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, MICHIGAN, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA , OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, WISCONSIN, and CONNECTICUT, THE COMMONWEALTHS OF MASSACHUSETTS, and VIRGINIA: and THE DISTRICT OF COLUMBIA; *ex rel.* KATHLEEN FRAGOULES Plaintiffs v. DAIICHI SANKYO, INC., FOREST PHARMACEUTICALS, INC. and FOREST LABORATORIES, INC. Defendants.	CIVIL ACTION NO._____ **FILED UNDER SEAL PURSUANT TO 31 U.S.C. §3730(b)(2)**

FALSE CLAIMS ACT COMPLAINT
INTRODUCTION

1. Kathleen Fragoules ("Relator") brings this action on behalf of the United States of America against Daiichi Sankyo, Inc. (hereinafter referred to as "Sankyo") and Forest Pharmaceuticals, Inc./Forest Laboratories, Inc. (hereinafter referred to as "Forest"), collectively

referred to as "Defendants," for treble damages and civil penalties arising from Defendants' conduct in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729, et seq. ("FCA").

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

3. The violations arise out of requests for payment by Medicare, Medicaid, TRICARE, and other federally-funded government healthcare programs (hereinafter referred to as "Government Healthcare Programs").

4. This Complaint describes a systematic course of conduct by Defendants to unlawfully promote the prescription drugs Benicar, Benicar HCT and Welchol.

INFORMATION ABOUT THE RELATOR AND THE DEFENDANTS

5. Relator, Kathleen Fragoules, is a resident of Michigan. She was employed by Sankyo from approximately March 1997 until January 2010.

6. Relator brings this action based on her direct knowledge and also on information and belief. None of the actionable allegations set forth in this Complaint are based on a public disclosure as set forth in 31 U.S.C. §3730(e)(4). Notwithstanding same, Relator is an original source of the facts alleged in this Complaint.

7. Relator is informed and believes that the pervasive kickbacks and false claims

described herein are ongoing, and date back at least six years.

8. Defendant, Daiichi Sankyo, Inc. ("Sankyo"), is a Delaware corporation with its headquarters located in Parsippany, New Jersey. It is the U.S. subsidiary of Tokyo-based Daiichi Sankyo Co., Ltd. Daiichi Sankyo was established in 2005 through the merger of Sankyo Co., Ltd. and Daiichi Pharmaceutical Co., Ltd., which were century-old pharmaceutical companies based in Japan.

9. Defendant, Forest Pharmaceuticals, Inc., is a Delaware Corporation with its principal place of business in St. Louis, Missouri. Defendant, Forest Laboratories, Inc., is a Delaware corporation with its principal place of business in New York. Both shall be referred to hereinafter as "Forest."

10. Each Defendant is a pharmaceutical company engaged in the manufacturing and/or marketing of pharmaceutical products, and do business throughout the United States.

11. At all times relevant hereto, Defendants acted through their agents and employees, and the acts of Defendants' agents and employees were within the scope of their agency and employment. The policies and practices alleged in this complaint were, on information and belief, established and/or ratified at the highest corporate levels of the Defendants.

FEDERAL JURISDICTION AND VENUE

12. The acts proscribed by 31 U.S.C. §3729 *et seq.* and complained of herein occurred in part in the District of Massachusetts, and both Defendants do business in the District of Massachusetts. Therefore, this Court has jurisdiction over this case pursuant to 31 U.S.C. 3732 (a),

as well as under 28 U.S.C. § 1345. This Court has 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), inasmuch as recovery is sought on behalf of said states which arises from the same transactions and occurrences as the claim brought on behalf of the United States.

13. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), because Defendants transact business in this District.

THE REGULATORY ENVIRONMENT

FDCA

14. The United States Food, Drug and Cosmetic Act (FDCA) establishes the framework for regulation of, inter alia, the sales and marketing activities of pharmaceutical manufacturers in the United States, including the introduction of new drugs into interstate commerce. When the United States Food and Drug Administration ("FDA") approves a drug, it approves the drug only for the particular use for which it was tested.

15. While a physician may prescribe a drug for a use other than one for which it is approved, the FDCA prohibits a drug manufacturer from marketing or promoting a drug for non-approved uses. 21 U.S.C. § 331(d), 355(a). It therefore is illegal for a drug manufacturer and its sales representatives to initiate discussions with medical professionals regarding any off-label use of the drug.

16. The dissemination of information or materials by a pharmaceutical manufacturer of any unapproved or off-label use, also known as "misbranding," constitutes unlawful promotional advertising of the drug, violates the FDCA, and can also serve as the basis for an FCA violation.

17. In addition to prohibiting manufacturers from directly marketing and promoting a product's unapproved use, Congress and the FDA have acted to prevent manufacturers from employing indirect methods to accomplish the same end. For example, the FDA regulates two of the most prevalent indirect promotional strategies: (A) manufacturer dissemination of medical and scientific publications concerning the off-label uses of their products; and (B) manufacturer support for Continuing Medical Education ("CME") programs and "speaker" programs, that focus on off-label uses.

18. With regard to the first practice—disseminating written information—the FDCA allows a manufacturer to disseminate information regarding off-label usage only in response to an "unsolicited request from a health care practitioner." 21 U.S.C. §360aaa-6. In any other circumstance, a manufacturer is permitted to disseminate information concerning the off-label uses of a drug only after the manufacturer has submitted an application to the FDA seeking approval of the drug for the off-label use; and has provided the materials to the FDA prior to dissemination. The materials must be submitted in an unabridged form and must not be false or misleading. 21 U.S.C. §§ 360aaa(b) & (c);360aaa-1.

19. The promotion of an off-label use for a prescription drug can interfere with the proper treatment of a patient. Off-label promotion can lull a physician into believing that the drug being promoted is safe and effective for the intended off-label use, and that the FDA has approved the drug for that use. Thus, off-label promotion can cause a doctor and patient to forgo treatment with an FDA-approved drug that has been proven to be safe and effective, and instead to substitute a treatment urged by the sales representative that is not known to be safe and effective, and that may in fact be harmful.

Anti-Kickback Act

20. Pursuant to the Anti-Kickback Act, 42 U.S.C. Section 1320a-7b(b), it is unlawful to knowingly offer or pay any remuneration in cash or in kind in exchange for the referral of any product (including a prescription drug product) for which payment is sought from any federally-funded health care program, including Medicare, Medicaid, and TRICARE.

21. The Anti-Kickback Act is designed to, inter alia, ensure that patient care will not be improperly influenced by inappropriate compensation from the pharmaceutical industry.

22. Every federally-funded health care program requires every provider or supplier to ensure compliance with the provisions of the Anti-Kickback Act and other federal laws governing the provision of health care services in the United States.

23. The Anti-Kickback Act prohibits suppliers such as pharmaceutical manufacturers from compensating, in cash or in kind, a health care provider when a purpose of the payment is to influence the provider's prescribing habits or to gain favor for its product over the product of any competitor.

False Claims Act

24. The False Claims Act (hereinafter referred to as "FCA"), 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 frauds to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the Government's behalf.

25. 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 records and statements to induce the Government to pay or approve false and fraudulent claims, is liable for a civil penalty ranging from $5,500 up to $11,000 for each such claim, plus three times the amount of the damages sustained by the federal Government.

26. 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.

27. The FCA provides, in pertinent part that:

> (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States 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 Government; (3) conspires to defraud the Government by getting a false or fraudulent claim paid or approved by the Government;
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> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount

> of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729.

GOVERNMENT HEALTHCARE PROGRAMS

28. Government Healthcare Programs cover prescription drugs. The programs include but are not limited to the following programs.

The Medicaid Program

29. The federal government enacted the Medicaid program in 1965 as 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. See 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. See 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").

30. Medicaid is a public assistance program providing for payment of medical expenses for approximately 55 million low-income patients. Funding for Medicaid is shared between the federal government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States.

31. Whether an FDA-approved drug is listed for a particular indication (i.e., use) determines whether a prescription for that use may be reimbursed under Medicaid.

32. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs." 42 U.S.C. §§ 1396b(I)(10), 1396r-8(k)(2), (3). Covered outpatient drugs are drugs that are used for "a medically accepted indication." Id. § 1396r-8(k)(3).

33. A medically accepted indication, in turn, is a use which is listed in the labeling approved by the FDA, or which is included in one of the drug compendia identified in the Medicaid statute. Id. § 1396r-8(k)(6).

The Medicare Program

34. Medicare is a government financial health insurance program administered by the Social Security Administration of the United States. Medicare was promulgated to provide payment for medical services, durable medical equipment and other related health items for individuals 65 and over. Medicare also makes payment for certain health services provided to additional classes of needy classes of individual healthcare patients pursuant to federal regulation.

35. The Medicare Prescription Drug benefit (Part D) covers all drugs that are considered "covered outpatient drugs" under 42 U.S.C. § 1396r-8(k) (as described above). Part A and Part B of the Medicare Program also cover prescription drugs that are "reasonable and necessary."

Reimbursement under other federal health care programs

36. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disabilities.

37. The Department of Veteran Affairs ("VA") maintains a system of medical facilities from which all pharmaceutical supplies, including prescription drugs, are dispensed to beneficiaries. It also supports a mail service prescription program as part of the outpatient drug benefit. The system serves approximately four million veterans.

38. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors.

39. Coverage of off-label drug use under these programs is similar to coverage under the Medicare and Medicaid programs. See, e.g., TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

FEDERAL LAW PROHIBITS DRUG MANUFACTURERS FROM ENGAGING IN ILLEGAL OFF-LABEL MARKETING

40. A drug's FDA-approved uses and dosages are called the drug's "indication." "Off-label" prescribing of drugs occurs when a drug is used by a medical professional beyond the drug's indication. This includes prescribing a drug for a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or to treat a different patient population (e.g. treating a child with the drug when the drug is approved to treat adults).

41. Pursuant to the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), an off-label use of a drug can cease to be off-label only if the manufacturer conducts studies and submits a new drug application demonstrating to the satisfaction of the FDA that the product is safe and effective for the proposed new use or uses. 21U.S.C. §360aaa(b) and (c).

42. Because of its inherent dangers, off-label marketing by pharmaceutical companies is closely regulated by the FDA and the law. These regulations protect patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an ostensibly independent, scientific governmental body, the FDA.

43. Absent Defendant's unapproved, illegal off-label marketing, which included false representations, and its gifts to physicians, the subject drugs would not have been prescribed by physicians for off-label indications. Defendant's off-label marketing programs have been extremely successful, leading to the submission of claims to the Government Healthcare Programs for medically unnecessary and imprudent prescriptions which otherwise would not have been paid.

44. Because prescriptions for off-label uses generally are not eligible for reimbursement

under Government Healthcare Program regulations, submission of a claim for reimbursement for a drug prescribed off-label constitutes a false claim for the purposes of the Federal and State False Claims Acts. While it is a pharmacy, by virtue of the reimbursement system, which unwittingly submits the false prescription drug claim, the person or persons who knowingly cause(s) such a claim to be presented to the Government Healthcare Programs is liable under the law.

45. The unwitting participation of the pharmacies in the submission of false claims was not only foreseeable; it was an intended consequence of Defendants' scheme of fraud.

FALSE CLAIMS DUE TO OFF-LABEL MARKETING OF BENICAR AND BENICAR HCT BY DAIICHI SANKYO AND FOREST

A. The Benicar Drugs

46. **Benicar** (olmesartan medoxomil) became FDA-approved in 2002 "for the treatment of hypertension … [to] be used alone or in combination with other antihypertensive agents." Tablets are supplied as follows:

	5 mg	20 mg	40 mg
Bottle of 30	NDC 65597-101-30	NDC 65597-103-30	NDC 65597-104-30
Bottle of 90		NDC 65597-103-90	NDC 65597-104-90
Blister 10 cards		NDC 65597-103-10	NDC 65597-104-10

47. **Benicar HCT** (olmesartan medoxomil-hydrochlorothiazide) became FDA-approved in June 2003 "for the treatment of hypertension … [but not] for initial therapy."

Bottle of 30 tablets	NDC 65597-105-30	NDC 65597-106-30	NDC 65597-107-30
Bottle of 90 tablets	NDC 65597-105-90	NDC 65597-106-90	NDC 65597-107-90
10 Blister cards of 10 tablets	NDC 65597-105-10	NDC 65597-106-10	NDC 65597-107-10
Bottle of 1000 tablets	NDC 65597-105-11	NDC 65597-106-11	NDC 65597-107-11

48. Benicar and Benicar HCT are both high blood pressure medicines in a family or class referred to as "A-II Receptor Blockers" ("ARB"), with the active ingredient, olmesartan. Benicar contains a single ingredient, olmesartan. Benicar HCT is a combination form which is made of olmesartan (an ARB), and hydrochlorothiazide (a diuretic).

49. Benicar and Benicar HCT are discussed together since both drugs contain olmesartan, and the false claims arise out of the same facts. They are collectively referenced to herein as "BENICAR."

50. Forest co-promoted BENICAR from its launch in May 2002 through 2007. The allegations against Forest in this lawsuit only relate to its marketing of Benicar and Benicar HCT.

B. The Conduct Which Caused the Submission of False Claims to Government Healthcare Programs

51. This off-label marketing case concerning olmesartan (the principal active ingredient in brands Benicar and Benicar HCT) involves: 1) an unambiguously narrow FDA-label for olmesartan, coupled with 2) very successful illegal marketing which persuaded physicians to believe that all Angiotensin-II Receptor Blockers ("ARB's") provide the same range of clinical benefit.

52. Defendants encouraged and induced physicians to prescribe BENICAR for indications it lacked, but which had been conferred on other members of the "class." The prescriptions were written mostly by internists and family practitioners, followed by nephrologists and cardiologists.

53. The ARB class is currently comprised of seven ARB's on the market in the U.S. They are: Atacand (candesartan), Avapro (irbesartan), Benicar (olmesartan), Cozaar (losartan), Diovan (valsartan), Micardis (telmesartan), and Teveten (eprosartan). These ARB's are additionally marketed in diuretic or calcium channel blocker combinations to enhance anti-hypertensive potency. None are available in generic form.

54. BENICAR has only secured a label indication for essential hypertension. The other six ARB's and their FDA-approved indications are set forth in Appendix I.

55. Defendants misrepresented to physicians that BENICAR had all of the beneficial product label indications of the other ARB's, including protection against heart failure, left ventricular dysfunction, and diabetic kidney disease, in addition to blood pressure control, when in fact the BENICAR label only recognized blood pressure control as an approved indication. As a result, physicians prescribed BENICAR to treat patients with heart failure, left ventricular dysfunction, and diabetic nephropathy, among other indications.

56. Defendants marketed BENICAR to physicians for multiple indications in addition to hypertension, yet BENICAR did not have the FDA-approval for these indications. Defendants did so by convincing physicians of the "class effect" of ARB's: that since olmesartan was an ARB, that it also was effective in the conditions for which other ARB's were FDA-approved:

- For the treatment of congestive heart failure,
- For the treatment of diabetic nephropathy,
- To reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy,
- For the reduction of cardiovascular mortality in clinically stable patients with left ventricular failure/dysfunction following myocardial infarction(heart attack),
- For the treatment of heart failure in adults with left ventricular systolic dysfunction

- To reduce cardiovascular death and to reduce heart failure hospitalizations (Atacand), and
- For reduction of the risk of myocardial infarction, stroke or death from cardiovascular causes (Micardis).

57. Having falsely represented that olmesartan had the same ability to treat the additional indications described above since it also is an ARB in the same class, Defendants then attempted to convince physicians that olmesartan was actually more effective at treating these conditions, since it had been demonstrated to be a superior ARB in treating hypertension. Therefore, the Defendants' marketing pitch was that by a "class effect", olmesartan is effective at the off-label indications, and moreover, should be used over all of the other ARB's for any or all of these conditions (whether patients suffered from them independently of hypertension and/or coexistent with hypertension).

58. Limited studies, experimental at best, have been performed to determine the effect of olmesartan on any of these conditions. Upon information and belief, the longest peer-reviewed studies of olmesartan are merely of two months' duration.

59. Sales Representatives were trained to use various reprints to promote off-label; for example, to promote BENICAR off-label for congestive heart failure. Sales Representatives were trained to use a reprint of "A Review of Olmesartan Medoxomil Monotherapy: Discussion," from the November/December 2002 issue of Congestive Heart Failure, by Mark Greathouse, M.D., one of Sankyo's speakers. Sales Representatives used this reprint until 2006.

C. FDA Previously Warned Both Defendants

60. Defendants continued to make these false representations about BENICAR despite having previously received a detailed Warning Letter from the FDA admonishing it to cease from making superiority claims versus other ARB drugs, and also for making false representations concerning BENICAR's ability to decrease MI (heart attack). See Warning Letter from FDA to Sankyo, dated January 6, 2006.

61. At the time, the FDA admonished Defendants for making superiority claims over the other ARB's:

> Your sales aid contains numerous claims and presentations that suggest that Benicar and Benicar HCT are more effective than other angiotensin II receptor antagonists and their hydrochlorothiazide combination products. The references provided in support of these claims, as is further detailed in the examples provided below, do not constitute substantial evidence or substantial clinical experience to support these claims and representations. [page 3]
> The sales aid contains unsubstantiated effectiveness and superiority claims and omits information on the risks associated with Benicar and Benicar HCT, and, therefore, misbrands the drugs in violation of section 502(a) of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 352(a). [page 8]

62. The FDA also admonished Defendants for advocating off-label uses that were unsubstantiated, such as falsely representing to physicians that BENICAR has been shown to decrease the chance of a patient having an MI (stroke):

> Page eleven of the sales aid presents data obtained from the Hypertension Optimal Treatment (HOT) trial with the claim "Lower diastolic blood pressure associated with fewer MIs." This presentation is framed by the efficacy claims "Reaching aggressive BP goals with BENICAR" and "GREAT BP REDUCTIONS FOR MORE AGGRESSIVE GOALS." When these myocardial infarction (MI) claims are considered in combination with the numerous claims throughout the sales aid (including on the page of the sales aid that faces this presentation) promoting Benicar's ability to lower diastolic blood pressure, the inescapable suggestion is that treatment with Benicar has been shown to decrease the chance of a patient having an MI. This claim is false or misleading. Benicar was not included in the HOT trial

> itself, and FDA is not aware of substantial evidence or substantial clinical experience that would support a claim that Benicar may lower the risk of a patient having an MI. [page 7]

FALSE CLAIMS DUE TO OFF-LABEL MARKETING OF WELCHOL BY DAIICHI SANKYO

63. In May 2000, Welchol (colesevelam hydrochloride) was approved for adults as a lipid-lowering bile acid sequestrant in the dose strength of 625 mg (total daily dose of 3.8 g/day). In January 2008, Welchol was approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. In 2010, Welchol was approved as therapy in pediatric subjects with hyperlipidemia.

64. Sankyo marketed Welchol to physicians for multiple indications in addition to treatment of elevated LDL, yet Welchol did not have the FDA-approval for these indications. Sankyo did so by convincing physicians of the "class effect" of lipid-lowering drugs: that since colesevelam was a lipid-lowering drug, that it also was effective in the conditions for which other lipid-lowering drugs were FDA-approved.

65. Sankyo did this even though Sankyo's FDA-approved indication had modest efficacy at best. On page 6 of the FDA's Clinical Review of the Sankyo pediatric Supplemental NDA, reviewer Eileen Craig, M.D. wrote:

> In conclusion, colesevelam 3750 mg as monotherapy provides modest LDL-lowering efficacy. However, the limited additional LDL-lowering efficacy when colesevelam is added to a statin along with the substantial body of evidence that demonstrates that statin therapy lowers risk of myocardial infarction, cardiovascular death, stroke, and need for coronary revascularization procedures in adults, raises the issue of whether colesevelam 3750 mg should primarily be used in statin-intolerant children or in children who are on optimally-dosed statin and have not reached their LDL-C goal.

66. On page 4, the reviewer wrote:

> Bile acid sequestrant drugs effect quite modest reductions in total and LDL-C, particularly in comparison to currently marketed doses of statins.

67. Sankyo marketed Welchol as an equivalent to Lipitor, Crestor, Zocor, and other LDL-lowering agents, for indications that they and other drugs had, yet no outcome studies had been conducted on Welchol to substantiate the same claims made by Sankyo. Sankyo falsely represented that in lowering LDL-C, (1) Welchol also was safe and effective to lower the risk for heart attack and stroke, both in patients who have heart disease; and in patients with risk factors for heart disease; (2) Welchol was also safe and effective to lower the risk for heart attack or stroke in patients with diabetes and risk factors for diabetes.

68. Welchol, however, does not have FDA-approval for such indications and no clinical studies with any scientific basis have been conducted to substantiate such claims. The effect of colesevelam alone, or in combination with a statin on cardiovascular morbidity and mortality has not been established.

69. Studies upon which FDA-approval were based show that with the higher dose of statins, there are better results in reducing heart attacks, strokes, and death, yet Sankyo falsely promoted that the combination of Welchol with low dose statin would give the same effect. For example, the Welchol "10+6 = 80" pitch started in 2002 and went through 2009. It was based on initial studies with Welchol of 75 patients which showed that while Lipitor 10mg only had a 38% mean reduction in LDL-D from baseline - and Lipitor 80mg had a 53% reduction - Lipitor 10mg plus 6 tablets of Welchol had a 48% reduction. The tag line in 2002 was "LDL-C reduction with Welchol and Atorvastatin10mg is Not Statistically Significantly Different From That of Atorvastatin 80mg",

falsely suggesting that the same beneficial lowering of risks that Lipitor had gained FDA-approval for would be applicable to this Lipitor/Welchol combination.

70. Defendant also knowingly targeted physicians to use Welchol for patients with known cardiovascular risks, even without suggesting combining therapy with a statin lipid agent such as Lipitor, Zocor, or Crestor. In 2005, Defendant created a spot showing results with the elderly "men greater than 65 years showing a 22% reduction in LDL-C "well suited for the patients for whom systemic risk is a concern, such as the elderly or those with multisystem disease."

DEFENDANTS' UNLAWFUL PROMOTIONS TACTICS

71. Defendants' management trained and directed its sales force to promote the subject drugs for off-label uses that were not covered under any Government Healthcare Program.

72. Defendants began planning national, aggressive, off-label marketing campaign for the subject drugs even before receiving FDA-approval.

73. Through this planning Defendants funded journal and other periodical articles advocating off-label uses, which ultimately Defendants planned to be used by its sales representatives to promote the subject drugs. Indeed, Relator was given such articles by Sankyo with the expectation that she learn the details of the studies backwards and forwards and use the talking points provided by Sankyo, in promoting the subject drugs off-label.

74. By focusing on the other members of the class FDA-approvals, rather than the Defendant's indications that were FDA-approved, Defendants intended to overcome the subject drugs' lack of FDA-approved indications for certain indications.

75. Defendants' off-label promotion raises safety issues, has adversely affected the

treatment of patients, and undermined the FDA drug approval process. Defendants undertook this illegal off-label promotion for their own financial gain, despite the potential risk to patients' health and lives.

76. Anticipating the possibility of resistance from physicians in prescribing the subject drugs for the off-label uses, Defendants specifically trained their sales representatives on how to respond to doctors' concerns about the off-label uses.

77. Through its communications to its sales force and to doctors, Defendants deliberately omitted:

a. Negative evidence about the subject drugs;

b. Information that virtually all publications and studies that allegedly supported the subject drugs' off-label uses had been initiated and funded by Sankyo, and those that were not initiated and funded by Sankyo were utilized to distort the real conclusions of the study.

c. Information that the doctors who were involved in peer selling had been paid substantial subsidies to use Sankyo drugs on their patients for non-medically accepted or non-medically necessary purposes;

d. Information related to dangerous side effects revealed through Sankyo's internal research, adverse event reports, and independent research.

78. Through its communications to the sales force and physicians, Defendants' suggested mechanisms of action that could explain the subject drugs' efficacy, safety profile, and use for the off-label uses, even though the subject drugs' mechanisms of action are not fully researched; and even though the explanations were a stretch at best.

79. Defendants gave the sales force the incentive and the tools to market off-label:

a. Relator and colleagues received training from Defendants' corporate training officials on subjects such as how to induce physicians to ask "unsolicited" questions about the subject drugs' off-label uses and to focus the marketing message on class effect and benefits.

b. Defendants reinforced this training by providing mandatory role playing sessions designed to replicate what the sales person would experience in the field when calling on physicians.

c. In addition to communicating such practices during frequent regional and district sales conferences, Defendants engrained its off-label marketing messages during annual national sales meetings; Division, Territory, and District meetings; and other specific gatherings.

d. Once out on the field, Relator and her colleagues were given marketing materials and "detail aids" useable for selling in the off-label market. Defendants' sales materials were the creation of the Brand Team for each drug, the division within each Defendant responsible for developing the marketing and promotional selling message for each of the subject drugs in the United States.

e. Defendants monitored the success of the off-label promotional program by carefully monitoring sales revenues of each sales representative and setting high sales goals expected to be met as an ostensible measure of job performance. This includes rewarding sales representatives for off-label as well as on-label prescriptions. The only way that specific goals attributable to sales representatives could be met was through a compensation system that was related to their off-label promotion of the drugs.

f. Defendants bestowed sales representatives with large budgets to expend upon

physicians to maintain and expand the subject drugs' off-label market, resulting in extraordinary revenues.

g. Defendants facilitated the use of physician speakers to further carry its message.

h. At physician speaker meetings there were no corrections or admonitions by anyone on behalf of Defendants if speakers deviated from on-label discussion. Moreover, additional slides which suggested or prompted off-label use were presented by physician-speakers with no oversight by Defendants.

i. Physicians were even "groomed" by Defendants to be speakers by attending all expense paid speaking seminars in resort-like atmospheres. These seminars were in truth designed to market the subject drugs for off-label uses.

j. Relator, having worked in the pharmaceutical sales prior to Sankyo, vocally questioned the Sankyo managers about the legality of marketing practices being taught, and she questioned the off-label nature of each of the marketing campaigns.

Claims Submitted to Government Healthcare Programs for Off-Label Uses Were Not Covered

80. In the Medicaid Program, states will not receive FFP ("Federal Financial Participation") if a drug, as prescribed, is not for a medically acceptable use. FFP is available to states only for "covered outpatient drugs." 42 U.S.C. § 1396b(i)(10). As a result, states' own laws and pharmacy regulations require that drugs must be used for a medically accepted use and therefore fit the definition of a covered outpatient drug.

81. "Covered outpatient drugs" do not include drugs that are "used for a medical indication which is not a medically accepted indication." Id. § 1396r-8(k). A medically accepted indication is defined as a use "which is approved under the Federal Food Drug and Cosmetic Act" ("FDCA") or which is "supported by one or more citations included or approved for inclusion" in specified drug compendia. Id. § 1396r-8(k)(6). 42 U.S.C.§ 1396r-8(g)(1)(B)(I) identifies the compendia to be consulted: American Hospital Formulary Service Drug Information; United States Pharmacopeia-Drug Information; and the DRUGDEX Information System. The compendia will hereinafter be referred to collectively as "the Drug Compendia."

82. Medicare Part A generally pays for inpatient services for eligible beneficiaries in hospital, hospice and skilled nursing facilities, as well as some home healthcare services. 42 U.S.C. §§1395e - 42 U.S.C. §§1395i-5. Prescription drugs are covered under Medicare Part A only if they are administered on an inpatient basis in a hospital or similar setting, and are "reasonable and necessary."

83. Medicare Part B pays for some types of prescription drugs that are not administered in a hospital setting, and that are "reasonable and necessary.". 42 U.S.C. §1395k(a); 42 U.S.C. §1395x(s)(2); 42 C.F.R. §405.517. These typically include drugs administered by a physician or other provider in an outpatient setting, some orally administered anti-cancer drugs and antiemetics (drugs which control the side effects caused by chemotherapy), and drugs administered through durable medical equipment such as a nebulizer. 42 U.S.C. §1395k(a); 42 U.S.C. §1395x(s)(2); 42 C.F.R. §405.517.

84. The Medicare program Part D drug benefit covers all drugs that are considered "covered outpatient drugs" under 42 U.S.C. §1396r-8(k).

85. The off-label uses discussed herein were not covered by any of the Government Healthcare Programs. They are not supported by any legitimate clinical research, and could not, under any circumstances, be determined to be "medically accepted as safe and effective" or "reasonable and necessary"for such uses or supported by the compendia set forth in 42 U.S.C. § 1396r-8(k) for such uses. Claims for such off-label uses were therefore not covered by Government Healthcare programs.

86. Defendants were aware that the natural and probable consequence of its promotion of off-label uses of the subject drugs, was that health care providers would submit claims for payment to Government Healthcare Programs for the off-label uses.

87. Notwithstanding this knowledge, Defendants illegally, vigorously, and without any thought to the possible negative health effects to which it subjected patients, promoted these off-label uses. Defendants are aware that its illegal promotion did in fact result in false claims to these and other government payors for the off-label uses. Defendants were aware that its promotion activities was a substantial factor in producing the claims.

88. When pharmacies, physicians and other healthcare providers submitted claims based upon a physician's prescription for the off-label uses, the claims they submitted were false because such off-label uses were not supported by a citation in one of the Drug Compendia specified by 42 U.S.C. § 1396r-8(g)(1)(B)(I), (Medicaid) not supported by "clinical research that appears in peer-reviewed medical literature," and could not, under any circumstances, be determined to be "medically accepted generally as safe and effective"or "reasonable and necessary." (Medicare) and not covered by other Government Healthcare Programs. See, e.g., TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2,

Section 22.1, Art. II (A)(2) (June 6, 2002).

89. Since Defendants cannot submit claims directly to Government Healthcare Programs, it intentionally defrauded physicians to prescribe the subject drugs by engaging in a nationwide materially misleading off-label marketing campaign for the intended and foreseeable effect of causing physicians and pharmacists to submit claims to publicly-funded health plans that were ineligible for reimbursement pursuant to these programs' regulations.

90. False claims to these government healthcare programs for off-label prescribing was the direct and proximate result of unlawful off-label marketing efforts by Defendants. Defendant caused the submission of these claims.

91. Defendants caused the submission of false claims, since healthcare providers submitted Pharmacy Claim Forms and CMS-1500 Forms to Government Healthcare Programs, and the states submitted Form CMS-64 to the Federal Government, all claiming reimbursement for the subject drugs for such off-label uses.

KICKBACKS

92. Kickbacks were used to help sell the products off-label. Each Sales Representative had the methods described herein available to them, and depending upon their personalities, need, etc., utilized from several to all of the methods.

93. Sankyo knew that its kickbacks would generate prescriptions. In the plan of action guide from 2005, and copied to top management in the company under "promotional programs," Sankyo management wrote:

"Plain and simple, POD programs and other promotional meetings generate NRx's.

You will have appropriate funding for these valuable resources at your disposal for Benicar and Welchol".

94. In the years shortly after the launch, Sankyo provided inducements to physicians, including tickets to concerts, theatre, and other events such as Bill Cosby, David Copperfield, Paula Poundstone, Ragtime, Ragtime, Rent, Elton John/Billy Joel, and Ringling Brothers. Defendant also provided physicians with Dine & Dash, free car washes, free golf, free strip clubs, free cooking classes, free lift tickets, free boating, free hunting, free massages, free wine tastings, and tickets to horse racing and to NBA, NHL and MLB games.

95. Defendants organized events called "Cardiovascular Health Consortiums" ("CVHC"), where physicians were paid $250 - $350 simply to attend – the speakers were paid $1,000 or more. Each representative put together about five per year; they occurred from the launch in 2002, through January/February 2005. Per an April 9, 2004 memo there were 900 openings for CVHC speakers. They were initially called District Advisory Councils. These meetings were for the alleged purpose of getting input/feedback from physicians on drug performance but in practice, off-label use of the drugs were promoted. During the Advisory Council meetings, honorariums, lavish entertainment, and expenses for physicians were paid for by the Defendants. Some were "Fly-Aways" (up to 2005) where physicians were paid between $750 - $1,000 and the meeting was held at a resort location.

96. Sales Representatives were able to obtain "honorarium" fees for physicians in their territories. Set up by Sales Representatives, they were ostensibly compensation to physicians for agreeing to speak at or attend a function, such as a dinner. In most instances, they were payoffs for prescriptions, and even in some instances, the physician never spoke at all. Up to 2004, there was no limit on the number of "speaker" honorariums that Sales Representatives could provide. The amount

of the speaker payments depended upon the length of the program and also the geographic coverage of the speaker.

97. "Round-tables" were conducted from 2002 – 2004, prior to the inception of the PODS program. Local physicians would attend, and the speaker was paid up to $1,000 per round-table. They were typically held at restaurants. Some round-tables included free travel and entertainment for each physician.

98. In 2005, Sankyo started a program called Physician Opinion Discussion ("POD"), which is still operative at present. Reps set up each POD with a minimum of three and maximum of eight local physicians in the POD. Physician leaders received $500, and more recently, $600 per POD. The locations were typically in a restaurant, over breakfast, lunch or dinner; ranging from as short as 20 minutes to as long as an hour or so. Each physician attendee was provided with a POD kit which consisted of a welcome letter, a discussion guide with questions and answers, many times one or two (inappropriate) reprints, and sometimes printed marketing materials. The lead physician would go over the packet with the other physicians in attendance. All physicians in the POD eventually were able to lead their POD, up to five per year. In the fourth quarter of 2008, Sankyo removed the limitation of five, so that representatives are now allowed to do as many PODs as they can get registered. Reps used to deliver the checks in person, but it was recently changed so all checks are mailed out by SCS Healthcare.

99. The topic of each POD was determined by the POD packet. There were 17 POD packets for Benicar, and 21 POD packets for Welchol. Representatives would recruit their top decile (highest prescribers) physicians in the respective therapeutic class to attend. POD topics included such off-label programs as arterial stiffness and diabetic nephropathy. Physicians would sign up to

be a POD speaker by written agreement, and underwent training through SCS Healthcare, 2000 Wyckoff Ave., Mahwah, NJ 07430.

100. Preceptorships began in 1997 and officially ended in 2009. The main purpose was to get money into the physician's hands. Sales representatives were encouraged to arrange them with their top physicians, to go in and spend time with them and pay them up to $800 for the day. Representatives could do one preceptorship per therapeutic class, which in Relator's case meant two, a total of $1,600 yearly for each selected physician.

101. Each Sales Representative had the discretion to spend money on physicians for entertainment purposes. Each representative had an entertainment budget of at least $20,000 per year. Most of it has been spent on lunches for the physician offices – feeding whole offices in exchange for time with the physicians.

102. Money was paid to physicians to review their charts, essentially paying the physician for writing prescriptions. Relator is specifically aware, in 2004 or 2005, of one Forest sales representative who paid one of Relator's top cardiologist, Dr. S., located in Lansing, MI the sum of $2,000 to actually go in and pull patient charts. Before Welchol was launched, select physicians were flown to different locations in the country to learn about it. When they returned to their offices, they were allowed to do chart reviews in which they would put their patients on Welchol and get paid $25.00 for each patient – initially it was for ten charts, but later was increased to 40 charts.

103. There were also paperwork programs, though research-oriented on the surface, which were operated by Sankyo's Marketing Department. For instance, one physician in Westbranch, MI was paid $25 for each patient he put on Benicar. Relator believes it was her predecessor Sankyo representative who put him on the paperwork program in or about 2004.

104. Physician offices were provided with blood pressure cuffs (Sankyo's cost was $30.00 apiece). Representatives gave physicians anywhere from one to five or even ten blood pressure cuffs, depending upon the situation. They were included in the "Benicar Patient kit", which was furnished as a way to try to get physicians to switch patients to Benicar from Cozaar or Diovan, or sometimes to Benicar as a new start.

105. For high decile physicians, Sankyo provided ambulatory blood pressure machines (APBM) which measure blood pressure for 24 hours. Patients wear the device for a single 24-hour period and the device is programmed to inflate and record blood pressure at specified intervals.

106. Representatives also gave physician offices multiple other items of value, such as wireless computer mice – as many as they wanted.

107. Sales Representatives were allowed to give "grants" to physicians, physician groups, medical facilities, and managed care organizations, ostensibly for an educational program or research program. Subsequently, grants became very restrictive and Sales Representatives did not use grants as a marketing tool. Defendants required only (via grant request documentation) that the healthcare provider recipient represent that the grant would be used for "education." No further scrutiny occurred.

COUNT I—FALSE CLAIMS ACT

108. Relator realleges and incorporates by reference paragraphs 1 through 107 as though fully set forth herein.

109. This is a claim by Relator, on behalf of The United States, for treble damages and

penalties under the False Claims Act, 31 U.S.C. 3729-3733 against Defendants for knowingly causing to be presented false claims to Government Healthcare Programs. In the District of Massachusetts and elsewhere throughout the United States, Defendants have knowingly and willfully violated the False Claims Act by causing false claims to be submitted.

110. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment, knowing that such false claims would be submitted to state Government Healthcare Programs for reimbursement, and knowing that such Government Healthcare Programs were unaware that they were reimbursing prescriptions for prescriptions induced by kickbacks and/or for non-covered uses and therefore false claims. By virtue of the acts described in this Complaint, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval, in violation of 31 U.S.C. §3729(a)(1) and 31 U.S.C. §3729(a)(2).

111. Defendants have violated 31 U.S.C. §3729(a)(2) 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, were paid for in compliance with federal law. States submitted false claims to the United States Government because when the subject drugs were prescribed off-label, they were not prescribed for medically accepted indications, yet states sought reimbursement from the United States Government for all such expenditures.

112. Defendants caused false claims to be submitted, resulting in Government Program reimbursement to healthcare providers in the millions of dollars, in violation of the False Claims Act, 31 U.S.C. §3729 et. seq. and the Anti-Kickback Act 42 U.S.C. §1320a-7b(b)(2)(A).

113. 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 $5,500.00 and not more than $11,000.00 for each false claim presented or caused to be presented.

114. WHEREFORE, Relator respectfully requests this Court enter judgment against Defendants, 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 civil penalties of $11,000 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 II
CALIFORNIA FALSE CLAIMS ACT

115. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

116. 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.

117. 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.
> ...
> (8) 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.

118. In addition, the payment or receipt of bribes or kickbacks is prohibited under Cal. Bus. & Prof. Code § 650 and 650.1, and is also specifically prohibited in treatment of Medi-Cal patients pursuant to Cal. Welf. & Inst. Code §14107.2.

119. Defendants violated Cal. Bus. & Prof. Code § 650 and 650.1 and Cal. Welf. & Inst. Code § 14107.2 by engaging in the conduct described herein.

120. Defendants furthermore 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, including the FDCA, federal Anti-Kickback Act, Cal. Bus. & Prof. Code § 650-650.1 and Cal. Welf. & Inst. Code § 14107.2 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.

121. 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.

122. 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. Compliance with applicable California statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of California.

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

124. As a result of Defendants' violation 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.

125. 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.

126. This Court is requested to 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 this Court to 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 III
DELAWARE FALSE CLAIMS AND REPORTING ACT

127. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

128. 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.

129. 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.

130. In addition, 31 Del. C. § 1005 prohibits the solicitation or receipt of any remuneration

(including kickbacks, bribes or rebate) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or services for which payment may be made in whole or in part under any public assistance program.

131. Defendants violated 31 Del. C. § 1005 by engaging in the conduct described herein.

132. Defendants furthermore 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, including the FDCA, the Anti-Kickback Act, and 31 Del. C. § 1005 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.

133. 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.

134. 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. Compliance with applicable Delaware statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Delaware.

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

136. As a result of Defendants' violation 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.

137. 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.

138. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to 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 IV
FLORIDA FALSE CLAIMS ACT

139. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

140. 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.*

141. 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 or fraudulent claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid.

142. In addition, Fla. Stat. § 409.920 makes it a crime to:

> (c) knowingly charge, solicit, accept, or receive anything of value, other than an authorized copayment from a Medicaid recipient, from any source in addition to the amount legally payable for an item or service provided to a Medicaid recipient under the Medicaid program or knowingly fail to credit the agency or its fiscal agent for any payment received from a third-party source;
>
> * * *
>
> (e) knowingly, solicit, offer, pay or receive any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing of any item or service for which payment may be made, in whole or in part, under the Medicaid program, or in return for obtaining, purchasing, leasing, ordering, or arranging, for or recommending, obtaining, purchasing, leasing, or ordering any goods, facility, item, or service, for which payment may be made, in whole or in part, under the Medicaid program.

143. Fla. Stat. §456.054(2) also prohibits the offering, payment, solicitation, or receipt of a kickback to a healthcare provider, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for referring or soliciting patients.

144. Defendants violated Fla. Stat. § 409.920(c) and (e) and §456.054(2) by engaging in the conduct described herein.

145. Defendants furthermore 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, including the FDCA, federal Anti-Kickback Act, Fla. Stat. § 409.920(c) and (e) and §456.054(2) 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.

146. 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.

147. 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. Compliance with applicable Florida statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Florida.

148. 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 the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in

connection with that conduct.

149. As a result of Defendants' violation 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.

150. 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.

151. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

WHEREFORE, Relator respectfully request this Court to 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 $5,500 and not more than $11,000 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 V
GEORGIA FALSE MEDICAID CLAIMS ACT

152. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

153. 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.*

154. 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.

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

156. Defendants furthermore violated O.C.G.A. § 49-4-168 and knowingly caused false claims to be made, used and presented to the State of Georgia by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, 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.

157. 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.

158. 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. Compliance with applicable Georgia statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Georgia.

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

160. As a result of Defendants' violation 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.

161. 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.

162. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to 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 VI
HAWAII FALSE CLAIMS ACT

163. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

164. 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.

165. 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.

166. 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, including the FDCA and Anti-Kickback Act, 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.

167. 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.

168. 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. Compliance with applicable Hawaii statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Hawaii.

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

170. As a result of Defendants' violation 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.

171. 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.

172. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Hawaii in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to 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 VII
ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

173. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

174. 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

Ill. Comp. Stat. 175 *et seq.*

175. 740 Ill. Comp. Stat. 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.

176. In addition, 305 Ill. Comp. Stat. 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks) prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Illinois Medicaid program.

177. Defendants violated 305 Ill. Comp. Stat. 5/8A-3(b) by engaging in the conduct described herein.

178. Defendants furthermore violated 740 Ill. Comp. Stat. 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, including the FDCA, federal Anti-Kickback Act, and the Illinois Vendor Fraud and Kickback statute, 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.

179. 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.

180. 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. Compliance with applicable Illinois statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Illinois.

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

182. As a result of Defendants' violation of 740 Ill. Comp. Stat. 175/3(a), the State of Illinois has been damaged in an amount far in excess of millions of dollars exclusive of interest.

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

184. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to 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 Ill. Comp. Stat.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 VIII
INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

185. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

186. 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)...

187. In addition, Indiana Code 5-11-5.5 *et seq.* prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Indiana Medicaid program.

188. Defendants violated the Indiana Code 5-11-5.5 *et seq.* by engaging in the conduct described herein.

189. Defendants furthermore 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, including the FDCA, federal Anti-Kickback Act, and the Indiana Vendor Fraud and Kickback statute, 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.

190. 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.

191. 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. Compliance with applicable Indiana statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Indiana.

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

193. As a result of Defendants' violation 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.

194. 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.

195. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to 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 at least five thousand dollars ($5,000) and for up to three (3) times the amount of damages sustained by 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 IX
LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

196. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

197. 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. 46: 437.1 *et seq.*

198. La. Rev. Stat. 46: 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;

199. In addition, La. Rev. Stat. 46: 438.2(A) prohibits the solicitation, receipt, offering or payment of any financial inducements, including kickbacks, bribes, rebates, etc., directly or indirectly, overtly or covertly, in cash or in kind, for furnishing healthcare goods or services paid for in whole or in part by the Louisiana medical assistance programs.

200. Defendants violated La. Rev. Stat. 46: 438.2(A) by engaging in the conduct described herein.

201. Defendants furthermore violated La. Rev. Stat. 46: 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, including the FDCA, federal Anti-Kickback Act and La. Rev. Stat. 456: 438.2(A), 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.

202. 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.

203. 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. Compliance with applicable Louisiana statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Louisiana.

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

205. As a result of Defendants' violation of La. Rev. Stat. 46: 438.3 the State of Louisiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

206. 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. 46: 439.1(A) on behalf of herself and the State of Louisiana.

207. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to 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 up to $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 X
MICHIGAN MEDICAID FALSE CLAIMS ACT

208. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

209. This is a *qui tam* action brought by Relator on behalf of the State of Michigan to

recover treble damages and civil penalties under the Michigan Medicaid False Claims Act. MI ST Ch. 400.603 *et seq.*

> 400.603 provides liability in pertinent part as follows:
> Sec. 3. (1) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for medicaid benefits;
> (2)A person shall not knowingly make or cause to be made a false statement or false representation of a material fact for use in determining rights to a medicaid benefit...

210. In addition, MI ST Ch. 400.604 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Michigan Medicaid program.

Defendants violated MI ST Ch. 400.603 *et seq.* by engaging in the conduct described herein.

211. Defendants furthermore violated, MI ST Ch. 400.603 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Michigan by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, 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.

212. The State of Michigan, by and through the Michigan 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.

213. 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 Michigan in connection with Defendants' conduct.

Compliance with applicable Michigan statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Michigan.

214. Had the State of Michigan 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 the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

215. As a result of Defendants' violation of MI ST Ch. 400.603 *et seq.* the State of Michigan has been damaged in an amount far in excess of millions of dollars exclusive of interest.

216. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to MI ST Ch. 400.603 *et seq.* on behalf of herself and the State of Michigan.

217. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Michigan in the operation of its Medicaid program.

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

To the State of Michigan:

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

To Relator:

(1) The maximum amount allowed pursuant to MI ST Ch. 400.603 *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
MONTANA FALSE CLAIMS ACT
MONT. CODE ANN. § 17-8-403(1)(a)-(b)

218. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 107 above as if fully set forth herein.

219. This is a qui tam action brought by Relator on behalf of the State of Montana to recover treble damages and penalties under the Montana False Claims Act, Mont. Code Ann § 17-8-403(1)(a)-(b).

220. 17-8-403 provides liability for any person who:

> (a) knowingly presenting or causing to be presented to an officer or employee of the governmental entity a false claim for payment or approval;
> (b) knowingly making, using, or causing to be made or used a false record or statement to get a false claim paid or approved by the governmental entity;
> (c) conspiring to defraud the governmental entity by getting false claim allowed or paid by the governmental entity.
> (h) as a beneficiary of an inadvertent submission of a false claim to the governmental entity, subsequently discovering the falsity of the claim and failing to disclose the false claim to the governmental entity within
> a reasonable time after discovery of the false claim.

221. 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.

Compliance with applicable Montana statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Montana.

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

223. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' conduct.

224. By reason of the Defendants' acts, the State of Montana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

225. The State of Montana is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

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

To the State of Montana:

(1) Not less than two times and not more than 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 up to $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 Montana Code Ann. § 17-8-403(1)(A)-(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 XII
NEVADA FALSE CLAIMS ACT

226. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

227. 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, Nev. Rev. Stat. § 357.010, *et. seq.*

228. Nev. Rev. Stat. § 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.

229. In addition, Nev. Rev. Stat. § 422.560 prohibits the solicitation, acceptance or receipt of anything of value in connection with the provision of medical goods or services for which payment may be made in whole or in part under the Nevada Medicaid program.

230. Defendants violated Nev. Rev. Stat. § 422.560 by engaging in the conduct described

herein.

231. Defendants furthermore violated Nev. Rev. Stat.§ 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, including the FDCA, federal Anti-Kickback Act and Nev. Rev. Stat. § 422.560, 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.

232. 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.

233. 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. Compliance with applicable Nevada statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Nevada.

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

235. As a result of Defendants' violation of Nev. Rev. Stat. § 357.040(1) the State of Nevada has been damaged in an amount far in excess of millions of dollars exclusive of interest.

236. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Nev. Rev. Stat. § 357.080(1) on behalf of

herself and the State of Nevada.

237. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to 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 $2,000 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 Nev. Rev. Stat. § 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 XIII
THE NEW HAMPSHIRE HEALTH CARE FALSE CLAIMS ACT

238. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

239. 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.* provides:

240. 1. Any person shall be liable who...

> (a) knowingly presents, or causes to be presented, to an officer or employee of the department 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 department;
> (c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.
> (f) Is a beneficiary of an inadvertent submission of a false claim to the department, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the department within a reasonable time after discovery of the false claim

241. In addition, N.H. Rev.Stat. Ann. prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the New Hampshire Medicaid program.

242. Defendants violated the N.H. Rev.Stat. Ann by engaging in the conduct described herein.

243. Defendants furthermore 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, including the FDCA, federal Anti-Kickback Act, and the New Hampshire Vendor Fraud and Kickback statute, 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.

244. 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.

245. 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. Compliance with applicable New Hampshire statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of New Hampshire.

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

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

248. 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 *et seq.* on behalf of herself and the State of New Hampshire.

249. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Hampshire in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to 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 *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
NEW JERSEY FALSE CLAIMS ACT

250. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

251. 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 *et seq.* (2008) *et seq.*

252. N.J. Stat. § 2A:32C-3 provides liability for any person who:

(a) knowingly presents, or causes to be presented, to an 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;
(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 by the State.

253. In addition, Section 17 of P.L. 1968, c.413 (C.30:4D-17) of the New Jersey False Claims Act prohibits the solicitation, offer or receipt of any remuneration, including any kickback, rebate or bribe in connection with the furnishing of items or services for which payment is or may be made in whole or in part under the New Jersey Medicaid program.

254. Defendants violated Section 17 of P.L. 1968, c.413 (C.30:4D-17) by engaging in the conduct described herein.

255. Defendants furthermore violated N.J. Stat. § 2A:32C-1 *et seq.* 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, including the FDCA, federal Anti-Kickback Act, and the New Jersey False Claims Act and Kickback statute, 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.

256. 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.

257. 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. Compliance with applicable New Jersey statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of New Jersey.

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

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

260. 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.

261. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Jersey in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to 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 and not more than the civil penalty allowed under the federal False Claims Act (31 U.S.C. s.3729 *et seq.*) 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 *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
NEW MEXICO MEDICAID FALSE CLAIMS ACT AND NEW MEXICO FRAUD AGAINST TAXPAYERS ACT

262. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

263. 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 Medicaid False Claims Act N.M. Stat. Ann§§ 27-14-1 *et seq.*

264. Section 4 provides liability in pertinent part as follows:

> A person ...shall be liable...if the person:
> A. presents, or causes to be presented, to the state a claim for payment under the medicaid program knowing that such claim is false or fraudulent;
> B. presents, or causes to be presented, to the state a claim for payment under the medicaid program knowing that the person receiving a medicaid benefit or payment is not authorized or is not eligible for a benefit under the medicaid program;
> C. makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the medicaid program paid for or approved by the state knowing such record or statement is false;
> D. conspires to defraud the state by getting a claim allowed or paid under the medicaid program knowing that such claim is false or fraudulent;

265. It is also 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 § 44-9-1 *et seq*. provides liablity in pertinent part as follows:

266. § 44-9-3(A) A person shall not:

> (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;

267. In addition, N.M. Stat. Ann§§ 30-44-7 *et seq.* prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the New Mexico Medicaid program.

268. Defendants violated N.M. Stat. Ann§§ 30-44-7 et seq by engaging in the conduct described herein.

269. Defendants furthermore 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, including the FDCA, federal Anti-Kickback Act, 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 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.

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 New Mexico in connection with Defendants' conduct. Compliance with applicable New Mexico statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of New Mexico.

272. 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 the subject drugs, 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' violation 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.

274. 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.

275. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Mexico in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to 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 XVI
NEW YORK FALSE CLAIMS ACT

276. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

277. 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

278. Section 189 provides liability for any person who:

> 1.(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;
> 1. (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;
> 1. (c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

279. In addition, the New York State Consolidated Laws prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be

made in whole or in part under the New York Medicaid program.

280. Defendants violated the New York State Consolidated Laws by engaging in the conduct described herein.

281. Defendants furthermore violated, 2007 N.Y. Laws 58, Section 39, Article XIII, 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, including the FDCA, federal Anti-Kickback Act, and the New York Vendor Fraud and Kickback statute, 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.

282. 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.

283. 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. Compliance with applicable New York statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of New York.

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

285. As a result of Defendants' violation 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.

286. 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.

287. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New York in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to 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, 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
NORTH CAROLINA FALSE CLAIMS ACT

288. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

289. 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. Gen. Stat. §§ 1-605 *et seq.*

290. N.C. Gen. Stat. § 1-607(a) 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), (4), (5), (6), or (7) of this section;
> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State.

291. In addition, North Carolina Statutes prohibit the solicitation, receipt, offering or payment of any financial inducements, including kickbacks, bribes, rebates, etc., directly or indirectly, overtly or covertly, in cash or in kind, for furnishing healthcare goods or services paid for in whole or in part by the North Carolina Medicaid program.

292. Defendants violated N.C. Gen. Stat. § 1-607(a) and knowingly caused hundreds of thousands of 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, including the FDCA, federal Anti-Kickback Act and the North Carolina False Claims Act N.C. Gen. Stat. § 1-605 *et seq.* , 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.

293. 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.

294. 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. Compliance with applicable North Carolina statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of North Carolina.

295. Had the State of North Carolina known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

296. As a result of Defendants' violation of N.C. Gen. Stat. § 1-605 *et seq.*, and its anti kickback statutes, the State of North Carolina has been damaged in an amount far in excess of millions of dollars exclusive of interest.

297. 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. Gen. Stat. § 1-605(b) on behalf of herself and the State of North Carolina.

298. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the

State of North Carolina in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to 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 $5,000 and not more than $10,000 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. Gen. Stat. § 1-605 *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 XVIII
OKLAHOMA MEDICAID FALSE CLAIMS ACT

299. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

300. 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.*

301. 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.

302. In addition, 56 Okl. St. § 1005 (2008) of the Oklahoma Medicaid Program Integrity Act prohibits the solicitation or receipt of any benefit, pecuniary benefit, or kickback in connection with goods or services paid or claimed by a provider to be payable by the Oklahoma Medicaid Program.

303. Defendants violated 56 Okl. St. § 1005 *et seq.* by engaging in the conduct described herein.

304. Defendants furthermore 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, including the FDCA, federal Anti-Kickback Act, and the Oklahoma Medicaid Program Integrity Act and Kickback statute, 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.

305. 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.

306. 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.

Compliance with applicable Oklahoma statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Oklahoma.

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

308. As a result of Defendants' violation 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.

309. 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.

310. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Oklahoma in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to 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 XIX
RHODE ISLAND STATE FALSE CLAIMS ACT

311. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

312. 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.*

313. R.I. Gen. Laws § 9-1.1-3 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.

314. In addition, R.I. Gen. Laws § 40-8.2-3(2)(i) prohibits the solicitation, receipt, offer or payment of any remuneration, including any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Rhode Island Medicaid program.

315. Defendants violated R.I. Gen. Laws § 40-8.2-3 *et seq.* by engaging in the conduct described herein.

316. 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, including the FDCA, federal Anti-Kickback Act, and the Rhode Island General Laws and Kickback statute, 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.

317. 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.

318. 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. Compliance with applicable Rhode Island statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Rhode Island.

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

320. As a result of Defendants' violation 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.

321. 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.

322. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Rhode Island in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to 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 XX
TENNESSEE FALSE CLAIMS ACT

323. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

324. 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 False Claims Act, Tenn. Code Ann. § 4-18-101 *et seq.* and Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*

325. § 4-18-103(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 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 claim allowed or paid by the state of by any political subdivision.

§ 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.

326. Defendants violated Tenn. Code Ann. § 4-18-103(a) and § 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, including the FDCA and Anti-Kickback

Act, 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.

327. 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.

328. 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. Compliance with applicable Tennessee statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Tennessee.

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

330. As a result of Defendants' violation of Tenn. Code Ann. § 4-18-103(a) and § 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.

331. 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. § 4-18-103(a) and § 71-5-183(a)(1) on behalf of herself and the State of Tennessee.

332. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the

State of Tennessee in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to 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 XXI
TEXAS MEDICAID FRAUD PREVENTION LAW

333. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

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

335. Tex. 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

(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;

(5) ... knowingly or intentionally charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or continued service to a Medicaid recipient if the cost of the service provided to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program.

336. Defendants violated Tex. 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, including the FDCA, federal Anti-kickback Act and § 36.002, 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.

337. 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.

338. 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. Compliance with applicable Texas statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Texas.

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

340. As a result of Defendants' violation of Tex. 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.

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

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

343. This Court is requested to accept pendant jurisdiction of this related state claim as it is

predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to 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 or more than $15,000 pursuant to Tex. Hum.. Res. Code § 36.025(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 Tex. 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 XXII
WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT

344. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

345. 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.*

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

> (a) Knowingly presents or causes to be presented to any officer, employee, or agent of this state a false claim for medical assistance.
> (b) Knowingly makes, uses, or causes to be made or used a false record or statement to obtain approval or payment of a false claim for medical assistance.
> (c) conspires to defraud this State by obtaining 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;
> (g) 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.

347. In addition, Wis. Stat. § 49.49(2) of the Wisconsin Public Assistance Code prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Wisconsin Medicaid program.

348. Defendants violated Wis. Stat. § 49.49(2) by engaging in the conduct described herein.

349. Defendants furthermore 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, including the FDCA, federal Anti-Kickback Act, and the Wisconsin Public Assistance Code and Kickback statute, 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.

350. 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.

351. 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. Compliance with applicable Wisconsin statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Wisconsin.

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

353. As a result of Defendants' violation 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.

354. 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.

355. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Wisconsin in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to 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 XXIII
CONNECTICUT FALSE CLAIMS ACT

356. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

357. This is a *qui tam* action brought by Relator on behalf of the State of Connecticut to recover treble damages and civil penalties under the Connecticut False Claims Act, Public Act No. 09-5 *et seq.*, signed by the Governor on October 5, 2009.

358. Conn. Public Act No. 09-5 § 2(a) provides that no person shall:

> (1) Knowingly present, or cause to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval under medical assistance programs administrated by the Department of Social Services;
> (2) Knowingly make, or cause to be made or used a false record or statement to secure the payment by the state of a false or fraudulent

> claim under medical assistance programs administered by the Department of Social Services;
> (3) Conspire to defraud the state by securing the allowance of payment of a false claim under medical assistance programs administered by the Department of Social Services.

359. In addition, the payment or receipt of bribes or kickbacks is prohibited under Connecticut False Claims Act, Public Act No. 09-5 § 16(a).

360. Defendants furthermore violated Conn. Public Act No. 09-5 § 2(a) and knowingly caused false claims to be made, used and presented to the State of Connecticut by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Conn. Public Act No. 09-5 § 2(a) and § 16(a) 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.

361. The State of Connecticut, by and through the Connecticut 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.

362. 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 Connecticut in connection with Defendants' conduct. Compliance with applicable Connecticut statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Connecticut.

363. Had the State of Connecticut 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 the subject

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

364. As a result of Defendants' violation of Conn. Public Act No. 09-5 § 2(a), the State of Connecticut has been damaged in an amount far in excess of millions of dollars exclusive of interest.

365. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Connecticut False Claims Act, Public Act No. 09-5 *et seq*. on behalf of herself and the State of Connecticut.

366. This Court is requested to 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 Connecticut in the operation of its Medicaid program.

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

To the State of Connecticut:

(1) Three times the amount of actual damages which the State of Connecticut 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 Connecticut;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Connecticut False Claims Act, Public Act No. 09-5 *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 XXIV
MASSACHUSETTS FALSE CLAIMS ACT

367. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

368. 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 Chap. 12 § 5(A) *et seq.*

369. Mass. Gen. Laws 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 shall be liable to the commonwealth or political subdivision.

370. In addition, Mass. Gen. Laws Chap. 118E § 41 prohibits the solicitation, receipt or offering of any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any good, service or item for which payment may be made in whole or in part under the Massachusetts Medicaid program.

371. Defendants violated Mass. Gen. Laws Chap. 118E § 41 by engaging in the conduct

described herein.

372. Defendants furthermore violated Mass. Gen. Laws 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, including the FDCA, federal Anti-Kickback Act, Mass. Gen. Law Chap. 118E § 41 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.

373. 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.

374. 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. Compliance with applicable Massachusetts statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the Commonwealth of Massachusetts.

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

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

exclusive of interest.

377. 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 Chap. 12 § 5(c)(2) on behalf of herself and the Commonwealth of Massachusetts.

378. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Massachusetts in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to 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 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 XXV
VIRGINIA FRAUD AGAINST TAXPAYERS ACT

379. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

380. This is a *qui tam* action brought by Relator on behalf of the Commonwealth of Virginia for treble damages and penalties under Va. Code Ann. § 8.01-216.3a provides liability for any person who:

> 1. Knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth 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 Commonwealth;
> 3. Conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid;

381. In addition, Va. Code Ann. § 32.1-315 prohibits the solicitation, receipt or offering of any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any good, service or item for which payment may be made in whole or in part under the Virginia Medicaid program.

382. Defendants violated Va. Code Ann. § 32.1-315 by engaging in the conduct described herein.

383. Defendants furthermore violated Va. Code Ann. § §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, including the FDCA, federal Anti-Kickback Act, VA Code ANN § 32.1-315 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.

384. 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.

385. 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. Compliance with applicable Virginia statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the Commonwealth of Virginia.

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

387. As a result of Defendants' violation of Va. Code Ann. §8.01-216.3(A), the Commonwealth of Virginia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

388. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Va. Code Ann. § 8.01-216.3 on behalf of herself and the Commonwealth of Virginia.

389. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the

Commonwealth of Virginia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to 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 $5,500 and not more than $11,000 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
DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

390. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 107 above as if fully set forth herein.

391. 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.*

392. 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.

393. In addition, D.C. Code § 4-802(c) prohibits soliciting, accepting, or agreeing to accept any type of remuneration for the following:

> (1) Referring a recipient to a particular provider of any item or service or for which payment may be made under the District of Columbia Medicaid program, or
> (2) Recommending the purchase, lease, or order of any good, facility, service, or item for which payment may be made under the District of Columbia Medicaid Program.

394. Defendants violated D.C. Code § 4-802(c) by engaging in the illegal conduct described herein.

395. Defendants furthermore 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, including the FDCA, federal Anti-Kickback Act D.C. Code § 4-802(c), 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.

396. 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.

397. Compliance with applicable Medicare, Medicaid and the various other federal and stale 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. Compliance with applicable D.C. statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the District of Columbia.

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

399. As a result of Defendants' violation 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.

400. 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.

401. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the District of Columbia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to 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.

DATED: March 10, 2010.

Respectfully submitted,

By: Suzanne E. Durrell /RMT

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