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IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

[UNDER SEAL]

Relator,

v.

[UNDER SEAL],

Defendant.

Case No. 2:09-CV-3010 MCE JFM

COMPLAINT AND JURY TRIAL DEMAND

TO BE FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730

DO NOT ENTER INTO PACER

DO NOT PLACE IN PRESS BOX

UNITED STATES OF AMERICA ex rel. Frank Solis, Relator,	§
STATE OF ARKANSAS ex rel. Frank Solis, Relator,	§
STATE OF CALIFORNIA ex rel. Frank Solis, Relator,	§
STATE OF DELAWARE ex rel. Frank Solis, Relator,	§
DISTRICT OF COLUMBIA ex rel. Frank Solis, Relator,	§
STATE OF FLORIDA ex rel. Frank Solis, Relator,	§
STATE OF GEORGIA ex rel. Frank Solis, Relator,	§
STATE OF HAWAII ex rel. Frank Solis, Relator,	§
STATE OF ILLINOIS ex rel. Frank Solis, Relator,	§
STATE OF INDIANA ex rel. Frank Solis, Relator,	§
STATE OF LOUISIANA ex rel. Frank Solis, Relator,	§
STATE OF MASSACHUSETTS ex rel. Frank Solis, Relator,	§
STATE OF MICHIGAN ex rel. Frank Solis, Relator,	§
STATE OF MONTANA ex rel. Frank Solis, Relator,	§

Case No.

COMPLAINT FOR DAMAGES UNDER THE FEDERAL FALSE CLAIMS ACT AND VARIOUS STATE FALSE CLAIMS ACTS AND DEMAND FOR JURY TRIAL

TO BE FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730

DO NOT ENTER INTO PACER

DO NOT PLACE IN PRESS BOX

STATE OF NEVADA ex rel. Frank Solis, Relator,	§
STATE OF NEW HAMPSHIRE ex rel. Frank Solis, Relator,	§
STATE OF NEW JERSEY ex rel. Frank Solis, Relator,	§
STATE OF NEW MEXICO ex rel. Frank Solis, Relator,	§
STATE OF NEW YORK ex rel. Frank Solis, Relator,	§
STATE OF OKLAHOMA ex rel. Frank Solis, Relator,	§
STATE OF RHODE ISLAND ex rel. Frank Solis, Relator,	§
STATE OF TENNESSEE ex rel. Frank Solis, Relator,	§
STATE OF TEXAS ex rel. Frank Solis, Relator,	§
STATE OF VIRGINIA ex rel. Frank Solis, Relator,	§
STATE OF WISCONSIN ex rel. Frank Solis, Relator,	§
vs.	§
MILLENNIUM PHARMACEUTICALS, INC., SCHERING-PLOUGH CORP.,	§
Defendants.	§

1. INTRODUCTION

1. Relator Frank Solis is informed and believes, and thereon alleges the following Complaint against Defendants.

2. Defendant Schering-Plough Corporation ("Schering") is a pharmaceutical company that produces, markets, sells, and distributes pharmaceutical and biological products in the area of cardiovascular disease, and in the area of immunology and infectious disease. Schering and Defendant Millennium Pharmaceuticals, Inc., ("Millennium") co-promote the prescription drug Integrilin, or eptifibatide, in the United States. Schering markets, sells, and distributes the antibiotic drug Avelox.

3. The Food and Drug Administration ("FDA") has approved Integrilin for the treatment of patients with acute coronary syndrome ("ACS") with unstable angina (UA) or non-ST-segment elevation myocardial infarction ("NSTEMI") who are to be managed medically or with percutaneous coronary intervention ("PCI"). Integrilin has also been approved for the treatment of patients undergoing PCI, including those undergoing intracoronary stenting. The FDA has approved Avelox for the treatment of adult patients with infections caused by a few susceptible strains of microorganisms.

4. Integrilin is an expensive drug, costing as much as $502 per dose. In addition, its market share is inherently limited, since it is approved for use only in patients with ACS with UA or NSTEMI for medical management or those

undergoing PCI. According to the American Heart Association, there are approximately 733,000 patients discharged annually with acute coronary syndrome (ACS), and of those between 53% to 71% have symptoms for which Integrilin is FDA approved, for a total potential patient population of 388,000 to 520,000. To overcome these problems and gain a larger market for this drug, Defendants created a plan to illegally market Integrilin off-label to treat STEMI patients, patients undergoing peripheral vascularization procedures, and other uses that are not approved by the FDA.

5. Defendants funneled millions of dollars in unrestricted grant money to physicians in order to encourage them to speak and publish articles supporting the use of Integrilin in patients whose cardiovascular event symptoms did not meet FDA criteria for Integrilin. Specifically, Defendants targeted, developed, and trained physician "Key Opinion Leaders" ("KOL"s), influential doctors whom Defendants supported monetarily. Defendants, in turn, expected these KOLs to support Defendants' prescription drug use among off-label patient populations. Defendants then pointed to the KOLs' use of Integrilin when promoting the drug widely to other physicians throughout the country.

6. Consistent with their scheme to provide illegal incentives to doctors who prescribed Integrilin, Defendants also gave kickbacks to physicians for off-label use of the drug, providing the physicians with speaking opportunities, unrestricted educational grants, lavish meals, and honoraria to promote and prescribe Integrilin

off-label, including paid travel included trips to Hawaii, Denver, and other locations. At these "fly-to" activities doctors would sometimes receive paid travel and also be paid as speakers, or would be given speaker training so they could receive additional speaker payments from Defendants in the future. Defendants encouraged the physicians' acceptance of the paid travel and speaking fees as a form of quid pro quo for increased sales of Integrilin.

7. Additionally, Integrilin is not superior to competing, similar prescription drugs on the market, and Defendants' scheme to promote broad off-label use of Integrilin among off-label patient populations and to influence studies promoting Integrilin for use in such patients threatens patient safety. A 2009 study published in the journal Circulation: Cardiovascular Interventions reveals that Integrilin's (off-label) use in the treatment of STEMI patients fails to show improved outcomes compared to much less expensive heparin treatment, and that Integrilin was associated with increased bleeding (See attached Exhibit 1).

8. A 2009 study published in the New England Journal of Medicine also reveals that Integrilin's use in the treatment of acute coronary syndrome (ACS) patients early in the hospital emergency department fails to show improved outcomes compared to less expensive later treatment with Integrilin in the catheterization lab, and is associated with an increased risk of bleeding and need for transfusion. Unfortunately, Integrilin was marketed for years prior by Defendants as a treatment that should be initiated in the hospital emergency department,

threatening patient safety and increasing health care costs for many thousands of patients. As described in this Complaint, Defendants' scheme to promote the drug for off-label use, and to pay kickbacks and give gifts to physicians who would agree to use Defendants' drugs, resulted in financial damage to federal and state health care systems (See attached Exhibit 2).

9. Avelox's market share is inherently limited, because it is approved for use only in patients with infections caused by susceptible strains of microorganisms. To overcome these problems and gain a larger market for these drugs, Defendants created a plan to illegally market Integrilin and Avelox to gain market share and formulary status at different hospitals.

10. In order to increase sales of Integrilin and Avelox, Defendants have illegally provided monetary and other incentives for physicians who were willing to prescribe the drugs. Defendants trained and instructed sales representatives, business and marketing managers, and other executives to offer physicians cash payments, expensive trips and meals, expensive gifts, and entertainment as kickbacks in exchange for the physicians' agreement to prescribe Integrilin and Avelox.

11. The pharmaceutical industry is highly regulated by the FDA. Pursuant to the Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301 et seq., the FDA strictly regulates the content of consumer and physician based advertising, direct to physician product promotion, and drug labeling information used by

pharmaceutical companies in promoting and selling-FDA approved prescription drugs.

12. Under 21 C.F.R. § 202.l(k)(2), any brochures, handouts, slide shows or other such promotional materials aimed at physicians are deemed to be "product labeling" and is regulated as such.

13. Under relevant FDA regulations, product labeling must be pre-approved by the FDA and conform to very exacting requirements concerning, inter alia, drug interactions, indicated uses and claims concerning competing products. See 21 C.F.R § 201.57.

14. All claims made in any labeling material must be truthful, not misleading and represent a fair balance of the information presented. Any presentations, promotions, or marketing to physicians for products for use other than that approved for labeling purposes by the FDA is considered "off label" marketing and is thus prohibited by FDA regulation.

15. Any failure to fairly and accurately represent the required information about a prescription drug is considered misbranding and is a false and fraudulent statement as a matter of law. See 21 U.S.C. §§ 331(a) and (b), 352(a), (f) and (n); 21 C.F.R. § 201.57.

16. Pharmaceutical promotional and marketing materials and presentations lacking in fair balance or that are otherwise false or misleading violate the Food Drug and Cosmetics Act, 21 U.S.C. §§ 301 et seq., and regulations promulgated

hereunder. Such violations exist where promotional and marketing materials and presentations for an FDA approved drug:

a. Minimize, understate or misrepresent the risks, contra-indications and complications associated with that drug;

b. Overstate or misrepresent the risks, contra-indications and complications associated with any competing drugs;

c. Reference "off label" uses of the drug for which it was not an approved indication by the FDA, or expressly or implicitly promote unapproved uses and dosing regimens for which the drug is not indicated;

d. Make comparative claims about the drug that have not been demonstrated by substantial evidence, such as comparisons with competing drugs and/or drug indications of patient usage, warnings and safety claims including side effects, physician preference, or

e. Are otherwise false, misleading or lacking in fair balance in the presentation of information about the drug being marketed or any competing drug.

17. When Defendants present physicians with false information about off-label use of Integrilin, and encourage physicians to prescribe and procure Integrilin for off-label use which are not approved by the FDA or substantiated by any relevant drug compendium, Defendants cause physicians and facilities to submit bills for off-label use of Integrilin that are based upon fraudulent and misleading

statements and are thus ineligible for reimbursement under federal Medicaid, Medicare, and TRICARE programs, and under state health care systems.

18. Had the United States and the several States known that the Defendants caused procurement of Integrilin for off-label uses and also caused Integrilin to be prescribed for off-label uses, they would not have provided reimbursement for such prescriptions. This course of conduct violates the False Claims Act, 31 U.S.C. §§ 3729 et seq and equivalent state statutes.

19. Federal laws and regulations governing Medicaid and Medicare and similar state statutes prohibit pharmaceutical manufacturers from providing kickbacks to physicians and medical care providers. Specifically, the federal healthcare program anti-kickback provision, 42 U.S.C. § 1320a-7b(b) (2)(B), provides:

> [W]hoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

20. The Medicare and Medicaid anti-kickback laws, 42 U.S.C. 1320a-7b(b), *et seq.*, regulate drug and device marketing in order to prevent over-utilization of medical care, medication, and medical drugs. Under the anti-kickback laws, companies may not offer or pay any remuneration, in cash or kind, to induce

physicians or others to order or recommend drugs or devices which may be paid for by a federal healthcare program such as Medicare or Medicaid. These regulations not only prohibit outright bribes and rebate schemes, but prohibit any payment, remuneration, gratuities, and other benefits paid by a company to a physician which has as one of its purposes inducing the physician to use the company's products.

21. In addition to the anti-kickback laws, §1877 of the Social Security Act, often referred to as the "Stark law," provides that a physician cannot (1) refer patients to an entity (2) for the furnishing of DHS (designated health services) (3) if there is a direct or indirect financial relationship between the referring physician (or an immediate family member of the referring physician) and the entity, (4) unless the financial relationship fits within one of the specific exceptions in the statute or regulations. *See* 42 U.S.C. §1395nn. Unlike the Medicare Anti-Kickback Statute, which is a criminal statute requiring at least some measure of criminal intent, the Stark Statute is a civil statute requiring strict compliance. Intent to violate or substantial compliance has no bearing on whether an activity is or is not legal. Violation, no matter how unintentional or technical, is sufficient to invoke the Stark Statute. Lastly, if a prohibited referral occurs under Stark, the DHS entity may not file or cause to be filed a claim under Medicare or Medicaid or a bill to any individual, third party payer, or other entity for the designated health services provided.

22. Had the United States and the several States known that Integrilin and

Avelox were being used by facilities because physicians in those facilities had accepted kickbacks from Defendants, the United States and the several States would not have funded these illegal kickbacks after the fact by providing reimbursement for Defendants' drugs.

23. Moreover, the kickbacks described in this Complaint are strictly illegal and have had the direct effect of greatly increasing the amount of Integrilin and Avelox that have been paid for and reimbursed by state and federal governments. Accordingly, the kickbacks have had the indirect effect of increasing the amount of money spent by the federal government and the States for payments and reimbursements covered by Medicaid, Medicare, and the TRICARE health care system for members of the military and their families. Defendants' kickbacks to physicians represent the inducement of payment from the government through a pattern of fraudulent conduct, constituting false claims within the meaning of 31 U.S.C. § 3729 and the relevant provisions of the state false claims and Medicaid fraud statutes.

2. PARTIES

24. Relator Frank Solis has worked in pharmaceutical sales since February 1998. In July 2003, Mr. Solis began working as a Sales Representative in Los Angeles for Millennium, promoting the cardiovascular prescription drug Integrilin. In or around September 2005, after Schering acquired exclusive U.S. marketing rights for Integrilin from Millennium, Mr. Solis became a Schering employee. Mr.

Solis participated in regular company training events, including events near Millennium's headquarters in Cambridge, Massachusetts and events near Schering's corporate offices in New Jersey. Mr. Solis also attended national and regional sales training conferences, where he interacted with Millennium and Schering's marketing executives and managers. Mr. Solis' primary duties at Schering and Millennium were as a Hospital Sales Specialist/Medical Center Sales Specialist, promoting Integrilin and Avelox, a prescription antibiotic. At present, Mr. Solis continues to work for Schering promoting Integrilin and Avelox. While at Millennium and Schering, Mr. Solis has developed first-hand knowledge of the acts set forth in this Complaint concerning the activities of Millennium and Schering.

25. The facts averred in this Complaint are based entirely upon the personal observations of Mr. Solis and documents in his possession.

26. Mr. Solis has provided or is providing to the United States Attorney and the Attorneys General of Arkansas, California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, New Hampshire, New Jersey, New Mexico, New York, Nevada, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin and the District of Columbia a full disclosure of substantially all material facts supporting this Complaint, as required by the False Claims Act, 31 U.S.C. § 3730(b)(2), and relevant state statutes.

27. Defendant, Schering-Plough Corp. ("Schering"), is a business incorporated

pursuant to the laws of the State of New Jersey with its principal offices in Kenilworth, New Jersey. Schering is a biopharmaceutical company engaged in the manufacture, promotion and sale of pharmaceutical products in interstate commerce regulated by the FDA, which activities are subject to the Food, Drug, and Cosmetic Act ("FDCA"), the Food and Drug Administration Modernization Act ("FDAMA") and regulations promulgated pursuant thereto. Schering markets, sells, and distributes the prescription drug Integrilin, which is indicated in the treatment of certain patients with cardiovascular events, and the prescription drug Avelox, which is indicated in the treatment of certain infections.

28. Defendant, Millennium Pharmaceuticals, Inc. ("Millennium"), is a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, a Japanese corporation, with its North American business, Takeda Pharmaceuticals North America, Inc., incorporated pursuant to the laws of the State of Illinois, with principle offices in Deerfield, Illinois.

29. Since 2005, Defendants Millennium and Schering have been co-conspirators and co-partners in the production, promotion, marketing, sales, and distribution of Integrilin and are thus jointly and severally liable for the acts described herein related to the production, promotion, marketing, sales, and distribution of Integrilin.

3. JURISDICTION AND VENUE

30. This action arises under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*

This Court has jurisdiction over this case pursuant to 31 U.S.C. §§ 3732(a) and 3730(b). This court also has jurisdiction pursuant to 28 U.S.C. § 1345 and 28 U.S.C. § 1331. This court has jurisdiction over the state law counts asserted in this Complaint under both 31 U.S.C. § 3732(b) and 28 U.S.C. § 1367, because the state claims arise from the same transaction or occurrence as the federal claims and because these claims are so related to the federal claims that they form part of the same case or controversy under Article III of the U.S. Constitution.

31. At all times material to this Complaint, Defendants regularly conducted substantial business within the State of California, maintained permanent employees and offices in California, and made and are making significant sales within California. Defendants are thus subject to personal jurisdiction in California.

32. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because Defendants transact business in this district, selling and promoting their drugs to multiple hospitals in this district.

4. FACTS

A. Defendants Illegally Engaged in the Promotion of Integrilin for Off-Label Use.

33. New pharmaceutical drugs may not be marketed in the United States until the sponsor of the drug has proven to the Food and Drug Administration (FDA) that the drug is safe and effective for specific indications at specified dosages (if applicable). The indications and dosages (if applicable) approved by the FDA are

set forth in the product's labeling, the content of which is also approved by the FDA. Although it is not unlawful for physicians to use drugs for indications or at dosages different than those set forth in a product's labeling, the Food Drug and Cosmetic Act prohibits pharmaceutical companies from marketing or promoting approved drugs for uses other than those set forth in the drug's approved labeling. This regulatory structure protects patients and consumers by ensuring that medical companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body.

34. The Medicaid and Medicare programs also rely on the FDA's findings regarding safe and effective uses for approved drugs. The Omnibus Budget Reconciliation Act of 1990 limited Medicare reimbursement for drugs or devices to "covered outpatient drugs" 42 U.S.C.§ 1396r-8(k)(2)(A). Covered outpatient drugs only include drugs used for "medically accepted indications." A medically accepted indication is a use which has been approved by the FDA or one which is supported by specific compendia set forth in the Medicare statutes. Until August, 1997, none of the compendia referenced in the statutes supported off-label usage of any approved drugs or devices. Even after August 1997, off-label usage was significantly restricted.

35. Off-label use of a medical product refers to the prescription or use of a product in a manner not approved by the FDA. Since Congress passed the Food and Drug Administration Modernization Act ("FDAMA") in November 1997,

manufacturers may provide off-label studies to the medical community only if certain conditions are met. Moreover, federal law prohibits manufacturers from promoting off-label uses through physician studies when the investigating physician is not truly independent or impartial, as well as when the physician is in fact an agent of the manufacturer based upon significant financial relationships. See 21 U.S.C. §§ 360aaa *et seq*.

36. Whether a drug is FDA-approved for a particular use will largely determine whether payment for that drug will be reimbursed under the federal and state Medicaid and Medicare programs. Thus, the off-label use of such drugs is not eligible for reimbursement under Medicaid. Likewise, many state health care agencies intend not to reimburse for drugs for off-label purposes because the agencies do not want to spend money on drugs not recognized as medically necessary in sources specified by federal law. Integrilin was not eligible for reimbursement from federal or state Medicaid or Medicare programs when prescribed for use in off-label patients.

37. Integrilin's FDA New Drug Application ("NDA") number is NDA 20-718/S-028. The FDA's approved use of Integrilin is limited to the treatment of patients with acute coronary syndrome ("ACS") with unstable angina (UA) or non-ST-segment elevation myocardial infarction ("NSTEMI") who are to be managed medically or with percutaneous coronary intervention ("PCI"). Integrilin has also been approved for the treatment of patients undergoing PCI, including those

undergoing intracoronary stenting (See attached Exhibit 3).

38. Defendants created a plan to illegally market Integrilin off-label to treat STEMI patients, patients undergoing peripheral vascularization procedures, and other uses that are not approved by the FDA.

39. Defendants' conduct caused physicians to submit bills for Integrilin that were ineligible for reimbursement under Medicaid and Medicare because the drugs were used for off-label purposes. Defendants' actions caused physicians, hospitals, and cardiac clinics to prescribe, purchase and use Integrilin. Such prescriptions, purchases and use were not eligible for reimbursement under Medicaid and Medicare because the drugs were for an off-label use. According to Frank Solis, up to 50% to 60% of Integrilin use at some hospitals was for off-label purposes. Defendants thus caused the submission of false claims for payment of money under the federal Medicaid and Medicare programs and state health care programs.

40. Additionally, the United States military's payments to cover the use of Integrilin for off-label patient populations were not eligible for coverage under the TRICARE health care plan for members of the military and their families (formerly known as CHAMPUS), or through direct purchasing by the military. The Department of Defense will generally pay for the costs only of "proven" drugs, meaning drugs that have been found to be "safe and effective" by the FDA. 32 C.F.R. § 199.4(g)(15)(i)(A). TRICARE will pay for off-label use of a drug only if the use is determined to be a "medical necessity" and if the program can determine

that the off-label use is "safe and effective and in accordance with nationally accepted standards of practice in the medical community." *Id.* TRICARE will not pay for a drug unless "reliable evidence shows that the medical treatment or procedure has been the subject of well-controlled studies of clinically meaningful endpoints." 32 C.F.R. § 199.4(g)(15)(i)(C). The studies Defendants supported to promote the use of Integrilin off-label did not meet these standards. Had TRICARE known this, it would not have covered or reimbursed the off-label use of Integrilin.

41. In limited situations, investigational drugs may be used by the military. However, whenever a member of the armed forces receives a drug unapproved for its applied use, the member must be given notice and consent to such use. 10 U.S.C. § 1107. In order to waive consent for the purposes of using such an "investigational drug" in battle, the Secretary of Defense must request a waiver from the President. No such waiver was requested for Integrilin.

42. As described in this Complaint, Defendants have, since 2002 through the present, knowingly and intentionally violated the regulatory schemes described above in its marketing of Defendants' products. Defendants knew or should have known that thousands of physicians (chiefly through their hospitals under applicable diagnostic related groups ("DRGs")) would routinely and necessarily file false claims with the federal government when the physicians sought federal reimbursement for Integrilin and Defendants' related products. But for Defendants' actions most, if not all, of the false claims for the purchase of Defendants' products

would never have been filed. Although in some cases the physicians did not directly contract with the federal government, Defendants were the indirect beneficiary of all of the false claims described in this Complaint.

43. While all on-label and off-label sales made or effected by the health care providers receiving unlawful kickbacks or engaging in improper self-referral cause false claims to be filed, the unlawful promotion of off-label uses of Defendants' products provides an additional, independent, and, under the circumstances, far more urgent basis for the government to interdict this activity—the public health is at risk.

1. ***Training of Medical Science Liaisons and Sales Representatives to Promote Off-Label Use of Integrilin.***

44. Defendants' sales representatives and Medical Science Liaisons were trained to use knowingly off-label information to persuade physicians to use Defendants' drugs. Defendants trained and directed sales staff to tell doctors that Defendants' drugs are effective for a variety of off-label claims; none of which were indications which the FDA had approved for Defendants' drugs. These efforts were successful, as relator Frank Solis has indicated that up to 50% to 60% of some hospital's use of Integrilin was for off-label use on STEMI patients.

45. For example, Defendants' sales representatives were given information from Defendants to provide to doctors promoting the use of Integrilin off-label for STEMI patients. The information was included in a Schering letter to physicians which was supposed to be used only for unsolicited requests for off-label

information from physicians. However, Defendants' District Managers routinely ordered sales reps to make available off-label information to hospitals and physicians in order to realize a boost in sales, and in order to get Defendants' MSL's invited to give additional off-label information to doctors promoting the use of Integrilin for STEMI patients. (See attached Exhibit 4).

46. The same Schering off-label letter made the off-label claim that STEMI patients would experience significantly faster blood flow through blocked arteries if they were given Integrilin early in the emergency department (See attached Exhibit 5).

47. For example, Schering managers and Medical Science Liaisons gave sales reps material from a 2006 study supported by a Schering grant and published in the American Heart Journal by Dr. Michael Gibson that claimed STEMI patients who received off-label Integrilin early in the emergency department had improved blood flow and improved outcomes (See attached Exhibit 6).

48. For example, Defendants' managers and Medical Science Liaisons gave sales reps material from a 2001 study in the American Journal of Cardiology by Dr. Cutlip that claimed STEMI patients who received off-label Integrilin early prior to primary Percutaneous Coronary Intervention ("PCI") had improved blood flow (See attached Exhibit 7).

49. For example, Schering managers and Medical Science Liaisons gave sales reps material from a 2005 study in the European Heart Journal by Dr. Zeymer that

claimed STEMI patients who received off-label Integrilin early prior to planned primary PCI had improved blood flow (See attached Exhibit 8).

50. For example, Schering managers and Medical Science Liaisons gave sales reps material from a 2007 study in the journal Cardiology by Dr. Midei that claimed STEMI patients who received either medication Integrilin or ReoPro had similar outcomes (See attached Exhibit 9).

51. For example, Schering managers and Medical Science Liaisons gave sales reps material from a 2008 study in the Journal of the American College of Cardiology by Dr. Gurm that claimed STEMI patients who received either medication Integrilin or ReoPro had similar outcomes, but that Integrilin patients had fewer episodes of gastrointestinal bleeding (See attached Exhibit 10).

52. For example, Schering managers and Medical Science Liaisons gave sales reps material from a 2007 study in the journal Mayo Clinic Proceedings by Dr. Raveendran that claimed STEMI patients who received either medication Integrilin or ReoPro had similar outcomes (See attached Exhibit 11).

53. Schering held national or regional sales meetings at least twice a year, where they shared "best practices." These company meetings provided off-label sales training to both sales representatives and medical science liaisons in the uses of Integrilin for patients with STEMI patients undergoing PCI, even though such use of Integrilin was not approved by the FDA. The sales representatives and medical science liaisons were also taught how to approach physicians about these

off-label uses of Integrilin at teleconferences and at local and regional meetings.

54. Defendants trained their medical science liaisons to promote Integrilin as particularly effective for STEMI patients undergoing PCI, even though such use of Integrilin was not approved by the FDA.

55. For example, a 2009 study published in the journal Circulation: Cardiovascular Interventions showed that Defendants never should have sold Integrilin for treating STEMI patients, because the drug failed to show improved outcomes compared to much less expensive heparin treatment, and it was associated with increased bleeding (See attached Exhibit 1).

56. For example, a 2009 study published in the Journal of the American College of Cardiology showed that Defendants never should have sold Integrilin for treating STEMI patients, because the drug when given at standard non-STEMI doses was associated with an increased risk of major bleeding (See attached Exhibit 53).

57. Despite the lack of a true protective or restorative effect by Integrilin in STEMI and early emergency department patients, Defendants trained and instructed its sales reps on every sales call to promote the drug as superior to competing drugs if used early during patient admission to the emergency department because the company claimed it could prevent death or myocardial infarction.

58. For example, a 2009 study published in the New England Journal of Medicine showed that Defendants never should have sold Integrilin with the idea of

treating Acute Coronary Syndrome (ACS) patients early, because the drug failed to show improved outcomes compared to less expensive later treatment with Integrilin, and was associated with an increased risk of bleeding and need for transfusion (See attached Exhibit 2).

59. On information and belief, Schering' promotion of Integrilin off-label as an early treatment for ACS patients and as an off-label treatment for STEMI patients continue to this day, as evidenced by a June 19, 2009 Schering information letter on the off-label use of Integrilin for STEMI patients. The letter promotes Integrilin as an effective treatment for STEMI patients undergoing PCI, and was to be given to physicians in response to their unprompted queries about off-label uses of Integrilin. However, according to Frank Solis, Schering District Managers would routinely instruct sales reps to make available off-label information to hospitals and physicians in order to realize a boost in sales, and instruct the sales reps to bring in MSL's to have off-label conversations with doctors promoting the use of Integrilin for STEMI (See attached Exhibit 4).

60. Defendants set goals for the sales representatives to promote the use of Integrilin off-label, and to develop "key opinion leaders" or KOLs who would support and promote the use of Integrilin off-label. Sales reps were instructed to push for the referral of patients for off-label STEMI treatment. These efforts were successful, as relator Frank Solis has indicated that up to 50% to 60% of some hospitals' use of Integrilin was for off-label use on STEMI patients.

61. For example, a December 12, 2007 note in a Schering Hospital Project Plan business plan for UCLA/Santa Monica hospital noted that a Schering sales rep had eaten lunch with Schering's off-label key opinion leader and paid speaker Dr. Mike Lee. Dr. Lee had told the sales rep that UCLA had experienced a "recent surge of Integrilin use" - "due to STEMI patients where he used Integrilin". (See attached Exhibit 12).

62. For example, a Schering sales rep noted in a December, 2007 business plan for Providence Holy Cross Medical Center that "Integrilin is being used more common for the really hot ACS patients as well as STEMI's". (See attached Exhibit 13).

63. For example, a Schering sales rep noted in a March 17, 2008 business plan for Valley Presbyterian Hospital in Van Nuys, CA that Dr. Arora was "still reserving Integrilin for super high-risk, STEMI patients". (See attached Exhibit 14.)

64. For example, in the August, 2008 Hospital Project Plan for UCLA/Santa Monica, Schering sales staff indicated that they were finding opportunities to pay Dr. Mike Lee as a KOL speaker, while at the same time discussing with him the fact that he was using Integrilin off-label for STEMI patients. Schering was aware that Dr. Mike Lee used Integrilin for STEMI patients, and that he spoke to other doctors about that use at their paid dinners. Instead of refusing to allow him to speak about off-label uses of their drug at Schering-funded dinner events, Schering

encouraged him in the activity, and built his off-label talks into their sales plans (See attached Exhibit 15).

65. For example, in another portion of the August, 2008 Hospital Project Plan for UCLA/Santa Monica, the Schering sales staff indicated that they found Dr. Mike Lee was "instrumental at driving existing sales" with his off-label dinner talks, and that they planned on using him "more often" over the next year, including sending him to Hawaii (See attached Exhibit 16).

66. Mr. Solis and other sales reps were instructed to schedule paid KOL speakers to deliver off-label talks on using Integrilin for STEMI patients on numerous occasions.

67. For example, according to a March 18, 2008 Field Coaching Report of Frank Solis by his manager Catherine Galvin, Solis followed Schering instructions by having off-label STEMI patient proponent Dr. Michael Gibson speak about Integrilin to "key targets" at St. John's hospital in Santa Monica, CA (See attached Exhibit 17).

68. For example, according to an August 14, 2008 Hospital Project Plan for St. John's Health Center in Santa Monica, Schering sales staff had off-label STEMI patient proponent Dr. Michael Gibson speak about Integrilin to seven doctors and two nurse practitioners. Schering staff noted that Dr. Gibson gave an "excellent lecture", and that there were "great questions about STEMI/NSTEMI" (See attached Exhibit 18).

69. Schering paid for many continuing medical education ("CME") programs to promote Integrilin use off-label to doctors in hospitals and clinics nationwide. In fact, Frank Solis' records show Defendants paid lavish meals and promotional events for cardiac and other physicians at these facilities, all intended to establish a relationship in which Schering sales representatives could promote Integrilin for off-label uses.

70. For example, an August 23, 2009 CME presentation noted that Dr. Michael Gibson was supported by Schering, and that Dr. Gibson's Schering-funded TITAN study was being used to show that off-label use of Integrilin with STEMI patients was achieving increased blood flow results, in effect promoting Integrilin off-label for use with STEMI patients to physicians who viewed the presentation (See attached Exhibit 19).

71. As part of their scheme to promote Integrilin for off-label use, Schering trained its sales representatives and MSLs to prompt physicians to ask questions about Integrilin. For example, although Schering told its sales representatives that they could not talk about off-label uses of Integrilin unless a physician asked a specific question about the product, sales representatives were trained to describe particular patient profiles that would fit an off-label use, and use probing questions to elicit a discussion with the physician about that off-label use. Sales representatives could talk about the clinical research in which Schering was engaged, including Schering clinical research trials on the use of Integrilin in

patients with STEMI and other off-label uses.

72. When a physician then asked a question about off-label uses of Integrilin, the MSL was allowed to respond, and was trained to provide the physician with further information on the off-label uses of the drug. In other words, after a sales representative prompted a question about Integrilin from a physician, he would then direct Schering's medical science liaisons to send the physician a Schering document (via fax, e-mail or postal service), or share a presentation on the off-label use of the Integrilin in STEMI patients, and other uses. Relator alleges these efforts were successful in convincing some hospitals to devote up to 50% to 60% of their Integrilin use to off-label STEMI patients.

73. Although Federal regulations did not permit Schering to promote unapproved uses of their drugs, Schering was permitted to distribute publications created by "third parties" that described results of off-label uses of Schering drugs, if such material was distributed in response to non-solicited requests from physicians. Schering decided to exploit this narrow exception by creating events and programs that would allow special Schering employees and independent contractors under Schering's control to promote off-label usage under circumstances that would allow Schering to deny, wrongfully, that it had solicited off-label usage.

2. Defendants Sponsored Seminars, Symposia, and Other Continuing Medical Education Programs that Promoted the Use of Integrilin in STEMI patients, and Other Uses.

74. Specifically, as part of its scheme to promote Integrilin widely for use to treat off-label patient populations, Schering sought out influential cardiologists and proffered kickbacks to them in return for conducting research and implementing policies promoting the use of Integrilin in those off-label cases. As set forth below, most of this "research" consisted of paying a physician to prescribe Integrilin and report some simple findings. The Schering marketing department made the decisions on which doctors to pay to do case studies and be involved in research protocols based on their Integrilin prescribe volume, showing that Schering was not paying those doctors for a legitimate research purpose. In effect, Schering paid these influential physicians to prescribe their patients with Schering drugs in order to expand its market share. Schering also paid these "Key Opinion Leaders" and "Champions" to promote the use of Integrilin at seminars and other events for referring cardiologists, clinic staff, and prescribing drugs in patients.

75. The Schering "Champions" included Dr. Harry Balian and Dr. Michael Lee from Los Angeles, Dr. Michael Gibson from Harvard, and Dr. Jorge Saucedo from Oklahoma, among others.

76. Another means by which Defendants paid kickbacks to physicians for the promotion of off-label use of Defendants' drugs was through programs billed as Continuing Medical Education seminars (CME). These conferences and seminars were set up to appear to qualify for an exception to the FDA's off-label marketing restrictions which permit physicians to learn about off-label uses of drugs at

independent seminars. Such seminars, however, must be truly independent of the pharmaceutical companies. The pharmaceutical companies may make "unrestricted grants" for the purpose of a seminar, but may not be involved in formulating the content of the presentations, picking the speakers or selecting the attendees.

77. None of these requirements were observed with regard to the CME seminars sponsored by Defendants for the promotion of Defendants' drugs. While Defendants retained third-party organizations such as the Advanced Health Media marketing company to present the event seminars and provide Defendants' sales reps with checks to pay the speaking doctors, Defendants retained control of virtually every aspect of these events, and the seminar companies obtained Defendants' approval for all content presented at the seminars. Defendants also paid all expenses, including all of the seminar company's fees.

78. More importantly, Defendants paid for these so-called continuing medical education programs and designed them to instruct physicians on how to justify off-label use of Defendants' drugs.

79. Dinner events were held at lavish restaurants, and often had almost no educational component at all. On many occasions the speaker would be a doctor who received $1,000 or more to attend the meal, and who received the speaker fee as a benefit for using a high volume of Defendants' drugs. The speakers were given slides by Defendants to use at the dinners, and did not have to prepare their own. Speakers would sometimes set up a laptop on a table with a PowerPoint

presentation running, but not give the presentation and just have dinner with other doctors. Defendants did not always require doctors to sign in for dinner on sign-in sheets.

80. Defendants also founded a speaker's bureau, another method to make large and numerous payments to physicians who recommended Defendants' drugs at teleconferences, lunch meetings, dinner meetings, consultant meetings, educational seminars and other events. These speakers repeatedly gave short presentations relating to Defendants' drugs for which they were paid anywhere from several hundred to several thousand dollars per event, commonly $1,500 or more. The presentations were effectively "canned" content provided by Defendants. Defendants targeted opinion leader physicians, most of whom were high volume prescribers and were influential. The payments that these doctors received were far in excess of the fair value of the work that they performed for Defendants. Speakers who most zealously advocated Defendants' drugs for off-label purposes were hired most frequently for speaking events, notwithstanding the fact that many of these events purported to be independent medical education seminars where independent information was supposed to be delivered.

81. Some doctors demanded payment in the form of speaker fees or research fees from Defendants in return for using Integrilin or helping to put it on a formulary or hospital guideline. For example, Dr. Balian asked Mr. Solis to be paid as a speaker, and was trained as a speaker by Defendants, was given multiple

speaking opportunities for fees of $1,000 to $2,000, and was even paid by Schering to speak at his own dinner party for his own catheterization lab staff (See attached Exhibit 20).

82. For example, Dr. Michael Gibson from Harvard was a frequent speaker, including at a July 21, 2005 dinner at Tina's Ristorante Italiano restaurant in Lancaster, California. Dr. Gibson was conducting off-label research on the use of Integrilin for STEMI patients, and was paid between $2,000-3,000 per event. He often spoke about off-label use of Integrilin for STEMI patients. He also was listed as a paid consultant for Schering on Schering funded off-label studies of Integrilin (See attached Exhibit 21).

83. For example, Dr. Mike Lee from UCLA Medical Center's cardiology department received between $1,000 to $1,500 per dinner to speak. He was developed as a national speaker by Defendants' marketing personnel, who knew that he discussed his own use of Integrilin off-label for STEMI patients at all meetings (See attached Exhibit 22).

84. Defendants also sponsored continuing medical education programs that promoted the use of Integrilin off-label for STEMI patients and other uses.

85. A common means by which Defendants funneled illegal payments to physicians to encourage them to prescribe off-label was through "consultant" meetings or by inviting them to join paid marketing "Advisory Boards". Under this guise, Defendants recruited physicians to dinners or conferences and paid them to

hear presentations about off-label uses of Defendants' drugs. Under the guise that these doctors were acting as "consultants," Defendants sometimes had the doctors sign sham "consulting agreements". At these meetings, Defendants would give these doctors presentations related to Defendants' drugs, sometimes regarding off-label usage. Presentations would be made by Defendants' employees or physician speakers hired by Defendants for the purpose of promoting Defendants' drugs.

86. For example, in the Schering Hospital Project Plan for Valley Presbyterian Hospital, Schering sales reps wrote about the goal of getting Dr. Ramesh Arora to attend a paid Advisory Board meeting in July, 2007, in order to "build advocacy thru this meeting" (See attached Exhibit 23).

87. For example, the Schering Hospital Project Plan for Lancaster Community Hospital Schering calls for the goal of getting Dr. Sameh Gadallah to attend a paid Advisory Board meeting in August, 2007, where he would receive an honorarium of approximately $1,000. After Dr. Gadallah attended the paid meeting, Schering noted that Dr. Gadallah "acknowledged the need for more aggressive upstream treatment" using Integrilin (See attached Exhibit 24).

88. This scheme was also carried out by the making of false statements and kickbacks to non-cardiology physicians, nurse practitioners, and nurses concerning the efficacy and safety of Defendants' drugs for off-label uses. In some cases, Defendants promoted Defendants' drugs off-label to these allied healthcare professionals in order to streamline the process of prescribing drugs and

overcoming authorization requirements of Medicaid, Medicare and other insurance payors.

89. For example, a June 11, 2004, lunch was paid for by Millenium for three nurses at the Sunshine Cafe in Santa Monica, CA (See attached Exhibit 25).

3. *Defendants Provided Financing and Other Support for Questionable Research to Support and Promote the Use of Integrilin in off-label patient populations.*

90. Defendants engaged in a researching and publishing campaign under which it paid physicians to engage in off-label studies of Integrilin in STEMI patients, and other uses. These studies were heavily influenced by bias, since the physicians were paid by Defendants; the research was often coordinated by Defendants; and in many cases, Defendants' employees were included as researchers on the projects. In sum, Defendants deliberately pursued a scheme under which they paid for biased research and studies to support the use of Integrilin off-label in STEMI patients, and other uses.

91. Defendants also ran a number of nationwide studies which engaged a large number of investigators, each of whom enrolled a few patients each, and for which doctors were remunerated up to several thousand dollars per enrolled patient, in order to create brand loyalty with the physicians, often for off-label uses.

92. Defendants' research and publication campaign had a clear purpose: to support and promote the off-label use of Integrilin for STEMI patients, and other uses.

93. Indeed, independent studies based on randomized, controlled clinical trials reveal that in this context, Integrilin therapy in off-label patient populations has not shown the level of effectiveness claimed in Defendants' promotions. In fact, according to the scientific literature, STEMI patients undergoing primary PCI on a background of aspirin and 600 mg of clopidogrel, the use of heparin plus upfront Integrilin was not superior to heparin alone. Specifically, the addition of Integrilin did not reduce the incidence of death, myocardial infarction, or severe recurrent ischemia. Integrilin was also associated with increased bleeding (*See* Le May, Wells, Glover, et al, Primary Percutaneous Coronary Angioplasty With and Without EPtifibatide in ST-Segment Elevation Myocardial Infarction: A Safety and Efficacy Study of Integrilin-Facilitated Versus Primary Percutaneous Coronary Intervention in ST-Segment Elevation Myocardial Infarction (ASSIST), *Circulation: Cardiovascular Interventions*, August, 2009), attached Exhibit 1).

B. Defendants Promoted Integrilin for Use in Patients For Off-Label Purposes Even in the Face of Mounting Evidence of Harm.

94. Defendants continue to promote Integrilin for use in off-label patient populations, even in the face of evidence that such use led to an increased risk of internal bleeding and even death. In fact, upon information and belief, Schering continues to promote Integrilin for off-label use in off-label patient populations in the same manner as set forth in this Complaint today.

95. For example, a 2009 study published in The New England Journal of Medicine noted that Integrilin was associated with an increased risk of bleeding and

need for transfusion (See attached Exhibit 2).

96. For example, a 2009 study published in the journal Circulation: Cardiovascular Interventions showed thatSchering never should have sold Integrilin with the idea of treating STEMI patients, as it failed to show improved outcomes compared to much less expensive heparin treatment, and it was associated with increased bleeding (See attached Exhibit 1).

97. Given these risks, it is difficult to see how the benefits of using Integrilin for patients with STEMI or other off-label indications outweigh the risks.

C. Defendants Illegally Promoted Use of Integrilin and Avelox by Providing Kickbacks to Physicians and Researchers.

98. Defendants used illegal kickbacks and quid pro quo arrangements to ensure that physicians would continue to prescribe Defendants' drugs. None of these incentives have anything to do with true scientific or medical research or with the safety of patients. These incentives include cash payments to "consultants" and "preceptors," cash payments for a "speakers bureau" and to national and regional "advisory boards" and for participation in teleconferences, post-market research, "case studies," as well as the other activities described herein.

99. Defendants rewarded doctors with kickbacks for prescribing large quantities of Integrilin and Avelox. Some doctors, who prescribed a large number of Defendants' drugs, were given gifts including expensive meals. Defendants also expected sales representatives to supply some doctors with wine and alcohol at dinner. Frank Solis has personal knowledge of alcohol provided at dinners.

100. Defendants established formal internal guidelines for the award of these benefits to physicians, in effect pushing "prescribe to play," quid pro quo-focused sales strategies which are based entirely on the amount of prescriptions written by the physicians and the ability of the physician to influence other physicians to begin prescribing Defendants' drugs. The recipients of these awards and benefits were selected by Defendant marketers based on the recipients' ability to prescribe Integrilin and Avelox and to influence other doctors to do so.

101. Doctors demanded payment from Defendants as a speaker, a researcher in order to use Defendants' drugs, or demanded Defendants pay for lunch or dinner for the physicians' entire office or the physicians' friends. Defendants' managers would generally agree to pay, and would instruct sales representatives to arrange the paid activity for the doctor. Defendants' sales representatives were then responsible for following through to ensure that Defendants generated Integrilin and Avelox sales based on the provision of the quid pro quo payment.

102. Defendants knew that its provision of kickbacks to these physicians and researchers was illegal and made efforts to conceal its illegal, fraudulent scheme by funneling some payments through third-party consulting organizations. Defendants also understood that its provision of these kickbacks actually caused Integrilin to be used for off-label purposes. Many of these drugs were paid for by Medicaid, Medicare, and the TRICARE health care system for military members and their families. Had the United States and the several States known that these drugs were

used due to a fraudulent kickback scheme, they would not have provided reimbursement for these drugs.

1. ***Defendants Paid Physicians Honoraria, and Lavish Meals to Attend or Speak at Events Promoting the Use of Integrilin and Avelox.***

103. In their efforts to promote the use of Integrilin in off-label patient populations, Defendants provided honoraria, and lavish meals to key opinion leaders and other physicians to attend or speak at dinners, lunches, conferences, symposia, and other events where Integrilin was being promoted.

104. The meals directly took into account the volume and value of the business generated, and were given to physicians who had used or would agree to use or promote the use of Integrilin.

105. Many dinner meetings consisted of lavish dinners at local restaurants. The emphasis at some of these meetings was also on off-label uses of Integrilin, and hundreds to thousands of dollars worth of honoraria were paid to physicians who spoke about off-label uses at these meetings. High volume prescribing doctors and local opinion leaders were targeted for invitation. High volume prescribing Medicaid and Medicare doctors were often specifically targeted for invitation. At all of the events physicians were encouraged to increase their use of Schering drugs.

106. For example, a February 3, 2004 dinner was held at the expensive Arnie Morton's Steakhouse in Beverly Hills for high prescriber Dr. Raj Makkar and some fellows from high-use hospital Cedars Sinai (See attached Exhibit 26).

107. For example, on April 21, 2004 Millennium paid $1,211.23 for a dinner at the expensive Arnie Morton's Steakhouse in Burbank, CA for dinner for Dr. Bill Gifford, among others (See attached Exhibit 27).

108. For example, on July 16, 2004, Millennium paid $671.44 to take cardiologists and staff from Los Robles Regional Medical Center out for dinner and drinks at the expensive Nobu Malibu restaurant in Malibu. According to Frank Solis, there was no educational component, and the doctors were taken to dinner because they were known for being the highest volume sales account at the time (See attached Exhibit 28).

109. For example, on September 14, 2004, Millennium paid $938.31 for dinner at the expensive Mastro's Beverly Hills restaurant for "Olive View/UCLA cardiology customers" (See attached Exhibit 29).

110. For example, on November 17, 2004, Millennium paid $1,213.70 for dinner at Arnie Morton's Steakhouse in Burbank, CA for St. Joseph's hospital emergency department and cath lab staff customers (See attached Exhibit 30).

111. For example, on December 4, 2004, Millennium paid $507.84 for dinner and drinks for a portion of the Cedars Sinai cardiology department Christmas party at the Hard Rock Cafe in Los Angeles (See attached Exhibit 31).

112. For example, on June 21, 2005, Millennium paid $797.19 for dinner and drinks at the expensive Koi restaurant in West Hollywood for Cedars Sinai cardiology doctors and staff. According to Frank Solis, the doctors asked for the

restaurant, because it was a "hip" spot, and there was no educational component (See attached Exhibit 32).

113. For example, in a Schering Hospital Project Plan for St. John's Health Center for 2008, a plan had been written to take the cath lab staff and Dr. Prabhtej Brara "for happy hour" in the first quarter of 2008. Ultimately, Schering sales reps intended to use the happy hour, and various paid lunches and dinners to convince St. John's cardiologists to "give [emergency department] the ok to start appropriate patients on Integrilin." The use of Integrilin was typically started in the catheterization lab, after the patient had been admitted to the hospital, but Schering found that their profits could be greatly increased by starting patients on Integrilin in the emergency department, thereby doubling the dose of Integrilin many patients received by the time they finished their catheterization lab procedures. However, this practice of initiating early use in emergency departments has been exposed as expensive, ineffective, and unsafe due to increased risks of bleeding and use of transfusion in a 2009 study published in the New England Journal of Medicine (See attached Exhibit 33).

114. For example, an August 2008 Schering business plan targeted a dinner with high Integrilin prescriber Dr. Mike Lee from UCLA's Santa Monica Medical Center for dinner with he and some fellows at an expensive Morton's Steakhouse (See attached Exhibit 34).

115. Defendants ensured that cash and meals were often targeted specifically at

high Medicare and Medicaid prescribing doctors, to increase market share within the Medicaid and Medicare programs, and to influence the market share status of Defendants' drugs within the Medicaid and Medicare programs. In addition, cash and meals were often targeted at high Medicaid and Medicare volume facilities in order to increase Defendants' reimbursements through State and Federal health care systems. Also, formulary committee members at high volume Medicaid facilities were specifically targeted for cash and meals to place Defendants' drugs on their approved drug formularies and hospital protocols, and to purchase Defendants' drugs for their inventories and increase Schering's reimbursements.

116. For example, the Schering Hospital Project Plan for Glendale Adventist Hospital noted that Schering payment for lunch for Clinical Pharmacist Romic Eskandarian resulted in Romic's commitment "to buying in [sic] a large amount of Integrilin prior to the holiday" (See attached Exhibit 35).

117. Schering's "hospital project action plans" often included tracking of hospitals by their volume of Medicare cardiology in-patients, average length of stay for Medicare patients, and the average charge to different hospitals for Medicare patients. Schering management utilized this Medicare volume information in order to determine which hospitals to target for expensive meals and cash payments.

118. For example, in the 2006 Schering hospital business plan for Antelope Valley Hospital in Lancaster, CA, Schering tracked 609 cardiology Medicare in-patients, a 5.57 day average length of stay, and a $25,801 average charge per

patient. In order to increase the amount of Medicare business from the facility, Schering targeted Antelope Valley Hospital for expensive meals with off-label speakers such as Dr. Michael Gibson from Harvard who was normally paid more than $2,500 to speak on the off-label use of Integrilin for STEMI patients (See attached Exhibit 36).

119. For example, in the March 23, 2006 Schering hospital business plan for Glendale Memorial Hospital in Glendale, CA, Schering tracked 787 cardiology Medicare in-patients, a 4.7 day average length of stay, and a $30,565 average charge per patient. In order to increase the amount of Medicare business from the facility, Schering targeted attending cardiologist Dr. Don Lee to receive a $5,000 grant to support his cardiology seminar in Las Vegas (See attached Exhibit 37).

120. Defendants' sales representatives were instructed to distribute checks for speakers, and invitations to lavish meals exclusively to targeted high volume prescribers or referral sources in order to meet the representatives' required sales levels for bonus payouts each quarter. Defendants' sales representatives were instructed to target cardiologists, catheterization lab physicians, and internal medicine physicians for prescriptions, and buy them expensive meals, and sign them up for paid speaking engagements.

121. For example, in the Schering 2007 Hospital Project Action Plan for Glendale Adventist hospital, Frank Solis was instructed to increase Integrilin sales to $260,000 by training high prescribing doctor Harry Balian as a speaker, and

scheduling him to be paid $1,500 for separate speaking engagements (See attached Exhibit 38).

122. For example, Schering planned a $500 lunch for high prescribing doctors at Foothill Cardiology clinic on April 30, 2007 (See attached Exhibit 39).

123. For example, in a March 18, 2008 Field Coaching Report of Frank Solis, District Manager Catherine Galvin stated that Frank was doing a good job of grooming high prescriber Dr. Mike Lee as a speaker, and that plans were underway to send Dr. Lee him to Hawaii (See attached Exhibit 40).

124. For example, the January 27, 2009 Schering hospital project action plan for Glendale Adventist Hospital stated that a lunch was given to the largest admitter of catheterization lab patients at Memorial and Adventist hospitals in Glendale, Dr. Mesrobian (See attached Exhibit 41).

125. For example, on June 30, 2009, Schering paid $288.65 for a catered lunch from Pescado Mojado restaurant for the Glendale Adventist hospital cath lab doctors and staff (See attached Exhibit 49).

126. For example, on July 9, 2009, Schering paid $263.87 for a catered lunch from Pescado Mojado restaurant for the Glendale Adventist hospital emergency department doctors and staff (See attached Exhibit 50).

127. For example, on August 17, 2009, Schering paid $264.96 for a catered lunch from Pescado Mojado restaurant for the Glendale Adventist hospital cath lab doctors and staff (See attached Exhibit 51).

128. For example, on August 27, 2009, Schering paid $291.63 for a catered lunch from Pescado Mojado restaurant in LA for the Glendale Adventist hospital emergency department doctors and staff (See attached Exhibit 52).

129. Payment for dinner and other incentives to increase referrals to a physician for the use of Integrilin and Avelox is inappropriate and illegal. According to the federal Health and Human Services Office of the Inspector General (HHS OIG), paid meals would be inappropriate if they are tied directly or indirectly to the generation of federal health care program business for the manufacturer, or for the purposeful inducement of business. See, e.g., 68 F.R. 23738. ("these arrangements [entertainment, recreation, travel, meals, etc.] potentially implicate the anti-kickback statute if any one purpose of the arrangement is to generate business.")

2. ***Defendants Concealed Some Illegal and Fraudulent Payments to Physicians by Funneling Them through Third Party Consultant Companies.***

130. In order to hide illegal payments to physicians, Defendants made many payments to doctors through the Advanced Health Media marketing company. Advanced Health Media arranged for expensive meals and sent payments to sales reps to be given to speakers for promoting Defendants' drugs off-label.

131. For example, Schering contracted with Advanced Health Media to pay a $1,500 speaker fee for Dr. Harry Balian to speak at Glendale Memorial Hospital on February 3, 2009 on the Integrilin-related topic of "Treatment Strategies in PCI". Advanced Health Media provided sign-in sheets for guests, reviewed unauthorized

charges on the food and beverage bill, collected meeting evaluations, and provided a credit card authorization for expenses (See attached Exhibit 42).

3. ***Defendants Knew Their Payments to Physicians Were Illegal Because They Were Intended for the Purposeful Inducement of Business.***

132. Defendants knew their payments to physicians were illegal kickbacks. In fact, it provided its personnel with guidelines that indicated that field employees could occasionally provide modest meals or snacks to health care professionals where the primary purpose is an informational presentation. In contrast, Defendants' dinner events with paid speakers were often a sham, with the speaker getting paid $1,000 or more but having no real responsibility. Doctors received prepared slides from Defendants to speak from, so that the doctors did not have to put forth any effort to prepare a presentation. Doctors sometimes simply opened a laptop on the table at dinner with some slides on it, and then only spoke for five to ten minutes, or did not speak at all and simply enjoyed the lavish dinner with the other attendees.

4. ***Defendants' Payment of Illegal Kickbacks to Physicians Actually Affected the Use of Integrilin and Avelox in Hospitals and Cardiology Clinics***

133. Defendants' scheme to pay physicians resulted in specific sales. Defendants, like most branded drug companies, monitor the relationship of its sales to its promotional efforts over a very short timeframe; Defendants would be concerned about a drop in sales within a certain therapeutic regime not after a year look-back, or even a quarterly look-back, but over a period of just weeks.

Defendants' marketing and sales strategy documents show that at least on a weekly basis Defendants were tracking prescription volume by hospital, and tracking the percentage change in prescribing habits of physicians for Defendants' drugs. In addition, Defendants tracked the return on investment ("ROI") of paid travel and expensive meals for physicians. Defendants' sales representatives were instructed to ask physicians for additional prescriptions when the physicians were paid to speak at a lavish meal event, and told to track follow-up prescriptions by the physician, and to hold the physicians accountable if the physicians did not increase prescriptions of Defendants' drugs. Physicians were made aware by sales representatives that the physicians would not continue to be invited to lavish meals if the physicians did not remain in the high volume prescriber range, and if the physicians did not prescribe Defendants' drugs. Physicians who did not continue to prescribe Defendants' drugs were tracked on a quarterly basis by Defendants' marketing and sales personnel, and were sometimes penalized by being taken off target lists for invitations to future lavish meals and offers of speaking engagements, paid research opportunities, and other perks. Defendants' pushed "prescribe to play," quid pro quo-focused sales strategies, which are based entirely on the amount of prescriptions written by the physicians and the ability of the physician to influence other physicians to begin prescribing Defendants' drugs. The recipients of these awards and benefits were selected by Defendants' marketers based on the recipients' ability to prescribe Integrilin and Avelox and to influence

other doctors to do so.

134. For example, Schering's Hospital Project Plan for Olive View/UCLA Medical Center in Sylmar, CA included the objective to "meet with influential physicians and work on getting Avelox on formulary." The Plan noted in November, 2008 that the County formulary was the problem, and that sales reps should continue to work closely with Dr. Fred Abrahamian and Dr. Gregory Moran to get Avelox onto the formulary (See attached Exhibit 43).

135. For example, the Schering Hospital Project Plan for Glendale Adventist hospital in Glendale, CA stated that a dinner meeting with Dr. Fred Abrahamian and Clinical Pharmacist Romic Eskandarian at the expensive Smitty's Grill in December, 2008 "will hopefully benefit cause of getting [Avelox] on formulary." According to Frank Solis, the expensive dinner meeting was successful, as Glendale Adventist recently added Avelox to its hospital formulary (See attached Exhibit 44).

136. For example, Schering's January 27, 2009 Hospital Project Action Plan includes information about a Schering paid lunch for Dr. Keushkerian's office. Dr. Keushkerian promised the sales rep that he would write additional prescriptions of Avelox "in an effort to bring to the attention of pharmacy that demand does exist for Avelox" (See attached Exhibit 45).

137. Defendants' sales representatives provided meals and other favors for physician members of formulary committees and hospital guideline committees and

their staffs, including committees which affected large Medicaid and Medicare patient populations, such as hospitals with large Medicaid and Medicare populations. Defendants' management directed sales staff to invite formulary committee members and guideline committee members to lavish meals and offer paid speaking opportunities, paid research, and other perks. Defendants' management arranged inducements for influential formulary and guideline committee members in order to put Integrilin or Avelox on their formulary or guidelines or standing orders, or to purchase Schering drugs into inventory.

138. Defendants also instructed physicians' office staff and clinic personnel to maximize Medicaid and Medicare billing. Defendants' field representatives gave billing seminars, and paid billing maximization speakers such as Sandra Sieck to give presentations, in which the Defendants' representatives suggested how to bill Medicare in order to receive maximum revenues. The field representatives also reviewed prior billings for some facilities, and suggested additional billings that Medicaid or Medicare were known to pay for without question (See attached Exhibit 46).

139. Defendants also instructed its sales representatives to review patient conditions at doctor's offices and to help them select high risk patients to receive Integrilin instead of competitor drugs.

140. For example, a Schering Hospital Project Plan for St. John's Health Center in Santa Monica, CA indicated on March 22, 2007 that a sales rep had helped staff

"identify high-risk patients" and Integrilin dosing for those patients (See attached Exhibit 47).

141. For example, one Schering sales representative wrote in the Hospital Project Plan for Valley Presbyterian Hospital that on March 29, 2007 they had worked with Dr. Ramesh Arora to identify patients "who benefit most from Integrilin". Then, on April 15, 2008 the sales rep noted that they had discussed a specific patient case with Dr. Ramesh Arora, and that after they had identified clinical and angiographic risk together, Dr. Arora used Integrilin on the patient (See attached Exhibit 48).

COUNT ONE

FEDERAL FALSE CLAIMS ACT VIOLATIONS BASED ON THE PAYMENT OF KICKBACKS (31 U.S.C. § 3729)

142. Relator re-alleges and incorporate the allegations above as if fully set forth herein.

143. Defendants' payment of kickbacks to physicians and other health care providers violated the Medicaid Anti-Kickback statute and other statutes and regulations controlling the payment of governmental employees and military personnel and caused false claims to be submitted to the federal government. Since the Medicaid Anti-Kickback statue is a critical provision of Medicaid, compliance with it is material to the government's treatment of claims for reimbursement. Had the United States and the several states known that Integrilin had been prescribed

because physicians had been paid kickbacks by Defendants to do so, neither the United States nor the States would have provided reimbursement for these drug prescriptions. As the United States and the States were unaware of the illegality of the claims, and in reliance on the accuracy and legality thereof, made payment upon the false or fraudulent claims, the United States and the States were damaged.

144. The kickbacks described herein are strictly illegal and have had the direct effect of greatly increasing the amount of Integrilin procured and used by the government and under the auspices of government programs. The kickbacks have had the indirect effect of increasing the amount of money spent by the federal government and the states for reimbursement of drugs covered by Medicaid, Medicare, and TRICARE. The payment of these kickbacks represents the inducement of federal payments through a pattern of fraudulent conduct and constitutes false claims within the meaning of 31 U.S.C. § 3729.

COUNT TWO

SCHERING'S PAYMENT OF KICKBACKS AS CONSPIRACY TO SUBMIT FALSE CLAIMS (31 U.S.C. § 3729(A)(3))

145. Relator re-alleges and incorporate the allegations above as if fully set forth herein.

146. Defendants combined, conspired, and agreed together with physicians and others to defraud the United States by knowingly causing false and illegal claims to be submitted to the United States for the purpose of having those claims paid and ultimately profiting from those false claims. Defendants committed other overt acts

set forth above in furtherance of that conspiracy, all in violation of 31 U.S.C. §3729(a)(3), causing damage to the United States.

COUNT THREE
FEDERAL FALSE CLAIMS ACT VIOLATIONS FOR CAUSING SUBMISSION OF OFF-LABEL BILLS (31 U.S.C. §3729)

147. Relator re-alleges and incorporate the allegations above as if fully set forth herein.

148. By presenting physicians with false information about off-label uses of Integrilin and encouraging physicians to prescribe Integrilin for such uses and procure the drug for such uses which were not approved by the FDA or any relevant drug compendium, Defendants caused physicians and facilities to submit numerous bills for Integrilin that were ineligible for reimbursement under Medicaid, Medicare, and TRICARE because the drug were used for an off-label use. Defendants also caused the procurement of Integrilin for off-label uses. Such procurement should not have been paid for or reimbursed by Medicaid, Medicare, or TRICARE because it was for an off-label use. Thus, Defendants knowingly caused such physicians and healthcare facilities expressly or impliedly to make false certifications about the Integrilin's indications and efficacy. Defendants therefore caused the submission of false claims for payment of money under the federal Medicaid and Medicare programs and TRICARE. Had the United States known that the Defendants caused procurement of Integrilin for unapproved uses and also caused Integrilin to be prescribed for unapproved, off-label uses, the

United States would not have provided reimbursement for such prescriptions under its Medicaid and Medicare plans and under TRICARE.

149. This course of conduct violated the False Claims Act, 31 U.S.C. §§ 3729 *et seq*.

150. The United States, unaware of the falsity of the claims, and in reliance on the accuracy thereof, made payment upon the false or fraudulent claims and was therefore damaged.

COUNT FOUR

SCHERING'S SCHEME WITH RESPECT TO OFF-LABEL BILLINGS AS CONSPIRACY TO SUBMIT FALSE CLAIMS (31 U.S.C. §3729(A)(3))

151. Relator re-alleges and incorporate the allegations above as if fully set forth herein.

152. Defendants combined, conspired, and agreed together with physicians and others to defraud the United States by knowingly causing false claims to be submitted to the United States for the purpose of having those claims paid and ultimately profiting from those false claims. Defendants committed other overt acts set forth above in furtherance of that conspiracy, all in violation of 31 U.S.C. §3729(a)(3), causing damage to the United States.

COUNT FIVE

FEDERAL FALSE CLAIMS ACT VIOLATIONS FOR DEFENDANTS' FRAUDULENT PROMOTION OF INTEGRILIN (31 U.S.C. §3729)

153. Relator re-alleges and incorporate the allegations above as if fully set forth

herein.

154. Defendants represented to physicians that Integrilin was safe and effective for use in off-label patient populations. Such representations were false and fraudulent. However, relying on these false representations, physicians recommended and prescribed Integrilin for use in off-label patient populations.

155. Integrilin is extremely expensive. As such, Defendants caused the government and the states to incur unneeded and unwarranted costs to cover the use of Integrilin in off-label patient populations.

156. This course of conduct violated the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*

157. The United States, unaware of the falsity of the claims, and in reliance on the accuracy thereof, made payment upon the false or fraudulent claims and was therefore damaged.

PRAYER FOR RELIEF UNDER THE FEDERAL FALSE CLAIMS ACT

Relator respectfully requests this Court to enter judgment against Defendants, as follows:

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

(b) That civil penalties at the maximum amount allowed by law be imposed for each and every false claim that Defendants presented to the United States;

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

(d) That the Court grant permanent injunctive relief to prevent any recurrence of violations of the False Claims Act for which redress is sought in this Complaint;

(e) That the Relator be awarded the maximum percentage of any recovery allowed to him pursuant the False Claims Act, 31 U.S.C. §3730(d)(1),(2);

(f) That this Court award such other and further relief as it deems proper.

COUNT SIX

VIOLATION OF THE ARKANSAS MEDICAID FRAUD FALSE CLAIMS ACT

158. Relator re-alleges and incorporate the allegations above as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the State of Arkansas. Upon information and belief, Defendants' actions described herein occurred in the State of Arkansas as well.

159. This is a qui tam action brought by Relator and the Arkansas to recover

treble damages and civil penalties under the Arkansas Medicaid Fraud False Claims Act, A.C.A. § 20-77-901 et seq.

160. The Arkansas Medicaid Fraud False Claims Act § 20-77-902 provides liability for any person who-

> Knowingly makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under the Arkansas Medicaid program;
>
> At any time knowingly makes or causes to be made any false statement or representation of a material fact for use in determining rights to a benefit or payment;

161. In addition, A.C.A. § 20-77-902(7)(A) prohibits soliciting, accepting, or agreeing to accept any type of remuneration for the following:

> Recommending the purchase, lease, or order of any good, facility, service, or item for which payment may be made under the Arkansas Medicaid program.

162. Defendants violated the Arkansas Medicaid Fraud False Claims Act § 20-77-902(1) (2) & (7)(A) from at least 2002 to the present by engaging in the fraudulent and illegal practices described herein.

163. Defendants furthermore violated Arkansas Medicaid Fraud False Claims Act § 20-77-902(1) & (2) and knowingly caused thousands of false claims to be made, used and presented to Arkansas from at least 2001 to the present by its violation of federal and state laws, including A.C.A. § 20-77-902(7)(A), the Anti-Kickback Act and Stark Act Requirements, as described herein.

164. Arkansas, by and through the Arkansas Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third payers in connection

therewith.

165. 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 Arkansas is connection with Defendants' fraudulent and illegal practices.

166. Had the Arkansas known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

167. As a result of Defendants' violations of § 20-77-902(1) (2) & (7)(A), the State of Arkansas has been damaged in an amount far in excess of millions of dollars exclusive of interest.

168. Frank Solis is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to A.C.A. § 20-77-911(a) on behalf of himself and the State of Arkansas.

169. This Court is requested to accept supplemental 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 Arkansas in the operation of its Medicaid program.

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

A. To the STATE OF ARKANSAS:

Three times the amount of actual damages which the State of Arkansas has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Arkansas;

Prejudgment interest; and

All costs incurred in bringing this action.

B. To RELATOR:

The maximum amount allowed pursuant to A.C.A. § 20-77-911(a) and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

COUNT SEVEN

VIOLATION OF THE CALIFORNIA FALSE CLAIMS ACT
(Cal. Gov't Code § 12650 et seq.)

171. Relator re-alleges and incorporate the allegations above as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants.

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

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

Knowingly presents, or causes to be presented, to an officer or employee of the state of any political division thereof, a false claim for payment or approval;

Knowingly makes, uses, or causes to be made or used a false record of

statement to get a false claim paid or approved by the state or by any political subdivision;

Conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state of by any political subdivision.

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.

174. 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.

175. Defendants violated Cal Bus. & Prof. Code §§ 650 and 650.1 and Cal. Welf. & Inst. Code § 14107.2 from at least 2002 to the present by engaging in the fraudulent and illegal practices described herein.

176. Defendants 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 from at least 2001 to the present by its violation of federal and state laws, including Cal. Bus. & Prof. Code §§ 650 and 650.1 and Cal. Welf. & Inst. Code § 14107.2, the Anti-Kickback Act and Stark Act Requirements, as described herein.

177. The State of California, by and through the California Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

178. Compliance with applicable Medicare, Medi-Cal and the various other

federal and state laws cited herein was implied, and upon information and belief, also an express condition of payment of claims submitted to the State of California in connection with Defendants' fraudulent and illegal practices.

179. Had the State of California known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

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

181. Frank Solis is a private person with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of himself and the State of California.

182. This Court is requested to accept supplemental 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.

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

A. To the STATE OF CALIFORNIA:

Three times the amount of actual damages which the State of California has sustained as a result of Defendants' fraudulent and illegal practices;

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

Prejudgment interest; and

All costs incurred in bringing this action.

B. To RELATOR:

The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT NINE

VIOLATION OF THE DELAWARE FALSE AND REPORTING CLAIMS ACT

184. Relator re-alleges and incorporate the allégations in paragraphs 1-177 as if fully set forth herein. Additionally, Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the State of Delaware. Upon information and belief, Defendants' actions described herein occurred in Delaware as well.

185. This is a qui tam action brought by Relator and the State of Delaware to recover treble damages and civil penalties under the Delaware Medicaid False Claims Act, 6 Del. C. § 1201 et seq.

186. 6 Del. C. § 1201 et seq. provides liability for any person who—

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;

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;
>
> Conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;
>
> Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, increase or decrease an obligation to pay or transmit money or property to or from the Government

187. Further, 31 Del. C. § 1005 provides that—

> It shall be unlawful for any person to offer or pay any remuneration (including any kickback, bribe or rebate) directly or indirectly, in cash or in kind to induce any other person . . . [t]o purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any property, facility, service, or item of medical care or medical assistance for which payment may be made in whole or in part under any public assistance program.

188. Defendants violated 6 Del. C. § 1201 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Delaware from 2001 to the present by its violation of federal and state laws, including 31 Del. C. §1005, and Anti-Kickback Act and the Stark Act Requirements, as described herein.

189. The State of Delaware, by and through the Delaware Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care 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 Delaware in connection with Defendants' fraudulent and illegal practices.

191. Had the State of Delaware known that Defendants were violating the federal and state laws cited herein, it wound not have paid the claims submitted by health care providers and third party payers in connection with Schering's fraudulent and illegal practices.

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

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

194. Frank Solis is a private person with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to 6 Del. C. § 1203(b) on behalf of himself and the State of Delaware.

195. This Court is requested to accept supplemental 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.

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

A. To the STATE OF DELAWARE:

Three times the amount of actual damages which the State of Delaware has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty on not less then $5,500 and not more than $ 11,000 for each false claim which Defendants caused to be presented to the State of Delaware;

Prejudgment interest; and

All costs incurred in bringing this action.

B. To RELATOR:

The maximum amount allowed pursuant to 6 Del C. § 1205,and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT NINE

VIOLATION OF THE DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

197. Relator re-alleges and incorporate the allegations in paragraphs 1-190 as if fully set forth herein. Additionally, Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the District of Columbia. Upon information and belief, Defendants' actions described herein occurred in the District of Columbia as well.

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

199. D.C. Code § 2-30814(a) provides liability for any person who-

> Knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval;
>
> 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;
>
> Conspires to defraud the District by getting a false claim allowed or paid by the District;
>
> 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.

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

> 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
>
> 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.

201. Defendants violated D. C. Code § 4-802(c) from at least 2001 to the present by engaging in the fraudulent and illegal practices described herein.

202. Defendants furthermore violated D. C. Code § 2-308.14(a) and knowingly caused thousands of false claims to be made, used and presented to the District of Columbia from at least 2001 to the present by its violation of federal and state laws, including D. C. Code § 4-802(c), the Anti-Kickback Act and the Stark Act, as described herein.

203. The District of Columbia, by and through the District of Columbia Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health

care providers and third party payers in connection therewith.

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

205. Had the District of Columbia known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

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

207. Frank Solis is a private person with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to D.C. Code § 2-308.15(b) on behalf of himself and the District of Columbia.

208. This Court is requested to accept supplemental 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.

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

A. To the DISTRICT OF COLUMBIA:

Three times the amount of actual damages which the District of Columbia has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the District of Columbia;

Prejudgment interest; and

All costs incurred in bringing this action.

B. To RELATOR:

The maximum amount allowed pursuant to D. C. Code § 2-308.15(f) and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

COUNT ELEVEN

VIOLATION OF THE FLORIDA FALSE CLAIMS ACT

210. Relator re-alleges and incorporate the allegations in paragraphs 1-203 as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the State of Florida. Upon information and belief, Defendants' actions described herein occurred in the State of Florida as well.

211. This is a qui tam action brought by Relator and the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, West's F.S.A. § 68.081 et seq.

212. West's F.S.A. § 68.082 provides liability for any person who-

Knowingly presents or causes to be presented to an officer or employee of an agency a false claim for payment or approval

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

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

213. Defendants violated West's F.S.A. § 68.082 from at least 2001 to the present by engaging in the fraudulent and illegal practices described herein.

214. Defendants furthermore violated West's F.S.A. § 68.082 and knowingly caused thousands of false claims to be made, used and presented to the State of Florida from at least 2001 to the present by its violation of federal and state laws, including the Anti-Kickback Act, and the Stark Act, as described herein.

215. The State of Florida, by and through the State of Florida Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third payers in connection therewith.

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

217. Had the State of Florida known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and

illegal practices.

218. As a result of Defendants' violations of West's F.S.A. § 68.082 the State of Florida has been damaged in an amount far in excess of millions of dollars exclusive of interest.

219. Frank Solis is a private person with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to West's F.S.A. § 68.083(2) on behalf of himself and the State of Florida.

220. This Court is requested to accept supplemental 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.

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

A. To the STATE OF FLORIDA:

Three times the amount of actual damages which the State of Florida has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Florida;

Prejudgment interest; and

All costs incurred in bringing this action.

B. To RELATOR:

The maximum amount allowed pursuant to West's F.S.A. § 68.085 and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

COUNT ELEVEN

VIOLATION OF THE GEORGIA STATE FALSE MEDICAID CLAIMS ACT

222. Relator re-alleges and incorporate the allegations in paragraphs 1-215 as if fully set forth herein. Additionally, Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the State of Georgia. Upon information and belief, Defendants' actions described herein occurred in Georgia as well.

223. This is a qui tam action brought by Relator and the State of Georgia to recover treble damages and civil penalties under the Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168, *et seq*.

224. Ga. Code Ann. § 49-4-168.1 *et seq*. provides liability for any person who—

> Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
>
> Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;
>
> Conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid;
>
> Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay, repay or transmit money or property to the State of Georgia.

225. Defendants violated Ga. Code Ann. § 49-4-168.1 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of

Georgia from 2001 to the present by its violation of federal and state laws, including the Anti-Kickback Act and the Stark Act, as described herein.

226. The State of Georgia, by and through the Georgia Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

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

228. Had the State of Georgia known that Defendants were violating the federal and state laws cited herein, it wound not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

229. As a result of Defendants' violations of Ga. Code Ann. § 49-4-168.1, the State of Georgia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

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

State regarding the claims for reimbursement at issue.

231. Frank Solis is a private person with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Ga. Code Ann., § 49-4-168.2(b) on behalf of himself and the State of Georgia.

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

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

A. To the STATE OF GEORGIA:

Three times the amount of actual damages which the State of Georgia has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty on not less then $5,500 and not more than $ 11,000 for each false claim which Defendants caused to be presented to the State of Georgia;

Prejudgment interest; and

All costs incurred in bringing this action.

B. To RELATOR:

The maximum amount allowed pursuant to Ga. Code Ann., § 49-4-168.2(i),and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

/ / /

COUNT TWELVE

VIOLATION OF THE HAWAII FALSE CLAIMS ACT

234. Relator re-alleges and incorporate the allegations in paragraphs 1-227 as if fully set forth herein. Additionally, Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the State of Hawaii. Upon information and belief, Defendants' actions described herein occurred in Hawaii as well.

235. This is a qui tam action brought by Relator and the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661.21 et seq.

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

> Knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;
>
> 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;
>
> Conspires to defraud the state by getting a false or fraudulent claim allowed or paid; or
>
> 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.

237. Defendants 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 from at least 2001 to the present by its violation of federal and state laws, including the Anti-Kickback Act, and Stark Act, as described herein.

238. The State of Hawaii, by and through the Hawaii Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

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

240. Had the State of Hawaii known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

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

242. Frank Solis is a private person with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Haw. Rev. Stat. § 661-25(a) on behalf of himself and the State of Hawaii.

243. This Court is requested to accept supplemental 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.

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

A. To the STATE OF HAWAII:

Three times the amount of actual damages which the State of Hawaii has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Hawaii;

Prejudgment interest; and

All costs incurred in bringing this action.

B. To RELATOR:

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

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT THIRTEEN

VIOLATION OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

245. Relator re-alleges and incorporate the allegations in paragraphs 1-238 as if fully set forth herein. Additionally, Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the State of Illinois. Upon information and belief, Defendants' actions described herein occurred in Illinois as well.

246. This is a qui tam action brought by Relator and the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward

and Protection Act, 740 ILCS 175 *et seq*.

247. 740 ILCS 175/3(a) provides liability for any person who—

> 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;
>
> knowingly makes, uses, of causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
>
> Conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

248. 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 of service for which payment may be made in whole or in part under the Illinois Medicaid program.

249. Defendants violated 305 ILCS 5/8A-3(b) from at least 2001 to the present by engaging in the fraudulent and illegal practices described herein.

250. Defendants 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 from at least 2001 to the present by its violation of federal and state laws, including 305 ILCS 5/8A-3(b), the Anti-Kickback Act and the Stark Act, as described herein.

251. The State of Illinois, by and through the Illinois Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers

in connection therewith.

252. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein with an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Illinois in connection with Defendants' fraudulent and illegal practices.

253. Had the State of Illinois known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

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

255. Frank Solis is a private person with direct and independent knowledge of the allegation of this Complaint, who have brought this action pursuant to 740 ILCS 175/3(b) on behalf of himself and the State of Illinois.

256. This court is requested to accept supplemental 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.

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

A. To the STATE OF ILLINOIS:

Three times the amount of actual damages which the State of Illinois has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Illinois;

Prejudgment interest; and

All costs incurred in bringing this action.

C. To RELATOR:

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

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT FOURTEEN

VIOLATION OF THE INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

258. Relator re-alleges and incorporate the allegations in paragraphs 1-251 as if fully set forth herein. Additionally, Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the State of Indiana. Upon information and belief, Defendants' actions described herein occurred in Indiana as well.

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

260. IC 5-11-5.5-2 provides liability for any person who—

(1) presents a false claim to the state for payment or approval;

(2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state;

(3) with intent to defraud the state, delivers less money or property to the state than the amount recorded on the certificate or receipt the person receives from the state;

(4) with intent to defraud the state, authorizes issuance of a receipt without knowing that the information on the receipt is true;

(5) receives public property as a pledge of an obligation on a debt from an employee who is not lawfully authorized to sell or pledge the property;

(6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;

(7) conspires with another person to perform an act described in subdivisions (1) through (6); or

(8) causes or induces another person to perform an act described in subdivisions (1) through (6).

261. In addition, IC 12-15-24-1 & IC 12-15-24-2 prohibits the provision of a kickback or bribe in connection with the furnishing of items or services or the making or receipt of the payment under the Indiana Medicaid program.

262. Defendants violated IC 12-15-24-1 & IC 12-15-24-2 from at least 2001 to the present by engaging in the fraudulent and illegal practices described herein.

263. Defendants furthermore violated IC 5-11-5.5-2 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Indiana from at least 2001 to the present by its violation of federal and state laws, including IC 12-15-24-1 & IC 12-15-24-2, the Anti-Kickback Act and the Stark Act, as described herein.

264. The State of Indiana, by and through the Indiana Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal

practices, paid the claims submitted by health care providers and third party payers in connection therewith.

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

266. Had the State of Indiana known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

267. As a result of Defendants' violations of IC 5-11-5.5-2, the State of Indiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

268. Frank Solis is a private person with direct and independent knowledge of the allegation of this Complaint, who have brought this action pursuant to IC 5-11-5.5-4 on behalf of himself and the State of Indiana.

269. This court is requested to accept supplemental 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.

270. WHEREFORE, Relator respectfully requests this Court to award the

following damages to the following parties and against Defendants:

A. To the STATE OF INDIANA:

Three times the amount of actual damages which the State of Indiana has sustained as a result of Defendants' fraudulent and illegal practices;

Prejudgment interest; and

All costs incurred in bringing this action.

D. To RELATOR:

The maximum amount allowed pursuant to IC 5-11-5.5-6 and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT FIFTEEN

VIOLATION OF THE LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

271. Relator re-alleges and incorporate the allegations in paragraphs 1-264 as if fully set forth herein. Additionally Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the State of Louisiana. Upon information and belief, Defendants' actions described herein occurred in Louisiana as well.

272. This is a qui tam action brought by Relator and 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.

273. La. Rev. Stat. Ann. § 438.3 provides –

No person shall knowingly present or cause to be presented a false or

fraudulent claim;

No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medial assistance programs funds;

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;

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

275. Defendants violated La. Rev. Stat. Ann § 438.2(A) from at least 2001 to the present by engaging in the fraudulent and illegal practices described herein.

276. Defendants 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 from at least 2001 to the present by its violation of federal and state laws, including La. Rev. Stat. Ann. § 438.2(A), the Anti-Kickback Act and Stark Act, as described herein.

277. The State of Louisiana, by and through the Louisiana Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care 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 Louisiana in connection with Defendants' fraudulent and illegal practices.

279. Had the State of Louisiana known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants's fraudulent and illegal practices.

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

281. Frank Solis is a private person with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to La. Rev. Stat. Ann. § 439.1(A) on behalf of himself and the State of Louisiana.

282. This Court is requested to accept supplemental 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.

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

A. To the STATE OF LOUISIANA:

Three times the amount of actual damages which the State of Louisiana has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Louisiana;

Prejudgment interest; and

All costs incurred in bringing this action.

B. To RELATOR:

The maximum amount allowed pursuant to La. Rev. Stat. § 439.4(A) and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award or reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT SIXTEEN

VIOLATION OF THE MASSACHUSETTS FALSE CLAIMS ACT

284. Relator re-alleges and incorporate the allegations in paragraphs 1-277 as if fully set forth herein. Additionally, Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the Commonwealth of Massachusetts. Upon information and belief, Defendants' actions described herein occurred in Massachusetts as well.

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

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

Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

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;

Conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;

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 reason able time after discovery of the false claim.

287. In addition, Mass. Gen. Laws Ann. Chap. 118E § 41 prohibits the solicitation, receipt or offering of any remuneration, including any bribe ore 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.

288. Defendants violated Mass. Gen. Laws Ann. Chap. 118E § 41 from at least 2001 to the present by engaging in the fraudulent and illegal practices described herein.

289. Defendants 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 State of Massachusetts from at least 2001 to the present by its violation of federal and state laws, including Mass. Gen. Laws Ann. Chap. 118E § 41, the Anti-Kickback Act and the Stark Act, as described herein.

290. The State of Massachusetts, by and through the Massachusetts Medicaid program and other state health care programs, and unaware of Defendants'

fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

291. 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 Massachusetts in connection with Defendants' fraudulent and illegal practices.

292. Had the State of Massachusetts known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

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

294. Frank Solis is a private person with direct and independent knowledge of the allegations of the Compliant, who have brought this action pursuant to Mass. Gen. Laws Ann Chap. 12 § 5(c(2) on behalf of himself and the State of Massachusetts.

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

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

A. To the STATE OF MASSACHUSETTS:

Three times the amount of actual damages which that State of Massachusetts has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Massachusetts;

Prejudgment interest; and

All costs incurred in bringing this action.

B. To RELATOR:

The maximum amount allowed pursuant to Mass. Gen. Laws Ann. Chap. 12 § 5F and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT SEVENTEEN

VIOLATION OF THE MICHIGAN MEDICAID FALSE CLAIM ACT

297. Relator re-alleges and incorporate the allegations in paragraphs 1-290 as if fully set forth herein. Additionally, Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in Michigan. Upon information and belief, Defendants' actions described herein occurred in Michigan as well.

298. This is a qui tam action brought by Relator and State of Michigan for treble damages and penalties under Michigan Medicaid False Claim Act, M.C.L.A. 400.601 *et seq.*

299. M.C.L.A. 400.607 provides liability for any person who, among other things—

> Causes to be made or presented to an employee or officer of this state a claim under the social welfare act, Act No. 280 of the Public Acts of 1939, as amended, being sections 400.1 to 400.121 of the Michigan Compiled Laws, upon or against the state, knowing the claim to be false.
>
> Presents or causes to be made or presented a claim under the social welfare act, Act No. 280 of the Public Acts of 1939, which he or she knows falsely represents that the goods or services for which the claim is made were medically necessary in accordance with professionally accepted standards.

300. In addition, M.C.L.A. 400.604 prohibits the solicitation, receipt or offering of a kickback or bribe in connection with the furnishing of goods or services for which payment is or may be made in whole or in part pursuant to the Michigan Medicaid program.

301. Defendants violated M.C.L.A. 400.604 from at least 2001 to the present by engaging in the fraudulent and illegal practices described herein.

302. Defendants furthermore violated M.C.L.A. 400.607 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Michigan from at least 2001 to the present by its violation of federal and state laws, including M.C.L.A. 400.604, the Anti-Kickback Act and the Stark Act, as described herein.

303. The State of Michigan, by and through the Michigan Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

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

305. Had the State of Michigan known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

306. As a result of Defendants' violations of M.C.L.A. 400.607 the State of Michigan has been damaged in an amount far in excess of millions of dollars exclusive of interest.

307. Frank Solis is a private person with direct and independent knowledge of the allegations of the Compliant, who have brought this action pursuant to M.C.L.A. 400.610a on behalf of himself and the State of Michigan.

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

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

A. To the STATE OF MICHIGAN:

All damages to which the State of Michigan is entitled pursuant to M.C.L.A. 400.612;

Civil penalties for each false claim which Defendants caused to be presented to the State of Michigan;

Prejudgment interest; and

All costs incurred in bringing this action.

B. To RELATOR:

The maximum amount allowed pursuant to M.C.L.A. 400.610a(9) and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT EIGHTEEN

VIOLATION OF THE MONTANA FALSE CLAIMS ACT

310. Relator re-alleges and incorporate the allegations in paragraphs 1-303 as if fully set forth herein. Additionally, Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in Montana. Upon information and belief, Defendants' actions described herein occurred in Montana as well.

311. This is a qui tam action brought by Relator and State of Montana for treble damages and penalties under Montana False Claims Act, MT ST 17-8-401 *et seq*.

312. MT ST 17-8-403 provides liability for any person who—

knowingly presenting or causing to be presented to an officer or employee of the governmental entity a false claim for payment or approval;

knowingly making, using, or causing to be made or used a false record or statement to get a false claim paid or approved by the governmental entity;

conspiring to defraud the governmental entity by getting a false claim allowed or paid by the governmental entity.

313. In addition, MT ST 45-6-313 prohibits the solicitation, receipt or offering any remuneration, including but not limited to a kickback, bribe, or rebate, other than an amount legally payable under the medical assistance program, for furnishing services or items for which payment may be made under the Montana Medicaid program.

314. Defendants violated MT ST 45-6-313 from at least 2001 to the present by engaging in the fraudulent and illegal practices described herein.

315. Defendants furthermore violated MT ST 17-8-403 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Montana from at least 2001 to the present by its violation of federal and state laws, including MT ST 45-6-313, the Anti-Kickback Act and the Stark Act, as described herein.

316. The State of Montana, by and through the Montana Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

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

connection with Defendants' fraudulent and illegal practices.

318. Had the State of Montana known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

319. As a result of Defendants' violations of MT ST 17-8-403 the State of Montana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

320. Frank Solis is a private person with direct and independent knowledge of the allegations of the Compliant, who have brought this action pursuant to MT ST 17-8-406 on behalf of himself and the State of Montana.

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

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

A. To the STATE OF MONTANA:

Three times the amount of actual damages which that State of Montana has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of $10,000 for each false claim which Defendants caused to be presented to the State of Montana;

Prejudgment interest; and

All costs incurred in bringing this action.

B. To RELATOR:

The maximum amount allowed pursuant to MT ST 17-8-410 and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT NINETEEN

VIOLATION OF THE NEVADA FALSE CLAIMS ACT

323. Relator re-alleges and incorporate the allegations in paragraphs 1-316 as if fully set forth herein. Additionally, Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the State of Nevada. Upon information and belief, Defendants' actions described herein occurred in Nevada as well.

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

325. N.R.S. § 357.040(1) provides liability for any person who—

Knowingly presents or causes to be presented a false claim for payment or approval;

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;

Conspires to defraud by obtaining allowance or payment of a false claim;

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.

326. 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.

327. Defendants violated N.R.S. § 422.560 from at least 2001 to the present by engaging in the fraudulent and illegal practices described herein.

328. Defendants 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 from at least 2001 to the present by its violation of federal and state laws, including N.R.S. § 422.560, the Anti-Kickback Act and the Stark Act, as described herein.

329. The State of Nevada, by and through the Nevada Medicaid program and other health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

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

331. Had the State of Nevada known that Defendants were violating the federal

and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

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

333. Frank Solis is a private person with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to N.R.S. § 357.080(1) on behalf of himself and the State of Nevada.

334. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicted 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.

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

A. To the STATE OF NEVADA:

Three times the amount of actual damages which the State of Nevada has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $2,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Nevada;

Prejudgment interest; and

All costs incurred in bringing this action.

B. To RELATOR:

The maximum amount allowed pursuant to N.R.S § 357.210 and/or any other

applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT TWENTY

VIOLATION OF THE NEW HAMPSHIRE FALSE CLAIMS ACT

336. Relator re-alleges and incorporate the allegations in paragraphs 1-329 as if fully set forth herein. Additionally, Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the New Hampshire. Upon information and belief, Defendants' actions described herein occurred in New Hampshire as well.

337. This is a qui tam action brought by Relator and State of New Hampshire for treble damages and penalties under New Hampshire False Claims Act, N.H. Rev. Stat. § 167:61-b *et seq*.

338. N.H. Rev. Stat. § 167:61-b provides liability for any person who—

Knowingly presents, or causes to be presented, to an officer or employee of the department, a false or fraudulent claim for payment or approval.

Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the department.

Conspires to defraud the department by getting a false or fraudulent claim allowed or paid.

339. Defendants violated N.H. Rev. Stat. § 167:61-b and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of

New Hampshire from at least 2001 to the present by its violation of federal and state laws, including the Anti-Kickback Act and the Stark Act as described herein.

340. The State of New Hampshire, by and through the New Hampshire Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

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

342. Had the State of New Hampshire known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

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

344. Frank Solis is a private person with direct and independent knowledge of the allegations of the Compliant, who have brought this action pursuant to N.H. Rev. Stat. § 167:61-c on behalf of himself and the State of New Hampshire.

345. This Court is requested to accept supplemental jurisdiction of this related

state claim as it is predicated upon that 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.

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

A. To the STATE OF NEW HAMPSHIRE:

Three times the amount of actual damages which that State of New Hampshire has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New Hampshire;

Prejudgment interest; and

All costs incurred in bringing this action.

B. To RELATOR:
The maximum amount allowed pursuant to N.H. Rev. Stat. § 167:61-e and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT TWENTY-ONE

VIOLATION OF THE NEW JERSEY FALSE CLAIMS ACT

347. Relator re-alleges and incorporate the allegations in paragraphs 1-340 as if fully set forth herein. Additionally, Defendants conduct business in the New Jersey. Upon information and belief, Defendants' actions described herein occurred in New Jersey as well.

348. This is a qui tam action brought by Relator and State of New Jersey for treble damages and penalties under New Jersey False Claims Act, N.J.S.A. 2A:32C-1 et seq.

349. N.J.S.A. 2A:32C-3 provides liability for any person who—

> Knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;
>
> 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;
>
> Conspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State.

350. In addition, N.J.S.A. 30:4D-17 prohibits solicitation, offers, or receipt of any kickback, rebate or bribe in connection with the furnishing of items or services for which payment is or may be made in whole or in part under the New Jersey Medicaid program, or the furnishing of items or services whose cost is or may be reported in whole or in part in order to obtain benefits or payments under New Jersey Medicaid.

351. Defendants violated N.J.S.A. 30:4D-17 from at least 2001 to the present by engaging in the fraudulent and illegal practices described herein.

352. Defendants furthermore violated N.J.S.A. 2A:32C-3 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Nevada from at least 2001 to the present by its violation of federal and state laws, including N.J.S.A. 30:4D-17, the Anti-Kickback Act and the Stark Act, as described herein.

353. The State of New Jersey, by and through the New Jersey Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

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

355. Had the State of New Jersey known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

356. As a result of Defendants' violations of N.J.S.A. 2A:32C-3 the State of New Jersey has been damaged in an amount far in excess of millions of dollars exclusive of interest.

357. Frank Solis is a private person with direct and independent knowledge of the allegations of the Compliant, who have brought this action pursuant to N.J.S.A. 2A:32C-5 on behalf of himself and the State of New Jersey.

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

Medicaid program.

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

A. To the STATE OF NEW JERSEY:

Three times the amount of actual damages which that State of New Jersey has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New Jersey;

Prejudgment interest; and

All costs incurred in bringing this action.

B. To RELATOR:

The maximum amount allowed pursuant to N.J.S.A. 2A:32C-7and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT TWENTY-TWO

VIOLATION OF THE NEW MEXICO MEDICAID FALSE CLAIMS ACT AND THE FRAUD AGAINST TAXPAYERS ACT

360. Relator re-alleges and incorporate the allegations in paragraphs 1-353 as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the State of New Mexico. Upon information and belief, Defendants' actions described herein occurred in the State of New Mexico as well.

361. This is a qui tam action brought by Relator and the State of New Mexico to

recover treble damages and civil penalties under the New Mexico Medicaid False Claims Act, N. M. S. A. 1978, § 27-14-1 et seq. and the New Mexico Fraud Against Taxpayers Act, N. M. S. A. 1978, § 44-9-1 *et seq*.

362. N. M. S. A. 1978, § 27-14-4 provides liability for any person who-

> Presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that the person receiving a Medicaid benefit or payment is not authorized or is not eligible for a benefit under the Medicaid program
>
> Makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false
>
> Conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing that such claim is false or fraudulent

363. N.M.S.A. 1978 § 44-9-3 provides liability for any person who-

> knowingly presents, or causes 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;
>
> knowingly makes or uses, or causes 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;
>
> conspires to defraud the state by obtaining approval or payment on a false or fraudulent claim;
>
> conspires to make, use or cause to be made or used, a false, misleading or fraudulent record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state.

364. Defendants violated N. M. S. A. 1978, § 27-14-4 and N.M.S.A. 1978 § 44-9-3 from at least 2001 to the present by engaging in the fraudulent and illegal practices described herein.

365. Defendants furthermore violated N. M. S. A. 1978, § 27-14-4 and N.M.S.A. 1978 § 44-9-3 and knowingly caused thousands of false claims to be made, used and presented to the State of New Mexico from at least 2001 to the present by its

violation of federal and state laws, including the Anti-Kickback Act, and Stark Act, as described herein.

366. The State of New Mexico, by and through the State of New Mexico Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third payers in connection therewith.

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

368. Had the State of New Mexico known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

369. As a result of Defendants' violations of N. M. S. A. 1978, § 27-14-4 and N.M.S.A. 1978 § 44-9-3 the State of New Mexico has been damaged in an amount far in excess of millions of dollars exclusive of interest.

370. Frank Solis is a private person with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to N. M. S. A. 1978, § 27-14-7 and N. M. S. A. 1978, § 44-9-5 on behalf of himself and the State of New Mexico.

371. This Court is requested to accept supplemental 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.

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

A. To the STATE OF NEW MEXICO:

Three times the amount of actual damages which the State of New Mexico has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New Mexico;

Prejudgment interest; and

All costs incurred in bringing this action.

B. To RELATOR:

The maximum amount allowed pursuant to N. M. S. A. 1978, § 27-14-9 and N. M. S. A. 1978, § 44-9-7 and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

COUNT TWENTY-THREE

VIOLATION OF THE NEW YORK FALSE CLAIMS ACT

373. Relator re-alleges and incorporate the allegations in paragraphs 1-366 as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the New York. Upon information and belief, Defendants'

actions described herein occurred in New York as well.

374. This is a qui tam action brought by Relator and State of New York for treble damages and penalties under New York False Claims Act, McKinney's State Finance Law § 187 *et seq*.

375. McKinney's State Finance Law § 189 provides liability for any person who—

> Knowingly presents, or causes to be presented, to any employee, officer or agent of the state or a local government, a false or fraudulent claim for payment or approval;
>
> 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 a local government;
>
> Conspires to defraud the state or a local government by getting a false or fraudulent claim allowed or paid.

376. Defendants violated § 189 from at least 2001 to the present by engaging in the fraudulent and illegal practices described herein.

377. Defendants furthermore violated § 189 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Nevada from at least 2001 to the present by its violation of federal and state laws, including the Anti-Kickback Act and the Stark Act, as described herein.

378. The State of New York, by and through the New York Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

379. Compliance with applicable Medicare, Medicaid and the various other

federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New York in connection with Defendants' fraudulent and illegal practices.

380. Had the State of New York known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

381. As a result of Defendants' violations of § 189 the State of New York has been damaged in an amount far in excess of millions of dollars exclusive of interest.

382. Frank Solis is a private person with direct and independent knowledge of the allegations of the Compliant, who have brought this action pursuant to McKinney's State Finance Law § 190(2) on behalf of himself and the State of New York.

383. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that 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.

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

A. To the STATE OF NEW YORK:

Three times the amount of actual damages which that State of New York has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New York;

Prejudgment interest; and

All costs incurred in bringing this action.

B. To RELATOR:

The maximum amount allowed pursuant to McKinney's State Finance Law § 190(6) and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT TWENTY-FOUR

VIOLATION OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT

385. Relator re-alleges and incorporate the allegations in paragraphs 1-378 as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the State of Oklahoma. Upon information and belief, Defendants' actions described herein occurred in the State of Oklahoma as well.

386. This is a qui tam action brought by Relator and the State of Oklahoma to recover treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, 63 Okl. St. Ann. § 5053 *et seq.*.

387. 63 Okl. St. Ann. § 5053.1 provides liability for any person who-

Knowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;

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;

Conspires to defraud the state by getting a false or fraudulent claim allowed or paid;

388. In addition, 56 Okl. St. Ann. § 1005 prohibits solicitation or acceptance of a benefit, pecuniary benefit, or kickback in connection with goods or services paid or claimed by a provider to be payable by the Oklahoma Medicaid Program.

389. Defendants violated 56 Okl. St. Ann. § 1005 from at least 2001 to the present by engaging in the fraudulent and illegal practices described herein.

390. Defendants furthermore violated 63 Okl. St. Ann. § 5053.1 and knowingly caused thousands of false claims to be made, used and presented to the State of Oklahoma from at least 2001 to the present by its violation of federal and state laws, including 56 Okl. St. Ann. § 1005, the Anti-Kickback Act, and Stark Act, as described herein.

391. The State of Oklahoma, by and through the State of Oklahoma Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third payers in connection therewith.

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

393. Had the State of Oklahoma known that Defendants were violating the

federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

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

395. Frank Solis is a private person with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to 63 Okl. St. Ann. § 5053.2(B) on behalf of himself and the State of Oklahoma.

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

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

A. To the STATE OF OKLAHOMA:

Three times the amount of actual damages which the State of Oklahoma has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Oklahoma;

Prejudgment interest; and

All costs incurred in bringing this action.

B. To RELATOR:

The maximum amount allowed pursuant 63 Okl. St. Ann. § 5053.4 and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

COUNT TWENTY-FIVE

VIOLATION OF THE RHODE ISLAND FALSE CLAIMS ACT

398. Relator re-alleges and incorporate the allegations in paragraphs 1-391 as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the State of Rhode Island. Upon information and belief, Defendants' actions described herein occurred in the State of Rhode Island as well.

399. This is a qui tam action brought by Relator and the State of Rhode Island to recover treble damages and civil penalties under the Rhode Island False Claims Act, Gen. Laws 1956, § 9-1.1-1 *et seq*.

400. Gen. Laws 1956, § 9-1.1-3 provides liability for any person who-

knowingly presents, or causes to be presented, to an officer or employee of the state or a member of the guard a false or fraudulent claim for payment or approval;

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;

conspires to defraud the state by getting a false or fraudulent claim allowed or paid.

401. In addition, Gen. Laws 1956, § 40-8.2-3 prohibits the solicitation, receipt, offer, or payment of any remuneration, including any kickback, bribe, or rebate, directly or indirectly, in cash or in kind, to induce referrals from or to any person in

return for furnishing of services or merchandise or in return for referring an individual to a person for the furnishing of any services or merchandise for which payment may be made, in whole or in part, under the Rhode Island Medicaid program.

402. Defendants violated Gen. Laws 1956, § 40-8.2-3 from at least 2001 to the present by engaging in the fraudulent and illegal practices described herein.

403. Defendants furthermore violated Gen. Laws 1956, § 9-1.1-3 and knowingly caused thousands of false claims to be made, used and presented to the State of Rhode Island from at least 2001 to the present by its violation of federal and state laws, including Gen. Laws 1956, § 40-8.2-3, the Anti-Kickback Act, and Stark Act, as described herein.

404. The State of Rhode Island, by and through the State of Rhode Island Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third payers in connection therewith.

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

406. Had the State of Rhode Island known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by

health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

407. As a result of Defendants' violations of Gen. Laws 1956, § 9-1.1-3 the State of Rhode Island has been damaged in an amount far in excess of millions of dollars exclusive of interest.

408. Frank Solis is a private person with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Gen. Laws 1956, § 9-1.1-4(b) on behalf of himself and the State of Rhode Island.

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

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

A. To the STATE OF RHODE ISLAND:

Three times the amount of actual damages which the State of Rhode Island has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Rhode Island;

Prejudgment interest; and

All costs incurred in bringing this action.

B. To RELATOR:

The maximum amount allowed pursuant Gen. Laws 1956, § 9-1.1-4(d) and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

COUNT TWENTY-SIX

VIOLATION OF THE TENNESSEE FALSE CLAIMS ACT

411. Relator re-alleges and incorporate the allegations in paragraphs 1-404 as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the State of Tennessee. Upon information and belief, Defendants' actions described herein occurred in Tennessee as well.

412. This is a qui tam action brought by Relator and 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.

413. Section 71-5-182(a)(1) provides liability for any person who—

Presents, or causes to be presented to the state, a claim for payment under the Medicaid program knowing such claim is false or fraudulent;

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 a approved by the state knowing such record or statement is false;

Conspires to defraud the State by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent.

414. Defendants violated Tenn. Code Ann. § 71-5-182(a)(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Tennessee from at least 2001 to the present by its violation of federal and

state laws, including the Anti-Kickback Act and the Stark Act, as described herein.

415. The State of Tennessee, by and through the Tennessee Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

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

417. Had the State of Tennessee known that Defendants violated the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

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

419. Frank Solis is a private person with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Tenn. Code Ann. § 71-5-183(a)(1) on behalf of himself and the State of Tennessee.

420. This Court is requested to accept supplemental 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.

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

A. To the STATE OF TENNESSEE:

Three times the amount of actual damages which the State of Tennessee has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Tennessee;

Prejudgment interest; and

All costs incurred in bringing this action.

B. To RELATOR:

The maximum amount allowed to Tenn. Code Ann. §71-5-183(c) and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT TWENTY-SEVEN

VIOLATION OF THE TEXAS FALSE CLAIMS ACT

422. Relator re-alleges and incorporate the allegations in paragraphs 1-415 as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the State of Texas. Defendants' actions described herein occurred in Texas as well.

423. This is a qui tam action brought by Relator and the State of Texas to recover double damages and civil penalties under the Texas False Claims Act, V.T.C.A. Hum. Res. Code § 36.001 et seq.

424. V.T.C.A. Hum. Res. Code § 36.002, in relevant part, provides liability for any person who—

> (1) knowingly makes or causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;
> (2) knowingly conceals or fails to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;
> (3) knowingly applies for and receives a benefit or payment on behalf of another person under the Medicaid program and converts any part of the benefit or payment to a use other than for the benefit of the person on whose behalf it was received
>
> * * *
>
> (5) except as authorized under the Medicaid program, knowingly pays, 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 product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program;
>
> * * *
>
> (9) knowingly 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 or a fiscal agent;
>
> * * *
>
> (12) knowingly makes, uses, or causes the making or use of a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to this state under the Medicaid program.

425. Defendants 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 from at least 2001 to the present by its violation of federal and state laws, including, the Anti-Kickback Act and the Stark Act, as described herein.

426. The State of Texas, by and through the Texas Medicaid program and other state healthcare programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

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

428. Had the State of Texas known that Defendants were violating the federal and state laws cited herein, it wound not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

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

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

431. Frank Solis is a private person with direct and independent knowledge of

the allegations of this Complaint, who have brought this action pursuant to V.T.C.A. Hum. Res. Code § 36.101 on behalf of himself and the State of Texas.

432. This Court is requested to accept supplemental 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.

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

A. To the STATE OF TEXAS:

Damages at two times the value of any payment or monetary or in-kind benefit provided under the Medicaid program, directly or indirectly, as a result of the unlawful acts set forth above, as provided by the Texas Human Resources Code § 36.052(a)(1) & (4)

Civil penalties of $15,000 for each and every unlawful act set forth above that resulted in injury to a person younger than 18 years of age, as provided by the Texas Human Resources Code § 36.052(3)(A)

Pre- and post-judgment interest, Tex. Hum. Res. Code § 36.052(a)(2),

B. To RELATOR

The maximum amount allowed pursuant to V.T.C.A. Hum Res. Code § 36.110(a), and/or any other applicable provision of law;

Reimbursement for reasonable expenses and costs which Relator incurred in connection with this action, Tex Hum Res. Code §§ 36.007 & 36.110(c);;;

Reasonable attorneys' fees which the Relator necessarily incurred in bringing and pressing this case, Tex Hum Res. Code §§ 36.007 & 36.110(c); and

Such further relief as this Court deems equitable and just.

COUNT TWENTY-EIGHT

VIOLATION OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT

434. Relator re-alleges and incorporate the allegations in paragraphs 1-427 as if

fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the Commonwealth of Virginia. Upon information and belief, Defendants' actions described herein occurred in the Commonwealth of Virginia as well.

435. This is a qui tam action brought by Relator and the Commonwealth of Virginia to recover treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 et seq.

436. Va. Code Ann. § 8.01-216.3 provides liability for any person who-

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

DEMAND FOR JURY TRIAL

Relator hereby demands a jury trial.

///

Dated: October 27, 2009

UNITED STATES OF AMERICA, ex rel.

Relator

By: _____

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