IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, ex rel. Frank Garcia, STATE OF CALIFORNIA, ex rel. Frank Garcia and Christine Driscoll, STATE OF DELAWARE, ex rel. Frank Garcia and Christine Driscoll, DISTRICT OF COLUMBIA, ex rel. Frank Garcia and Christine Driscoll, STATE OF FLORIDA, ex rel. Frank Garcia and Christie Driscoll, STATE OF HAWAII, ex rel. Frank Garcia and Christine Driscoll, STATE OF ILLINOIS, ex rel. Frank Garcia and Christine Driscoll, COMMONWEALTH OF MASSACHUSETTS, ex rel. Frank Garcia and Christine Driscoll, STATE OF NEVADA, ex rel. Frank Garcia and Christine Driscoll, STATE OF TENNESSEE, ex rel. Frank Garcia and Christine Driscoll. STATE OF TEXAS, ex rel. Frank Garcia and Christine Driscoll, and COMMONWEALTH OF VIRGINIA, ex rel. Frank Garcia and Christine Driscoll, **Plaintiffs,** **v.** **SERONO, INC.** **Defendant.**	**Case No. 03-CV-11892 (GAO) (<u>In Camera and Under Seal</u>)**

AMENDED COMPLAINT FOR DAMAGES AND OTHER RELIEF
<u>UNDER THE FEDERAL AND STATE FALSE CLAIMS ACTS</u>

INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America and eleven states arising from false statements and claims made and caused to be made by the Defendant, Serono, Inc., its agents and, employees in violation of the Federal False Claims Act, 31 U.S.C. § 3729 *et seq.* as amended ("The Federal FCA") and eleven parallel state statutes (collectively "The State False Claims Acts" or "State FCAs").

2. The false and fraudulent claims described herein are based on two forms of illegal activity. First, Defendant Serono, Inc. ("Serono") has made direct and indirect payments to health care providers as inducements for the writing of drug prescriptions for its drug product Serostim and manipulated test data related thereto. The offering or paying of remuneration to induce health care providers to write drug prescriptions constitutes an illegal kickback under the Medicare and Medicaid Protection Act of 1987, as amended, 42 U.S.C. § 1320-a-7b (the "Anti-Kickback Statute"). Second, Defendant Serono has violated the Federal Food Drug and Cosmetic Act, 21 U.S.C. §§ 331(z), 333(a)(1)-(2), 360aaa, by promoting "off-label" *i.e.*, unapproved use of Serostim. Both categories of statutory violations have led to the submission of false and fraudulent claims against state and federal government health insurance programs, as defined and described more fully below, in violation of the State and Federal False Claims Acts.

JURISDICTION AND VENUE

3. This Court has jurisdiction over this action under the Federal FCA, 31 U.S.C. §§ 3732(a) and 3730(h), and 28 U.S.C. §§ 1331 and 1345, and has pendent jurisdiction over the state FCA claims pursuant to 28 U.S.C. § 1367. Venue is proper in

this district because the Defendant transacts business in this judicial district, and acts proscribed by the Federal FCA have been committed by the Defendant in this judicial district.

4. Relator Frank Garcia originally filed this action in the United States District Court for the District of Connecticut on June 26, 2002. On September 5, 2003, the case was ordered transferred to this Court (on the government's unopposed motion) and consolidated with two other *qui tam* actions originally filed in Massachusetts and Maryland, respectively. All three actions remain under seal at this time.

PARTIES

5. Frank Garcia resides at 34 Weaver Street, in Greenwich, Fairfield County, Connecticut. Garcia was employed by Serono as a pharmaceutical sales representative in the Connecticut area from March 1, 1999 to September 19, 2000. Garcia brings this action for violations of 31 U.S.C. § 3729 *et seq.*, on behalf of himself and the United States Government pursuant to 31 U.S.C. § 3730(b)(1), and the following states which have comparable False Claims Acts: California, Delaware, District of Columbia, Florida, Hawaii, Illinois, Massachusetts, Nevada, Tennessee, Texas, and Virginia. Mr. Garcia has direct and independent personal knowledge of the violations described herein, and is an "original source" under the State and Federal FCAs.

6. Relator Christine Driscoll ("Driscoll") is a former employee of Serono, currently residing in Plymouth County, Massachusetts. She is a relator in the related case of United States of America *ex rel.* Driscoll v. Serono Laboratories, Inc. et. al., Civ. No. 00-11680 (GAO). Driscoll brings this action on behalf of the following states which have False Claims Acts comparable to the federal statute: California, Delaware, District

of Columbia, Florida, Hawaii, Illinois, Massachusetts, Nevada, Tennessee, Texas, and Virginia. Mr. Garcia and Ms. Driscoll have direct and independent personal knowledge of the violations described herein, and are "original sources" under the state and federal False Claims Acts. For purposes of this action, Driscoll and Garcia are co-relators with respect to the pendent state claims outlined below in Counts 4-36.

7. Defendant Serono is a corporation organized and existing under the provisions of the laws of the State of Delaware with its principal place of business located at One Technology Place, Rockland, Massachusetts.

FEDERAL AND STATE HEALTH INSURANCE PROGRAMS

8. The Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.* (hereinafter "Medicare"), is a Health Insurance Program administered by the Government of the United States that is funded by taxpayer revenue. The program is overseen by the United States Department of Health and Human Services ("HHS") through the Centers for Medicare and Medicaid Services ("CMS"). Medicare was designed to be a health insurance program and to provide for, among other things, the payment of hospital services, medical services and certain medications for persons over sixty-five (65) years of age and others who qualify under the terms and conditions of the Medicare Program. Payments made under the Medicare Program include payment by licensed and approved physicians for services which are reasonable and medically necessary for the diagnosis or treatment of an illness or injury.

9. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (hereafter "Medicaid"), is a Health Insurance Program administered by the Government of the United States and the various individual States and is funded by

State and Federal taxpayer revenue. The Medicaid Program is overseen by HHS through CMS. Medicaid was designed to assist participating states in providing, among other things, hospital and medical services and prescription drugs to financially needy individuals who qualify for Medicaid.

10. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") (now known as "TRICARE"), 10 U.S.C. §§ 1071-1106, provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the Uniformed Services and to spouses and children of active duty, retired and deceased members. The program is administered by the Department of Defense and funded by the Federal Government. CHAMPUS pays for, among other items and services, tests and procedures and prescription drugs for its beneficiaries.

11. The Federal Employees Health Benefits Program ("FEHBP") provides health care benefits for qualified federal employees and their dependents. It pays for, among other items and services, tests and procedures and prescription drugs for its beneficiaries. (Together these programs described in paragraphs 7-10 shall be referred to as "Government Health Care Programs").

FEDERAL AND STATE LAWS

12. The Federal False Claims Act ("Federal FCA"), 31 U.S.C. § 3729(a)(1), makes "knowingly" presenting or causing to be presented to the United States any false or fraudulent claim for payment, a violation of law for which the affected government party may recover three times the amount of the damages the government sustains and a

civil monetary penalty of between $5,000 and $10,000 per claim ($5,500 and $11,000 for claims made on or after September 29, 1999 under the Federal FCA).

13. The Federal FCA, 31 U.S.C. § 3729(a)(2), makes "knowingly" making, using, or causing to be used or made a false record or statement to get a false or fraudulent claim paid or approved by the United States a violation of law for which the affected government party may recover three times the amount of the damages the government sustains and a civil monetary penalty of between $5,000 and $10,000 per claim ($5,500 and $11,000 for claims made on or after September 29, 1999 under the Federal FCA).

14. The Federal FCA, 31 U.S.C. § 3729(a)(3), makes any person who conspires to defraud the United States by getting a false or fraudulent claim allowed or paid, liable for three times the amount of the damages the affected government party sustains and a civil monetary penalty of between $5,000 and $10,000 per claim ($5,500 and $11,000 for claims made on or after September 29, 1999 under the Federal FCA).

15. The Federal FCA, 31 U.S.C. § 3729(b), defines "knowing" or "knowingly" to mean that a person, with respect to relevant information: (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (c) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

16. The Federal FCA, 31 U.S.C. § 3729(c), defines a "claim" to include any request or demand, whether under contract or otherwise, for money or property which is made to the government, its representative, contractor, grantee, or other person if the government party in question (*i.e.*, the United States) provides any portion of the money

or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

17. As set forth below, several states have passed similar False Claims Act legislation, which in most instances closely tracks the federal statute: California False Claims Act, Cal. Gov't Code § 12650 *et seq.*, Delaware False Claims and Reporting Act, Del. Code Ann. Tit. 6, § 1201 *et seq.*, District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.13 *et seq.*, Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*, Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*, Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1 *et seq.*, Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5A *et seq.*, Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq.*, Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*, Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.001 *et seq.*, and Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.* These State False Claims Acts apply to the state portion of Medicaid fraud losses caused by false Medicaid claims to the jointly funded Medicaid program. Each of the statutes listed above contains *qui tam* provisions governing a relator's right to claim a share of the State's recovery.

18. The Medicare-Medicaid Anti-Fraud and Abuse Amendments, known as the Medicare Anti-Kickback Act ("AKA"), 42 U.S.C. §1320a-7b(b), makes it illegal to offer, receive, or solicit any remuneration, kickback, bribe, or rebate, whether directly or indirectly, overtly or covertly, in cash or in kind, to or from, any person in order to induce such person to purchase, lease, or order, or to arrange for or recommend the purchasing,

leasing, or ordering of any good, service, or item for which payment may be made in whole or in part under a Government Health Care Program.

19. The AKA seeks to prohibit such activities in order to secure proper medical treatment and referrals, and to limit the possibility of a patient having to undergo unnecessary treatments or having to accept specific items or services which are based not on the needs of the patient but on the incentives given to others, thereby limiting the patient's right to choose proper medical care and services.

20. The Federal Food, Drug, and Cosmetic Act provides criminal penalties for the dissemination of certain written information to health care providers regarding the safety, effectiveness, or benefit of the use of a drug that is not described in the approved labeling of the drug. 21 U.S.C. §§ 331(z), 333(a)(1)-(2), 360aaa. A manufacturer may disseminate information on a new use of a drug only if it meets the specific requirements set forth in 21 U.S.C. § 360aaa(b). The specific requirements set forth in 21 U.S.C. §360aaa(b) include:

> (1)(A) in the case of a drug, there is in effect for the drug an application filed under subsection (b) or (j) or section 355 of this title or a biologics license issued under section 262 of Title 42:
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> ...
>
> (2) the information meets the requirements of section 360aaa-1 of this title;
>
> (3) the information to be disseminated is not derived from clinical research conducted by another manufacturer or if it was derived from research conducted by another manufacturer, the manufacturer disseminating the information has the permission of such other manufacturer to make the dissemination;
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> (4) the manufacturer has, 60 days before such dissemination, submitted to the Secretary-
>
> (A) a copy of the information to be disseminated; and

> (B) any clinical trial information the manufacturer has relating to the safety or effectiveness of the new use, any reports of clinical experience pertinent to the safety of the new use, and a summary of such information;
>
> (5) the manufacturer has complied with the requirements of section 360aaa-3 of this title (relating to a supplemental application for such use);
>
> (6) the manufacturer includes along with the information to be disseminated under this subsection –
>
> (A) a prominently displayed statement that discloses –
>
> (i) that the information concerns a use of a drug or device that has not been approved or cleared by the Food and Drug Administration;
>
> (ii) if applicable, that the information is being disseminated at the expense of the manufacturer;
>
> (iii) if applicable, the name of any authors of the information who are employees of, consultants to, or have received compensation from, the manufacturer, or who have a significant financial interest in the manufacturer;
>
> (iv) the official labeling for the drug or device and all updates with respect to the labeling;
>
> (v) if applicable, a statement that there are products or treatments that have been approved or cleared for the use that is the subject of the information being disseminated pursuant to subsection (a)(1) of this section; and
>
> (vi) the identification of any person that has provided funding for the conduct of a study relating to the new use of a drug or devise for which such information is being disseminated; and
>
> (B) a bibliography of other articles from a scientific reference publication or scientific or medical journal that have been previously published about the use of the drug or device covered by the information disseminated (unless the information already includes such bibliography).

21. A manufacturer may disseminate written information on a new use of a drug only if the information is about a clinical investigation with respect to the drug and is contained in an article published in a scientific or medical journal, which is peer-reviewed by experts, or in a reference publication. 21 U.S.C. §360aaa-1 states in part:

> (a) Authorized information – A manufacturer may disseminate information under section 360aaa of this title on a new use only if the information –

(1) is in the form of an unabridged –

(A) reprint or copy of an article, peer-reviewed by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device involved, which was published in a scientific or medical journal (as defined in section 360aaa-5(5) of this title), which is about a clinical investigation with respect to the drug or device, and which would be considered to be scientifically sound by such experts; or

(B) reference publication, described in subsection (b) of this section that includes information about a clinical investigation with respect to the drug or device that would be considered to be scientifically sound by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device that is the subject of such a clinical investigation; . . .

FACTUAL ALLEGATIONS

22. Serono International, S.A., is a global biotechnology company headquartered in Geneva, Switzerland. Serono, Inc. (formerly Serono Laboratories, Inc.) is its U.S. Subsidiary. Serono manufactures Serostim, which is the trade name for the drug Somatropin, a human growth hormone. The Food and Drug Administration approved Serostim to treat AIDS wasting in HIV-infected patients on August 23, 1996. The use of Serostim for the treatment of lypodystrophy was not described in the approved labeling of the drug. Serostim is the propriety name or trademark given by Serono to the pharmaceutical product identified by the generic name "Somatropin." Serostim is a mammalian cell derived human growth hormone (r-hGH) which is identical to endogenous human growth hormone. Serostim is delivered in lyophilized powder form intended for injection by the consumer.

23. Relator Frank Garcia is a former employee of Serono. Serono employed him as a sales representative, beginning in February, 1999. Garcia was assigned to the southern New England area and was specifically assigned to promote Serostim. In

connection with his job duties, Garcia received training from Serono, attended company-wide seminars and conferences concerning the promotion of Serostim in all of Serono's market areas, and conferred with other sales representatives both in and outside his area concerning the promotion of the product. He thus developed knowledge of the company's sales practices nation-wide. Garcia was laid off in September, 2000.

24. Relator Christine Driscoll is a former employee of Serono. Serono employed her for approximately seven years, first as a Reimbursement Specialist from 1995 until 1997 and then as a Clinical Consultant, the title originally given by Serono to its sales representatives, from 1997 to 2002, when she resigned. As a sales representative, Driscoll was assigned to the Northeast region and at various times covered each of the New England states and was assigned to promote the company's metabolic and immune therapies, specifically including Serostim. In connection with her job duties, Driscoll received training from Serono, attended company-wide seminars and conferences concerning the promotion of Serostim in all of Serono's market areas, and conferred with other sales representatives both in and outside her area concerning the promotion of the product. She thus developed knowledge of the company's sales practices nation-wide.

FRAUDULENT MANIPULATION OF TEST DATA

25. Throughout the United States, Serono provided its sales representatives with Bioelectrical Impedance Analysis ("BIA") machines in order to determine a patient's lean body mass, a prerequisite to a diagnosis of AIDS wasting. In order to encourage indigent patients to take a BIA test performed by a Serono sales agent, in or about 1999 and 2000, Serono provided patients gift certificates,

phone cards and bus tokens in exchange for taking a BIA test. The test results were furnished to the patients' physicians. Often, Serono employees and agents would manipulate the BIA test results to provide a false positive reading of wasting.

26. Also from the time Serostim was first approved, Serono engaged in a pattern of conduct that fraudulently induced physicians who prescribed Serostim to bill HCFA improperly for BIA, a medical diagnostic test that evaluates body composition by running a faint electrical current through the body. BIA tests were necessary to justify a three-month prescription of Serostim. In most cases, BIA testing was required for each Serostim patient on a quarterly basis.

27. Serono instructed its sales staff to perform BIA testing using BIA machines that Serono owned and provided to its sales representatives. Serono then instructed its sales representatives to tell the physician to bill HCFA under Code 93720 and the physician would be reimbursed by HCFA $101.50 for each submitted test.

28. Serono's BIA machines were deliberately programmed to generate a deceptive report. The report, which in fact documents testing performed by a Serono sales representative, was printed with a heading that states ". . . created by (the treating physician) . . . ." Additionally, at the bottom of the report form, billing codes are listed with the clear intent of facilitating the billing process. The BIA report thus appears to be a report generated in the course of the prescribing doctor's medical practice by a technician in the prescribing doctor's office, when in fact the Serono sales force was the primary generating force of the document.

29. On information and belief, with Serono's assurance that the billing procedure was appropriate, the physicians would submit and be paid for these tests. Thus, Serono was able to provide an improper financial incentive for doctor's to prescribe Serostim. Moreover, Serono insured its own profits by maintaining control over the tests that supported the prescription of Serostim. By training Serono's sales representatives to operate the BIA machines (and manipulate the data therefrom), and counseling the sales representatives to offer their services to conduct the BIA tests, Serono used ostensibly objective tests, which were under its employees' control, to justify and increase the sale of Serostim.

CASH INDUCEMENTS AND KICKBACKS

30. In addition, in 1999 and 2000, Serono, through its sales representatives, offered or presented outright checks or BIA machines to physicians or physician assistants either in direct exchange or as an indirect inducement for the writing of a Serostim prescription for patients, including Medicaid recipients. Relators are aware that these practices occurred throughout the country. By offering or providing such direct and indirect financial inducements, Serono physicians violated the Anti-Kickback Statute.

31. Similarly, Serono, through its sales representatives, offered to or paid for the cost of transportation of patients, who sought to be treated with the drug Serostim, to physicians who were known to write prescriptions for Serostim. These patients included Medicaid recipients. Relators are aware that these practices occurred throughout the country. By offering or providing transportation services for patients solely to get a prescription for Serostim, Serono has further violated the Anti-Kickback Statute.

"OFF-LABEL USE" OF SEROSTIM

32. In addition to the financial inducements, Serono, through its sales representative agents, provided physicians throughout the United States with unsolicited articles about the benefit of the drug Serostim for the treatment of lypodystrophy. Articles distributed by Serono, upon information and belief, were not submitted to the Secretary of the Food and Drug Administration ("FDA") prior to dissemination. The written materials did not provide a prominently displayed statement that disclosed, *inter alia*, that the information concerned use that had not been approved by the FDA, that the information was being disseminated at the expense of the manufacturer, or the official labeling for the drug. In addition, the articles were not peer-reviewed and published in scientific or medical journals or reference publications, as required by law. Relator Garcia was expressly encouraged to distribute these unapproved articles concerning lypodystrophy to doctors, for the purpose of increasing Serostim sales. Upon information and belief, Relator Garcia avers that this practice occurred nation-wide.

33. By distributing such articles on off-label use, and promoting the benefits of Serostim for the treatment of lypodystrophy, Serono violated the Federal Food, Drug, and Cosmetic Act. Based in part on this unapproved literature, physicians across the United States have prescribed Serostim for Medicaid patients whom they have treated for lypodystrophy. These practices resulted in the submission of false and fraudulent Medicaid claims for reimbursement of the cost of the drug.

34. Serono failed to disclose these violations of the Federal Food, Drug, and Cosmetic Act and the Anti-Kickback Statute, and as a result, claims related to Serostim filed with the Government Health Care Programs have contained material omissions and

defects. Serono has thus caused false and fraudulent claims to be filed against the Government Health Care Programs, including the jointly funded Medicaid program.

35. As required by law, Relators have served detailed Disclosure Statements upon the United States. Pursuant to their statutory obligations, Relators will serve the original and supplemental Disclosure Statements upon the appropriate State officials, and the supplemental Disclosure Statement upon the United States. These statements provide additional details concerning the Defendant's conduct and Relators' basis of knowledge.

COUNT ONE

VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT

31 U.S.C. § 3729(a)(1)

36. Relator Garcia restates and realleges the allegations contained in Paragraphs 1-35 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

37. The Federal False Claims Act, 31 U.S.C. § 3729(a)(1), specifically provides, in part, that any person who:

> (a)(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;
>
> . . .
>
> 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 . . . .

38. Defendant Serono knowingly caused to be presented to Government Health Care Programs false and fraudulent claims for payment and approval, claims

which failed to disclose the material violations of the Anti-Kickback Statute and the Food, Drug and Cosmetic Act, in violation of 31 U.S.C. § 3729(a)(1).

39. The United States has paid said claims and has suffered financial losses because of these acts by the Defendant.

COUNT TWO

VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT

31 U.S.C. § 3729(a)(2)

40. Relator Garcia restates and realleges the allegations contained in Paragraphs 1-39 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

41. The Federal False Claims Act, 31 U.S.C. § 3729(a)(2), specifically provides, in part, that any person who:

> (a)(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;
>
> . . .
>
> 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 . . . .

42. Defendant Serono knowingly made and caused to be made, false records and statements to get false and fraudulent claims paid and approved by the government, in violation of 31 U.S.C. § 3729(a)(2).

43. The United States has paid said claims and has suffered financial losses because of these acts by the Defendant.

COUNT THREE

FALSE CLAIMS ACT CONSPIRACY

31 U.S.C. § 3729(a)(3)

44. Relators Garcia restates and realleges the allegations contained in Paragraphs 1-43 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

45. The Federal False Claims Act, 31 U.S.C. § 3729(a)(3), specifically provides, in part, that any person who:

> (a)(3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;
>
> . . .
>
> 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 . . . .

46. Defendant Serono knowingly conspired with its employee sales representatives, third-party providers, and others to defraud the United States by getting false and fraudulent claims allowed and paid, in violation of 31 U.S.C. § 3729(a)(3).

47. The United States has paid said claims and has suffered financial losses because of these acts by the Defendant.

COUNT FOUR

VIOLATIONS OF THE CALIFORNIA FCA

Cal. Gov't Code § 12651(a)(1)

48. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-47 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

49. The California False Claims Act, Cal. Gov't Code § 12651(a)(1), specifically provides, in part:

> (a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state . . . for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:
>
> (1) Knowingly presents or causes to be presented to an officer or employee of the state . . . a false claim for payment or approval.

50. Defendant Serono knowingly caused to be presented to the California Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the Anti-Kickback Statute and the Food, Drug and Cosmetic Act, in violation of Cal. Gov't Code § 12651(a)(1).

51. The State of California paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in California, because of these acts by the Defendant.

COUNT FIVE

VIOLATIONS OF THE CALIFORNIA FCA

Cal. Gov't Code § 12651(a)(2)

52. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-51 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

53. The California False Claims Act, Cal. Gov't Code § 12651(a)(2), specifically provides:

> (a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state . . . for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:
>
> . . .
>
> (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 . . . .

54. Defendant Serono knowingly made, and caused to be made false records and statements to get false and fraudulent claims paid and approved by the California Medicaid program, in violation of Cal. Gov't Code § 12651(a)(2).

55. The State of California paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in California, because of these acts by the Defendant.

COUNT SIX

VIOLATIONS OF THE CALIFORNIA FCA

Cal. Gov't Code § 12651(a)(3)

56. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-55 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

57. The California False Claims Act, Cal. Gov't Code § 12651(a)(3), specifically provides:

> (a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state . . . for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:
>
> . . .
>
> (3) Conspires to defraud the state . . . by getting a false claim allowed or paid by the state . . . .

58. Defendant Serono conspired with its employee sales representatives, third-party providers, and others to defraud the State of California by getting false and fraudulent claims allowed and paid, in violation of Cal. Gov't Code § 12651(a)(3).

59. The State of California paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in California, because of these acts by the Defendant.

COUNT SEVEN

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT

Del. Code Ann. tit. 6, § 1201(a)(1)

60. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-59 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

61. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(1), specifically provides, in part, that any person who:

> (a)(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;
>
> . . .
>
> shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

62. Defendant Serono knowingly caused to be presented, directly and indirectly, to the Delaware Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the Anti-Kickback Statute and the Food, Drug and Cosmetic Act, in violation of Del. Code Ann. tit. 6, § 1201(a)(1).

63. The State of Delaware paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Delaware, because of these acts by the Defendant.

COUNT EIGHT

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT

Del. Code Ann. tit. 6, § 1201(a)(2)

64. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-63 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

65. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(2), specifically provides, in part, that any person who:

> (a)(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;
>
> . . .
>
> shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

66. Defendant Serono knowingly made, used and caused to be made and used, directly and indirectly, false records and statements to get false and fraudulent claims paid and approved by the State of Delaware, in violation of Del. Code Ann. tit. 6, § 1201(a)(2).

67. The State of Delaware paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Delaware, because of these acts by the Defendant.

COUNT NINE
VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT

Del. Code Ann. tit. 6, § 1201(a)(3)

68. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-67 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

69. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(3), specifically provides, in part, that any person who:

> (a)(3) Conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;
>
> . . .
>
> shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

70. Defendant Serono knowingly conspired with its employee sales representatives, third-party providers, and others to defraud the State of Delaware by getting false and fraudulent claims allowed and paid, in violation of Del. Code Ann. tit. 6, § 1201(a)(3).

71. The State of Delaware paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Delaware, because of these acts by the Defendant.

COUNT TEN

VIOLATIONS OF THE DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

D.C. Code § 2-308.14(a)(1)

72. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-71 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

73. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(1), specifically provides, in part:

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:
>
> (1) Knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval.

74. Defendant Serono knowingly caused to be presented to the District of Columbia Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the Anti-Kickback Statute and the Food, Drug and Cosmetic Act, in violation of D.C. Code § 2-308.14(a)(1).

75. The District of Columbia paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in the District of Columbia, because of these acts by the Defendant.

COUNT ELEVEN

VIOLATIONS OF THE DISTRICT OF THE COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

D.C. Code § 2-308.14(a)(2)

76. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-75 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

77. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(2), specifically provides, in part:

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:
>
> . . .
>
> (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;

78. Defendant Serono knowingly made, used and caused to be made and used, directly and indirectly, false records and statements to get false and fraudulent claims paid and approved by the District of Columbia, in violation of D.C. Code § 2-308.14(a)(2).

79. The District of Columbia paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in the District of Columbia, because of these acts by the Defendant.

COUNT TWELVE

VIOLATIONS OF THE DISTRICT OF THE COLUMBIA PROCUREMENT REFORM AMENDEMNT ACT

D.C. Code § 2-308.14(a)(3)

80. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-79 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

81. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(3), specifically provides:

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:
>
> . . .
>
> (3) Conspires to defraud the District by getting a false claim allowed or paid by the District;

82. Defendant Serono conspired with its employee sales representatives, third-party providers, and others to defraud the District of Columbia by getting false and fraudulent claims allowed and paid, in violation of D.C. Code § 2-308.14(a)(3).

83. The District of Columbia paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in the District of Columbia, because of these acts by the Defendant.

COUNT THIRTEEN

VIOLATIONS OF THE FLORIDA FCA

Fla. Stat. § 68.082(2)(a)

84. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-83 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

85. The Florida False Claims Act, Fla. Stat. § 68.082(2)(a), specifically provides, in part, that any person who:

> (a) Knowingly presents or causes to be presented to an officer or employee of an agency a false claim for payment or approval;
>
> . . .
>
> is liable to the state for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

86. Defendant Serono knowingly caused to be presented to the Florida Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the Anti-Kickback Statute and the Food, Drug and Cosmetic Act, in violation of Fla. Stat. § 68.082(2)(a).

87. The State of Florida paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Florida, because of these acts by the Defendant.

COUNT FOURTEEN

VIOLATIONS OF THE FLORIDA FCA

Fla. Stat. § 60.082(2)(b)

88. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-87 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

89. The Florida False Claims Act, Fla. Stat. § 68.082(2)(b), specifically provides, in part, that any person who:

> (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;
>
> . . .
>
> is liable to the state for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

90. Defendant Serono knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by an agency of the State of Florida, in violation of Fla. Stat. § 68.082(2)(b).

91. The State of Florida paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Florida, because of these acts by the Defendant.

COUNT FIFTEEN

VIOLATIONS OF THE FLORIDA FCA

Fla. Stat. § 68.082(2)(c)

92. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-91 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

93. The Florida False Claims Act, Fla. Stat. § 68.082(2)(c), specifically provides, in part, that any person who:

> (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;
>
> . . .
>
> is liable to the state for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

94. Defendant Serono conspired with its employee sales representatives, third-party providers, and others to submit a false claim to Government Health Care Programs and to deceive Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of Fla. Stat. § 680.82(2)(c).

95. The State of Florida paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Florida, because of these acts by the Defendant.

COUNT SIXTEEN

VIOLATIONS OF THE HAWAII FCA

Haw. Rev. Stat. § 661-21(a)(1)

96. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-95 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

97. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(1), specifically provides, in part, that 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;
>
> . . .
>
> shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the State sustains due to the act of that person.

98. Defendant Serono knowingly caused to be presented to the Hawaii Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the Anti-Kickback Statute and the Food, Drug and Cosmetic Act, in violation of Haw. Rev. Stat. § 661-21(a)(1).

99. The State of Hawaii paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Hawaii, because of these acts by the Defendant.

COUNT SEVENTEEN

VIOLATIONS OF THE HAWAII FCA

Haw. Rev. Stat. § 661-21(a)(2)

100. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-99 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

101. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(2), specifically provides, in part, that any person who:

> (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;
>
> . . .
>
> shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the State sustains due to the act of that person.

102. Defendant Serono knowingly made, used and caused to be made, used, and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by the State of Hawaii, in violation of Haw. Rev. Stat. § 661-21(a)(2).

103. The State of Hawaii paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Hawaii, because of these acts by the Defendant.

COUNT EIGHTEEN

VIOLATIONS OF THE HAWAII FCA

Haw. Rev. Stat. § 661-21(a)(3)

104. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-103 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

105. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(3), specifically provides, in part, that any person who:

> (3) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid.
>
> . . .
>
> shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the State sustains due to the act of that person.

106. Defendant Serono conspired with its employee sales representatives, third-party providers, and others to defraud the State of Hawaii by getting false and fraudulent claims allowed and paid, in violation of Haw. Rev. Stat. § 661-21(a)(3).

107. The State of Hawaii paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Hawaii, because of these acts by the Defendant.

COUNT NINETEEN

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

740 Ill. Comp. Stat. § 175/3 (a)(1)

108. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-107 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

109. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a)(1), specifically provides, in part, that any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the State or member of the Guard a false or fraudulent claim for payment or approval;
>
> . . .
>
> is liable to the State 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 State sustains because of the act of that person.

110. Defendant Serono knowingly caused to be presented to the Illinois Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the Anti-Kickback Statute and the Food, Drug and Cosmetic Act, in violation of 740 Ill. Comp. Stat. § 175/3(a)(1).

111. The State of Illinois paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Illinois, because of these acts by the Defendant.

COUNT TWENTY

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

740 Ill. Comp. Stat. § 175/3(a)(2)

112. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-111 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

113. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a)(2), specifically provides, in part, that any person who:

> (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;
>
> . . .
>
> is liable to the State 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 State sustains because of the act of that person.

114. Defendant Serono knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by the State of Illinois, in violation of 740 Ill. Comp. Stat. § 175/3(a)(2)

115. The State of Illinois paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Illinois, because of these acts by the Defendant.

COUNT TWENTY-ONE

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

740 Ill. Comp. Stat. § 175/3(a)(3)

116. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-115 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

117. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a)(3), specifically provides, in part, that any person who:

> (2) conspires to defraud the State by getting a false or fraudulent claim allowed or paid;
>
> . . .
>
> is liable to the State 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 State sustains because of the act of that person.

118. Defendant Serono conspired with its employee sales representatives, third-party providers, and others to defraud the State of Illinois by getting false and fraudulent claims allowed and paid, in violation of 740 Ill. Comp. Stat. § 175/3(a)(3).

119. The State of Illinois paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Illinois, because of these acts by the Defendant.

COUNT TWENTY-TWO

VIOLATIONS OF THE MASSACHUSETTS FCA

Mass. Gen. Laws Ch. 12, § 5B(1)

120. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-119 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

121. The Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5B(1), specifically provides, in part, that any person who:

> (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> . . .
>
> shall be liable to the commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person.

122. Defendant Serono knowingly caused to be presented to the Massachusetts Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the Anti-Kickback Statute and the Food, Drug and Cosmetic Act, in violation of Mass. Gen. Laws Ch. 12, § 5B(1).

123. The Commonwealth of Massachusetts paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Massachusetts, because of these acts by the Defendant.

COUNT TWENTY-THREE

VIOLATIONS OF THE MASSACHUSETTS FCA

Mass. Gen. Laws Ch. 12, § 5B(2)

124. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-123 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

125. The Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5B(2), specifically provides, in part, that any person who:

> (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 any political subdivision thereof;
>
> . . .
>
> shall be liable to the commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person.

126. Defendant Serono knowingly made, used and caused to be made and used, false records and statements to obtain payment and approval of claim by the Commonwealth of Massachusetts, in violation of Mass. Gen. Laws Ch. 12, § 5B(2).

127. The Commonwealth of Massachusetts paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Massachusetts, because of these acts by the Defendant.

COUNT TWENTY-FOUR

VIOLATIONS OF THE MASSACHUSETTS FCA

Mass. Gen. Laws Ch. 12, § 5B(3)

128. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-127 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

129. The Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5B(3), specifically provides, in part, that any person who:

> (3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;
>
> . . .
>
> shall be liable to the commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person.

130. Defendant Serono conspired with its employee sales representatives, third-party providers, and others to defraud the Commonwealth of Massachusetts through the allowance and payment of fraudulent claims in violation of Mass. Gen. Laws Ch. 12, § 5B(3).

131. The Commonwealth of Massachusetts paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Massachusetts, because of these acts by the Defendant.

COUNT TWENTY-FIVE

VIOLATIONS OF THE NEVADA FCA

Nev. Rev. Stat. § 357.040(1)(a)

132. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-131 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

133. The Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1)(a), specifically provides, in part, that a person who:

> With or without specific intent to defraud, does any of the following listed acts is liable to the state or a political subdivision, whichever is affected, for three times the amount of damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than $2,000 or more than $10,000 for each act:
>
> (a) Knowingly presents or causes to be presented a false claim for payment or approval.

134. Defendant Serono knowingly caused to be presented to the Nevada Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the Anti-Kickback Statute and the Food, Drug and Cosmetic Act, in violation of Nev. Rev. Stat. § 357.040(1)(a).

135. The State of Nevada paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Nevada, because of these acts by the Defendant.

COUNT TWENTY-SIX

VIOLATIONS OF THE NEVADA FCA

Nev. Rev. Stat. § 357.040(1)(b)

136. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-135 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

137. The Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1)(b), specifically provides, in part, that a person who:

> With or without specific intent to defraud, does any of the following listed acts is liable to the state or a political subdivision, whichever is affected, for three times the amount of damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than $2,000 or more than $10,000 for each act:
>
> . . .
>
> (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.

138. Defendant Serono knowingly made, used and caused to be made and used, false records and statements to obtain payment and approval of false claims, in violation of Nev. Rev. Stat. § 357.040(1)(b).

139. The State of Nevada paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Nevada, because of these acts by the Defendant.

COUNT TWENTY-SEVEN

VIOLATIONS OF THE NEVADA FCA

Nev. Rev. Stat. 357.040(1)(c)

140. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-139 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

141. The Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1)(c), specifically provides, in part, that a person who:

> With or without specific intent to defraud, does any of the following listed acts is liable to the state or a political subdivision, whichever is affected, for three times the amount of damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than $2,000 or more than $10,000 for each act:
>
> . . .
>
> (c) Conspires to defraud by obtaining allowance or payment of a false claim.

142. Defendant Serono conspired with its employee sales representatives, third-party providers, and others to defraud the Commonwealth of Massachusetts by obtaining allowance and payment of false claims, in violation of Nev. Rev. Stat. 357.040(1)(c).

143. The State of Nevada paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Nevada, because of these acts by the Defendant.

COUNT TWENTY-EIGHT

VIOLATIONS OF THE TENNESSEE MEDICAID FCA

Tenn. Code Ann. § 71-5-182(a)(1)(A)

144. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-143 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

145. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(A), specifically provides, in part, that 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;
>
> . . .
>
> is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person.

146. Defendant Serono knowingly caused to be presented to the Tennessee Medicaid program claims for payment under the Medicaid program knowing such claims were false and fraudulent, claims which failed to disclose the material violations of the Anti-Kickback Statute and the Food, Drug and Cosmetic Act, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(A).

147. The State of Tennessee paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Tennessee, because of these acts by the Defendant.

COUNT TWENTY-NINE

VIOLATIONS OF THE TENNESSEE MEDICAID FCA

Tenn. Code Ann. § 71-5-182(a)(1)(B)

148. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-147 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

149. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(B), specifically provides, in part, that any person who:

> (B) Makes, uses, or causes to 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;
>
> . . .
>
> is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person.

150. Defendant Serono made, used and caused to be made and used, records and statements to get false and fraudulent claims under the Medicaid program paid and approved by the State of Tennessee knowing such records and statements were false, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(B).

151. The State of Tennessee paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Tennessee, because of these acts by the Defendant.

COUNT THIRTY

VIOLATIONS OF THE TENNESSEE MEDICAID FCA

Tenn. Code Ann. § 71-5-182(a)(1)(C)

152. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-151 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

153. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(C), specifically provides, in part, that any person who:

> (C) Conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent;
>
> . . .
>
> is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person.

154. Defendant Serono conspired with its employee sales representatives, third-party providers, and others to defraud the State of Tennessee by getting claims allowed and paid under the Medicaid program knowing such claims were false and fraudulent, in violation of Nev. Rev. Stat. 357.040(1)(C).

155. The State of Tennessee paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Tennessee, because of these acts by the Defendant.

COUNT THIRTY-ONE

VIOLATIONS OF THE TEXAS MEDICAID FRAUD PREVENTION LAW

Tex. Hum. Res. Code § 36.002(1)(A)

156. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-155 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

157. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.001(1)(A), specifically provides, in part, that a person commits an unlawful act if the person:

> (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.

158. Defendant Serono knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the Texas Medicaid program, claims which failed to disclose the material violations of the Anti-Kickback Statute and the Food, Drug and Cosmetic Act, in violation of Tex. Hum. Res. Code § 36.002(1)(A).

159. The State of Texas paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Texas, because of these acts by the Defendant.

COUNT THIRTY-TWO

VIOLATIONS OF THE TEXAS MEDICAID FRAUD PREVENTION LAW

Tex. Hum. Res. Code § 36.002(4)(B)

150. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-159 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

151. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.002(4)(B), specifically provides, in part, that a person commits an unlawful act if the person:

> (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;

162. Defendant Serono by knowingly and intentionally causing to be made, inducing, and seeking to induce the making of false statements and misrepresentations of material facts concerning information required to be provided by state and federal law, rule, regulation and provider agreements pertaining to the Medicaid program, in violation of Tex. Hum. Res. Code § 36.002(4)(B).

163. The State of Texas paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Texas, because of these acts by the Defendant.

COUNT THIRTY-THREE

VIOLATIONS OF TEXAS MEDICAID FRAUD PREVENTION LAW

Tex. Hum. Res. Code § 36.002(9)

164. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-163 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

165. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.002(9), specifically provides, in part, that a person commits an unlawful act if the person:

> (9) knowingly or intentionally enters into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another person in obtaining an unauthorized payment or benefit from the Medicaid program . . . .

166. Defendant Serono knowingly and intentionally conspired with its employee sales representatives, third-party providers, and others to defraud the State of Texas by aiding another person in obtaining an unauthorized payment from the Medicaid program, in violation of Tex. Hum. Res. Code §.36.002(9).

167. The State of Texas paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Texas, because of these acts by the Defendant.

COUNT THIRTY-FOUR

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT

Va. Code Ann. § 8.01-216.3(A)(1)

168. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-167 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

169. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(1), specifically provides, in part, that any person who:

> 1. Knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval;
>
> . . .
>
> shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

170. Defendant Serono knowingly caused to be presented, to the Virginia Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the Anti-Kickback Statute and the Food, Drug and Cosmetic Act, in violation of Va. Code Ann. § 8.01-216.3(A)(1).

171. The Commonwealth of Virginia paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Virginia, because of these acts by the Defendant.

COUNT THIRTY-FIVE

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT

Va. Code Ann. § 8.01-216.3(A)(2)

172. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-171 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

173. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(2), specifically provides, in part, that any person who:

> 2. Knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth;
>
> . . .
>
> shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

174. Defendant Serono knowingly made, used and caused to made and uses, false records and statements to get false and fraudulent claims paid and approved by the Commonwealth of Virginia, in violation of Va. Code Ann. §.8.01-216.3(A)(2).

175. The Commonwealth of Virginia paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Virginia, because of these acts by the Defendant.

COUNT THIRTY-SIX

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT

Va. Code Ann. § 8.01-216.3(A)(3)

176. Relators Garcia and Driscoll restate and reallege the allegations contained in Paragraphs 1-175 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

177. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(3), specifically provides, in part, that any person who:

> 3. Conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid;
>
> . . .
>
> shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

178. Defendant Serono conspired with its employee sales representatives, third-party providers, and others to defraud the Commonwealth of Virginia by getting false and fraudulent claims allowed and paid, in violation of Va. Code Ann.§ 8.01-216.3(A)(3).

179. The Commonwealth of Virginia paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Virginia, because of these acts by the Defendant.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff/Relator Garcia prays for judgment against the defendant as follows:

1. That defendant cease and desist from violating 31 U.S.C. § 3729 *et seq.*

2. That the Court enter judgment against Defendant in an amount equal to three times the amount of damages the United States has sustained as a result of the Defendant's actions, as well as a civil penalty against the Defendant of the statutory maximum for each violation of 31 U.S.C. § 3729;

3. That Plaintiff/Relator Garcia be awarded all costs and expenses of this action under the Federal False Claims Act, including attorneys fees; and

4. That the Plaintiffs/Relator Garcia be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d); and

WHEREFORE, the State Plaintiffs/Relators Garcia and Driscoll further pray for judgment against the defendant under the pendent State claims as follows:

4. That defendant cease and desist from violating Cal. Gov't Code § 12650 *et seq.*; Del. Code Ann. Tit. 6, § 1201 *et seq.*; D.C. Code § 2-308.13 *et seq.*; Fla. Stat. § 68.081 *et seq.*; Haw. Rev. Stat. § 661-21 *et seq.*; 740 Ill. Comp. Stat. § 175/1 *et seq.*; Mass. Gen. Laws Ch. 12, § 5A *et seq.*; Nev. Rev. Stat. § 357.010 *et seq.*; Tenn. Code Ann. § 71-5-181 *et seq.*; Tex. Hum. Res. Code § 36.001 *et seq.*, and Va. Code Ann. § 8.01-216.1 *et seq.*;

5. That the Court enter judgment against Defendant in an amount equal to three times the amount of damages that California, Delaware, District of Columbia, Florida, Hawaii, Illinois, Massachusetts, Nevada, Tennessee, and Virginia have sustained, respectively, as a result of the Defendant's actions, as well as a civil penalty against the Defendant of a statutory maximum for each violation of Cal. Gov't Code § 12651; Del. Code Ann. Tit. 6, § 1201; D.C. Code § 2-308.14; Fla. Stat. § 68.082; Haw. Rev. Stat. § 661-21; 740 Ill. Comp. Stat. § 175/3; Mass. Gen. Laws Ch. 12, § 5B; Nev. Rev. Stat. § 357.040, Tenn. Code Ann. § 71-5-182; and Va. Code Ann. § 8.01-216.3;

6. That the Court enter judgment against Defendant in an amount equal to two times the amount of damages that Texas has sustained as a result of the Defendant's actions, as well as a civil penalty against the Defendant of a statutory maximum for each violation of Tex. Hum. Res. Code § 36.002;

7. That the Plaintiffs/Relators Garcia and Driscoll be awarded the maximum amount allowed pursuant to Cal. Gov't Code 12652(g); Del. Code Ann. Tit. 6, § 1205; D.C. Code § 2-308.14(f); Fla. Stat. § 68.085; Haw. Rev. Stat. § 661-27; 740 Ill. Comp. Stat. § 175/4(d); Mass. Gen. Laws Ch. 12, § 5F; Nev. Rev. Stat. §§ 357.210, 357.220, Tenn. Code Ann. § 71-5-183(c); Tex. Hum. Res. Code § 36.110, and Va. Code Ann. § 8.01-216.7;

8. That Plaintiffs/Relators Garcia and Driscoll be awarded all costs and expenses associated with the pendent State claims, including attorneys fees; and

9. That the United States, the States and Plaintiffs/Relators Garcia and Driscoll receive all such other relief as the Court deems just and proper.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, plaintiffs hereby request a jury trial on all counts so triable.

Respectfully submitted,

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Dated: October 6, 2003