § 2-308.14(a) provides liability for any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the District;
> (3) conspires to defraud the District by getting a false claim allowed or paid by the District;
> (8) is the beneficiary of an inadvertent submission of a false claim to the District, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the District.

407. Defendants violated D.C. Code § 2-308.14(a) and knowingly caused thousands of false claims to be made, used and presented to the District of Columbia by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its illegal conduct were even eligible for reimbursement by the government-funded healthcare programs.

408. The District of Columbia, by and through the District of Columbia Medicaid program and other state healthcare programs, and unaware of Defendants' illegal conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

409. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the District of Columbia in connection with Defendants' illegal conduct.

410. Had the District of Columbia known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Actos, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

411. As a result of Defendants' violations of D.C. Code § 2-308.14(a), the District of Columbia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

412. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to D.C. Code § 2-308.15(b) on behalf of herself and the District of Columbia.

413. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the District of Columbia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the District of Columbia:

(1) Three times the amount of actual damages which the District of Columbia has sustained as a result of Defendants' illegal conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the District of Columbia;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to D.C. Code § 2-308.15(f) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

PRAYER FOR RELIEF

WHEREFORE, Relator, on behalf of the United States and on her own behalf, demands judgment against Defendants, as follows:

A. That Defendants cease and desist from violating 31 U.S.C.§3729 et. seq., and the equivalent provisions of the state statutes set forth above.

B. That this Court enter judgment against the Defendants in an amount equal to three times the amount of damages the United States Government has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each false claim, together with the costs of this action, with interest, including the cost to the United States Government for its expenses related to this action.

C. That this Court enter judgment against the Defendants for the maximum amount of actual damages and civil penalties permitted under the false claims statutes of the respective States discussed in this Complaint.

D. That Relator be awarded all costs incurred, including her attorneys' fees.

E. That, in the event the United States Government intervenes in this action, Relator be awarded 25% of any proceeds of the claim, and that, in the event the United States Government does not intervene in this action, Relator be awarded 30% of any proceeds.

F. That the United States and Relator receive all relief, both in law and in equity, to which they are entitled.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of Federal Rules of Civil Procedure, Plaintiffs and Relator hereby demand a trial by jury.

Dated: April 5, 2012

Respectfully submitted,

/s/ Michael Sullivan

Michael Sullivan, Esq., BBO# 487210
The Ashcroft Group, LLC
1 Post Office Square, Suite 3750
Boston, MA 02109
Telephone: (617) 617-573-9400
Facsimile: (617) 617-573-9400

Michael L. Baum, Esq.
Ronald L. M. Goldman, Esq.
Bijan Esfandiari, Esq.
A. Ilyas Akbari, Esq.
BAUM HEDLUND ARISTEI & GOLDMAN, P.C.
12100 Wilshire Blvd., Suite 950
Los Angeles, CA 90025
Telephone: (310) 207-3233
Facsimile: (310) 820-7444

John Roddy, BBO# 424240
RODDY, KLEIN & RYAN
727 Atlantic Avenue, Second Floor
Boston, MA 02111
Telephone: (617) 357-5500
Facsimile: (617) 357-5030

Attorneys for Relator, Helen Ge, M.D.