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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA; AND THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, WISCONSIN, THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; and THE DISTRICT OF COLUMBIA; *ex rel.* BRIAN SHIELDS Plaintiffs and Relator, v. GENENTECH, INC.; OSI PHARMACEUTICALS, INC.; and NOVARTIS PHARMACEUTICALS CORPORATION Defendants.	CIVIL ACTION NO.: CV 11 0822 MEJ **FILED UNDER SEAL** PURSUANT TO 31 U.S.C. § 3730(b)(2) **SECOND AMENDED FALSE CLAIMS ACT COMPLAINT** BY FAX

1. Brian Shields ("Relator") brings this action on behalf of the United States of America against Genentech, Inc., OSI Pharmaceuticals, Inc. and Novartis Pharmaceuticals Corporation for treble damages and civil penalties arising from conduct in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729, et seq. ("FCA").

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

3. The violations arise out of false claims made to Medicare, Medicaid, TRICARE, and other federally-funded government healthcare programs (hereinafter referred to as "Government Healthcare Programs") caused by the Defendants.

4. This Complaint describes a systematic course of conduct by Defendants (as specified herein) to unlawfully promote several prescription drugs: Defendants Genentech and OSI (1) promoted Tarceva for first-line off-label use in patients with advanced or metastatic non-small cell lung cancer (NSCLC). In particular, Defendants concentrated on two patient populations with advanced NSCLC: (a) patients who had never smoked (Never Smokers); and (b) females with adenocarcinoma. (2) Defendants promoted Tarceva within its label to treat patients with advanced NSCLC, it did so by misrepresenting the efficacy of Tarceva as described herein. (3) Defendants promoted Tarceva off-label for maintenance treatment well prior to its FDA approval for such use

in 2010. In addition, Defendants Genentech and Novartis unlawfully promoted Xolair off-label for the entire allergic cascade.

5. Much of the off-label prescribing, and some of the on-label prescribing, was fueled by the provision of kickbacks to health care providers and to patients. These include but are not limited to phony and /or excessive payments to health care providers for advisory boards, speaking fees; and for Defendant OSI, further provided excessive and/or phony payments to physicians for preceptorships and phase IV clinical trials. Moreover, for these and every other drug sold by Defendant Genentech, adverse events reported by patients, otherwise required to be reported to the U.S. Food and Drug Administration (FDA), were intentionally not reported to the FDA by Defendant Genentech.

INFORMATION ABOUT THE RELATOR AND THE DEFENDANTS

6. Relator Brian Shields is a resident of the State of California. He was an employee of Defendant Genentech from 2007-2011.

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

8. Relator is informed and believes that the pervasive kickbacks and false claims described herein are ongoing, and date back at least six years from Relator's initial Complaint.

9. Defendant Genentech, Inc., is a corporation organized under the laws of the State of Delaware, having a principal place of business at 1 DNA Way, South San Francisco, California.

Genentech manufactures and markets multiple products for cancer, and other diseases and conditions throughout the United States.

10. Defendant OSI Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business in Melville, New York. In 2010, it became a wholly owned subsidiary of Astellas U.S. Holding Inc., a holding company owned by Astellas Pharma Inc.

11. Defendant Novartis Pharmaceuticals Corporation, is a Delaware corporation with headquarters in East Hanover, New Jersey. Novartis is a wholly-owned subsidiary of Novartis Pharma AG.

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

FEDERAL JURISDICTION AND VENUE

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. § 3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. In addition, 31 U.S.C. § 3732(b) specifically confers jurisdiction on this Court over the State-law claims. Under 31 U.S.C. § 3730(e), and under the comparable provisions of the State statutes, there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint.

14. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a), which authorizes nationwide service of process and because the Defendants have minimum

contacts with the United States. Moreover, all Defendants do business within the District and Defendant Genentech can be found in and transacts business in this District.

15. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a) because all Defendants do business within this District and Defendant Genentech can be found in and transacts business in this District. Defendants regularly conducted substantial business within this District, maintained employees in this District, and/or made significant sales within this District. In addition, statutory violations, as alleged herein, occurred in this District.

THE REGULATORY ENVIRONMENT

FDCA

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

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

18. While a physician may prescribe a drug for a use other than one for which it is approved, the FDCA prohibits a drug manufacturer from marketing or promoting a drug for non-approved uses. 21 U.S.C. § 331(d), 355(a). It, therefore, is illegal for a drug manufacturer and its

sales representatives to initiate discussions with medical professionals regarding any off-label use of the drug.

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

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

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

22. The promotion of an off-label use for a prescription drug can interfere with the proper treatment of a patient. Off-label promotion can lull a physician into believing that the drug being promoted is safe and effective for the intended off-label use, and that the FDA has approved

the drug for that use. Thus, off-label promotion can cause a doctor and patient to forgo treatment with an FDA-approved drug that has been proven to be safe and effective, and instead to substitute a treatment urged by the sales representative that is not known to be safe and effective, and that may in fact be harmful.

Anti-Kickback Act

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

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

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

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

False Claims Act

27. The False Claims Act (hereinafter referred to as "FCA"), 31 USC § 3729, was originally enacted in 1863, and was substantially amended in 1986, and again in 2009. Congress

enacted the 1986 amendments to enhance and modernize the Government's tools for recovering losses sustained by frauds against it after finding that federal program fraud was pervasive. The amendments were intended to create incentives for individuals with knowledge of Government frauds to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the Government's behalf. The 2009 amendments were intended to further this intent by plugging the loopholes created since the 1986 amendments to ensure that the False Claims Act reaches all fraud schemes.

28. The FCA provides that any person who knowingly presents, or causes to be presented, false or fraudulent claims for payment or approval to the United States Government, or knowingly makes, uses, or causes to be made or used false records and statements to induce the Government to pay or approve false and fraudulent claims, is liable for a civil penalty ranging from $5,500 up to $11,000 for each such claim, plus three times the amount of the damages sustained by the federal Government.

29. The FCA allows any person having information about false or fraudulent claims to bring an action for himself and the Government, and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of 60 days (without service on the Defendant during that time). Based on these provisions, *qui tam* plaintiff/relator seeks through this action to recover all available damages, civil penalties, and other relief for state and federal violations alleged herein.

30. The FCA provides, in pertinent part that:

> (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; (3)

> conspires to defraud the Government by getting a false or fraudulent claim paid or approved by the Government;
>
> * * *
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729.

GOVERNMENT HEALTHCARE PROGRAMS

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

Medicare

32. Medicare is a federally-funded health insurance program primarily benefiting the elderly. Medicare was created in 1965 when Title XVIII of the Social Security Act was adopted. The Medicare program is administered through the Department of Health and Human Services' Centers for Medicare and Medicaid Services.

33. The Medicare program has four parts: Part A, Part B, Part C and Part D. Medicare Part A, the Basic Plan of Hospital Insurance, covers the cost of inpatient hospital services and post-hospital nursing facility care. Medicare Part B, the Voluntary Supplemental Insurance Plan, covers the cost of services performed by physicians and certain other healthcare providers, both inpatient and outpatient, if the services are medically necessary and directly and personally provided by the provider. Medicare Part C covers certain managed care plans, and Medicare Part D provides subsidized prescription drug coverage for Medicare beneficiaries.

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

which has a 25 percent co-payment, is also laden with annual "doughnut hole" — reached when a patient's total drug costs hit $2,700, after which the patient must shoulder the next $3,000 or so before coverage resumes.

(1) Off-label Coverage Under Medicare

35. Medicare provides for drug coverage only where the use of a drug has been shown to be safe and effective and is otherwise reasonable and necessary. 42 U.S.C. § 1395y(a)(1)(A). Drugs approved for marketing by the FDA are generally considered safe and effective when used for indications specified on the labeling.

36. Medicare coverage of an outpatient drug for an off-label use occurs only where the use is medically accepted, taking into account the major drug compendia: Drugdex, American Hospital Formulary Service (AHFS), American Medical Association Drug Evaluations (AMADE) and U.S. Pharmacopeia-Drug Information (USPDI), authoritative medical literature, and/or accepted standards of medical practice. *See* Medicare Benefit Policy Manual Chap. 6 § 30 & Chap. 15, § 50.4.1. & .2.

(2) Off-Label Coverage Under Medicare for Cancer

37. The 1993 Omnibus Budget Reconciliation Act mandated that Medicare provide coverage for off-label uses of drugs in anti-cancer chemotherapy regimens if those uses were supported by designated compendia. From 1993 – 2008, Medicare had specific requirements that must be met before it would pay for an off-label use of an anti-cancer drug. The coverage policy is articulated in Section 2049.4 of the Medicare Carriers Manual (MCM):

> FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. In

> the case of drugs used in anti-cancer chemotherapeutic regimen, unlabeled uses are covered for a medically
> accepted indication as defined as § 2049.4.C.
>
> Section 2049.C provides, in part:
>
> Contractors must not deny coverage based solely on the absence of FDA approved labeling for the use, if the use is supported by one of the following and the use is not listed as "not indicated" in any of the three compendia … American Hospital Formulary Service Drug Information … American Medical Association Drug Evaluations (AMADE) … United States Pharmacopoeia Drug Information (USPDI), … or "use supported by clinical research that appears in peer-reviewed medical literature."

38. In fall 2007, CMS announced that it would use its statutorily allowed discretion to review and update the list of compendia that are available as references for off-label coverage. At the conclusion of its first review cycle in 2008, CMS added three new compendia to the list of designated publications: the National Comprehensive Cancer Network Drugs and Biologics Compendium, MicroMedex DrugPoints, and Clinical Pharmacology. AHFS continues to be recognized (while the USPDI and AMADE have been discontinued). CMS also articulated that contractors may consider scientific evidence if published in one of 26 designated peer-reviewed journals.

39. In October 2008, CMS issued a revision to the Medicare Benefit Policy Manual consistent with the earlier 2008 directive, stating that contractors will consider the following points when considering coverage: 1) whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence; 2) whether the administered chemotherapy regimen is adequately represented in the published evidence; 3) whether the reported study outcomes represent clinically meaningful outcomes experienced by patients; and 4) whether the study is appropriate to address the clinical question.

40. The Medicare Benefit Policy Manual Chapter 15, Section 50.4.5 ("Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen") effective as of October 24, 2008, provides in part:

> D. Generally
>
> FDA-approved drugs and biologicals may also be considered for use in the determination of medically accepted indications for off-label use if determined by the contractor to be reasonable and necessary.
>
> If a use is identified as not indicated by the Centers for Medicare and Medicaid Services (CMS) or the FDA, or if a use is specifically identified as not indicated in one or more of the compendia listed, or if the contractor determines, based on peer-reviewed medical literature, that a particular use of a drug is not safe and effective, the off-label usage is not supported and, therefore, the drug is not covered.

The Medicaid Program

41. The federal Government enacted the Medicaid program in 1965 as a cooperative undertaking between the federal and state governments to help the states provide health care to low-income individuals. The Medicaid program pays for services pursuant to plans developed by the states and approved by the U.S. Department of Health and Human Services ("HHS") Secretary through CMS. *See* 42 U.S.C. §§ 1396a(a)-(b). States pay doctors, hospitals, pharmacies, and other providers and suppliers of medical items and services according to established rates. *See* 42 U.S.C. §§ 1396b(a)(1), 1903(a)(1). The federal Government, then, pays each state a statutorily established share of "the total amount expended ... as medical assistance under the State plan ..." *See* 42 U.S.C. § 1396b(a)(1). This federal-to-state payment is known as federal financial participation ("FFP").

42. Medicaid is a public assistance program providing for payment of medical expenses for approximately 55 million low-income patients. Funding for Medicaid is shared between the federal Government and state governments. The Medicaid program subsidizes the purchase of more

prescription drugs than any other program in the United States.

43. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal Government will pay for through its funding of state Medicaid programs.

44. Reimbursement under Medicaid is, in most circumstances, available only for "covered outpatient drugs." 42 U.S.C. § 1396b(i)(10). Covered outpatient drugs do not include drugs that are "used for a medical indication which is not a medically accepted indication." *Id.* § 1396r-8(k)(3). A medically accepted indication is defined as a use "which is approved under the Federal Food Drug and Cosmetic Act" or which is *supported* by a citation in specified drug compendia. *Id*. (emphasis added); § 1396r-8(k)(6). 42 U.S.C.§ 1396r-8(g)(1)(B)(i) identifies the compendia to be consulted: American Hospital Formulary Service Drug Information; United States Pharmacopeia-Drug Information (not in publication since July 2007); the DRUGDEX Information System; and the American Medical Association Drug Evaluations (not in publication since June 2008). Providers use Healthcare Common Procedure Coding System (HCPCS) J-codes to bill the Medicaid program for injectable prescription drugs, including cancer drugs. All other drugs are billed to Medicaid by identifying their National Drug Codes (NDC's).

Reimbursement Under Other Federal Healthcare Programs

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

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

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

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

INFORMATION ABOUT TARCEVA

49. Tarceva (erlotinib) received initial U.S. Food and Drug Administration ("FDA") approval in 2004, for second-line non-small cell lung cancer ("NSCLC"). Its second-line use is set forth in the package insert as indicated for: treatment of locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen (FDA-approved on 11/18/2004).

50. Defendants did not obtain FDA-approval of Tarceva in 2004 with clean hands. Defendants intentionally grouped all NSCLC patients into its study results, instead of dividing them by biomarker. Defendants did so intentionally for market reasons, and even the Clinical Team Leader, when considering Tarceva's FDA-approval, remarked about it. The Clinical Team Leader in his/her Review of the Tarceva NDA Data (Review dated July 30, 2004) at page 56 wrote:

> A conclusion that Tarceva is not beneficial in receptor negative patients would cut the Applicant's market in half. About half of study patients with known receptor status are receptor negative. The Applicant has a strong disincentive to provide information on patient receptor status and has argued forcefully in this application that receptor status is not important. This is an emerging problem that we have seen in at least one other NDA for a targeted anticancer therapy. The FDA must work proactively to assure that this important information is publically available for this drug and for future targeted drugs.

51. In April 2010, the FDA granted supplemental approval for Tarceva as a maintenance therapy for non-small-cell lung cancer patients; a decision that defied the negative 12-to-1 panel vote December 2009 by the Oncologic Drugs Advisory Committee. Analysts and reviewers during the Committee meeting pointed to a lack of data showing that maintenance treatment is more effective than waiting to treat patients until once the disease has progressed. (See *BioWorld Today*, Dec. 17, 2009.) The maintenance indication set forth in the package insert reads: "maintenance treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose disease has not progressed after four cycles of platinum-based first-line chemotherapy." (FDA-approved on 4/16/2010)

52. Subsequent to its approval, the FDA required Defendants to issue communications concerning potential dangers of Tarceva use. In September 2008, a "Dear Healthcare Professional" letter was issued to warn that patients with hepatic impairment who are treated with Tarceva should be closely monitored during therapy. In May 2009, a "Dear Healthcare Professional" letter was issued to warn patients taking Tarceva about GI perforation, exfoliative skin conditions and corneal perforation/ulceration.

Information About Lung Cancer And Its Treatment

53. There are various types of non-small cell lung cancers, each with different kinds of cancer cells, which grow and spread in different ways. NSCLC types include:

1. Squamous cell carcinoma is a cancer that begins in squamous cells, which are thin, flat cells that look like fish scales. This is also called epidermoid carcinoma.
2. Large cell carcinoma is a cancer that may begin in several types of large cells.
3. Adenocarcinoma is a cancer that begins in the cells that line the alveoli and make substances such as mucus.

54. A subset of patients with NSCLC will have tumors with activating mutations in the epidermal growth factor receptor (EGFR) gene. EGFR mutation is a biomarker which can be detected in NSCLC tumor samples.

Defendants Had Knowledge That They Were Misleading Physicians and the Public

55. Defendants had knowledge that they were misleading physicians and the public regarding Tarceva, by touting Tarceva's overall efficacy in a *broad market*; however, Tarceva only worked in a very small subset of patients.

56. It is undisputed that Tarceva works in patients whose tumors have a mutation in the gene for EGFR (referred to herein as "EGFR positive" or "EGFR mutant"). In all other patient populations (referred to herein as "EGFR Wild-Type" or "EGFR negative"), Tarceva only slightly delayed the median progression of NSCLC, far less than necessary for FDA-approval. But Defendants' persisted in both on and off-label marketing in these patient populations as well, in place of therapy that patients could have been taking which were effective treatments first–line and second-line. For example, Alimta, a more traditional chemotherapy sold by Eli Lilly, didn't just slow tumor progression, it also increased survival for patients with non-small-cell lung cancer by a

median 2.8 months, extending survival to 13.4 months. Moreover, patients who are inappropriately prescribed Tarceva first-line never get the opportunity for appropriate second-line therapy, due to disease progression, affecting about 40% of first-line NSCLC patients. Patients who are inappropriately prescribed Tarceva second-line also never get the appropriate second-line therapy.

57. Published results before Tarceva was FDA-approved in 2004 showed that there were "dramatic responders" with IRESSA (also TKI inhibitor). They all were confirmed to have had specific mutations in the tyrosine kinase (TK) domain of the EGFR gene.

58. Defendants knew no later than 2004 that they were promoting both on and off-label, in a patient population in which Tarceva did not work. One example (and not the only one) are the results of the clinical trial known as TRIBUTE, which concluded in 2004. It was presented as an Abstract Session at the 2004 ASCO Annual Meeting, was a phase III trial of erlotinib HCl combined with carboplatin and paclitaxel (CP) chemotherapy in advanced non-small cell lung cancer (NSCLC). The study concluded that Erlotinib combined with carboplatin and paclitaxel chemotherapy did not confer a survival advantage over carboplatin and paclitaxel alone in patients with previously untreated advanced NSCLC.

59. A 2007 email exchange between the senior leadership of OSI Pharmaceuticals and Genentech acknowledged that the statistics for Tarceva were not favorable, and that the success of any subset was tied to the presence of the EGFR gene mutation.

60. The FDA's files are complete with confirmation:

a. In the Clinical Review for Tarceva's NDA 21-743, dated October 8, 2004, the clinical reviewer was concerned that the median overall survivor number was significantly

beneficial to the patient only because the EGFR positive (FISH) patients pulled the number higher than placebo:

> A question was raised as to whether the improved overall survival results of erlotinib treatment was accounted for by EGFR positive patients. This issue was discussed with the sponsor.

Page 25, Clinical Review for NDA 21-743, dated October 8, 2004. OSI responded almost with a non sequitur:

> The sponsor stated that "A series of subsets … were examined in exploratory univariate analyses to assess the robustness of the overall survival results (Table 6). These are underpowered exploratory analyses, and no adjustments were made for the multiplicity from theses subsets."

Page 25, Clinical Review for NDA#21-743, dated October 8, 2004 (See also Pages 25-27)

b. The Clinical Team Leader confirms that there was no survival benefit in the never smokers EGFR negative group:

> In the never smokers EGFR positive subgroup Tarceva prolongs survival (HR=O.279, p=O.OO3). But in the never smokers EGFR negative subgroup Tarceva has no apparent survival effect (HR=1.42, p=O.579).

Page 6, Clinical Team Leader Review of NDA, dated July 30, 2004

c. The Clinical Team Leader is fairly definitive about the lack of benefit in the EGFR negative group in general:

> Patients were not stratified by EGFR status prior to randomization, so there could be imbalances in important prognostic factors in the EGFR subgroups. The FDA statistician, Dr. Sridhara's analyses of this issue are presented below. There are imbalances of some prognostic factors in the subgroup of patients with known EGFR status, some favoring Tarceva and some favoring Placebo.
>
> The imbalances in prognostic factors in the subgroup with known EGFR status are addressed by performing three Cox Proportional Hazard analyses each in the EGFR positive and negative subgroups. These three Cox Proportional Hazard analyses are for treatment alone,

> for treatment using the prerandomized stratification factors in the model and for treatment using all factors that were imbalanced between treatment groups in the model. This latter analysis is done with and without baseline alphaI acid glycoprotein (AAG) concentrations.
>
> The favorable Tarceva survival effect is consistently seen in all analyses in the EGFR positive subgroup. In the EGFR negative subgroup the lack of Tarceva survival effect is consistent in the treatment only model (HR=1.01), in the model with treatment and all of the imbalanced factors (HR=1.03) and in the model with treatment and all of the imbalanced factors including AAG (HR= 1.16). But in the model using treatment and the four prerandomization stratification factors, the HR is 0.93, indicating a possible small Tarceva survival effect in the EGFR negative subgroup.

Page 37, Clinical Team Leader Review of NDA, dated July 30, 2004

d. The FDA statistician was definitive with the EGFR positive v. negative difference:

> A significant survival benefit is demonstrated in the subgroup of EGFR positive patients. A significant progression-free survival and higher response rate were also observed in this subgroup with EGFR positive status.
>
> The demonstrated survival benefit appears to be robust with significant benefit in all subgroups except in the subgroup of patients with EGFR negative status…

Page 39, Statistical Review and Evaluation – Clinical Studies, Review Completion Date: October 1, 2004

> The results of these exploratory analyses in the subgroups, suggest a significant survival benefit in the EGFR positive patients.
>
> The observed survival benefit due to erlotinib in the EGFR positive patients even after adjusting for imbalances appears to be significant. However adjusted models in the EGFR negative patients are sensitive in addition or deletion of covariates and erlotinib effect appears to be marginal.
>
> Although statistically not significant, EGFR positive patients appear to have better survival than the EGFR negative patients in erlotinib treated patients. However EGFR negative patients appear to have

> better survival compared to EGFR positive patients in the placebo treated patients.
>
> …Cox regression analysis including an interaction term was conducted in patients with known EGFR status (Tables 22-24). Although the treatment effect was present in all the models, the treatment HR changed by more than 14% when the interaction term was included, suggesting significant interaction effect.

Page 18, Statistical Review and Evaluation – Clinical Studies, Review Completion Date: October 1, 2004

Misleading Tactics To Promote Tarceva

61. Defendants' management trained and directed its sales force to promote Tarceva for the entire NSCLC patient population, including for the EGFR Wild-Type patients.

62. Defendants conducted national and regional sales meetings, designed specifically for the purpose of training employees on sales and marketing techniques to communicate Tarceva's efficacy in the entire NSCLC patient population.

63. Defendants' promotion raises safety issues, has adversely affected the treatment of patients, and undermined the FDA drug approval process. The fact is, EGFR Wild-Type patients would not benefit from Tarceva, and Defendants knew this. Defendants undertook this promotion for their own financial gain, despite the potential risk to patients' health and lives.

64. Through its communications to its sales force and to doctors, Defendants deliberately omitted or misrepresented:

a. Negative evidence about Tarceva's effectiveness in EGFR Wild-Type NSCLC patients, including but not limited to the data and conclusions concerning the BR21 Trial, the data and conclusions concerning earlier trials with Tarceva carboplatin/paclitaxel combinations, and the earlier trials concerning another TKI inhibitor, Iressa.

b. Information that the doctors who were involved in peer selling had been paid substantial subsidies to use Tarceva on their patients without regard to EGFR mutation status.

65. Defendants discouraged the use of any testing for the mutation status of patients to determine whether Tarceva would be suitable or not, despite knowledge that the testing would be in the best interests of the patients. Since shortly after Tarceva's approval, many diagnostic companies have been marketing their test for EGFR mutations to the oncology community as a predictive marker for the use of Tarceva in NSCLC, among other drugs. Defendants' management team conducted multiple analyses to determine the effect on sales if patients were tested for the biomarker. Defendants concluded that they would achieve greater sales *without* the biomarker testing – so Defendants counter-promoted this type of testing, even though it would have helped physicians to determine if Tarceva treatment would be best for their NSCLC patients. Even in 2007, the Commissioner of the FDA communicated:

> The example of Iressa and Tarceva, two drugs used to treat lung cancer, demonstrates the potential benefits of having appropriate and validated biomarkers. Each of these drugs has had strikingly positive benefits for some of the patients who have taken them, reducing tumors by up to 50 percent and extending life expectancy. Unfortunately, only 10 percent of patients treated with the drugs actually experience these benefits. Researchers have found that the patients who respond to these drugs have a common genetic mutation in their tumors. This mutation can serve as a "marker" to identify the patients who are best treated with these medications. Over time, similar discoveries related to other tumors and drugs are expected to yield a major public health impact – and that is the point of the Critical Path.

Statement of Andrew C. Von Eschenbach, M.D., Commissioner of Food and Drugs, before the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Senate Committee on Appropriations, June 1, 2007.

66. Once out on the field, the sales force was given marketing materials and detail aids, useable for selling Tarceva to the entire NSCLC market, and to discourage the use of mutation testing.

67. Defendants facilitated the use of physician speakers to further carry their message. Speakers were provided with inducements to promote Tarceva in the broad market, such as clinical trial involvement, grants, publications support, speaking engagements, CME grants, and slide development support.

68. Physicians, nurses, and other clinicians were "groomed" by Defendants to be speakers by attending all-expense paid speaking seminars in resort-like atmospheres. These seminars were, in truth, designed to market Tarceva for the broad NSCLC market.

69. The misleading promotion of Tarceva began with its approval in 2004, and continued even as Tarceva was FDA-approved for its maintenance indication. For instance, on July 13, 2009, Roche released the following in a press release re the SATURN study:

> Tarceva is already a well established treatment in second-line management of advanced NSCLC after the failure of chemotherapy and is proven to extend survival for a *broad range of patients* in this setting.
>
> [Emphasis supplied]

70. Roche footnoted the above statement by citing Shepherd FA, Rodrigues Pereira JR, Ciuleanu T, et al. Erlotinib in Previously Treated Non-Small Cell Lung Cancer. N Eng J Med 2005; 353:123-132, based on the BR21 Trial. The BR21 Trial does not support the statement that "Tarceva … is proven to extend survival for a broad range of patients in this setting." Roche knew or should have known that the statement was false.

71. Several weeks later, on August 1, 2009, OSI Pharmaceuticals put out its own press release, with its own similar misinformation. In it, OSI asserted:

> "The overall SATURN results continue to reinforce our belief that Tarceva therapy for NSCLC patients whose cancers have an EGFR mutation has the potential to result in a major advancement in personalized medicine using targeted therapies – even as they continue to demonstrate the *broad-based benefit of Tarceva therapy* in treating the overall NSCLC population," stated David Epstein, Senior Vice President, Oncology Research at OSI Pharmaceuticals.
>
> [Emphasis supplied]

72. This, despite clear evidence that everyone was aware of. For instance, the FDA Advisory Committee, when considering the maintenance indication, questioned whether to include the EGFR (ICH) negative subgroup in the indication.

> The first issue is that the OS HR in the EGFR (IHC) Negative subgroup is 0.91. …Thus Erlotinib appears to have at best a weak OS effect in this subgroup. This raises the question whether the EGFR (ICH) Negative subgroup should be included in any approval.

Page 11, FDA Briefing Document Oncologic Drugs Advisory Committee Meeting, December 16, 2009 (NDA 21743/S016)

Most On-Label Use Of Tarceva Was Not Covered:
Government Healthcare Programs "Reasonable and Necessary" Requirement

73. The Medicare Act, codified at 42 U.S.C. § 1395, *et seq*., bars payment for items or services that are not "reasonable and necessary": "no payment may be made . . . for any expenses incurred for items or services -- which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

74. The Medicare contractors may make determinations of what payments are barred under the "reasonable and necessary" standard in local coverage determinations. Local coverage determinations are defined as "determination[s] by a fiscal intermediary or a carrier under part A or

part B of this subchapter, as applicable, respecting whether or not a particular item or service is covered . . . in accordance with section 1395y(a)(1)(A)." Id. § 1395ff(f)(2)(B). In other words, Medicare contractors may apply the "reasonable and necessary" standard to specific payments by Medicare contractors through local coverage determinations.

75. In 2006, Part D began to cover a range of outpatient prescription drugs, which previously had been covered only in select instances. These Part D benefits are provided by a plan sponsor, which, broadly described, is required to provide qualified prescription drug coverage, 42 U.S.C. § 1395w-102(a)(1), and can provide supplemental prescription drug coverage, 42 U.S.C. § 1395w-102(a)(2). A Part D plan sponsor need not provide coverage for a Part D drug that is not reasonable and necessary for circumstances specified in the statutory framework or that is not prescribed in accordance with the plan or the Medicare Act. See 42 U.S.C. §§ 1395w-102(e)(3) and 1395y(a). To qualify for coverage, an outpatient prescription drug must be used as approved under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, or used as supported by at least one citation included or approved for inclusion in specified Compendia, see 42 U.S.C. § 1396r-8(k)(6).[1] It must also be reasonable and necessary.

76. Other Government Healthcare Programs also require that a drug is used for a medically accepted indication and is reasonable and necessary for the patient.

77. Medicare and all other Government Healthcare Programs require that prescribed drugs must be “reasonable and necessary” for the individual patient. Even if the statutory coverage criteria are met but the drug is not reasonable and necessary for the individual patient, the prescription is non-covered.

[1] In addition to the stated provisions, Congress expanded the definition of "medically accepted indication" effective January 1, 2009, to include drugs utilized in an anticancer chemotherapeutic regimen as supported by peer-reviewed medical literature. See 42 U.S.C. § 1395w-102(e)(4)(A)(i).

78. Tarceva was not reasonable and necessary for any patient as prescribed because none of the patients prescribed Tarceva were tested to be EGFR mutation positive. Accordingly, all prescriptions for Tarceva were non-covered and therefore false claims.

79. Notwithstanding the above, Tarceva was not reasonable and necessary for 90% of the patient prescriptions because over 90% of the patient population actually prescribed Tarceva was EFGR-Wild Type (by extrapolation). Accordingly, over 90% of the prescriptions for Tarceva were non-covered, and therefore false claims.

80. In violation of USC §§3729(a)(2) and the state False Claims Act statutes set forth in this Complaint, Defendants have used a variety of false documents, including false submissions to the United States FDA and false marketing materials, to cause the United States to pay claims for reimbursement under the Medicare, Medicaid, and other Government Healthcare Programs which would not have been reimbursed had the United States known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the lack of efficacy of Tarceva in EGFR Mutant patients.

Tarceva Off-Label Marketing

81. Defendants promoted Tarceva for first-line off-label use in patients with advanced NSCLC. With no scientific support for such uses, and even evidence that it was worse than placebo for EGFR Wild-Type patients, Defendants promoted Tarceva for first-line off-label use in two patient populations with advanced NSCLC: (1) Never Smokers; and (2) females with adenocarcinoma.

82. Defendants also promoted Tarceva for maintenance use in NSCLC patients for many years prior to its 2010 FDA-approval for maintenance use. Tarceva would have had only modest sales "but for" the off-label promotion.

83. Defendants promoted first-line use of Tarceva in metastatic NSCLC by cooking and molding what it called "retrospective exploratory analyses subset data", such that the end result was favorable statistics for the sales force to promote Tarceva off-label for first-line NSCLC in 1) female patients with adenocarcinoma; and 2) patients who had never smoked ("Never Smokers").

84. Defendants promoted Tarceva in Never Smokers by misleading physicians into believing that the Tarceva registration trial indicated that all non-smokers using Tarceva experienced 13 months of survival (versus statistics for first-line combination treatments did not reach 13 months). This was not true, as Defendants knew that the survival rate for patients without the EGFR mutation would be much less, likely to be equal or even worse than placebo.

85. Never Smokers who received Tarceva first-line, but were negative for the EGFR mutation could have been put on a therapy other than Tarceva, and would be alive for years longer. Worse, patients who were candidates for the prescription drug crizotinib (Pfizer) could have received it in a clinical trial and be alive today. Cancer patients only get one shot at first-line treatments and Defendants took that opportunity away. Defendants instead promoted Tarceva for all patients, even though it knew that roughly half of its off-label market would have tested negative for the EGFR mutation. Defendants also knew that if they were tested, they would lose half the business in the first-line setting because the data was clear that Tarceva did not work in the EGFR Mutant Never Smoker population. For these patients, Defendants caused them to die earlier and faster, with more pain. Defendants took the one shot these patients had at beating (if only temporarily) NSCLC – all in the name of greed.

86. Defendants also promoted Tarceva off-label as first-line use for all females who were suffering from the adenocarcinoma NSCLC by pointing to heightened survival rates (supposedly ten months) for female patients; but Defendants failed to point out that there was NO BENEFIT for female patients with adenocarcinoma who had a history of smoking, and specifically lied about this in promotional pieces.

87. These off-label uses neither appear in the Medicaid compendia nor are supported by clinical research that appears in the applicable peer-reviewed medical literature, and wholly fail to meet the criteria set forth in the applicable Medicare Manual and Part D Compendia for coverage of off-label uses, yet Defendants promoted it for such use.

INFORMATION ABOUT XOLAIR

88. In June of 2003, the FDA approved Xolair® omalizumab, which Defendant Genentech jointly has marketed with Defendant Novartis Pharmaceutical Corp. Xolair® is approved by the FDA for moderate to severe persistent asthmatics (age greater than or equal to 12 years old) who have a demonstrated sensitivity to a perennial aeroallergen, (e.g., dust mites, molds, animal dander, and cockroaches) and who have significant symptoms, despite inhaled corticosteroid treatment.

89. The FDA approved only very specific indications for Xolair. Patients must have moderate-persistent to severe-persistent asthma, be older than 12 years, have a positive skin test to a perennial aeroallergen (e.g., dust mites, cats, dogs, and mold), and be symptomatic with inhaled corticosteroids.

90. Asthma is a respiratory disorder characterized by increased responsiveness of the trachea and bronchi to various stimuli, resulting in the narrowing of the airways, along with mucous

secretion. This airway hyper-responsiveness is reversible either spontaneously or through therapy. The symptom triad includes wheezing, cough, and dyspnea, which can vary widely in severity and duration, although a typical attack does not last for more than several hours. Attacks can be triggered by a number of factors, including allergic triggers, smoke and pollution, cold air, colds and other respiratory infections, exercise, and strong emotions.

FDA Warnings

91. In February 2007, the FDA issued an 'Alert' regarding Xolair® following receipt of reports of serious, life-threatening allergic reactions (anaphylaxis) after treatment with omalizumab (Xolair®). The FDA reported that usually these reactions occurred within two hours of receiving a Xolair® subcutaneous injection. On July 2, 2007 a Black Box Warning was placed on Xolair as follows:

> Anaphylaxis, presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after administration of Xolair. Anaphylaxis has occurred as early as after the first dose of Xolair, but also has occurred beyond 1 year after beginning regularly administered treatment. Because of the risk of anaphylaxis, patients should be closely observed for an appropriate period of time after Xolair administration, and health care providers administering Xolair should be prepared to manage anaphylaxis that can be life-threatening. Patients should also be informed of the signs and symptoms of anaphylaxis and instructed to seek immediate medical care should symptoms occur (see WARNINGS, and PRECAUTIONS, Information for Patients).

92. In April 2009, the FDA issued a Warning Letter to Defendant Genentech concerning websites for several of its drugs, including for Xolair. In it, the FDA admonished Defendant Genentech as follows:

> The sponsored link for Xolair misleadingly broadens the indication for Xolair by implying that all patients with allergic asthma are candidates for Xolair

therapy (“Are you suffering from allergic asthma? The cause might be IgE”; presented along with the name of the drug), when this is not the case. Rather, as stated in its PI, Xolair is only indicated for patients 12 years and older with moderate to severe persistent asthma “who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.” Additionally, the sponsored link fails to convey that the safety and efficacy of Xolair has not been established in other allergic conditions.

93. On July 16, 2009 the FDA issued an "Early Communication about an Ongoing Safety Review of Omalizumab (marketed as Xolair)." The FDA told the public that it is evaluating interim safety findings from an ongoing study of Xolair (omalizumab) titled Evaluating the Clinical Effectiveness and Long-Term Safety in Patients with Moderate to Severe Asthma (EXCELS) that suggests a disproportionate increase in heart attacks, abnormal heart rhythms, heart failure, fainting, mini-strokes and blood clots. The EXCELS study is ongoing and final results are not expected until 2012.

Xolair Off-Label Marketing

94. Defendants Genentech and Novartis promoted Xolair as an effective drug for the entire allergic cascade, including improving positive outcomes of immunotherapy. Defendants Genentech and Novartis promoted Xolair for food allergy (especially peanuts), for latex allergy, Allergic rhinitis, eczema, and atopic dermatitis.

95. Defendants Genentech and Novartis have also promoted Xolair to pediatric patients aged 12 and under, although Xolair is not FDA-approved for any use in the pediatric population.

96. The package label itself acknowledges that Defendants had not completed pediatric studies in children ages 0 – 6. There exists no Pharmacokinetic, pharmacodynamic, efficacy, or safety data to support use of Xolair in the pediatric population ages 0 – 6. Worse, the package label

at section 8.4 discusses two studies in 926 asthma patients ages 6 to 12, and concludes that the risk of anaphylaxis and malignancy outweighs the benefit ("modest efficacy") of treating patients aged 6 to 12 with Xolair. Upon information and belief, the FDA rejected Xolair's FDA application for pediatric patients aged 6 through 12, which supplemental biologic licensing application was submitted by Genentech to the FDA in December, 2008!

97. Defendants knew that their off-label promotion for pediatric use was unlawful.

98. These off-label uses neither appear in the compendia nor are supported by clinical research that appears in the applicable peer-reviewed medical literature, yet Defendants promoted it for such use.

UNLAWFUL PROMOTIONAL TACTICS FOR OFF-LABEL USES OF TARCEVA AND XOLAIR

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

100. In order to successfully carry out the off-label promotion, Defendants conducted national and regional sales meetings, designed specifically for the purpose of training employees on off-label sales and marketing techniques: (a) copying and distributing studies, abstracts, reviews, Continuing Medical Education (CME) monographs, DVD's, movies, and slide presentations, all containing off-label usage; (b) sales calls to both clinicians, patients and their families solely for the purpose of off-label selling; and (c) the use of inducements.

101. Through this planning, Defendants funded abstract, journal, and other articles advocating off-label uses, which ultimately, Defendants planned to be used by its sales representatives to promote the subject drugs. Indeed, the sales force was given such articles with the

expectation that he learn the details backwards and forwards, and use the talking points provided by Defendants in promoting the subject drugs off-label.

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

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

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

a. Negative evidence about the subject drugs;

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

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

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

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

a. The sales force received training from Defendants' corporate training officials on subjects such as how to induce physicians to ask "unsolicited" questions and "lead discussions" about the subject drugs' off-label uses.

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

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

d. Once out on the field, the sales force was given marketing materials and detail aids, useable for selling in the off-label market.

e. Defendants monitored the success of the off-label promotional program by carefully monitoring sales revenues of each drug and each region, territory, and area. The sales goals included rewarding management for off-label, as well as on-label prescriptions. The only way that specific goals could be met was through a compensation system that was related to the off-label promotion of the drugs.

f. Defendants facilitated the use of physician speakers to further carry its message. Speakers were provided with inducements to deliver the off-label messages; the sales force was directed to find out what the "advocate" needs, such as clinical trial involvement, medical school grants, publications support, speaking engagements, CME grants, slide development support, visiting professorships, clinical guidelines development support, disease management programs, advisory panels, and consultancy agreements /contracts.

g. Physicians, nurses, and other clinicians were “groomed” by Defendants to be speakers by attending all-expense paid speaking seminars in resort-like atmospheres. These seminars were, in truth, designed to market the subject drugs for off-label uses.

107. At clinician speaker meetings there were no corrections or admonitions by anyone on behalf of Genentech if speakers deviated from on-label discussion, and in fact, it was encouraged. Moreover, additional slides which suggested or prompted off-label use were presented by clinician-speakers on behalf of Genentech.

108. Clinicians were even "groomed" by Defendants to be speakers by attending all expense paid speaking seminars in resort-like atmospheres. These seminars were in truth designed to market their drugs, including off-label. Defendants also retained clinicians to speak to other clinicians, during peer-to-peer sessions, about the off-label use of their drugs.

UNLAWFUL COVERAGE TACTICS FOR OFF-LABEL USES OF TARCEVA AND XOLAIR

109. Defendant Genentech was aware that off-label uses of its drugs would not be covered and payable by Medicare, Medicaid, or other Government Healthcare Programs unless Defendant caused the coverage to occur by active lobbying and promotion of the off-label uses to Medicare contractors, or the applicable compendia. Defendant did in fact actively promote the off-label uses to Medicare contractors and the compendia, at times using misleading tactics to attain the goal.

110. Defendant Genentech was aware that its improper attempts to remove coverage blocks and facilitate off-label coverage from Medicare Contractors and the compendia did in fact result in claims to Medicare, Medicaid, and other Government Healthcare programs for the off-label uses. Defendant was aware that its promotion activities was a substantial factor in producing the coverage of various off-label uses and doses. For instance, Defendant Genentech made payments to

Board members of the "National Comprehensive Cancer Network Drugs and Biologics Compendium" as part of its coordinated plan to influence coverage.

111. Defendant was also aware that its coaching of physicians on how to bill to receive payment for off-label uses, without necessarily disclosing the off-label use in the claims coding, caused the payment of off-label claims.

CLAIMS SUBMITTED TO GOVERNMENT HEALTHCARE PROGRAMS FOR OFF-LABEL USES OF TARCEVA AND XOLAIR WERE NOT COVERED

112. As stated by the National Cancer Institute:

> Use of a drug off label may cause harm when the drug's effect against a kind of cancer has not been demonstrated and there is no medical reason to believe the drug might be an effective treatment for that kind of cancer. All drugs have side effects; the side effects of cancer drugs vary depending on the kind of cancer being treated. When a drug's effect against a type of cancer has not been demonstrated, and its side effects are unknown, the possible risks of giving the drug may outweigh the possible benefits.

(www.cancer.gov/clinicaltrials/education/approval-process-for-cancer-drugs/allpages, retrieved on Oct. 11, 2010).

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

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

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

116. Absent Defendants' illegal off-label marketing, which included false representations and unlawful inducements to physicians, the subject drugs would not have been prescribed by physicians for off-label indications. Defendants' off-label marketing programs have been extremely successful, leading to the submission of claims to the Government Healthcare Programs for medically unnecessary and imprudent prescriptions.

117. Because prescriptions for off-label uses generally are not eligible for reimbursement under Government Healthcare Program regulations, submission of a claim for reimbursement for a drug prescribed off-label constitutes a false claim for the purposes of the Federal and State False Claims Acts. While it is a pharmacy, by virtue of the reimbursement system, which unwittingly submits the false prescription drug claim, the person or persons who knowingly cause(s) such a claim to be presented to the Government Healthcare Programs is liable under the law.

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

119. When pharmacies, physicians, and other health care providers submitted claims based upon a physician's prescription for the off-label uses, the claims they submitted were false

because such off-label uses were not supported by a citation in one of the Drug Compendia specified by 42 U.S.C. § 1396r-8(g)(1)(B)(I) (Medicaid); not supported by the compendia or "clinical research that appears in peer-reviewed medical literature," and could not, under any circumstances, be determined to be "medically accepted generally as safe and effective" or "reasonable and necessary" (Medicare); and not covered by other Government Healthcare Programs, See, e.g., TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

120. Since Defendants cannot submit claims directly to Government Healthcare Programs, they intentionally defrauded physicians to prescribe the subject drugs by engaging in a nationwide materially misleading off-label marketing campaign for the intended and foreseeable effect of causing physicians and pharmacists to submit claims to Government Healthcare Programs that were ineligible for reimbursement.

121. False claims to these Government Healthcare Programs for off-label prescribing were the direct and proximate result of unlawful off-label marketing efforts by Defendants. Defendants caused the submission of these claims.

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

PRICING VIOLATIONS

123. Defendant Genentech entered into a Rebate Agreement with the U.S. Secretary of Health and Human Services. In that Agreement, Defendant agreed to comply with 42 U.S.C.

§1396r-8, and hence:

(a) Agreed to report its Best Price, inclusive of cash discounts, free goods contingent upon any purchase requirements, volume discounts and rebates, etc.

(b) Agreed that it would determine its Best Price based upon its AMP, calculated as "net sales divided by numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements)" and that it would include that in the calculation, cash discounts and all other price reductions "which reduce the actual price paid"; and

(c) Agreed that the Best Price would not take into account nominal prices, defined as prices that are less than 10 percent of the AMP in that quarter, so long as the sale of product at a nominal price was not contingent on any other sale.

124. Since the first quarter of 2005, Defendant reported its AMP and Best Price in each quarter, to the Medicaid Program on Form CMS-367. However, Defendant failed to take into account the conduct described below when reporting its Best Price for its drugs, Tarceva and Xolair. As a result, Defendant's Best Price, for Quarterly Reports submitted for at least since 2005, were inflated, which reduced the percentage difference between AMP and Best Price, thereby reducing the rebate amount that Defendant ultimately paid to each state Medicaid program.

125. Defendant Genentech used the aggressive inducements described in this Complaint to increase utilization, but in doing so failed to abide by the Anti-kickback Law or to properly disclose these payments in Government Pricing Reports.

126. Defendant Genentech provided incentives for its contracts with: National Account Customers ("NAC") Group Purchasing Organizations ("GPO") and Specialty Pharmacies ("SP"). These include GPOs such as International Oncology Network and U.S. Oncology, and SPs such as Accredo Nova Factor, Inc., Advanced Care Scripts, Inc., Biologics, Inc., BioScrip, Inc., CuraScript Pharmacy, Inc.; to name a few.

127. To induce SPs, Genentech paid them through "data" and "compliance and persistency" programs. Compliance and persistency programs contemplated clinical nurses assisting

patients, but Genentech had its own nurse hotline and did not need to pay the Specialty Pharmacies for "compliance and persistency" programs. Genentech did so to generate more sales from the payments to specialty pharmacies.

128. To induce NACs and GPOs as well as their members, Defendant Genentech would include monetary incentives in the contracts, in addition to the negotiated pricing structure. The monetary incentives on the surface would be for medical and patient advice programs, for data agreements, and other miscellaneous ostensibly legitimate purposes.

129. Defendant Genentech did not include the incentives for government price reports. Thus, Defendant Genentech's government price reports were, and are, false statements either to avoid paying monies to the government or to obtain reimbursement monies from the government based on these reports.

130. At all relevant times mentioned herein, Defendant Genentech was a signatory to a Rebate Agreement with CMS under which the Medicaid Program would receive rebates determined by Defendant's price reports of AMP and Best Price.

131. Pursuant to the Rebate Agreement, Defendant Genentech submitted price reports directly to CMS purportedly reflecting AMP and Best Price for its covered products.

132. Defendant Genentech submitted fraudulent quarterly price reports with respect to its products by intentionally misrepresenting AMP and Best Price by willfully excluding price cuts and other inducements offered to its customers that resulted in higher AMP and/or lower Best Price than the prices reported to CMS.

133. Defendant Genentech intentionally submitted these false reports to avoid paying higher rebates as required by federal law and its Rebate Agreement.

134. Defendant Genentech knowingly made and used these false price reports and other

false records and statements with the intent to conceal, avoid, or decrease an obligation to pay or transmit money to the government, e.g. its mandatory Medicaid rebate payments.

135. Defendant Genentech had the authority and responsibility to make such reports, improperly abused the exercise of such authority, and as a direct and proximate result, the false record and statements were made to the government, and the federal and states' Medicaid programs were deprived of the much-needed appropriate rebate payments as a result of Defendant's intentionally inaccurate reporting of AMP and Best Price.

136. In addition to blatantly violating the Medicaid Rebate Program price reporting requirements, Defendant repeatedly ran afoul of the price reporting rules of Medicare and nearly a dozen other Government Healthcare Programs, including: the Railroad Retirement Medicare program, 45 U.S.C. § 231, which provides Medical coverage for retired railroad workers; the Indian Health Service, 42 U.S.C. §§ 2002 2005, which provides healthcare for Native Americans; the Federal Employees Health Benefits Program ("FEHBP"), 5 U.S.C. §§ 8901 8914, which provides healthcare for federal employees and their dependants; the Tri Care program (formerly CHAMPUS), 10 U.S.C. §§ 1071 1106, which provides healthcare for Uniformed Services members and their dependants in civilian facilities; the State Legal Immigrant Assistance Grants ("SLIAG"), 8 U.S.C. § 1255a, 45 C.F.R. § 402.10, which provides funds to States for immigrant healthcare; and the State Children's Health Insurance Program ("SCHIP" or "CHIP"), 42 U.S.C. § 1397, which provides federal, matching funds for coverage for low-income children who are not eligible for Medicaid.

137. These Government Healthcare Programs have their own price reporting rules. Medicare Part B reimbursement, for instance, is determined based on a manufacturer's quarterly report of a price calculation, Average Sales Price (ASP). Other Government Healthcare Programs

rely on similarly reported pricing information, such as the manufacturer's reported Best Price, Average Manufacturer Price (AMP), Non-Federal Average Manufacturer Price (Non-FAMP) and Most Favored Customer pricing. Other federal agencies, including the Department of Defense and the Bureau of Prisons, look to the Federal Supply Schedule, which lists the maximum prices for drugs based solely on the manufacturers' reported prices.

138. Defendant failed to include these kickbacks in its reported pricing, thus submitting false pricing information, including false ASPs, AMPs, Non-FAMPs and Best Prices, to Government Healthcare Programs. Defendants submitted this false information with the intent that the Government Healthcare Programs would rely on these false reports in making their payment calculations and decisions.

139. Defendant's false pricing information defrauded, and continues to defraud, Government Healthcare Programs, including Medicaid, Medicare, the Railroad Retirement Medicare program, the Indian Health Service, FEHBP, Tri Care, SLIAG and SCHIP.

140. Accordingly, when Government Healthcare Programs purchased Defendant's products, directly or indirectly, in reliance upon Defendant's falsely reported prices, Defendant made a false record or statement to get a false or fraudulent claim paid or approved, and presented and caused to be presented a false or fraudulent claim for payment or approval in violation of the federal False Claims Act, 31 U.S.C. § 3729(a)(1) and (a)(2). In addition, when a Government Healthcare Program relied upon Defendant's falsely reported prices in calculating a rebate owed to that program based on utilization of Defendant's products, Defendant made a false record or statement to conceal, avoid, or decrease an obligation to pay money to the Government in violation of the federal False Claims Act, 31 U.S.C. § 3729(a)(7).

141. The Plaintiff States' false claims acts protect the States' share of Medicaid spending.

The liability provisions of the Plaintiff States' false claims acts largely follow the language of the federal False Claims Act liability provisions, 31 U.S.C. § 3729(a)(1), (a)(2) and (a)(7). Thus, the Genentech pricing schemes that impacted the Medicaid dollar violate the federal and state False Claims Acts.

KICKBACKS

Speaker Programs

142. Defendant Genentech had an active speaker's bureau (known by the acronym GENIE) to market its drugs, including but not limited to Tarceva, Avastin, Xolair, and Herceptin. The speakers were nominated by the sales force. Scientific affairs had no involvement with the GENIE program. When they did a ROI analysis of the number of additional prescriptions generated from the attendees, Defendants determined that it had a negative ROI. However, because the speakers *themselves* were such high prescribers, a decision was made to continue the speakers bureau, for these speakers were writing a tremendous number of prescriptions, which more than made up for the cost of the programs.

143. At all of these events for Tarceva, typically dinner programs, the speakers promoted the inflated survival benefits of, and the use of Tarceva as a first-line treatment. At all of these events for Avastin, the speakers promoted the off-label combination use of Avastin plus Tarceva.

144. The slides for the GENIE speakers were prepared by Genentech. The GENIE core slides themselves contained the off-label exploratory subset data.

145. Defendant Genentech's GENIE program was a kickback program. An internal audit was conducted from 2006 through the 1st quarter of 2007 for the Genie speaker programs. The auditors concluded that the primary risks of the program were "related to anti-kickback issues raised

by GENIE practices around speaker selection, training, use and payments," and that in 2008, at a payout cost of $2-3 million, 450 speakers were trained but never used! Speakers were paid honorariums of over $2,300 to attend one speaker training event.

146. Defendants also conducted “A&T” Programs – promoting the use of combination Avastin and Tarceva. These were funded 50/50 by each brand internally. Reps also handed out Phase 1/2 Trial by Dr. Roy Herbst, promoting this off-label treatment of NSCLC.

147. Defendants spent approximately $7 million each year on Xolair speaker programs.

148. Physicians were largely selected based upon criteria directly related to prescription writing, and not related to the identified purpose of the services in the contract, and not related to the expertise level necessary for a physician to be a speaker in the specific topic that they were paid to speak about.

149. Defendants Genentech and OSI, from at least 2006 through current, paid kickbacks to physicians in exchange for speaking at purported CME events. Genentech’s own ROI analysis showed that, on average, two doctors would show up to an event; most of the attendees were office staff, seemingly looking for a free meal. At several events, no attendees showed up; yet the speaker-physician still pocketed $2,500-$3,000.

150. For “high profile” physicians, OSI sales reps would offer to shepherd through $5,000-$10,000 “medical grants” to pay these targeted physicians for speaking engagements. These ad hoc medical grant speaking engagements placed no restrictions on the speakers. In turn, physicians could use their own materials and peddle off-label uses of Defendants’ products. Oftentimes, speakers would simply revisit old slides from Genentech or OSI Advisory Boards, promoting off-label uses of Defendants’ products.

151. Frequently, OSI would pack several speaking engagements into one day, lining the doctors' pockets with tens of thousands of dollars. Several physicians did not join the speakers bureau because they could name their own price, and make more money through the "medical grant" speaker programs.

152. Relator attended several "medical grant" speaking engagements set up by OSI, including a presentation by Dr. Belani at the Palm Beach Cancer Institute. Relator estimates that there were 50-100 "Medical Grant" speaker programs across the country each year.

Advisory Boards

153. Defendant Genentech used advisory boards for marketing purposes. Called NSCLC advisory boards consisted of the following: 1) community ad boards (CABs); 2) regional ad boards (RABs); 3) national ad board; 4) EGFR summit; 5) diagnostic NAB. Defendant Genentech spent $1.5 million each year for Tarceva advisory boards, and a relatively similar amount for Xolair Primary Care and other advisory boards.

154. These meetings were for the ostensible purpose of getting input/feedback from physicians on drug performance, how they treat disease states, etc.; although internal e-mails clearly admit otherwise. That is, the purpose was to convey messages to the physicians to promote additional sales of their products, both on and off-label. For instance, the PowerPoint presentation for the 2010 Brand Plan lists the goal of the advisory Boards as "increase perception of primary care physicians." For the Advisory Board meetings, honorariums, lavish entertainment and expenses for physicians, were paid for by Defendants.

155. Advisory board meetings were held at lavish resort locations. The Defendants never used the information or "lessons" gleaned from these meetings. Doctors would bring their families,

as the Advisory Board honorarium more than covered the travel costs of their family members.

156. There were more Advisory Boards for Tarceva than any other drug. Organized by Defendants themselves, two community advisory board meetings were held every month. For regional Advisory Boards, the reps worked with a third-party company for recruiting purposes, such as Cadent Medical Communications (subsidiary of inVentiv Group). National Advisory Board meetings were largely organized by Physicians Education Resource, LP and P4 Healthcare, LLC. P4 approached large physician groups and organizations to attend Genentech's "Advisory Board Meeting" after they held their own meetings.

Copayments

157. Copayment is the portion of the cost of an item or service which the Medicare (and other Government Healthcare Programs) beneficiary must pay. The copayment amount at all material times for Medicare has generally been 20 percent of the cost of the pharmaceutical product.

158. A supplier who routinely waives Medicare and Medicaid co-payments may be held liable under the Medicare and Medicaid anti-kickback statute, 42 U.S.C. § 1320a-7b(b). Under the anti-kickback statute, it is illegal to, inter alia, offer or pay anything of value as an inducement to generate business payable by any Government Healthcare Program.

159. Defendant facilitated independent non-profits (INP) like the "Chronic Disease Fund" to provide a "grant" for patients in the amount of their co-pay costs. The Specialty Pharmacies were paid electronically directly from the INP's, instead of the "grant" being paid to the patient.

160. Defendants coordinated with the INP's and specialty pharmacies to routinely waive patient copayments, as Defendants knew that such a waiver would influence the patients' selection of a particular drug.

161. At no time did Defendants or any of the INP's/ specialty pharmacies determine in good faith that any patient for which the copayment was waived was actually in financial need.

162. It was an inherent and routine part of Defendants' marketing programs to solicit new patients and retain existing patients by offering and actualizing copayment waivers of their products. These kickbacks caused additional prescriptions to be written on-label, as well as off-label.

Lavish Meals

163. Sales Representatives across the country were allowed and instructed to spend lavishly on all physicians, typically at CME events, for both the speakers and invitees. In addition to honorarium payments by check, kickbacks were paid in-kind in the form of high-end food, wine and entertainment. Sales representatives were given an unlimited budget to wine and dine physicians.

Phase IV Trials

164. Defendant OSI set up clinical trials solely for the purpose of generating sales. Unlike legitimate clinical trials: (1) The clinical trials were placed and managed by OSI's sales force, not any research or "scientific affairs"-type division; (2) Their primary role was to generate sales for the sales force, not produce legitimate results which could be used for research.

Marketing the Spread

165. The difference between the acquisition cost for providers, and the price paid by Government Healthcare Programs is referred to as "the spread." Defendants maintained a spread to use the profit margin as a selling tool to induce providers to prescribe Xolair.

166. Defendants intentionally fixed their pricing so that its customers obtained Xolair at a price substantially less than the Government Healthcare Program reimbursement amounts.

Defendants and their marketing and sales teams told customers that they would make more money the more Xolair they prescribed.

167. Defendants educated and trained its sales representatives Field Reimbursement Managers ("FRMs") to help healthcare providers maximize reimbursement. FRMs demonstrated the financial benefit of prescribing Xolair because each vial was worth at least several hundred dollars from the spread.

168. Since oncologists are reimbursed at ASP+6% under Medicare, for instance, practices made a significant amount of money from Genentech's Rituxan, Avastin, and Herceptin, as well as Xolair, which were purchased for less than ASP. For each patient treated, physicians were told that they could make $600 on the spread alone.

169. These "marketing the spread" promotions were especially prevalent when it came to the promotion of Xolair. For example, Defendants Genentech and Novartis used "Practice Management" speaker programs (as well as Advisory Boards) to tout the tremendous profits available to doctors when they administered Xolair out of their offices to Government Healthcare Program beneficiaries.

170. Defendant Genentech deployed an army of reimbursement specialists, who were trained to discuss with doctors the lucrative rewards of establishing a Xolair infusion clinic.

171. Novartis sales representatives expanded the reach of Defendant Genentech's efforts by specifically targeting primary care doctors across the country.

172. If a doctor was unable to foot the initial costs of buying the drugs, Defendant Genentech entered the doctor in a "Xolair Distribution Pilot" program, which allowed the doctor to float the costs on a cosignment basis.

173. To further promote the financial rewards of starting a Xolair infusion clinic, Defendant Genentech held sham advisory board meetings and launched a robust "Practice Management" Speakers Bureau.

174. Defendant Genentech's Senior Management closely tracked the return-on-investment of these "Starter Programs"

Field Reimbursement Inducements

175. Genentech employed an army of FRMs organized by region, deployed to doctors' offices across the country, to educate doctors on how they could bill for off-label and on-label uses of its products. The FRMs main contacts were the business offices/practice managers of physician practices. The FRMs were tasked to help them either obtain free Genentech products, obtain reimbursement for using Genentech products (through coding tips and support of the claims adjudication process) or obtain help getting a patient to fill out the Access Solutions information for drug benefits. FRMs were typically hired from large community-based practices, as they were required to have a solid understanding of physician pharmaceutical reimbursement.

176. Genentech orchestrated FRM programs through its Sales Department, blasting doctors' offices with invitations to lavish dinners, where doctors would receive step-by-step instructions on how to code for Defendants' products. For instance, in Relator's territory the sales reps for Rituxan, Avastin, Herceptin, and Tarceva (Relator) were involved in setting up lunches, dinners, and 1:1 sessions with the business office personnel of a doctor's office.

177. FRMs were also trained to discuss with doctors the lucrative rewards of establishing a Xolair infusion clinic. Novartis sales representatives expanded the reach of Genentech's efforts by specifically targeting primary care doctors across the country. To funnel patients to the Xolair-

prescribing doctors, Defendants promoted these "Xolair Centers" for doctors at no charge, on the Defendants' Web sites.

178. If a doctor was unable to foot the initial costs of buying the drugs, Genentech entered the doctor in a "Xolair Distribution Pilot" program, which allowed the doctor to float the costs on a consignment basis. Closely related and designed to work in conjunction, Defendants began a Xolair Starter Program to increase utilization as well. A Genetech/Novartis webpage describes the Starter Program: "The XOLAIR Starter Program may help your eligible patients begin treatment prior to the conclusion of their insurance provider's decision process. While your newly prescribed patients await a coverage decision from their carrier, the program provides XOLAIR—at no charge for up to 12 weeks—allowing eligible patients to receive their first injection closer to the time you determine that XOLAIR would be appropriate for them." The web page further describes the process: 1) Fill our Starter Program Request Form, Statement of Medical Necessity (SMN), and Patient Authorization Notification (PAN) form; (2) schedule the first Xolair injection for 14 days after the SMN/PAN submission date. (See http://www.xolairhcp.com/xolairhcp/XOLAIR-starter-program.html) Genentech's Senior Management closely tracked the return-on-investment of the "Starter Programs."

Preceptorships – OSI Only

179. From at least April 2007 through the fourth quarter of 2009, Defendant OSI Pharmaceuticals unlawfully bought prescriptions from doctors by paying for preceptorships across the country. The preceptorships permitted the OSI Sales Representatives to shadow doctors as they saw patients, reviewed charts, and, most importantly, as they inked prescriptions for patients.

180. On average, doctors received $1,000 per day, but doctors could negotiate higher payments. Doctors would receive full payment, even when they only permitted the Sales Representatives to shadow a few patient visits. Doctors were primarily selected based on their prescription-writing potential, as preceptorships were used to generate prescriptions to increase utilization.

Payments to Patients

181. Defendants further inflated the sales of their products by devising and implementing an elaborate patient marketing scheme that offered substantial kickbacks to patients themselves.

182. In early 2010, Defendant Genentech launched a "Patient Ambassador Program," which recruited, trained, and paid patients to talk up the benefits of Defendants' products to other patients. This program was modeled after an earlier program that Genentech had launched in 2008 to push its breast cancer injectible, Herceptin.

183. Patient Ambassadors were paid a set fee every single time they spoke to an audience of potential, current, or former Tarceva patients. Most of these events were Genentech-organized lunches or dinners, where Patient Ambassadors would reinforce the off-label benefits of Tarceva.

184. Defendants also inflated sales by paying for patient co-pays as set forth in paragraphs 160 through 165 of this Amended Complaint. This conduct included paying for Medicare patient "Donut Hole" expenses. The Donut Hole is the difference of the initial coverage limit and the catastrophic coverage threshold, as described in the Medicare Part D prescription drug program of the United States. After a Medicare beneficiary surpasses the prescription drug coverage limit, the Medicare beneficiary is financially responsible for the entire cost of prescription drugs until the expense reaches the catastrophic coverage threshold.

COUNT I—FALSE CLAIMS ACT

185. Relator realleges and incorporates by reference paragraphs 1 through 184 as though fully set forth herein.

186. This is a claim by Relator, on behalf of The United States, for treble damages and penalties under the False Claims Act, 31 U.S.C. 3729-3733 against Defendants for knowingly causing to be presented false claims to Government Healthcare Programs. From on or about 2005, in the Northern District of California and elsewhere throughout the United States, Defendants have knowingly and willfully violated the False Claims Act by submitting and causing false claims to be submitted.

187. Defendants have knowingly caused pharmacies and other health care providers to submit Pharmacy, CMS-1500, and other claim forms for payment, knowing that such false claims would be submitted to Government Healthcare Programs for reimbursement, and knowing that such Government Healthcare Programs were unaware that they were reimbursing prescriptions for prescriptions induced by kickbacks and/or for non-covered uses and/or otherwise non-covered because they were not reasonable and necessary; and therefore false claims. By virtue of the acts described in this Complaint, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

188. Defendants have also violated the False Claims Act by causing the states to submit false claims to the United States Government in Form CMS-64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program), which falsely certified that all drugs for which federal reimbursement was sought, were paid for in compliance with federal law. States submitted false claims to the United States Government because when the products described herein were

prescribed off-label, they were not prescribed for a medically accepted indication, were prescribed based upon kickbacks, and yet states sought reimbursement from the United States Government for all such off-label claims paid.

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

190. The United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each false claim presented or caused to be presented.

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

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

(b) That civil penalties of $11,000 be imposed for each and every false claim that Defendants caused to be presented to the Government Healthcare Programs under the Federal False Claims Act;

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

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

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

COUNT II
FALSE CLAIMS ACT
31 U.S.C. §§ 3729(a)(2) (*FDA Adverse Events*) (against Genentech, Inc. only)

191. Relator realleges and incorporates by reference paragraphs 1 through 54 and 88 through 93, as though fully set forth herein.

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

193. At all material times, the Food, Drug and Cosmetic Act ("FDCA") prohibits the sale of unapproved new drugs in interstate commerce: "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application [to the FDA] is effective with respect to such drug."21 U.S.C. § 355(a). A drug manufacturer or distributor obtains FDA approval by submitting a new drug application (NDA) or abbreviated new drug application (ANDA) in accordance with the FDCA and FDA regulations. See 21 U.S.C. § 355(b)-(b)(1); 21 C.F.R. § 314.50 (detailing contents of NDA).

194. In 21 U.S.C. §355(k), Congress mandated the establishment of the postmarket risk identification and analysis system to ensure, *inter alia*, the safety and efficacy of pharmaceuticals already on the market.

195. To implement Congress' mandate, the FDA promulgated 21 CFR 314.80, and 314.98, which require expedited reports of postmarketing adverse drug experiences (ADE) by drug manufacturers. Applicants with approved NDAs (§ 314.80) and abbreviated new drug applications (ANDAs) (§ 314.98) are among those subject to these laws and regulations.

196. The purpose of postmarketing Adverse Drug Experience (ADE) surveillance is to obtain information on rare, latent or long term drug effects not identified during premarket testing. Sponsors, manufacturers, packers and distributors are required to report all serious, unexpected (not listed in the drug product's current labeling) ADEs to FDA within 15 calendar days, in what is referred to as a "15-Day Alert Report." A serious ADE is one that is fatal or life threatening, is permanently disabling, (or requires inpatient hospitalization, or is a congenital anomaly, cancer or overdose.) In addition, manufacturers are required to file with the FDA "Postmarketing Periodic Reports." These Reports are due quarterly for the first three years after U.S. approval of the NDA, and yearly thereafter.

197. Sec. 314.80 (b) provides the affirmative duty that drug manufacturers "shall promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, ... postmarketing epidemiological/surveillance studies, ..."

198. Sec. 314.80(b) further provides that, "any person subject to the reporting requirements . . . shall also develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA."

199. Defendant Genentech maintained websites for all of its prescription drugs, which invited patients to answer questions about their usage. There were three websites for Avastin, one for Tarceva called "Lung Cancer Connection"; one called HER Connection for Herceptin; one called "Living With Lymphoma" for "Rituxan"; and one called "Asthma Matters" for Xolair. The websites were so successful they garnered survey responses from over 100,000 patients.

200. Relator noticed problems with the Xolair e-marketing efforts almost immediately. First, he noticed that the "Xpansions and Asthma Matters" web sites included a registration page for

patients. As patients go through the form, it asks about their asthma and any negative side effects they have encountered with their medicine. Relator discovered that Defendant Genentech was keeping a database of answers, but they were not reporting any of the adverse events that were disclosed about Xolair from this online form. In talking with his colleagues, he discovered that this was true for other of the Defendant's cancer drugs. As of Fall 2010, Defendant removed all of the patient surveys for Xolair and removed the multiple other remaining websites in their entirety. No reports were made to the FDA from the survey data.

201. Genentech has submitted false statements and records in connection with the Adverse Events reporting requirements of Genentech's New Drug Applications (NDAs) for its drugs. These false statements and records were made by Genentech to the FDA and caused false claims made to Government Healthcare Programs to be paid or approved.

202. Genentech suppressed knowledge of, and failed to submit full and complete Periodic Adverse Drug Experience Reports to the FDA, which would have shown that there were increased risks from Defendants' drugs associated with suicide, and with the in utero exposure of a developing fetus. Such conduct by Genentech deviated from the duties and conduct of a responsible pharmaceutical manufacturer and demonstrated a failure to ensure its own minimal compliance with requirements of the Federal Food Drug and Cosmetic Act.

203. During the previous six years, it is unknown how many patients died or were injured after receiving Defendants' drugs. Multiple deaths and injuries, however, were purposefully not reported to the FDA. Defendants knew or should have known of all these incidents through the voicemail system at InfoMedics, and at all times had in their possession or control hundreds of incidents of reported adverse events detailed and submitted by consumers.

204. Each time a consumer left a detailed message about an event that was both serious and unexpected, Genentech failed to record the information and then submit a post marketing 15 day "alert report" as required by Sec. 314.80 and applicable regulations. As Genentech failed to do so, it also failed to promptly investigate such adverse drug experiences and submit follow up reports within 15 calendar days of receipt of new information which Genentech should have taken steps to obtain, all as mandated by Sec. 314.80 and applicable regulations.

205. Genentech was also required to submit "Periodic Adverse Drug Experience Reports." It was required to submit each adverse drug experience not reported under paragraph (c)(1)(i) of section 314.80 at quarterly intervals, for 3 years from the date of approval of each NDA, and then at annual intervals. Genentech was required to submit each quarterly report within 30 days of the close of the quarter, and to submit each annual report within 60 days of the anniversary date of approval of the application.

206. Genentech submitted false "periodic adverse drug experience reports" to the FDA on a quarterly, and later, yearly basis. Genentech did so because it failed to include the detailed adverse events left by the callers to InfoMedics as described in this complaint, serious adverse events and otherwise. Genentech used these false "Periodic Adverse Drug Experience Reports" to get (false) claims paid in violation of the False Claims Act, to wit, claims for Defendant's drugs submitted to Government Healthcare Programs which would otherwise not have been paid or approved.

207. Genentech, by suppressing and failing to disclose the above described adverse events, and also by disseminating false information to physicians and the public about the safety and efficacy of Defendant's drugs, caused physicians and other health care providers to prescribe Defendant's drugs and submit claims for Defendant's drugs in violation of the False Claims Act, when they otherwise would not have prescribed Defendant's drugs for their patients.

208. Applicable laws and regulation, including Sec. 314.80(i), require Genentech "to maintain for a period of 10 years records of all adverse drug experiences known to the applicant, including raw data and any correspondence relating to adverse drug experiences." Genentech failed to do so.

209. Applicable laws and regulations, including Sec. 314.80(j), provide that if an applicant such as Genentech "fails to establish and maintain records and make reports required under this section, FDA may withdraw approval of the application and, thus, prohibit continued marketing of the drug product that is the subject of the application." Genentech indeed failed to establish and maintain the records and reports required; yet, had Genentech not submitted false reports or records to the FDA, the FDA would have either withdrawn approval of Defendant's drugs or instituted warnings and restrictions on Defendant's drugs which, at minimum, would have resulted in far less submissions of claims for Defendant's drugs to Government Healthcare Programs.

210. Defendant Genentech has used a variety of false documents, including false submissions to the United States FDA, to cause the United States to continue to pay and approve claims for reimbursement under the Government Healthcare Programs, which claims would not have been reimbursed had CMS known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Defendant Genentech's drugs.

211. From in or about 1999 to present, Defendant s conduct violated the False Claims Act, 31 U.S.C. §§ 3729(a)(2).

212. The United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each false claim paid or approved.

COUNT III [against Genentech, Inc. only]

31 U.S.C. § 3730(h)

213. Relator realleges and incorporates by reference the allegations made in paragraphs 1 through 184 of this Complaint.

214. Genentech, Inc. has a duty under the False Claims Act, 31 U.S.C. § 3730(h), to refrain from taking retaliatory actions against employees who take lawful actions in furtherance of a False Claims Act action, or who take action to stop violations of the False Claims Act.

215. Relator took lawful actions to stop violations of the False Claims Act, and in furtherance of a False Claims Act action, including but not limited to investigation for, testimony for, or assistance in an action filed under this section and, as such, engaged in protected activity under the False Claims Act and other laws.

216. During at least his last year of employment, Genentech, Inc. harassed and/or discriminated against Relator in the terms and conditions of employment.

a. In February, 2010, in a team meeting with the Tarceva Marketing team, the Relator explained that the Tarceva subset strategy was incorrect and that only female adenocarcinoma patients who were never smokers benefitted from Tarceva, contradicting the statements which appeared on Genentech, Inc. brochures. Following the meeting, the Relator was informed by a supervisor that he "was not a team player."

b. In March, 2010, Relator complained about the Tarceva marketing strategy and brochure. He was subsequently chastised by a supervisor stating that he was not a team player and because of the Relator, they would have to destroy marketing materials. As the result of this treatment, Relator decided to leave the Tarceva team and join the eMarketing Team.

c. In June, 2010, during an eMarketing staff meeting, Relator explained to eMarketing management that the patient web based programs were possibly under reporting adverse events. Relator's manager told him he was being too negative. Following this event, Relator lost most of his support on the eMarketing Team and subsequently received a lower than average long term compensation grant in October 2010.

d. In November, 2010, Relator observed significant off-label promotion and minimization of the risks of Xolair at an Advisory Board targeted towards Primary Care physicians. Relator then reported this event to his manager who became very angry and told the Relator that he "was not a fit "for his team. Relator's manager said that the Relator "had a bad reputation with the Tarceva team and Marketing Teams would probably never take him back." Relator reported this event to the Human Resources and Compliance Teams at Genentech, Inc.

e. In late November/December 2010, Relator's manager confronted him and said that he never heard Relator mention anything about the Advisory Board and that Relator was mistaken about his concerns. The manager also said that he did not know what the Relator's future on the eMarketing Team would be since he "was not a fit." Within the next few weeks, the Xolair team began to what appeared to be a gradual banishment process. The Relator's managers postponed and missed appointments with all of his major projects resulting in Relator's inability to complete his 2010 assigned projects.

f. In March 2011, Relator was given a poor performance review and told he would not be getting a bonus for 2011. Relator was informed that neither the Xolair nor eMarketing Teams wanted to work with him. Relator spoke with the Compliance and Human Resources Teams regarding these events and his concerns that these actions were retaliatory. Relator was informed that his prior compliance complaint just a few months earlier regarding the Xolair team was "substantiated" although he was never advised of this previously. The next day Relator was advised that his current reported event was not retaliation and that he could speak to someone else on the Human Resources Team if he wanted to.

217. In or about March 22, 2011, Genentech, Inc. constructively terminated Relator's

employment.

218. Relator was discriminated against in the terms and conditions of his employment by Genentech, Inc., by and through its officers, agents, and employees because of lawful acts done by him in the furtherance of his efforts to bring a False Claims Act action and to stop violations of the False Claims Act.

219. The actions of Genentech, Inc. damaged and will continue to damage Relator in violation of 31 U.S.C. § 3730(h), in an amount to be determined at trial.

220. Pursuant to 31 U.S.C. § 3730(h), Relator is entitled to litigation costs and reasonable attorneys' fees incurred in the vindication of his reputation and the pursuit of his retaliation claims.

COUNT IV [against Genentech, Inc. only]

Cal. Gov. Code § 12653 (b)

221. Relator realleges and hereby incorporates by reference each and every allegation contained in paragraphs 1 through 184 and paragraphs 216 a – f, of this complaint.

222. During his employment with Genentech, Inc., Relator lawfully investigated failures of Genentech, Inc. to comply with the State of California and Federal False Claims Acts in furtherance of False Claims Act actions. He complained to his superiors regarding the violations set forth in this Complaint, and as set forth in paragraphs 216 a – f.

223. Relator's actions in furthering a False Claims Act action and internally reporting Genentech, Inc.'s violations of laws were protected activities within the meaning of Cal. Gov. Code § 12653(b).

224. Genentech, Inc. was aware of the Relator's above complaints and reports, and the potential affect of same on receiving federal and state funds.

225. Relator's complaints put Genentech, Inc. on notice that Relator's complaints could lead to an action filed or to be filed under Section 12652.

226. In retaliation for investigating and reporting said violations, Genentech, Inc. harassed, threatened, discriminated and ultimately constructively discharged Relator in or about

March 22, 2011.

227. Genentech, Inc.'s actions were in violation of Cal. Gov. Code § 12653(b), and damaged Relator in violation of Cal. Gov. Code § 12653(b), in an amount to be determined at trial.

228. Pursuant to Cal. Gov. Code § 12653(c), Relator is entitled to reinstatement with seniority, two times the amount of back pay owed, interest on back pay, compensation for any special damages sustained as a result of the discriminatory treatment, litigation costs, and reasonable attorney's fees incurred in the vindication of his reputation and in pursuit of this retaliation claim.

229. As a direct and proximate result of Genentech, Inc.'s conduct as alleged herein, Relator has suffered damage to his reputation entitling Relator to general damages in an amount to be determined at trial.

230. Genentech, Inc.'s conduct as alleged above in harassing and ultimately, constructively terminating Relator, was willful, malicious, oppressive, and fraudulent, thereby entitling Relator to punitive damages.

COUNT V [against Genentech, Inc. only**]**

Retaliation - Public Policy

231. The allegations set forth in paragraphs 1 through 184, and paragraphs 216 a – f, are alleged and incorporated herein by reference.

232. Defendant Genentech, Inc. has retaliated against Relator in violation of California public policy, by engaging in a course of retaliatory conduct, as described in paragraphs 216 a – f of this Complaint. This conduct continued until Relator was constructively discharged in or about March 22, 2011. Relator believes and alleges that Genentech, Inc.'s termination of his employment (constructive discharge) contravenes fundamental public policy established both by statutory and regulatory provisions, in violation of California public policy.

233. At all times mentioned herein, Relator was willing and able to perform the duties and functions of his position and Relator did, in fact, perform those duties in an excellent fashion.

234. As a proximate result of Genentech, Inc.'s discriminatory actions against Relator as alleged above, Relator has been harmed in that Relator has suffered the loss of salary, benefits, and additional amounts of money he would have received if Genentech, Inc. had not terminated his employment. As a result of such discrimination and consequent harm, Relator has suffered such damages in an amount according to proof.

235. As a further proximate result of Genentech, Inc.'s discriminatory actions against Relator as alleged above, Relator has been harmed in that he has suffered humiliation, anguish, and emotional and physical distress. As a result of such discrimination and consequent harm, Relator has suffered such damages in an amount according to proof.

236. The above-recited actions of Genentech, Inc. were done with malice, fraud, and/or oppression, and in reckless disregard of Relator's rights entitling Relator to an award of punitive damages.

COUNT VI [against Genentech, Inc. only]

Retaliation - California Health and Safety Code Section 1278.5:

237. Relator realleges and incorporates by reference the allegations made in Paragraphs 1 through 184, and paragraphs 216 a – f of this Complaint.

238. California Health and Safety Code Section 1278.5(b)(1) provides that "No health facility shall discriminate or retaliate, in any manner, against any patient, employee, member of the medical staff, or any other health care worker of the health facility because that person has done either of the following: (a) Presented a grievance, complaint, or report to the facility, to an entity or agency responsible for accrediting or evaluating the facility, or the medical staff of the facility, or to any other governmental entity.

239. As described in this Complaint in paragraphs 1 through 184, and paragraphs 216 a –

f, Relator made complaints to Genentech, Inc. about violations of the False Claims Act and patient safety concerns. Within 120 days of the complaints and reporting, Genentech, Inc. discriminated against Relator Shields. Genentech, Inc. harassed and/or discriminated against Relator in the terms and conditions of employment, ultimately constructively discharging him in or about March 22, 2011.

240. Genentech, Inc.'s actions damaged Relator in violation of § 1278.5(b)(1) in an amount to be determined at trial.

WHEREFORE, as to Counts One through Six, plaintiff/relator requests that judgment be entered against Defendants as follows:

a. Defendants pay an amount equal to three times the amount of damages the United States have sustained because of Defendants' actions, plus a civil penalty against Defendants of not less than $5,500, and not more than $11,000 for each violation of 31 U.S.C. § 3729;

b. plaintiff/relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d);

c. plaintiff/relator be awarded all costs of this action, including attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d) and (h) and California law;

d. plaintiff/relator be awarded appropriate money damages and interest for unlawful discharge including, but not limited to, compensatory damages for harm, humiliation, embarrassment, and mental anguish and punitive damages for Genentech, Inc.'s conduct and the conduct of officers, agents, and employees of Defendant in violation of 31 U.S.C. § 3730 and/or California law;

e. the United States and plaintiff/relator be granted all such other relief as the Court deems just and proper.

COUNT VII
CALIFORNIA FALSE CLAIMS ACT

241. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

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

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

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

244. 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.

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

246. Defendants furthermore violated Cal. Gov't Code § 12651(a) and knowingly caused false claims to be made, used and presented to the State of California by their deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Cal. Bus. & Prof. Code § 650-650.1 and Cal. Welf. & Inst. Code § 14107.2 and by virtue of the fact that

none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government funded healthcare programs.

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

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

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

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

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

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

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

To the State of California:

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

To Relator:

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

COUNT VIII
COLORADO MEDICAL ASSISTANCE ACT

253. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

254. This is a *qui tam* action brought by Relator on behalf of the State of Colorado to recover treble damages and civil penalties under the Colorado Medical Assistance Act, Colo. Rev. Stat. §§ 25.5-4-304 *et seq*.

255. Colo. Rev. Stat § 25.5-4-305 provides that it is unlawful to:

(a) Intentionally or with reckless disregard make or cause to be made any false representation of a material fact in connection with a claim;

(b) Intentionally or with reckless disregard present or cause to be presented to the state department a false claim for payment or approval;

(c) Intentionally or with reckless disregard present or cause to be presented any cost document required by the medical assistance program that the person knows contains a false material statement…

256. In addition, the payment or receipt of bribes or kickbacks is prohibited under the Colorado Medical Assistance Act, Colo. Rev. Stat. §§ 25.5-4-305 (1)(e).

257. Defendants furthermore violated Colorado Medical Assistance Act, Colo. Rev. Stat. § 25.5-4-305 *et seq*. and knowingly caused false claims to be made, used and presented to the State of Colorado by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Colorado Medical Assistance Act, Colo. Rev. Stat. §§ 25.5-4-304 *et seq*. and Colo. Rev. Stat. § 25.5-4-305(1)(e) and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government funded healthcare programs.

258. The State of Colorado, by and through the Colorado Medical Assistance Act and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

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

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

261. As a result of Defendants' violation of Colo. Rev. Stat § 25.5-4-305, the State of Colorado has been damaged in an amount far in excess of millions of dollars exclusive of interest.

262. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Colorado Medical Assistance Act, Colo. Rev. Stat § 25.5-4-304 *et seq*. on behalf of himself and the State of Colorado.

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

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

To the State of Colorado:

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

To Relator:

(1) The maximum amount allowed pursuant to Colorado Medical Assistance Act, Colo. Rev. Stat § 25.5-4-304 *et seq*. and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT IX
CONNECTICUT FALSE CLAIMS ACT

264. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

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

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

> (1) Knowingly present, or cause to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval under medical assistance programs administrated by the Department of Social Services;
> (2) Knowingly make, or cause to be made or used a false record or statement to secure the payment by the state of a false or fraudulent claim under medical assistance programs administered by the Department of Social Services;
> (3) Conspire to defraud the state by securing the allowance of payment of a false claim under medical assistance programs administered by the Department of Social Services.

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

268. Defendants furthermore violated Conn. Public Act No. 09-5 § 2(a) and knowingly caused false claims to be made, used and presented to the State of Connecticut by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Conn. Public Act No. 09-5 § 2(a) and § 16(a) and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government funded healthcare programs.

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

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

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

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

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

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

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

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

To the State of Connecticut:

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

To Relator:

(1) The maximum amount allowed pursuant to Connecticut False Claims Act, Public Act No. 09-5 *et seq*. and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT X
DELAWARE FALSE CLAIMS AND REPORTING ACT

275. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

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

277. 6 Del. C. § 1201(a) provides liability for any person who-

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

278. In addition, 31 Del. C. § 1005 prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebate) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or services for which payment may be made in whole or in part under any public assistance program.

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

280. Defendants furthermore violated 6 Del. C. § 1201(a) and knowingly caused false

claims to be made, used and presented to the State of Delaware by its deliberate and systematic violation of federal and state laws, including the FDCA, the Anti-Kickback Act, and 31 Del. C. § 1005 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

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

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

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

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

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

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

the State of Delaware in the operation of its Medicaid program.

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

To the State of Delaware:

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

To Relator:

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

COUNT XI
FLORIDA FALSE CLAIMS ACT

287. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

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

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

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

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

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

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

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

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

293. Defendants furthermore violated Fla. Stat. § 68.082(2) and knowingly caused false claims to be made, used and presented to the State of Florida by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Fla. Stat. § 409.920 (c) and (e) and § 456.054(2) and by virtue of the fact that none of the claims submitted in

connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

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

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

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

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

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

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

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

To the State of Florida:

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

To Relator:

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

COUNT XII
GEORGIA FALSE MEDICAID CLAIMS ACT

300. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

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

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

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

(3) conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid.

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

304. Defendants furthermore violated O.C.G.A. § 49-4-168 and knowingly caused false claims to be made, used and presented to the State of Georgia by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

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

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

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

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

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

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

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

To the State of Georgia:

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

To Relator:

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

COUNT XIII
HAWAII FALSE CLAIMS ACT

311. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

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

661-21 *et seq.*

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

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

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

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

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

317. Had the State of Hawaii known that false representations were made to both the FDA

and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

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

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

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

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

To the State of Hawaii:

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

To Relator:

(1) The maximum amount allowed pursuant to Haw. Rev. Stat. § 661-27 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XIV
ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

321. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

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

323. 740 Ill. Comp. Stat. 175/3(a) provides liability for any person who:

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

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

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

326. Defendants furthermore violated 740 Ill. Comp. Stat. 175/3(a) and knowingly caused false claims to be made, used and presented to the State of Illinois by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and the Illinois Vendor Fraud and Kickback statute, and by virtue of the fact that none of the claims submitted in

connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

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

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

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

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

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

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

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

To the State of Illinois:

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

To Relator:

(1) The maximum amount allowed pursuant to 740 Ill. Comp. Stat.175/4(d) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XV
INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

333. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

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

> Sec. 2.(b) A person who knowingly or intentionally:
>
> (1) presents a false claim to the state for payment or approval;
> (2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state;
> (3) with intent to defraud the state, delivers less money or property to the state than the amount recorded on the certificate or receipt the person receives from the state;
> (4) with intent to defraud the state, authorizes issuance of a receipt without knowing that the information on the receipt is true;

> (5) receives public property as a pledge of an obligation on a debt from an employee who is not lawfully authorized to sell or pledge the property;
> (6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;
> (7) conspires with another person to perform an act described in subdivisions (1) through (6); or
> (8) causes or induces another person to perform an act described in subdivisions (1) through (6)...

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

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

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

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

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

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

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

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

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

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

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

To the State of Indiana:

(1) Three times the amount of actual damages which the State of Indiana has sustained as a result of Defendants' conduct;
(2) A Civil penalty of at least five thousand dollars ($5,000) and for up to three (3) times the amount of damages sustained by the State of Indiana;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Indiana Code 5-11-5.5 *et seq.* and/or any other applicable provision of law;

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

COUNT XVI
LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

344. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

345. This is a *qui tam* action brought by Relator on behalf of the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. 46: 437.1 *et seq.*

346. La. Rev. Stat. 46: 438.3 provides-

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

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

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

349. Defendants furthermore violated La. Rev. Stat. 46: 438.3 and knowingly caused false

claims to be made, used and presented to the State of Louisiana by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act and La. Rev. Stat. 456: 438.2(A), and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

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

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

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

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

354. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to La. Rev. Stat. 46: 439.1(A) on behalf of himself and the State of Louisiana.

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

the State of Louisiana in the operation of its Medicaid program.

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

To the State of Louisiana:

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

To Relator:

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

COUNT XVII
MARYLAND FALSE HEALTH CLAIMS ACT OF 2010

356. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

357. This is a *qui tam* action brought by Relator on behalf of the State of Maryland to recover treble damages and civil penalties under the Md. Health General Code Subtitle 6 §§ 2-601 *et seq*.

358. Md. Health General Code Subtitle 6 § 2-602 provides in pertinent part:

(a) A person may not:

(1) Knowingly present or cause to be presented a false or fraudulent claim for payment or approval;
(2) Knowingly make, use, or cause to be made or used a false record or statement material to a false or fraudulent claim ...

***

(9) Knowingly make any other false or fraudulent claim against a State health plan or a State health program.

359. Defendants furthermore violated Md. Health General Code Subtitle 6 § 2-602 *et seq*. and knowingly caused false claims to be made, used and presented to the State of Maryland by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

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

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

362. As a result of Defendants' violation of Md. Health General Code Subtitle 6 § 2-602 *et seq*., the State of Maryland has been damaged in an amount far in excess of millions of dollars exclusive of interest.

363. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Md. Health General Code Subtitle 6 § 2-602 *et seq*. on behalf of himself and the State of Maryland.

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

the State of Maryland in the operation of its Medicaid program.

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

To the State of Maryland:

(1) Three times the amount of damages that the State of Maryland sustains as a result of Defendants' conduct;
(2) A civil penalty of not more than $10,000 for each false claim which Defendants caused to be presented to the State Maryland;
(3) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Md. Health General Code Subtitle 6 § 2-602 *et seq*. and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XVIII
MICHIGAN MEDICAID FALSE CLAIMS ACT

365. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

366. This is a *qui tam* action brought by Relator on behalf of the State of Michigan to recover treble damages and civil penalties under the Michigan Medicaid False Claims Act. MI ST Ch. 400.603 *et seq.*

367. 400.603 provides liability in pertinent part as follows:

> Sec. 3. (1) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for Medicaid benefits;

> (2)A person shall not knowingly make or cause to be made a false statement or false representation of a material fact for use in determining rights to a Medicaid benefit...

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

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

370. Defendants furthermore violated, MI ST Ch. 400.603 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Michigan by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

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

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

373. Had the State of Michigan known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the

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

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

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

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

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

To the State of Michigan:

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

To Relator:

(1) The maximum amount allowed pursuant to MI ST Ch. 400.603 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XIX
MINNESOTA FALSE CLAIMS ACT

377. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

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

379. Minn. Stat. § 15C.02 provides civil liability for any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the state or a political subdivision a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes or 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 political subdivision;
>
> (3) knowingly conspires to either present a false or fraudulent claim to the state or a political subdivision for payment or approval or makes, uses, or causes to be made or used a false record or statement to obtain payment or approval of a false or fraudulent claim;...

380. In addition, the State of Minnesota prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Minnesota False Claims Act. Defendants violated Minn. Stat. § 15C.01, *et seq.* by engaging in the conduct described herein.

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

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

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

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

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

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

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

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

To the State of Minnesota:

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

To Relator:

(1) The maximum amount allowed pursuant to Minn. Stat. § 15C.01, *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XX
NEVADA FALSE CLAIMS ACT

388. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

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

390. Nev. Rev. Stat. § 357.040(1) provides liability for any person who-

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

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

392. Defendants violated Nev. Rev. Stat. § 357.040(1) and knowingly caused false claims to be made, used and presented to the State of Nevada by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

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

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

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

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

397. Relator is a private citizen with direct and independent knowledge of the allegations

of this Complaint, who has brought this action pursuant to Nev. Rev. Stat. § 357.080(1) on behalf of himself and the State of Nevada.

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

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

To the State of Nevada:

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

To Relator:

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

COUNT XXI
THE NEW HAMPSHIRE HEALTH CARE FALSE CLAIMS ACT

399. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

400. This is a *qui tam* action brought by Relator on behalf of the State of New Hampshire to recover treble damages and civil penalties under the New Hampshire Health Care False Claims

Law, N.H. Rev. Stat. Ann §167:61-b *et seq.*:

401. New Hampshire Health Care False Claims Law, N.H. Rev Stat. Ann §167:61-b *et seq.* provides:

402. Any person shall be liable who...

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

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

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

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

406. The State of New Hampshire, by and through the New Hampshire Medicaid program

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

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

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

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

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

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

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

To the State of New Hampshire:

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

To Relator:

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

COUNT XXII
NEW JERSEY FALSE CLAIMS ACT

412. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

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

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

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

415. In addition, Section 17 of P.L. 1968, c.413 (C.30:4D-17) of the New Jersey False

Claims Act prohibits the solicitation, offer or receipt of any remuneration, including any kickback, rebate or bribe in connection with the furnishing of items or services for which payment is or may be made in whole or in part under the New Jersey Medicaid program.

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

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

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

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

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

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

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

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

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

To the State of New Jersey:

(1) Three times the amount of actual damages which the State of New Jersey has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than and not more than the civil penalty allowed under the federal False Claims Act (31 U.S.C. s.3729 *et seq.*) which Defendants caused to be presented to the State of New Jersey;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.J. Stat. § 2A:32C-1 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXIII
NEW MEXICO MEDICAID FALSE CLAIMS ACT AND NEW MEXICO FRAUD AGAINST TAXPAYERS ACT

424. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184

above as if fully set forth herein.

425. This is a *qui tam* action brought by Relator on behalf of the State of New Mexico to recover treble damages and civil penalties under the New Mexico Medicaid False Claims Act N.M. Stat. Ann §§ 27-14-1 *et seq.*

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

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

427. It is also brought by Relator on behalf of the State of New Mexico to recover treble damages and civil penalties under the New Mexico Fraud Against Taxpayers Act N.M. Stat. Ann § 44-9-1 *et seq.*

428. New Mexico Fraud Against Taxpayers Act N.M. Stat. Ann § 44-9-1 *et seq*. provides: § 44-9-3(A) A person shall not:

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

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

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

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

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

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

434. Had the State of New Mexico known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party

payers in connection with that conduct.

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

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

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

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

To the State of New Mexico:

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

To Relator:

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

COUNT XXIV

NEW YORK FALSE CLAIMS ACT

438. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

439. This is a *qui tam* action brought by Relator on behalf of the State of New York to recover treble damages and civil penalties under the New York False Claims Act, 2007 N.Y. Laws 58, Section 39, Article XIII

440. Section 189 provides liability for any person who:

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

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

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

443. Defendants furthermore violated, 2007 N.Y. Laws 58, Section 39, Article XIII, and knowingly caused false claims to be made, used and presented to the State of New York by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and the New York Vendor Fraud and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement

by the government-funded healthcare programs.

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

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

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

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

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

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

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

To the State of New York:

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

To Relator:

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

COUNT XXV
NORTH CAROLINA FALSE CLAIMS ACT

450. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

451. This is a *qui tam* action brought by Relator on behalf of the State of North Carolina to recover treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. §§ 1-605 *et seq.*

452. N.C. Gen. Stat. § 1-607(a) provides liability for any person who:

(1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;
(2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
(3) Conspires to commit a violation of subdivision (1), (2), (4), (5), (6), or (7) of this section;

***

(7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State.

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

454. Defendants violated N.C. Gen. Stat. § 1-607(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of North Carolina by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act and the North Carolina False Claims Act N.C. Gen. Stat. § 1-605 *et seq*., and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

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

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

457. Had the State of North Carolina known that Defendants were violating the federal and state laws cited herein, and/or that the claims submitted in connection with Defendants' conduct

failed to meet the reimbursement criteria of the government-funded healthcare programs, or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

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

459. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.C. Gen. Stat. § 1-605(b) on behalf of himself and the State of North Carolina.

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

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

To the State of North Carolina:

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

To Relator:

(1) The maximum amount allowed pursuant to N.C. Gen. Stat. § 1-605 *et seq*. and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXVI
OKLAHOMA MEDICAID FALSE CLAIMS ACT

461. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

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

463. 63 Okl. St. § 5053.1 (2)(B) provides liability for any person who:

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

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

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

466. Defendants furthermore violated 63 Okl. St. § 5053.1 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Oklahoma by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and

the Oklahoma Medicaid Program Integrity Act and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

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

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

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

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

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

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

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

To the State of Oklahoma:

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

To Relator:

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

COUNT XXVII
RHODE ISLAND STATE FALSE CLAIMS ACT

473. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

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

475. R.I. Gen. Laws § 9-1.1-3 provides liability for any person who:

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

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

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

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

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

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

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

481. Had the State of Rhode Island known that false representations were made to both

the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

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

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

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

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

To the State of Rhode Island:

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

To Relator:

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

COUNT XXVIII
TENNESSEE FALSE CLAIMS ACT

485. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

486. This is a *qui tam* action brought by Relator on behalf of the State of Tennessee to recover treble damages and civil penalties under the Tennessee False Claims Act, Tenn. Code Ann. § 4-18-101 *et seq.* and Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*

487. § 4-18-103(a) provides liability for any person who-

> (1) Knowingly presents, or causes to be presented to an officer or employee of the state..., a false claim for payment or approval;
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
> (3) Conspires to defraud the state or any political subdivision by getting a claim allowed or paid by the state of by any political subdivision.
>
> § 71-5-182(a)(1) provides liability for any person who-
>
> (A) presents, or causes to be presented to the state, a claim for payment under the Medicaid program knowing such claim is false or fraudulent;
> (B) makes or uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;
> (C) conspires to defraud the State by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent.

488. Defendants violated Tenn. Code Ann. § 4-18-103(a) and § 71-5-1 82(a)(1) and knowingly caused false claims to be made, used and presented to the State of Tennessee by its deliberate and systematic violation of federal and state laws, including the FDCA and Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its

conduct were even eligible for reimbursement by the government-funded healthcare programs.

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

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

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

492. As a result of Defendants' violation of Tenn. Code Ann. § 4-18-103(a) and § 71-5-182(a)(1), the State of Tennessee has been damaged in an amount far in excess of millions of dollars exclusive of interest.

493. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tenn. Code Ann. § 4-18-103(a) and § 71-5-183(a)(1) on behalf of himself and the State of Tennessee.

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

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

To the State of Tennessee:

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

To Relator:

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

COUNT XXIX
TEXAS MEDICAID FRAUD PREVENTION LAW

495. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

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

497. Tex. Hum. Res. Code § 36.002 provides liability for any person who-

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

(2) knowingly or intentionally concealing or failing to disclose an event:

> (A) that the person knows affects the initial or continued right to a benefit or payment under the Medicaid program of.
>
> (I) the person, or
>
> (ii) another person on whose behalf the person has applied for a benefit or payment or is receiving a benefit or payment; and
>
> (B) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized;
>
> ***
>
> (4) knowingly or intentionally makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:
>
> (B) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;
>
> (5) ... knowingly or intentionally charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or continued service to a Medicaid recipient if the cost of the service provided to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program.

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

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

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

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

502. As a result of Defendants' violation of Tex. Hum. Res. Code § 36.002, the State of Texas has been damaged in an amount far in excess of millions of dollars exclusive of interest.

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

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

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

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

To the State of Texas:

(1) Two times the amount of actual damages which the State of Texas has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 or more than $15,000 pursuant to Tex. Hum. Res. Code § 36.025(a)(3) for each false claim which Defendants cause to be presented to the state of Texas;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Tex. Hum. Res. Code § 36.110, and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXX
WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT

506. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

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

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

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

> or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance Program;
>
> ***
>
> (g) knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, or decrease any obligation to pay or transmit money or property to the Medical Assistance Program.

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

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

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

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

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

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

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

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

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

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

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

To the State of Wisconsin:

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

To Relator:

(1) The maximum amount allowed pursuant to Wis. Stat. § 20.931 and/or any other applicable provision of law;

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

COUNT XXXI
MASSACHUSETTS FALSE CLAIMS ACT

518. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

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

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

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

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

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

523. Defendants furthermore violated Mass. Gen. Laws Chap. 12 § 5B and knowingly caused false claims to be made, used and presented to the Commonwealth of Massachusetts by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Mass. Gen. Law Chap. 118E § 41 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

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

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

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

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

dollars exclusive of interest.

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

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

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

To the Commonwealth of Massachusetts:

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

To Relator:

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

COUNT XXXII
VIRGINIA FRAUD AGAINST TAXPAYERS ACT

530. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

531. This is a *qui tam* action brought by Relator on behalf of the Commonwealth of

Virginia for treble damages and penalties under Virginia Fraud Against Taxpayers Act § § 01-216.1 *et seq.*

532. Va. Code Ann. § 8.01-216.3A provides liability for any person who:

> 1. Knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval;
> 2. Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth;
> 3. Conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid;

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

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

535. Defendants furthermore violated Va. Code Ann. § § 8.01-216.3a and knowingly caused false claims to be made, used and presented to the Commonwealth of Virginia by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, VA Code Ann § 32.1-315 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

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

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

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

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

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

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

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

To the Commonwealth of Virginia:

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

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the Commonwealth of Virginia;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Va. Code Ann. § 32.1-315 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXXIII
DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

542. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 184 above as if fully set forth herein.

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

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

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

545. In addition, D.C. Code § 4-802 (c) prohibits soliciting, accepting, or agreeing to

accept any type of remuneration for the following:

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

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

547. Defendants furthermore violated D.C. Code § 2-308.14(a) and knowingly caused thousands of false claims to be made, used and presented to the District of Columbia by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act D.C. Code § 4-802(c), and by virtue of the fact that none of the claims submitted in connection with its illegal conduct were even eligible for reimbursement by the government-funded healthcare programs.

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

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

550. Had the District of Columbia known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the

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

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

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

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

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

To the District of Columbia:

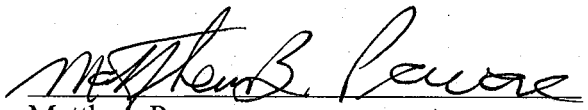
(1) Three times the amount of actual damages which the District of Columbia has sustained as a result of Defendants' illegal conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the District of Columbia;
(3) Prejudgment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

To Relator:

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

Dated: September 29, 2011.

NOLAN & AUERBACH, P.A.

By: 

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