UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA; and THE STATES OF ILLINOIS, CALIFORNIA, FLORIDA, TEXAS, DELAWARE, HAWAII, INDIANA, LOUISIANA, NEW HAMPSHIRE, NEVADA, TENNESSEE, MICHIGAN, NEW MEXICO, NEW YORK, and THE COMMONWEALTHS OF MASSACHUSETTS and VIRGINIA; and THE DISTRICT OF COLUMBIA; *ex rel.* CHER BEILFUSS and KATHLEEN O'CONNOR-MASSE Plaintiffs and Relators, v. ALLERGAN, INC. Defendant	CIVIL ACTION NO. **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)** **FALSE CLAIMS ACT COMPLAINT**

I. BACKGROUND

1. *Qui tam* Relators Cher Beilfuss and Kathleen O'Connor-Masse bring this action on behalf of the United States against Allergan Inc., (hereinafter referred to as Defendant) for treble damages and civil penalties arising from Defendant's conduct in violation of the Civil False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA"). The violations arise out of requests for payment by Medicaid, Medicare, TRICARE, and other federally-funded government healthcare programs (hereinafter collectively referred to as "Government Healthcare Programs").

2. This action is also brought under the respective qui tam provisions of False Claims Acts (or similarly named statutes) on behalf of the STATE OF ILLINOIS, the STATE OF CALIFORNIA, the STATE OF FLORIDA, the STATE OF TEXAS; the COMMONWEALTH OF MASSACHUSETTS; the STATE OF DELAWARE; the

2. This action is also brought under the respective qui tam provisions of False Claims Acts (or similarly named) on behalf of the STATE OF ILLINOIS, the STATE OF CALIFORNIA, the STATE OF FLORIDA, the STATE OF TEXAS; the COMMONWEALTH OF MASSACHUSETTS; the STATE OF DELAWARE; the DISTRICT OF COLUMBIA, the STATE OF HAWAII, the STATE OF INDIANA, the STATE OF LOUISIANA, the STATE OF NEW HAMPSHIRE, the STATE OF NEVADA, the STATE OF TENNESSEE, the STATE OF MICHIGAN, the STATE OF NEW MEXICO, THE STATE OF NEW YORK, and the COMMONWEALTH OF VIRGINIA. These states, along with the UNITED STATES, are hereafter collectively referred to as the Government.

3. The gravamen of Relators' claims is that the Defendant developed and successfully executed a sophisticated marketing plan with the purpose of inducing physicians to prescribe the prescription drug Botox® for particular off-label uses (and off-label dosages) which are neither FDA approved nor demonstrated to be safe and effective.

4. Defendant knew, when it initiated this illegal marketing program, that there was little, and in some cases absolutely no credible scientific basis to justify their assertion that Botox® was safe and effective for these off-label uses and/or doses. Nonetheless, Defendant's conduct has caused submission for reimbursement by Government Healthcare Programs of millions of dollars worth of prescriptions which were ineligible for such reimbursement.

5. This Complaint also describes unlawful remuneration, otherwise known as kickbacks, provided to physicians and other healthcare providers (hereinafter sometimes collectively referred to as "providers"), with a purpose of inducing them to prescribe Botox® for off-label use.

6. Relators have complied with all procedural requirements of the laws under which this case is brought.

II. JURISDICTION AND VENUE

7. Sufficient acts proscribed by 31 U.S.C. §3729 *et seq.* and complained of herein occurred within the District of Massachusetts, and Defendant does 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 supplemental jurisdiction over the state law actions pursuant to 31 U.S.C. §3732(b).

8. Venue lies under 31 U.S.C. § 3732(a).

9. The facts and circumstances which give rise to Defendant's violation of the False Claims Act have not been publicly disclosed in a criminal, civil, or administrative hearing, nor in any congressional, administrative, or General Accounting Office report, hearing, audit, or investigation, nor in the news media.

10. Relators are the original source of the information upon which this complaint is based, as that phrase is used in the False Claims Act and other laws at issue herein.

III. PARTIES

11. Relator Cher Beilfuss, a Minnesota resident, was employed by Defendant as a Regional Healthcare Policy Manager (RHPM) from 2005 to 2007 . In her position as an RHPM, she was fully trained to, and required to implement the coverage portion of the unlawful off-label marketing plan described in this Complaint.

12. Relator, Kathleen O'Connor-Masse, an Arizona resident, was a Payor

Reimbursement Account Manager from 2000 to 2004; and Director of Western Area Reimbursement Account Managers from 2004 until June 2005. In both positions, she was tasked with removing the barriers for off-label coverage for Botox therapeutic.

13. Relators bring this action based on their direct knowledge and, where indicated, 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), and Relators are an original source of the facts alleged in this Complaint.

14. Defendant ALLERGAN, INC., is a public company with its headquarters located at 2525 Dupont Drive, Irvine, CA 92612-1551. It is organized under the laws of the State of Delaware.

15. At all times relevant hereto, Defendant acted through its agents and employees, and the acts of Defendant's 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 Defendant.

IV. THE REGULATORY ENVIRONMENT

Regulation of Prescription Drug Sales and Marketing

16. 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, but after the drug is approved for a particular use, the FDCA does not regulate how the drug may be prescribed. Thus, a drug that has been tested and approved for one use only can also be prescribed by a physician for another use, known as an "off-label" use.

17. 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.

18. 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 and violates the FDCA.

19. 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 that focus on off-label uses.

20. 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 (emphasis added). 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.

21. In sum, the off-label regulatory scheme protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body—the FDA.

22. Reasons why Congress made off-label marketing and promotion by drug manufacturers illegal include, without limitation, the following:

(a) Off-label promotion diminishes or eliminates the drug manufacturer's incentive to study the use of its drug and obtain definitive safety and efficacy data;

(b) Off-label promotion harms patients as the result of unstudied uses that lead to adverse results, or are ineffective;

(c) Off-label promotion diminishes the use of evidence-based medicine; and

(d) Off-label promotion erodes the efficacy standard in medicine.

The Anti-Kickback Act

23. 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.

24. 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.

25. 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.

26. 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.

27. The Federal False Claims Act and Anti-kickback Statute

> The Federal 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;
> * * *
> 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.

V. FACTS

Botox®(Botulinum Toxin Type A)

28. Botox® is a prescription biological product that contains tiny amounts of highly purified botulinum toxin protein refined from a bacterium. The product is administered in small therapeutic doses by injection directly into the affected area, and works by blocking the release of acetylcholine (a neurotransmitter that signals the muscles to contract) at the

neuromuscular junction.

29. Botox® Therapeutic therapy was granted approval by the FDA in 1989 for the treatment of strabismus (crossed eyes) and blepharospasm (uncontrollable eye blinking) associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above. Botox® has since received approval in December 2000 for the treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia. In July 2004, Botox® therapeutic was granted FDA approval for the treatment of severe primary axillary hyperhidrosis (excessive underarm sweating) that is inadequately managed with topical agents.

30. Botox® is supplied in single use vial, and is to be reconstituted with sterile, non-preserved saline prior to intramuscular injection. Once reconstituted, it must be stored in a refrigerator and used within 4 hours.

31. Botox® therapeutic sales were $330,000,000 in 2006.

32. Approximately 80% of reimbursement for Botox® has been for off-label prescriptions.

33. The most common off-label uses/prescriptions for Botox® paid for by Government Healthcare Programs have generally been for adult spasticity patients, spasticity in pediatric cerebral palsy patients to treat spasticity issues, and headache patients.

Defendant's Illegal Off-Label Marketing Program

34. Promotion for off-label uses was facilitated by Defendant and accomplished

through various tactics and techniques, including:

a. The use of Regional Scientific Specialists (RSS), known in the industry as "medical liaisons," typically PhD's, pharmacists, or physicians by training, who worked closely with the sales force to target physicians for off-label use, enticing them with kickbacks (which have included clinical trials, studies, or grants). These RSS's worked with and under the direction of the sales and marketing department.

b. The Neurosciences Field Personnel Sample Vial Program allowing for sales representatives, and field personnel to receive free vials of Botox every quarter and to disseminate the free vials to physicians.

c. The use of Regional Business Managers f/k/a Provider Reimbursement Account Managers to target physicians and provide in-kind "consultation" services to them so that they may maximize reimbursement associated with prescribing off-label Botox. This includes reviewing physician claims payments, provide analysis, and prepare excel spreadsheets on maximizing reimbursement; it also includes the provision of meals and other remuneration to physicians, and the provision of "cost recoveries."

d. The use of RHPM's f/k/a Payor Reimbursement Account Managers to work with the sales force to identify physician advocates to advance the policy goals of obtaining off-label coverage of Botox and dose restriction/maximum elimination.

e. The use of a third party vendor, Alphamedica, to facilitate Botox reimbursement information. These presentations often involved off-label coverage discussions. Alphamedica also administered the "BOTOX Speakers Bureau," which enabled Defendant to pay physicians for prescriptions.

f. The use of "preceptorships" to pay healthcare providers for

prescriptions. For instance, Relator O'Connor-Masse "shadowed" a physician who saw 3 headache patients one morning and was paid approximately $1,000 by Defendant. Relator Beilfuss shadowed a physician who saw 2 headache patients and was paid approximately $1,000 by Defendant.

g. The use of "grants" to pay healthcare providers for prescriptions.

h. The use of physician speakers to pay them to influence other physicians to prescribe off-label.

i. The use of clinical trials to pay physicians to prescribe off-label.

j. The use of Botox® Advantage Program™ - Defendant sponsored a third party hotline administered by Covance Market Access and funded it with $5-10.million yearly. The purpose of the hotline was for physicians to be able to call and obtain off-label billing assistance including draft letters written for them to get Botox® paid for by the insurance companies or government healthcare programs. Covance Market Access would provide packets of studies containing off-label studies to the physicians.

k. The use of the "Temporary Price Allowance Program" - Defendant guaranteed targeted physicians a six-month dated price at which to purchase Botox®. The price they would pay is ASP plus 6% in effect, two quarters ago. They were always six months behind, minus any rebate, creating a "spread."

l. The use of organized third-party promotion of the use of Botox® for off-label uses, including "Alliance for Patient Access" ("AFPA"), which to this day is fully funded by Defendant. This organization assists with lowering coverage barriers by payors for off-label use. This also includes funding "WE MOVE," a not for profit corporation incorporated in and located in New York, NY. "WE MOVE" holds itself out as a "Worldwide Education

and Awareness for Movement Disorders Organization" and has available a copy of their "suggested Pediatric Botox ® Dosing" handout.

m. The use of Botox reimbursement hotline (800-44botox) for physicians and their offices to determine billing requirements "to produce a clean claim." This was part of the Botox Advantage Program at one time.

n. The use of physicians as "key opinion leaders" to influence other physicians, and as "advocates" to influence payors to cover off-label uses and doses.

o. The use of misrepresentations made directly to the sales force (which includes Regional Business Managers and Regional Healthcare Policy Managers) involving the intention of Defendant to undertake Phase III trials to obtain FDA-approval for various additional uses for Botox, including for headache and spasticity.

p. By using and paying physicians to be "traveling mentors" and take part in the "Physician Partnership Program" to promote off-label uses and doses.

q. By making sure of the availability and use of, appropriate "adequate codes for emerging and current uses of Botox.®"

r. By partnering and co-promoting with a pharmaceutical company that has FDA approved headache drugs, Defendant used this as an entry into off-label promotion to physicians who prescribed headache drugs. This resulted in increased sales of Botox® by Defendant.

Kickbacks to Health Care Providers In Exchange for Provision of Off-Label Marketing Services

35. Defendant illegally promoted the off-label uses of Botox® through offers and payments of remuneration in violation of the Anti-Kickback Statute. Activities prohibited by

the Anti-Kickback Act described in this Complaint include without limitation payments for consulting services, training sessions, for "clinical trials," for "unrestricted educational grants," for "promotional programs," for physician speaker bureau speaking fees, entertainment, travel and lodging expenses, and expensive meals and wine. Defendant spent $9,200,000 in 2006 alone for CME Programs, Professional CRM, Grants, and Residency Programs.

36. Defendant also paid physicians and other healthcare providers for participation in such programs as preceptorships. The "preceptorship" payments paid to physicians and healthcare providers were ostensibly to allow a sales representative, reimbursement business managers and regional healthcare policy managers to "shadow" the physician. Sales representatives were expected to conduct a set number of preceptorships per year. Preceptorships were simply paid-for sales-pitch opportunities.

37. "Preceptorships" are a sales tactic driven from Defendant's corporate offices in order to develop personal relationships between sales representatives and physicians.

38. Remuneration offered and paid physicians was determined in a manner that took into account the volume or value of business generated by the physician's prescriptions for off-label uses of Botox®, which were paid for in significant part by Government Health Care Programs.

39. Defendant was aware that its actions did in fact result in the prescribing of Botox®for off-label uses and that those prescriptions were paid for in significant part by Government Health Care Programs.

40. Defendant was aware that the payment of kickbacks to induce the ordering of drugs paid in whole or part by federal health care programs was in violation of the Anti-

Kickback Act.

41. Defendant was aware that violators of the Anti-Kickback Act are ineligible for payment under any federal health care program.

42. Notwithstanding this fact, Defendant intentionally and purposefully offered and paid illegal kickbacks to physicians. Defendant knew that the foreseeable consequence of these actions was the submission of false claims to federal health care programs by violators of the Anti-Kickback Act. Nevertheless, Defendant intentionally and purposefully implemented a strategy to caused the submission of increased false claims for the off-label use of Botox.®

PATIENT HARM

43. Not surprisingly, the policies and practices of the Defendant in actively promoting Botox® for multiple off-label uses and doses may have resulted in patient harm and death.

44. For instance, on February 8, 2008, FDA issued its "Early Communication about an Ongoing Safety Review Botox and Botox Cosmetic (Botulinum toxin Type A) and Myobloc (Botulinum toxin Type B)." In it, the FDA stated:

> FDA has received reports of systemic adverse reactions including respiratory compromise and death following the use of botulinum toxins types A and B for both FDA-approved and unapproved uses. The reactions reported are suggestive of botulism, which occurs when botulinum toxin spreads in the body beyond the site where it was injected. The most serious cases had outcomes that included hospitalization and death, and occurred mostly in children treated for **cerebral palsy-associated limb spasticity.** Use of botulinum toxins for treatment of limb spasticity (severe arm and leg muscle spasms) in children or adults is not an approved use in the U.S.

(Emphasis supplied.) It further stated:

> FDA is aware of the body of literature describing the use of botulinum toxins to treat limb spasticity in children and adults. **The safety, efficacy and dosage of botulinum toxins have not been established for the treatment of limb spasticity of cerebral palsy or for use in any condition in children less than 12 years of age.**

(Emphasis supplied.)

45. In a response set forth in a press release on the next day, Defendant made the following statements, emphasizing that the potential safety issue is not applicable to Botox® Cosmetic because, among other reasons, the dosing is much, much more when Botox® is used off-label to treat juvenile cerebral palsy spasticities:

> With respect to the therapeutic use of Botox® to treat juvenile cerebral palsy and other lower limb spasticities, one should keep in mind that the population, treatment paradigms and typical dosing of product is significantly greater than some of the other approved uses of the product, including specifically the FDA-approved use of Botox® Cosmetic to treat wrinkles between the brows.
>
> In particular, the FDA on its teleconference pointed out that this population of patients tends to be "very sick" and that, sadly, this population is generally subject to greater than usual serious adverse events and a higher mortality rate than a healthy population, regardless of the use of the product.
>
> Additionally, in actual practice the treatment of juvenile cerebral palsy tends to involve large lower limb muscles and the amount of Botox® used is typically far greater than the FDA-approved dosing for Botox® Cosmetic. In its "Early Communication," the FDA reported dose in the serious adverse events "ranged from 100 to 700 units" while the approved dosing for Botox® Cosmetic is 20 units.

Reimbursement Criteria Used by Government-funded Health Care Programs

46. The federal government pays for prescription drug benefits under a variety of health care programs. One of these programs is Medicaid, which provides health care coverage, including prescription drug benefits, for the poor and disabled. The Medicaid program, which is administered by the Centers for Medicare and Medicaid Services (CMS), is funded in part by the federal government. Other government-funded health care programs that pay for prescription drugs include Medicare, CHAMPUS/ Tricare, the Veteran's Health Administration, Federal Employees' Health Benefits Program, and the Indian Health Bureau.

47. While each government-funded health program establishes its own reimbursement criteria, none knowingly pay for medications that are not prescribed for a medically accepted indication, or that are prescribed as a result of false or misleading information disseminated by the pharmaceutical manufacturer to either the payors or the healthcare providers. In addition, none of the government-funded health care programs willingly pay for prescription drugs the prescribing of which was the result of, or was influenced by, unlawful inducements from or unlawful marketing activities by the pharmaceutical manufacturer.

48. The off-label uses at issue in this case such as spasticity in children and adults, headache, overactive bladder, pain, various movement disorders are

a. Not supported as medically acceptable by any major compendia such as those specified by 42 U.S.C. §1396r-8(g)(1)(B)(I) (describing federal Medicaid drug coverage);

b. Not capable of being medically accepted by any Medicare contractor based on supportive clinical evidence in certain peer-reviewed medical literature as set forth in 42 U.S.C. §1395(x)(1); or, if medically accepted, based upon misrepresentations of clinical trials and other data;

c. Not supported by reliable evidence as set forth in 32 C.F.R. §199.2 and TRICARE Policy Manual, Chapter 7, Section 2.1. (describing TRICARE drug coverage).

49. Similarly, the FDA doses were not supported by reliable evidence or otherwise medically acceptable.

Defendant Caused Submission of False Claims to Medicaid and Other Federally-Funded Health Programs

50. 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. 42 U.S.C. §§ 1396a(a)-(b). States pay doctors, hospitals, pharmacies, and other providers and suppliers of medical items and services according to established rates. 42 U.S.C. §§ 1396b(a)(1), 1903(a)(1). The federal government then pays each state a statutorily-established share of "the total amount expended ... as medical assistance under the State plan ..." See 42 U.S.C. §1396b(a)(1). This federal-to-state payment is known as federal financial participation ("FFP").

51. The Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program (Form CMS-64) is the accounting statement which states, in accordance with 42 C.F.R. § 430.30©, must submit each quarter under Title XIX of the Social Security Act (the Act). It shows the states' actual expenditures for the quarter being

reported and previous fiscal years, the recoupment made or refunds received, and income earned on grant funds. These amounts, including the amounts paid for prescription drugs, such as Botox®, have a direct effect on the amount of FFP paid by the federal government.

52. Although states may, under federal law, pay for any drug for any indication, they must do so without FFP if the 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). "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)(3). 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) These are American Hospital Formulary Service Drug Information; United States Pharmacopeia-Drug Information; and the Drugdex Information System ("the Drug Compendia").

53. When pharmacies, physicians and other healthcare providers submitted claims based upon a physician's prescription for Botox®to treat off-label and/or with off-label doses, the claims they submitted were false because Botox®was not medically indicated and necessary, and these 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).

54. This was clarified further on May 4, 2006 by Edward C. Gendron in "News for State Medicaid Directors" that was sent to all State Drug Rebate Technical Contacts and all Regional Administrators; Compendia Clarification: "We are also reiterating the

definition of medically accepted indication. Section 1927(k)(5) defines "medically accepted indication" to mean any use for a covered outpatient drug which is approved by the Food and Drug Administration, or a use which is supported by one or more citations included or approved for inclusion in the compendia specified in subsection (g)(1)(B)(II) – the American Hospital Formulary Service Drug Information, United States Pharmacopoeia-Drug Information (or its successor publications), and the Drugdex Information System. The statute requires coverage of off-label uses of FDA-approved drugs for indications that are supported (as opposed to listed) in the compendia specified in section 1927(g)(1)(B)(II) (the "Medicaid Compendia").

55. As noted, the Medicaid Act defines "medically accepted indication" to include uses supported by one or more citations included in the congressionally-designated compendia. None of the compendia has a section entitled "Uses Supported by Citation" (i.e., tracking the language of the statute), and each is arranged differently. Therefore, the requirements to cover drugs for their medically accepted indications must be operationalized by looking in the compendia to determine their organizational structure and where in that structure the supported uses are found.

56. The Medicaid Compendia fails to provide supportive citations for the use of Botox® for any type of spasticity in pediatric patients with cerebral palsy:

a. USP - "Acceptance Not Established"

b. American Hospital Formulary - No entry

c. Drugdex - For upper limb spasticity (in pediatric patients), Drugdex opines that the "evidence is inconclusive." For lower limb spasticity (in pediatric patients), Drugdex opines that "evidence favors efficacy." However, Drugdex only gives it a recommendation of "Pediatric, class IIb," and the actual citations do not amount to "supportive" citations for the use of Botulinum

Toxin A in lower limb spasticity.

57. The Medicaid compendia provide no supportive citations for the use of Botox® in adults with cerebral palsy for either lower limb or upper limb spasticity.

58. *There are no supportive citations using the Medicaid Compendia for* headaches including tension type headaches:

a. USP does not mention headaches at all

b. AHF does not mention headaches at all

c. Drugdex provides that the "Evidence is Inconclusive" to support the use of Botox® for tension-type headaches.

59. Defendant constantly pushed the promotion of greater dosage caps or no dosage caps, without regard to FDA-approved limits or patient safety. The following progress notes are illustrative:

> Dosing limitations=
> MediCal - Removed 200 unit dosing CAP. Dosing is now unlimited. Myobloc remains restricted to 10,000 max. Working on this initiative since 2003
> Florida - Increased dosing max from 300-400, higher doses approved through medical review.
> Iowa - Removed 100 unit cap. Dosing is now limited.

60. Defendant was aware that off-label uses of Botox®were not covered and payable by Medicaid. Defendant was aware that the natural and probable consequence of its promotion of off-label uses of Botox®was that health care providers would submit claims for payment to Medicaid and other government payors for the off-label use. Notwithstanding this fact, Defendant illegally promoted off-label uses of Botox®. Defendant was aware that its illegal promotion did in fact result in false claims to Medicaid and other

government payors for the off-label use. Defendant was aware that its promotion activities was a substantial causal factor in producing the claim.

61. As a result of Defendant's actions, healthcare providers submitted Pharmacy Claim Forms and CMS-1500, and other claim forms to state Medicaid programs, and the states submitted Form CMS-64, all claiming reimbursement for Botox®for such off-label use. Defendant caused the submission of these false claims.

62. The overwhelming majority of the claims for off-label prescribing of Botox®was the direct and proximate result of unlawful off-label marketing efforts by Defendant.

63. Defendant, through its illegal, off-label marketing campaigns, knowingly caused the submission of hundreds of thousands of false Medicaid claims which would not have been reimbursed had the responsible agencies known the circumstances under which such prescriptions were written.

Yearly Medicaid sales from 2002-2006 are as follows:

Labeler	Product Code	Product	Year	Amount
00023	1145	Botox	2006	$17,076,340
00023	1145	Botox	2005	$22,477,645
00023	1145	Botox	2004	$15,301,523
00023	1145	Botox	2003	$12,307,506
00023	1145	Botox	2002	$9,336,714
			Total	**$76,499,728.00**

64. In a presentation to HHSC (Texas Medicaid) in 2004, Defendant gave the following statistics: 86% of all Botox® used is within the pediatric population, primarily in

cerebral palsy; The remaining 14% is within the adult population, primarily adult spasticity.

Claims for Off-label Botox®Did Not Qualify for Medicare Coverage

65. Medicare Part A is funded primarily by a federal payroll tax, premiums paid by Medicare beneficiaries and appropriations from Congress. 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.

66. Medicare Part B is optional to beneficiaries and covers some healthcare benefits not provided by Medicare Part A. Medicare Part B is funded by appropriations from Congress and premiums paid by Medicare beneficiaries who choose to participate in the program. 42 U.S.C. §§1395j - 42 U.S.C. §§l 395w-4. Medicare Part B pays for some types of prescription drugs that are not administered in a hospital setting. 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.

67. On January 1, 2006, Part D of the Medicare program began providing drug coverage for all beneficiaries. The drug benefit covers all drugs that are considered "covered outpatient drugs" under 42 U.S.C. §1396r-8(k). The off-label uses discussed herein are 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" for such uses.

68. Defendant was aware that off-label uses of Botox® would not be covered and payable by Medicare, unless Defendant caused the coverage to occur by active lobbying and promotion of the off-label uses and doses to Medicare contractors. Defendant did in fact actively promote the off-label uses and doses to Medicare contractors, at times using misleading tactics to attain the goal.

69. Defendant was aware that its improper attempts to remove coverage blocks and facilitate off-label coverage to Medicare Contractors did in fact result in claims to Medicare and other government payors for the off-label uses. Defendant was aware that its promotion activities was a substantial factor in producing the coverage of various off-label uses and does. Defendant was also aware that its coaching of physicians on how to bill to receive payment for off-label uses, without necessarily disclosing the off-label use in the claims coding, caused the payment of off-label claims.

70. Claims to Medicare for off-label prescribing of Botox®was the direct and proximate result of misleading off-label marketing efforts by Defendant to Medicare Contractors. As a result of these efforts, Defendant caused the submission of these false claims.

Claims for Off-label Botox®Did not Qualify for Reimbursement Under Other Federal Health Care Programs

1. CHAMPUS/TRICARE, CHAMPVA and the FEHBP

71. In addition to Medicaid and Medicare, the federal government reimburses a portion of the cost of prescription drugs under several other federal health care programs,

including but not limited to CHAMPUS/TRICARE, CHAMPVA and the Federal Employees Health Benefit Program.

72. The off-label uses of Botox® promoted by Defendant were not eligible for reimbursement under any of the various federal health care programs. Coverage of off-label drug use under these programs is similar to coverage under the Medicaid program. 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).

2. Direct Purchases By Federal Agencies

73. In addition to reimbursing drug purchases through Medicare, Medicaid, and other federal health care programs, the United States is a significant direct purchaser of prescription drugs through various federal programs. The United States paid money for Botox®claims which were the result of Defendant's unlawful off-label marketing plan. For instance, the Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors.

3. Programs Administered by the Department of Veterans Affairs

74. 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.

4. Programs Administered By The Department of Defense

75. The Department of Defense ("DOD") provides prescription drug coverage to approximately eight million active duty personnel, retirees, and their families through three points of service: military treatment facility outpatient pharmacies, TRICARE managed care contractor retail pharmacies, and the National Mail Order Pharmacy Program. DOD negotiates independent contracts to purchase the majority of the prescription drugs provided through these programs.

76. Defendant was aware that off-label uses of Botox® were not covered and were not legally payable by any of these programs.

77. Defendant was aware that the natural and probable consequence of its promotion of off-label uses of Botox® was that health care providers would submit claims for payment to these and other government payors for the off-label use.

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

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

IV. FALSE AVERAGE SALES PRICE

80. Defendant has targeted high utilizing physicians with an off-invoice discount strategy each year by giving targeted physicians and other healthcare providers an off-invoice discount equal to the annual price increase for that year. The off-invoice discount

lasts for the first half of each year. The Defendant does this to allow reimbursement (ASP/AWP) to catch up with the new price so that there remains a spread between the physician acquisition cost of Botox® and the Medicare reimbursement amount for Botox®. The Defendant also gives "wholesaler prompt pay discounts." Upon information and belief, these discounts are off-invoice and not taken into account when Defendant calculated its Average Sales Price (ASP) for each given year. As a result, the weighted average sales price calculated by CMS has been artificially inflated, resulting in millions of dollars in overpayment in Medicare reimbursement for Botox®.

V. MARKETING THE SPREAD ON BOTOX®

81. Drug manufacturers provide average wholesale prices ("AWPs") to "national reporting services," such as the Red Book and First Data Bank. Both Medicare and most Medicaid programs use these AWPs as reported, as a benchmark for reimbursing certain providers. The national reporting services have published the AWP for Botox® each year since it was FDA-approved. These publications, in periodically announcing the average wholesale prices, simply published those prices that DEFENDANT had previously supplied to the reporting services. DEFENDANT knew and understood that, because the Medicare program relied upon the published prices to establish average wholesale prices and because DEFENDANT could precisely control the cost to the healthcare provider, Defendant could increase the profit obtained by healthcare providers from the Medicare Program by reducing the healthcare providers' acquisition cost of Botox® . The difference between the healthcare providers' acquisition cost, and the price paid by Medicare and other payors (AWP less a certain percentage), is referred to as "the spread."

82. Reimbursement Business Managers would demonstrate to healthcare providers the financial benefit of using Botox® on patients because each patient vial/injection was worth at least an additional approximately $50-$100 in revenue to the healthcare providers. Due to this inducement, many healthcare providers then determined that it would be profitable to start, continue and expand the treatment of patients with Botox®

83. Defendant Reimbursement Business Managers would present healthcare providers with a recovery analysis spreadsheet/chart with billing codes to demonstrate to them that billing for Botox® could earn them a margin when reimbursed by Medicare and other payors.

84. Defendant would educate and train its sales force so its Reimbursement Business Managers could help healthcare providers regarding reimbursement.

COUNT I—FALSE CLAIMS ACT

85. Relators reallege and incorporate by reference paragraphs 1 -84 as though fully set forth herein.

86. This is a claim by Relators, on behalf of The United States, for treble damages and penalties under the False Claims Act, 31 U.S.C. 3729-3733 against Defendant for knowingly causing to be presented false claims to Government Healthcare Programs. From on or about January 2000 through present, in the District of Massachusetts and elsewhere throughout the United States, Defendant has knowingly and willfully violated the False Claims Act by causing false claims to be submitted against

federal funds by engaging in a massive off-label marketing campaign for Botox®.

87. Defendant knowingly made, used, or caused to be made or used false records and/or statements to get false or fraudulent claims paid or approved by the Government, in violation of subsection 3729(a)(2). Each prescription that was written as a result of Defendant's illegal marketing practices and illegal kickbacks represents a false or fraudulent record or statement.

88. Defendant has knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Botox®, knowing that such false claims would be submitted to state Medicaid programs for reimbursement, and knowing that such Government Healthcare Programs were unaware that they were reimbursing prescriptions for non-covered uses and therefore false claims. By virtue of the acts described in this Complaint, Defendant 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).

89. Defendant has 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, including Botox®, were paid for in compliance with federal law. States submitted false claims to the United States Government because *when Botox® was prescribed off-label, it was not a "covered outpatient drug,"* yet states sought reimbursement from the United States Government for all Botox® expenditures.

90. Defendant caused false claims to be submitted for Botox®, 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).

91. 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.

WHEREFORE, Relators respectfully request this Court enter judgment against Defendant, 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 Defendant 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 Relators necessarily incurred in bringing and pressing this case;

(d) That the Relators 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
ILLINOIS WHISTLEBLOWER REWARD & PROTECTION ACT

92. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 84 above as if fully set forth herein.

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

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

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

94. In addition, 305 ILCS 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.

95. Defendant violated 305 ILCS 5/8A-3(b) by engaging in the conduct described herein.

96. Defendant furthermore violated 740 ILCS 175/3(a) and knowingly caused hundreds of thousands of 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.

97. The State of Illinois, by and through the Illinois Medicaid program and other

state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

98. 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 Defendant's 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.

99. Had the State of Illinois known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant 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.

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

101. Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to 740 ILCS 175/3(b) on behalf of themselves and the State of Illinois.

102. 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, RELATORS respectfully request this Court to award the following

damages to the following parties and against Defendant:

To the STATE OF ILLINOIS:

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

To RELATORS:

(1) The maximum amount allowed pursuant to 740 ILCS 175/4(d) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relators 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
CALIFORNIA FALSE CLAIMS ACT

103. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 84 above as if fully set forth herein.

104. This is a *qui tam* action brought by RELATORS 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.*

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

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

> getting a false claim allowed or paid by the state or by any political subdivision.
> (4) is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

106. 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.

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

108. Defendant furthermore violated Cal. Gov't Code § 12651(a) and knowingly caused hundreds of thousands of 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.

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

110. 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 Defendant's 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.

111. Had the State of California known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's 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.

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

113. RELATORS are private citizens 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 themselves and the State of California.

114. 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, RELATORS respectfully request this Court to award the following damages to the following parties and against Defendant:

To the STATE OF CALIFORNIA:

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

(2) A civil penalty of up to $10,000 for each false claim which Defendant presented or caused to be presented to the State of California;

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

To RELATORS:

(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 Relators 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

115. Plaintiff repeats and realleges each allegation contained in paragraphs I through 84 above as if fully set forth herein.

116. This is a *qui tam* action brought by RELATORS 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.*

117. Fla. Stat. § 68.082(2) provides liability for any person who-

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

118. 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.

119. 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.

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

121. Defendant furthermore violated Fla. Stat. § 68.082(2) and knowingly caused hundreds of thousands of 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.

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

123. 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 Defendant's 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.

124. Had the State of Florida known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's 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.

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

126. RELATORS are private citizens 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 themselves and the State of Florida.

127. 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, RELATORS respectfully request this Court to award the following damages to the following parties and against Defendant:

To the STATE OF FLORIDA:

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

To RELATORS:

(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 Relators 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
TEXAS FALSE CLAIMS ACT

128. Plaintiff repeats and realleges each allegation contained in paragraphs I through 84 above as if fully set forth herein.

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

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

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

(2) knowingly or intentionally concealing or failing to

disclose an event:

(a) that the person knows affects the initial or continued right to a benefit or payment under the Medicaid program of.

(i) the person, or

(ii) another person on whose behalf the person has applied for a benefit or payment or is receiving a benefit or payment; and

(b) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized;

(4) knowingly or intentionally makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:

(b) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;

(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.

131. Defendant violated V.T.C.A. Hum. Res. Code § 36.002 and knowingly caused hundreds of thousands of 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.

132. The State of Texas, by and through the Texas Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted

by healthcare providers and third party payers in connection therewith.

133. 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 Defendant's 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.

134. Had the State of Texas known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's 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.

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

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

137. RELATORS are private citizens with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to V.T.C.A. Hum.

Res. Code § 36.101 on behalf of themselves and the State of Texas.

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 Texas in the operation of its Medicaid program.

WHEREFORE, RELATORS respectfully request this Court to award the following damages to the following parties and against Defendant:

To the STATE OF TEXAS:

(1) Two times the amount of actual damages which the State of Texas has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $10,000 pursuant to V.T.C.A. Hum.. Res. Code § 36.025(a)(3) for each false claim which Defendant cause to be presented to the state of Texas;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To RELATORS:

(1) The maximum amount allowed pursuant to V.T.C.A. Hum. Res. Code § 36.110, and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relators 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
MASSACHUSETTS FALSE CLAIMS ACT

139. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 84 above as if fully set forth herein.

140. This is a *qui tam* action brought by RELATORS on behalf of the

Commonwealth of Massachusetts for treble damages and penalties under Massachusetts False Claims Act, Mass. Gen. Laws Ann. Chap. 12 § 5(A) *et seq.*

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

> (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or
> (3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;
> (9) is a beneficiary of an inadvertent submission of a false claim to the common wealth 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.

142. In addition, Mass. Gen. Laws Ann. 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.

143. Defendant violated Mass. Gen. Laws Ann. Chap. 118E § 41 by engaging in the conduct described herein.

144. Defendant furthermore violated Mass. Gen. Laws Ann. Chap. 12 § 5B and knowingly caused hundreds of thousands of 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

Ann. 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.

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

146. 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 Defendant's 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.

147. Had the Commonwealth of Massachusetts known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's 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.

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

149. RELATORS are private citizens with direct and independent knowledge of

the allegations of this Complaint, who has brought this action pursuant to Mass. Gen. Laws Ann. Chap. 12 § 5(c)(2) on behalf of themselves and the Commonwealth of Massachusetts.

150. 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, RELATORS respectfully request this Court to award the following damages to the following parties and against Defendant:

To the Commonwealth OF MASSACHUSETTS:

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

To RELATORS:

(1) The maximum amount allowed pursuant to Mass. Gen. Laws Ann. Chap. 12, §5F and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relators 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
TENNESSEE FALSE CLAIMS ACT

151. Plaintiff repeats and realleges each allegation contained in paragraphs 1

through 84 above as if fully set forth herein.

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

§ 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.

153. Defendant violated Tenn. Code Ann. § 71-5-1 82(a)(1) and knowingly caused hundreds of thousands of 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.

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

155. 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 Defendant's 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.

156. Had the State of Tennessee known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's 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.

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

158. RELATORS are private citizens with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tenn. Code Ann. § 71-5-183(a)(1) on behalf of themselves and the State of Tennessee.

159. 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, RELATORS respectfully request this Court to award the following damages to the following parties and against Defendant:

To the STATE OF TENNESSEE:

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

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

To RELATORS:

(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 Relators 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
DELAWARE FALSE CLAIMS AND REPORTING ACT

160. Plaintiff repeats and realleges each allegation contained in paragraphs I through 84 above as if fully set forth herein.

161. This is a *qui tam* action brought by RELATORS 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.

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.

162. 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.

163. Defendant violated 31 Del. C. § 1005 by engaging in the conduct described herein.

164. Defendant furthermore violated 6 Del. C. § 1201(a) and knowingly caused hundreds of thousands of 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.

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

166. 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 Defendant's 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.

167. Had the State of Delaware known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's 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.

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

169. RELATORS are private citizens 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 themselves and the State of Delaware.

170. 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, RELATORS respectfully request this Court to award the following damages to the following parties and against Defendant:

To the STATE OF DELAWARE:

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

To RELATORS:

(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 Relators 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
NEVADA FALSE CLAIMS ACT

171. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 84 above as if fully set forth herein.

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

173. N.R.S. § 357.040(1) provides liability for any person who-

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

174. In addition, N.R.S. § 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.

175. Defendant violated N.R.S. § 422.560 by engaging in the conduct described herein.

176. Defendant furthermore violated N.R.S. § 357.040(1) and knowingly caused

hundreds of thousands of 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 N.R.S. § 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.

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

178. 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 Defendant's 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.

179. Had the State of Nevada known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant' 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.

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

181. RELATORS are private citizens with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.R.S. § 357.080(1) on behalf of themselves and the State of Nevada.

182. 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, RELATORS respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the STATE OF NEVADA:

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

To RELATORS:

(1) The maximum amount allowed pursuant to N.R.S. § 357.210 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relators 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
LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

183. Plaintiff repeats and realleges each allegation contained in paragraphs 1

through 84 above as if fully set forth herein.

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

185. La. Rev. Stat. Ann. § 438.3 provides-

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

186. In addition, La. Rev. Stat. Ann. § 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.

187. Defendant violated La. Rev. Stat. Ann. § 438.2(A) by engaging in the conduct described herein.

188. Defendant furthermore violated La. Rev. Stat. Ann. §438.3 and knowingly caused hundreds of thousands of 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. Ann. § 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.

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

190. 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 Defendant's 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.

191. Had the State of Louisiana known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's 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.

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

193. RELATORS are private citizens with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to La. Rev. Stat. Ann. §439.1(A) on behalf of themselves and the State of Louisiana.

194. 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, RELATORS respectfully request this Court to award the following damages to the following parties and against Defendant:

To the STATE OF LOUISIANA:

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

To RELATORS:

(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 Relators 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
HAWAII FALSE CLAIMS ACT

195. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 84 above as if fully set forth herein.

196. This is a *qui tam* action brought by RELATORS 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.*

197. 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 d 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.

198. Defendant violated Haw. Rev. Stat. §661-21(a) and knowingly caused hundreds of thousands of 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.

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

200. 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 Defendant's 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.

201. Had the State of Hawaii known that Defendant was violating the federal and

state laws cited herein and/or that the claims submitted in connection with Defendant's 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.

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

203. RELATORS are private citizens 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 themselves and the State of Hawaii.

204. 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, RELATORS respectfully request this Court to award the following damages to the following parties and against Defendant:

To the STATE OF HAWAII:

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

To RELATORS:

(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 Relators 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
DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

205. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 84 above as if fully set forth herein.

206. This is a *qui tam* action brought by RELATORS 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.*

207. 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.

208. 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.

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

210. Defendant 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.

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

212. Compliance with applicable Medicare, Medicaid and the various other federal and 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 Defendant's 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.

213. Had the District of Columbia known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's

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.

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

215. RELATORS are private citizens 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 themselves and the District of Columbia.

216. 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, RELATORS respectfully request this Court to award the following damages to the following parties and against Defendant:

To the DISTRICT OF COLUMBIA:

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

To RELATORS:

(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 Relators 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
COMMONWEALTH OF VIRGINIA

217. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 84 above as if fully set forth herein.

218. This is a *qui tam* action brought by RELATORS on behalf of the Commonwealth of Virginia for treble damages and penalties under Virginia Fraud Against Tax Payers Act §8.01-216.3a 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 common wealth 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.

219. 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.

220. Defendant violated VA Code ANN § 32.1-315 by engaging in the conduct described herein.

221. Defendant furthermore violated Virginia Fraud Against Tax Payers Act §8.01-216.3a and knowingly caused hundreds of thousands of 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.

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

223. 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 Defendant's 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.

224. Had the Commonwealth of Virginia known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's 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.

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

226. RELATORS are private citizens with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Virginia Fraud Against Tax Payers Act §8.01-216.3 on behalf of themselves and the Commonwealth of Virginia.

227. 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, RELATORS respectfully request this Court to award the following damages to the following parties and against Defendant:

To the Commonwealth Of Virginia:

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

To RELATORS:

(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 Relators 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
THE NEW HAMPSHIRE HEALTH CARE FALSE CLAIMS LAW

228. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 84 above as if fully set forth herein.

229. This is a *qui tam* action brought by RELATORS 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.

!. Any person shall be liable who...

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

230. 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.

231. Defendant violated the N.H. Rev.Stat. Ann by engaging in the conduct

described herein.

232. Defendant furthermore violated N.H. Rev.Stat. Ann. §167:61-b, and knowingly caused hundreds of thousands of 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.

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

234. 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 Defendant's 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.

235. Had the State of New Hampshire known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant 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.

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

237. Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to N.H. Rev.Stat. Ann. §167:61-b on behalf of themselves and the State of New Hampshire.

238. 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, RELATORS respectfully request this Court to award the following damages to the following parties and against Defendant:

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

To RELATORS:

(1) The maximum amount allowed pursuant to N.H. Rev. Stat. Ann § 167:61-b and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relators 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 YORK FALSE CLAIMS ACT

239. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 84 above as if fully set forth herein.

240. This is a *qui tam* action brought by RELATORS 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

> 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.

241. 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.

242. Defendant violated the New York State Consolidated Laws by engaging in the conduct described herein.

243. Defendant furthermore violated, 2007 N.Y. Laws 58, Section 39, Article XIII, and knowingly caused hundreds of thousands of 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.

244. The State of New York, by and through the New York Medicaid program and other state healthcare programs, and unaware of Defendant's 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 York in connection with Defendant's 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.

246. Had the State of New York known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant 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.

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

248. Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to 2007 N.Y. Laws 58, Section 39, Article XIII, on behalf of themselves and the State of New York.

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 York in the operation of its Medicaid program.

WHEREFORE, RELATORS respectfully request this Court to award the following damages to the following parties and against Defendant:

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

To RELATORS:

(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 Relators 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
MICHIGAN MEDICAID FALSE CLAIMS ACT

250. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 84 above as if fully set forth herein.

251. This is a *qui tam* action brought by RELATORS 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

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 York in the operation of its Medicaid program.

WHEREFORE, RELATORS respectfully request this Court to award the following damages to the following parties and against Defendant:

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

To RELATORS:

(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 Relators 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
MICHIGAN MEDICAID FALSE CLAIMS ACT

250. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 84 above as if fully set forth herein.

251. This is a *qui tam* action brought by RELATORS 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...

252. 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.

253. Defendant violated MI ST Ch. 400.603 et seq. by engaging in the conduct described herein.

254. Defendant furthermore violated, MI ST Ch. 400.603 et seq. and knowingly caused hundreds of thousands of 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.

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

256. 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 Defendant's 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.

257. Had the State of Michigan known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant 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.

258. As a result of Defendant's violations 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.

259. Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to MI ST Ch. 400.603 et seq. on behalf of themselves and the State of Michigan.

260. 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, RELATORS respectfully request this Court to award the following damages to the following parties and against Defendant:

To the STATE OF Michigan:

(1) Three times the amount of actual damages which the State of Michigan has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Michigan;
(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS:

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

COUNT XVII
NEW MEXICO MEDICAID FALSE CLAIMS ACT

261. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 84 above as if fully set forth herein.

262. This is a *qui tam* action brought by RELATORS on behalf of the State of New Mexico to recover treble damages and civil penalties under the New Mexico Fraud Against Taxpayers Act N.M. Stat. Ann§§ 27-14-1 et seq.

Section 3 provides liability in pertinent part as follows:

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...

263. 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.

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

265. Defendant furthermore violated, N.M. Stat. Ann§§ 27-14-1 et seq. and knowingly caused hundreds of thousands of 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.

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

267. 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 Defendant's 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.

268. Had the State of New Mexico known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant 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.

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

270. Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to N.M. Stat. Ann§§ 27-14-1 et seq. on behalf of themselves and the State of New Mexico.

271. 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, RELATORS respectfully request this Court to award the following damages to the following parties and against Defendant:

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

To RELATORS:

(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 Relators 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

INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

272. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 84 above as if fully set forth herein.

273. This is a *qui tam* action brought by RELATORS 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

> (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
> (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)...
>
> a penalty or damages.

274. 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.

275. Defendant violated the INDIANA Code 5-11-5.5 et seq. by engaging in the conduct described herein.

276. Defendant furthermore violated INDIANA Code 5-11-5.5 et seq. and knowingly caused hundreds of thousands of 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.

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

278. 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 Defendant's 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.

279. Had the State of Indiana known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant 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.

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

281. Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to INDIANA Code 5-11-5.5 et seq. on behalf of themselves and the State of Indiana.

282. 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, RELATORS respectfully request this Court to award the following damages to the following parties and against Defendant:

To the STATE OF Indiana:

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

To RELATORS:

(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 Relators 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.

merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

WHEREFORE, RELATORS respectfully request this Court to award the following damages to the following parties and against Defendant:

To the STATE of Indiana:

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

To RELATORS:

(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 Relators 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 this 22nd day of February, 2008.

Respectfully submitted,

John Roddy, BBO # 424240
Roddy Klein & Ryan
727 Atlantic Ave
Second Floor
Boston, MA 02111
Telephone: (617) 357-5500
Telefax: (617) 357-5030

Of Counsel:
Nolan & Auerbach, P.A.
435 N. Andrews Ave., Suite 401
Fort Lauderdale, FL 33301
Phone: (954) 779-3943
Fax: (954) 779-3937