UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA ex rel. LEE R.CHARTOCK, M.D., THE STATE OF CALIFORNIA ex rel. LEE R.CHARTOCK, M.D., THE STATE OF DELAWARE ex rel. LEE R.CHARTOCK, M.D., THE DISTRICT OF COLUMBIA ex rel. LEE R.CHARTOCK, M.D., THE STATE OF FLORIDA ex rel. LEE R.CHARTOCK, M.D., THE STATE OF GEORGIA, THE STATE OF HAWAII ex rel. LEE R.CHARTOCK, M.D., THE STATE OF ILLINOIS ex rel. LEE R.CHARTOCK, M.D., THE STATE OF INDIANA ex rel. LEE R.CHARTOCK, M.D.,THE STATE OF LOUISIANA ex rel. LEE R.CHARTOCK, M.D., THE COMMONWEALTH OF MASSACHUSETTS ex rel. LEE R.CHARTOCK, M.D., THE STATE OF MICHIGAN ex rel. LEE R.CHARTOCK, M.D., THE STATE OF NEVADA ex rel. LEE R.CHARTOCK, M.D., THE STATE OF NEW HAMPSHIRE ex rel. LEE R.CHARTOCK, M.D., THE STATE OF NEW MEXICO ex rel. LEE R.CHARTOCK, M.D., THE STATE OF NEW YORK ex rel. LEE R.CHARTOCK, M.D.,THE STATE OF TENNESSEE ex rel. LEE R.CHARTOCK, M.D., THE STATE OF TEXAS ex rel. LEE R.CHARTOCK, M.D., and THE COMMONWEALTH OF VIRGINIA ex rel. LEE R.CHARTOCK, M.D., Plaintiffs, v. ELAN CORPORATION, PLC, EISAI COMPANY, LTD., and EISAI, INC. Defendants.	**CIVIL ACTION NO.** **04 11594 RWZ** ***FILED IN CAMERA and UNDER SEAL***

RESTATED AND AMENDED COMPLAINT

COMES NOW, LEE R.CHARTOCK, M.D., Plaintiff in the above-styled action, by and through his counsel of record, and states that this is an action brought on behalf of the United

States of America by LEE R.CHARTOCK, M.D. (hereinafter referred to as "Relator") against ELAN CORPORATION, PLC ("ELAN"), EISAI COMPANY, LTD. ("EISAI CO.") and EISAI INC. ("EISAI INC.") (the "Defendants") pursuant to the *Qui Tam* provisions of the Federal Civil False Claims Act, 31 U.S.C. §§ 3729-33 ("Federal FCA" or "FCA"), and on behalf of the above named states under their respective State False Claims Acts ("State FCAs") (together referred to herein as "*Qui Tam* Action"). Pursuant to 31 U.S.C. § 3730 (b)(2), and comparable provisions in State FCAs, this action is brought in camera and under seal.

Allegations regarding the unlawful activities of ELAN are attributed to all three defendants, ELAN, EISAI CO. and EISAI INC. The claims against EISAI CO. and EISAI INC. are based upon successor liability as well as their own conduct after the acquisition of Zonegran.

The Defendants in this case have violated the Federal and State FCAs, the Federal Food, Drug, and Cosmetic Act and the Medicare-Medicaid Anti-Kickback Act by engaging in the unlawful "off-label" marketing scheme for Zonegran from at least 2003. Defendants' actions and omissions have caused physicians around the United States to prescribe and administer this drug to their patients for off-label purposes and thereafter such physicians and/or pharmacists illegally billed Federal Health Care Programs.

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action under the Federal FCA pursuant to 28 U.S.C. § 1331 and 1345, and 31 U.S.C. §§ 3732(a) and 3730, and has pendent jurisdiction over the State FCA claims pursuant to 28 U.S.C. sec. 1367.

2. Venue is appropriate as to the Defendants in that ELAN, EISIA CO. and EISAI INC. can be found in, reside in, and/or transact business in this judicial district. Additionally, acts proscribed by 31 U.S.C. § 3729 have been committed by the Defendants in this judicial district.

Therefore, within the meaning of 28 U.S.C. § 1391(b) and (c) and 31 U.S.C. § 3732(a), venue is proper.

3. To Relator's knowledge, jurisdiction over this action is not barred by 31 U.S.C. Section 3730(e): there is no civil suit or administrative proceeding involving the allegations and transactions herein to which the United States is a party; there has been no "public disclosure" of these allegations or transactions; and Relator is the "original source" of the information on which these allegations are based.

THE PARTIES

4. Plaintiff Dr. Chartock is a citizen of the United States of America. He brings this *Qui Tam* action based upon direct and unique information obtained during the period of his practice as a physician/psychiatrist. As characterized by the Federal False Claims Act, Plaintiff will be referred to as "Relator" hereafter. Dr. Chartock has provided this information and a "Relator's disclosure statement" to the United States and to the Plaintiff States with this Complaint.

5. Defendant Elan Corporation, PLC ("ELAN") is a publicly-traded neuroscience-based biotechnology company. ELAN focuses on the discovery, development, manufacturing and marketing of therapies in the areas of neurology, autoimmune diseases and severe pain. The corporation is headquartered in Dublin, Ireland with operations in the United States and several other countries. Its principal place of business in the United States is 7475 Lusk Boulevard, San Diego, California 92121. ELAN is traded on the New York Stock Exchange under the symbol "ELN." ELAN conducts business in the Commonwealth of Massachusetts and every state within the United States. Until approximately April 27, 2004 ELAN manufactured, marketed and sold the anti-seizure medication Zonegran, at which time ELAN transferred its rights to Zonegran in

the United States and Europe. ELAN continues to manufacture Zonegran in Athlone, Ireland. Zonegran is an anti-seizure drug first approved by the FDA as an adjunctive therapy to treat partial seizures in adults.

6. Defendant Eisai Company Ltd., ("EISAI CO.") is a Japanese corporation with headquarters at 4-6-10 Koishikawa, Bunkyo-ku, Tokyo 112-8088, Japan. EISAI CO. manufactures and markets pharmaceutical drugs, over-the-counter drugs and Pharmaceuticals Production Systems and Equipment. Shares in EISAI CO. are traded on the Tokyo Stock Exchange. EISAI CO. conducts business in the Commonwealth of Massachusetts and every state within the United States. In or around April 27, 2004, EISAI CO. and EISAI INC. acquired ELAN's North American and European interests in Zonegran. The acquisition covered related assets, liabilities and the sales force of approximately 115 employees.

7. EISAI INC. ("EISAI INC.") is a United States subsidiary of EISAI CO., with headquarters at Glenpointe Centre West, 500 Frank W. Burr Boulevard, Teaneck, New Jersey 07666. EISAI INC. conducts business in the Commonwealth of Massachusetts and every state within the United States. In or around April 27, 2004, EISAI CO. and EISAI INC. acquired ELAN's North American and European interests in Zonegran. The acquisition covered related assets, liabilities and the sales force of approximately 115 employees

FEDERAL AND STATE LAWS

8. The Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §1395 et seq., (hereinafter "Medicare") is a Health Insurance Program administered by the Government of the United States that is funded by taxpayer revenue. The program is overseen by the United States Department of Health and Human Services. Medicare is a health insurance program that provides for the payment of prescription drugs, hospital services, medical services and durable

medical equipment to persons over sixty-five (65) years of age and others that qualify under the terms and conditions of the Medicare Program.

9. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. secs. 1396-1396v (hereafter "Medicaid"), is a Health Insurance Program administered by the Government of the United States and the various individual States and is funded by State and Federal taxpayer revenue. The Medicaid Program is overseen by the United States Department of Health and Human Services. Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to financially needy individuals that qualify for Medicaid.

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

11. The federal government, through its Departments of Defense and Veterans Affairs, Bureau of Prisons, Native and American Indian Health Services, and Public Health Service maintains and operates medical facilities including hospitals, and receives and uses federal funds to purchase prescription drugs for patients treated at such facilities and otherwise.

12. The Federal Employees Health Benefits Program ("FEHBP") provides health care benefits for qualified federal employees and their dependents. It pays for, among other items and services, prescription drugs for its beneficiaries. (Together these programs described in

paragraphs 8-12 shall be referred to as "Federal Health Care Programs" or "Government Health Care Programs").

13. The Federal Food, Drug and Cosmetic Act ("FFDCA") prohibit the distribution of new pharmaceutical drugs in interstate commerce unless the Food and Drug Administration ("FDA") has determined that the drug is safe and effective for its intended use. 21 U.S.C. § 355 (a) and (d). An approved drug may be prescribed by doctors for uses other than those approved by the FDA, though manufacturers are prohibited from marketing or promoting the drug for such unapproved or "off label" uses. 21 U.S.C. § 331 (d). If the manufacturer intends to promote the drug for a new unapproved use, the drug must be resubmitted to the FDA for testing and approval (or obtain an exemption therefrom) and the promotional materials must meet certain statutory requirements. 21 U.S.C. § 360 aaa, *et seq*.

14. Whether a drug is FDA-approved for a particular use will determine whether a prescription of the drug is reimbursed under the Medicaid. 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 includes a use "which is approved under the Federal Food Drug and Cosmetic Act" or which is included in a specified drug compendia. Id. §1396r-8(k)(6). Thus, unless a particular off-label use for a drug is included in one of the identified drug compendia, a prescription for the off-label use of that drug is not eligible for reimbursement under Medicaid. There is a single exception: in certain circumstances Medicaid will reimburse the prescription of certain single-source or multi-source innovator drugs for an "off label" use where the individual State has determined, inter alia, that the drug is essential to the health of beneficiaries. 42 U.S.C. §1396r8(a)(3).

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

> (1)(A) in the case of a drug, there is in effect for the drug an application filed under subsection (b) or (j) or section 355 of this title or a biologics license issued under section 262 of Title 42:
>
> (2) the information meets the requirements of section 360aaa-1 of this title;
>
> (3) the information to be disseminated is not derived from clinical research conducted by another manufacturer or if it were derived from research conducted by another manufacturer, the manufacturer disseminating the information has the permission of such other manufacturer to make the dissemination;
>
> (4) the manufacturer has, 60 days before such dissemination, submitted to the Secretary-
> (A) a copy of the information to be disseminated; and
> (B) any clinical trial information the manufacturer has relating to the safety or effectiveness of the new use, any reports of clinical experience pertinent to the safety of the new use, and a summary of such information;
>
> (5) the manufacturer has complied with the requirements of section 360aaa-3 of this title (relating to a supplemental application for such use);
>
> (6) the manufacturer includes along with the information to be disseminated under this subsection –
> (A) a prominently displayed statement that discloses –
> (i) that the information concerns a use of a drug or device that has not been approved or cleared by the Food and Drug Administration;
> (ii) if applicable, that the information is being disseminated at the expense of the manufacturer;
> (iii) if applicable, the name of any authors of the information who are employees of, consultants to, or have received compensation from, the manufacturer, or who have a significant financial interest in the manufacturer;
> (iv) the official labeling for the drug or device and all updates with respect to the labeling;
> (v) if applicable, a statement that there are products or treatments that have been approved or cleared for the use that is the subject of the information being disseminated pursuant to

subsection (a)(1) of this section; and
(vi) the identification of any person that has provided funding for the conduct of a study relating to the new use of a drug or devise for which such information is being disseminated; and
(B) a bibliography of other articles from a scientific reference publication or scientific or medical journal that have been previously published about the use of the drug or device covered by the information disseminated (unless the information already includes such bibliography).

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

> (a) Authorized information – A manufacturer may disseminate information under section 360aaa of this title on a new use only if the information –
>
> (1) is in the form of an unabridged –
>
> (A) reprint or copy of an article, peer-reviewed by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device involved, which were published in a scientific or medical journal (as defined in section 360aaa-5(5) of this title), which is about a clinical investigation with respect to the drug or device, and which would be considered to be scientifically sound by such experts; or
> (B) reference publication, described in subsection (b) of this section that includes information about a clinical investigation with respect to the drug or device that would be considered to be scientifically sound by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device that is the subject of such a clinical investigation ….

17. The Federal FCA, 31 U.S.C. § 3729(a)(1) makes "knowingly" presenting or causing to be presented to the United States any false or fraudulent claim for payment, a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between $5,000 and $10,000 per claim ($5,500 and $11,000 for claims made on or after September 29, 1999).

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

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

20. The Federal FCA, 31 U.S.C. § 3729(a)(7) makes it illegal for any person to "knowingly" make, use or cause 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 Government, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,000 and $10,000 per claim ($5,500 and $11,000 for claims made on or after September 29, 1999).

21. The Federal FCA defines a "claim" to include any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested.

22. The Medicare, Medicaid and Anti-Kickback Act ("AKA") 42 U.S.C. §1320a-7b (b), makes it illegal to offer, receive, or solicit any remuneration, kickback, bribe, or rebate, whether directly or indirectly, overtly or covertly, in cash or in kind, to or from any person in order to induce such person to purchase, lease, or order, or to arrange for or recommend the purchasing, leasing, or ordering of any good, service, or item for which payment may be made in whole or in part under a Federal Health Care Program. The AKA seeks to prohibit such activities in order to secure proper medical treatment and referrals, and to limit the possibility of a patient having to undergo unnecessary treatments or having to accept specific items or services which are based not on the needs of the patient, but on the incentives given to others, thereby limiting the patient's right to choose proper medical care and services. Many States have similar laws pertaining to the Medicaid program.

23. As set forth below, several states have passed False Claims Act legislation, which in most instances closely tracks the Federal FCA: California False Claims Act, Cal. Gov't Code § 12650 *et seq.*, Delaware False Claims and Reporting Act, Del. Code Ann. Tit. 6, § 1201 *et seq.*, District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.13 *et seq.*, Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*, Georgia False Medicaid Claims Act, 49 Ga. Code Ann. Chapter 4 at 49-4-168, *et seq*., Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*, Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1 *et seq.*, Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5, Louisiana Medical Assistance Programs Integrity Law, 46 La. Rev. Stat. c. 3, sec. 437.1 *et seq*., Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5A *et seq.*, Michigan Medicaid False Claims Act, MI ST Ch. 400, Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq.*, New Hampshire False Claims Act, N.H. RSA §§ 167:61-b, *et seq*., New Mexico Medicaid False Claims Act, 2004

New Mexico Laws Ch. 49 (H.B. 468), New York False Claims Act 2007, New York Laws 58, section 39, article 13, section 189 *et seq*., Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*, Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.001 *et seq.*, and Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.* These State False Claims Acts apply to the state portion of Medicaid fraud losses caused by false Medicaid claims to the jointly federal-state funded Medicaid program. Each of the statutes listed above contains *qui tam* provisions governing, *inter alia*, a relator's right to claim a share of the State's recovery.

FACTS AND ALLEGATIONS

24. From approximately April 2000-April 2004, ELAN manufactured, marketed and sold a drug with a trademark name of Zonegran under license from Dainippon, a Japanese corporation. Zonegran, whose chemical name is Zonisamide, is an anti-seizure drug first approved by the Food and Drug Administration on March 27, 2000. According to the FDA approved labeling Patient Information Leaflet[1], "Zonegran is a medicine to treat partial seizures in adults. It is taken with other seizures medicines to help control your seizures."

25. In 2001 Zonegran generated $37.8 million in sales. In 2002 sales increased to $43.1 million. In 2003 sales topped $80 million, an increase of 87%. On information and belief, this increase was due in large part to the illegal incentives provided to physicians in order to induce prescriptions of Zonegran as well as ELAN's unlawful marketing activities. For the first four months or so of 2004, before Zonegran was sold to EISAI, ELAN's revenues from Zonegran were about $41.2 million. Extrapolated over a twelve month period, ELAN was on track to sell about $99 million in 2004, another significant increase. However, in about April-May 2004,

1 NDA 20-789; Zonegran (Zonisamide) Capsules 100mg. FDA Approved labeling Text dated 3/27/00 (the "Approved Label").

EISAI began to market Zonegran in the United States. By the end of March 2005 (the end of EISAI's fiscal year), sales reached about $100 million; in the following twelve month period ended March 31, 2006, sales grew another 13% to $113 million in the United States, even though Zonegran lost its patent protection in December 2005 and was subject to competition from generics. Most recently, for the fiscal year ended March 31, 2007, Zonegran sales fell to about $27 million, less than in 2001 (its first full year on the market). In sum, ELAN sales of Zonegran in the United States totaled over $200 million (not counting its first part year on the market in 2000) while EISAI's sales to date total over $230 million.

Dr. Lee Chartock founder of Great Care Associates

26. Relator, Dr. Lee Chartock is a psychiatrist who, in 1996, founded Great Care Associates a psychiatric practice based in South Weymouth, Massachusetts. Relator specialized in the care of treatment-resistant patients, 95% of whom were on medication. Due largely to the profile of his patient base and intense work schedule, Relator was a high-volume prescription writer and, on information and belief, in the top 2% of the Commonwealth of Massachusetts for the prescription of psychotropic medications.

27. Tough clinical challenges combined with a personal willingness to try new treatments gave Relator the reputation of a "thought leader" in his field. Accordingly, Relator became a sales target for the pharmaceutical companies because, although he never conducted clinical trials, he was willing to share his clinical experience in the progressive use of new drugs with other doctors and pharmaceutical sales representatives.

Great Care Associates

28. The patient profile of Great Care Associates was such that there was an extremely small on-label requirement for Zonegran, in its approved use as an anti-seizure drug. Where

Relator suspected the condition in one of his patients, he would typically refer that patient to a more appropriate specialist. Relator estimates that less than 1% of his patients would be appropriate candidates for the label use of Zonegran.

29. However, a number of Relator's patients had asked about the drug specifically because it was rumored that it was also effective, off-label, as a mood stabilizer and weight loss agent. Relator was willing to investigate off-label uses, both as a forward-thinking professional and in order to identify new psychotropic agents for his school of treatment-resistant cases. Relator believed that if Zonegran was both a mood stabilizer and caused weight loss, it might be an effective drug for patients who had abandoned their treatment because of the weight gain associated with most psychotropic medicines.

Relator's First Contact with Elan

30. In or about January 2003, an Elan sales representative, Stacy Garson, "cold called" the Relator and arranged to pay a visit to his place of work. On or around January 30, 2003, Ms. Garson and the Relator met and discussed Zonegran. At that first meeting, the sales representative told Relator that Elan had organized a seminar in Florida and would like to send him, at the company's expense.

31. Stacy Garson explained that before she could ensure that Relator was eligible, he would have to begin writing prescriptions for Zonegran. Relator explained that, with his patients, there would be almost no clinical need for a drug to treat temporal lobe epilepsy in adults. During this initial discussion, Ms. Garson began to advocate Zonegran for its off-label use in weight loss and mood stabilization explaining that she understood Relator's position in the field and his willingness to pioneer unapproved uses. Ms. Garson also provided Relator with printed articles highlighting Zonegran's efficacy in weight loss. Some of these articles were peer

reviewed, others were not, or otherwise failed to comply with the legal requirements of 21 U.S.C. 360 aaa.

32. Relator was interested in learning more about Zonegran and, at the suggestion of Ms. Garson, called a Dr. Tosches, a prescriber of the drug. This call took place on March 13, 2003. Relator engaged in a question-and-answer session with Dr. Tosches regarding the safety and efficacy of Zonegran and his clinical experience of the drug. Relator was encouraged by what he learned. Subsequently, Relator started between ten and fifteen patients on Zonegran, principally as a supplementary or "adjunctive" therapy. In the short term, the only observable effect of the drug was that patients lost between 4 to 8 pounds in weight in the same number of weeks.

The Zonegran conference, Boca Raton, Florida

33. Relator agreed to attend one of the Zonegran conferences, or "advisory meetings," and requested a seat at a California conference. Relator was told that this would not be possible and instead he accepted a place at the conference in Boca Raton, Florida as first suggested. This conference took place between May 30, 2003 and June 1, 2003.

34. The conference was ostensibly an educational update about the use of Zonegran, but was described in the promotional material as an "Advisory Meeting" at which the invitees were to provide the "advice" and receive a sum of either $750 or $1250 for their time. In addition ELAN paid for airfare and hotel accommodation. However, the conference agenda followed the traditional model of educational seminars: a series of slide lectures followed by group discussion or "workshops." Relator attended the conference for his own education and was not solicited for his opinion or advice about Zonegran despite his putative status as "advisor." In any event, Relator would have been unable to provide any significant insight into

the clinical effectiveness of the drug due to his relative inexperience with it.

35. Sixty doctors attended from around the United States. The faculty comprised five members: Doctors W. Donald Shields and Kevan VanLandingham presented general material on the approved use of Zonegran; Doctors Charles Argoff, Claudia Baldassano and Bob Post presented material on off-label uses of the drug.

36. On behalf of ELAN the following individuals attended: Steve Jenner, Product Manager, Neurology; Steve P. James, M.D., Senior Director Medical Affairs; Kathleen R. Wessels, R.N., Senior Medical Science Liaison, Medical Affairs; Kevin Pecot, Direct Sales Manager; and Mike Tasos, Direct Sales Manager.

Dr. Baldassano on Zonegran for Mood Stabilization and Mania

37. Dr. Baldassano, a specialist in the area of bipolar disorder and Director of the Bipolar Disorder Clinic at the University of Pennsylvania, Philadelphia, Pennsylvania, discussed the off-label use of Zonegran for mood stabilization and the treatment of mania.
Dr. Baldassano's thesis on "Adjunctive Zonisamide as Acute Treatment for Bipolar Disorder Outpatients" was based on her own work presented as a "Poster" six months earlier at the Annual Meeting of the American Epilepsy Society.

38. While conceding that "Controlled trials are warranted to further investigate the use of ZNS [Zonegran] in bipolar disorder", the lecturer concluded that, "ZNS may be an effective and well-tolerated adjunctive treatment for refractory bipolar patients." The underlying study was based on only twelve patients, five of whom reported adverse events. This material, including these conclusions, was disseminated to all of the attendees of the Florida conference, but was not in conformity with the regulations for the dissemination of "authorized information" under 21 USC § 360 aaa-1.

Dr. Post on Zonisamide and Binge Eating Disorder Bulimia Nervosa

39. Dr. Post discussed the off-label use of Zonegran for the treatment of Binge Eating Disorder, Bulimia and Weight Loss. His presentation on "Zonisamide and Binge Eating Disorder" and "Zonisamide and Bulimia Nervosa" were attributed to the unpublished data of Susan L. McElroy, M.D.

40. The Binge Eating study, based on eight subjects, concluded that "Placebo-controlled studies are warranted to confirm these findings", the findings being that "Zonisamide can be useful in treating patients with binge eating disorder."

41. The "Zonisamide and Bulimia Nervosa" data was based on only two patients who had completed the study. Again, conceding that "Double-blind studies [are] warranted to investigate Zonisamide for the treatment of bulimia nervosa", the study concluded "Zonisamide appears to be useful for reducing frequency of binge episodes in patients with bulimia nervosa." This material and these conclusions, which were disseminated to all of the attendees of the Florida conference, were not peer-reviewed, and advocate the off-label use of Zonegran for patients with bulimia nervosa and binge eating disorders contrary to 21 USC § 360 aaa-1.

Dr. Argoff on Zonegran for Headache and Neuropathic Pain

42. Dr. Argoff, a pain management specialist and Director of the Cohn Pain Management Center, North Shore University Hospital, Manhasset, New York, discussed the off-label use of Zonegran for headache and neuropathic pain**.**

43. Dr. Argoff's topics: "Zonegran: Neuropathic Pain"; "Retrospective Case Series of Zonisamide in the treatment of Neuropathic Pain"; "Zonisamide for Complex Regional Pain Syndrome"; "Efficacy of Zonisamide the Treatment of Neuropathic Pain"; and "Zonisamide in the Treatment of Chronic Pain", all concluded with a positive endorsement of Zonegran as a pain

treatment and each time noted the need for further controlled studies. This material, including these conclusions, was disseminated to all of the attendees of the Florida conference, but was not in conformity with the regulations or the dissemination of "authorized information" under 21 USC § 360 aaa-1.

Dr. Shields on Safety Issues

44. Dr. Shields spoke on the "Safety Profile of Zonisamide." The presentation purported to be based on "900,000+ unique patients (1.9+ million patient-years of experience). In fact, the data presented was actually from "three multicenter, placebo-controlled, double blind, three-month clinical trials (two domestic and one European) in 499 patients" (the "Multicenter Study") from which the Zonegran Approved Labeling was derived. In context, the slide presentation made it appear that the side effects of use of Zonegran were based upon a larger sample size than they in fact were. In addition, Dr. Shields concluded his slide presentation with specific representations of incidences of weight loss side effects among Zonegran users. These representations used figures not found in the data from the FDA-approved label. This disparate treatment of weight loss data gave the impression that weight loss occurred in nearly 30% of users of Zonegran; that it was more common than the six "common side effects." In addition to the six common side effects, the FDA label lists eighteen other side effects that occur as frequently as or more frequently than weight loss. The FDA-approved label lists weight loss incidence of only 3% on Zonegran compared with 2% on placebo.

Dr. Shields on the Pediatric Use of Zonegran

45. Dr. Shields made a presentation entitled "Zonegran: Pediatric Update." The talk covered the treatment of epilepsy and infantile spasms in children and babies. In the course of his lecture, Dr. Shields discussed a study by Angus A. Wilfong and Timothy E. Lotze on the

treatment of infantile spasms (the "Wilfong Study").[2] In this study the average patient age was just twelve months. Dr Shields asserted that "33% of patients experienced complete and persistent seizure cessation." In fact, according to the original text, only "Six patients (26%) had complete control with cessation of spasms and clearing of hypsarrhythmia [abnormal ECG]."

46. In concluding his presentation on infantile spasms ("IS"), Dr. Shields continued to give a false impression of the efficacy of Zonegran in pediatric patients: "Two published papers on studies conducted in Japan in newly diagnosed IS: 33% had cessation of seizures with ZNS [Zonisamide]."[3] Dr. Shields wrongly summarized the rate of success in the Suzuki Study of eleven patients in stating that: "four had cessation of spasms and disappearance of the hypsarrhythmia." In fact the Suzuki Study makes it clear that two of the four "successes" relapsed less than six weeks later. Contrary to Dr. Shields unqualified success rate of 33%, less than 20% of patients achieved a cessation of spasms.

47. In the Yanai study Dr. Shields was equally cavalier: "Nine out of the twenty seven patients who were administered ZNS exhibited the disappearance of seizures." Again the original study notes that "The recurrence of seizures were observed in four of the nine cases." Dr. Shields did not qualify his 33% success rate in any way even though, again, success was only achieved with 22% of the control group.

48. The remainder of the doctor's slide presentation was equally lacking in substance, Dr. Shields continued his "pediatric update" on the basis of a previous study by A.A. Wilfong in 2001, a study by Oguni H *et al*. published fifteen years previously, "reports" (without citation) by Kyllerman and Ben-Menachem from 1998 and a "Poster" authored by DG Vossler and presented

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[2] "Zonisamide treatment for symptomatic infantile spasms" by Timothy E. Lotze, MD and Angus A. Wilfong, MD, NEUROLOGY 2004;62:296-298.

[3] The two studies in question were the "Suzuki Study" ("Zonisamide monotherapy in newly diagnosed infantile spasms" Epilepsia, Suzuki Y, Nagai T, Ono J, et al. 1997;38:1035-1038) and the "Yanai Study" ("Treatment of infantile spasms with zonisamide" Yanai S, Hanai T, Narazaki O, Brain Dev 1999; 21:157-161").

at the Zonegran "exhibit" at the AGM of the American Epilepsy Society six months previously.

49. Zonegran is not approved for the treatment of children and the FDA approved label carries a specific warning regarding the incidence of oligohydrosis (failure to perspire) and hyperthermia. Neither of these known risks appear among the slides in the "pediatric update." Instead Dr. Shields gave a false impression of the drug's safety. In the slide "*What we learned from the Japanese experience*" the speaker misleadingly asserted "Most Importantly – 900,000+ patients or 1.9+ million patient-years of exposure characterize safety profile." This misleads in numerous regards: as detailed in paragraph 44above; the statistical reference is inaccurate. The patient years measured are presumably those of adults, not children; and it also suggests that the drug is safe for children, contrary to the FDA warning that the drug is proven neither safe nor effective in children.

50. The only study referred to which might be regarded as recent was the Wilfong study submitted in 2003 but not published at that time. Dr. Shields incorrectly referred to twenty four patients in that study, whereas there were twenty three. It is also apparent from the text of the Wilfong Study, but not from Dr. Shields' slideshow, that Dr. Wilfong is on the Speakers' Bureau for Elan Pharmaceuticals Inc. Other cited studies were between five to fifteen years old at the time of presentation and would have been well know to an "advisory" group. In reality this "update" was a thinly-disguised means of promoting Zonegran as both safe and effective for pediatric patients whereas the FDA regards it as neither.

ELAN's Representation of Impending FDA Approval for Off Label Uses

51. At the 2003 Boca Raton conference, Relator was informed by an Elan representative, or employee, that Zonegran was going to be FDA approved for mood stabilization and an application would be filed for weight loss therapy. This prediction was stated as a fact.

In fact, even today the FDA has not approved Zonegran for either weight loss or mood stabilization.

Post Conference contact with Elan

52. Relator received frequent visits from Stacey Garson after the Florida Conference. She called approximately twice a month and was, on occasion, accompanied by her supervisor. On these occasions Ms. Garson would bring lunch for the office staff. Relator felt that the pressure to prescribe had increased after the Florida conference. Notwithstanding increased sales pressure, Relator was impressed with Zonegran and gradually increased his prescription level, until approximately 40 patients were receiving Zonegran, 70 – 80 % as an adjunctive therapy. Most patients were encouraged by the mild weight loss associated with the drug and, in the absence of side effects, helped them to adhere to their medical regime with this particular drug.

53. Ms. Garson offered to engage Relator to speak on behalf of the company about his clinical experience with Zonegran. Relator did not accept this invitation.

Unlawful Conduct

54. The information disseminated by ELAN at the Florida conference did not provide a prominently displayed statement, pursuant to 21 U.S.C. §360 aaa, that disclosed, *inter alia*: that the information concerned use that had not been approved by the FDA; that the information was being disseminated at the expense of the manufacturer; that there are other dugs which have been approved for weight loss, headache, pediatric care and mood stabilization; nor was there a bibliography of published, scientific articles addressing the off-label uses of Zonegran discussed at the conference. Moreover, there was no disclosure regarding the financial relationship between the authors and ELAN.

55. By distributing such information on off-label use, and promoting the benefits of

Zonegran for conditions such as, but not limited to, the treatment of mood stabilization, headache, pediatric care and weight loss, ELAN violated the FFDCA. Based in part on this unapproved literature, physicians across the United States have prescribed Zonegran for Medicaid and other Government Health Care Program patients whom they have treated for mood instability, headache, pediatric care and weight loss among other off label uses. These practices resulted in the submission of false and fraudulent claims for reimbursement of the cost of the drug. On information and belief, Zonegran is not a drug for which any State has determined that the drug is essential to the health and welfare of the beneficiaries that Medicaid will reimburse off label prescriptions and thus an exception within 42 USC § 1396r 8(a)(3). Defendants failed to disclose these violations of the Federal Food, Drug, and Cosmetic Act and, as a result, claims related to Zonegran filed with the Government Health Care Programs have contained material omissions and defects. Defendants have thus caused false and fraudulent claims to be filed against the Government Health Care Programs, including the jointly funded Medicaid program.

56. Relator has served a detailed Disclosure Statement upon the United States and the State parties to this action. The Disclosure Statement provides additional details concerning the Defendants' conduct and Relator's basis of knowledge.

SPECIFIC ACTS OF FEDERAL HEALTH CARE PROGRAM FRAUD

COUNT ONE

VIOLATIONS OF THE FEDERAL FCA: 31 U.S.C. sec. 3729(a)(1), (2), and (7)

57. Relator restates and realleges the allegations contained in Paragraphs 1-56 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

58. The Defendants knowingly presented or caused to be presented false or fraudulent claims to Federal Health Care Programs and knowingly made, used or caused to be made or used, false statements to get said claims paid by Federal Health Care Programs. Zonegran prescriptions for the purposes of weight loss, headache and/or mood stabilization would not have been presented but for the illegal incentives and unlawful promotional activities made by Defendants. As a result of this illegal scheme, these claims were improper in whole pursuant to 31 U.S.C. § 3729(a)(1)-(2).

59. These claims were also false or fraudulent and the statements and records were false because they were monetarily excessive, in violation of 31 U.S.C. sec. 3729(a)(1)-(2). Zonegran prescriptions for the purposes of weight loss, headache and/or mood stabilization cost more than comparative drugs with the same or superior efficacy.

60. In particular, these claims were also false or fraudulent and statements and records were false because the cost of Zonegran was inflated due to the Defendants having to cover their illegal expenditures and unlawful promotional activities, thereby inflating the cost of the product.

61. It is illegal to pass the costs of illegal kickbacks and unlawful promotional activities back to any Federal Health Care Program and it is also illegal to falsely report the true

cost of a drug. In addition to violating 31 U.S.C. sec. 3729(a)(1)-(2), Defendants' conduct violated 31 U.S.C. sec. 3729(a)(7).

COUNT TWO

CONSPIRACY TO DEFRAUD: FEDERAL FCA, 31 U.S.C. sec. 3729(a)(3)

62. Relator restates and realleges the allegations contained in Paragraphs 1-61 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

63. Defendants knowingly conspired to defraud the United States causing increased sales of Zonegran through unlawful promotion in violation of law. Defendants conspired to violate the AKA by unlawfully offering incentives to physicians that were in a position of authority to cause other physicians to prescribe Zonegran. Said actions constitute violations of 31 U.S.C. § 3729(a)(3).

64. Defendants knowingly conspired to violate the FCA by causing false or fraudulent claims to be presented and to make or use false statements which damaged the Federal Health Care Programs. Said claims were improper and should not have been made but for the unlawful promotional activities and unlawful incentives which caused the prescriptions of Zonegran to be made. Said claims were also monetarily excessive in cost due to the illegal kickbacks and unlawful promotional activities of the Defendants. Said actions constitute violations of 31 U.S.C. § 3729(a)(3).

65. The Defendants knowingly conspired to conceal their actions and they failed to alert the state or federal governments of their unlawful promotion of Zonegran. It is illegal to pass the costs incurred in paying illegal kickbacks and unlawful promotional activities back to

any Federal Health Care Program and it is also illegal to falsely report the true cost of a drug. Said actions constitute violations of 31 U.S.C. § 3729(a)(3).

COUNT THREE

VIOLATIONS OF THE ANTI-KICKBACK ACT ("AKA")

66. Relator restates and realleges the allegations contained in Paragraphs 1-65 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

67. The Defendants have offered and paid unlawful incentives or kickbacks in violation of the AKA. In order to sell its drugs, Defendants authorized their employees and agents to offer and award unlawful incentives. These expenditures were made to doctors to influence the doctors to write prescriptions for Zonegran.

68. The goal of the AKA in these circumstances is to prevent the prescription of a drug based not on whether or not it is necessary and appropriate, but on whether it is financially beneficial to the doctor prescribing the drug. Because of the Defendants' illegal actions, Zonegran has in fact been prescribed in violation of the AKA and the FCA.

COUNT FOUR

VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov't Code § 12651(a)(1)

69. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

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

(1) Knowingly presents or causes to be presented to an officer or employee of the state . . a false claim for payment or approval.

71. Defendants knowingly presented or caused to be presented to the California Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Cal. Gov't Code § 12651(a)(1).

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

COUNT FIVE

VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov't Code § 12651(a)(2)

73. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

(a) Any person who commits any of the following acts shall be liable to the state . . . for

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

(2) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state . . . .

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

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

COUNT SIX

VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov't Code § 12651(a)(3)

77. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

(a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state .

. . for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:

(3) Conspires to defraud the state . . . by getting a false claim allowed or paid by the state . .

79. Defendants conspired to defraud the State of California by getting false and fraudulent claims allowed and paid, in violation of Cal. Gov't Code § 12651(a)(3).

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

COUNT SEVEN

VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov't Code § 12651(a)(7)

81. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

82. The California False Claims Act, Cal. Gov't Code § 12651(a)(7), specifically provides:

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

(7) Knowingly makes, uses, or causes 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 state . . . .

83. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the correct rebate amounts to Medicaid, in violation of Cal. Gov't Code § 12651(a)(7).

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

COUNT EIGHT

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT Del. Code Ann. tit. 6, § 1201(a)(1)

85. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

(a)(1) Knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval;

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

87. Defendants knowingly presented or caused to be presented, directly and indirectly, to the Delaware Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Del. Code Ann. tit. 6, § 1201(a)(1).

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

COUNT NINE

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT Del. Code Ann. tit. 6, § 1201(a)(2)

89. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

> (a)(2) Knowingly makes, uses or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved;
>
> shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

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

92. The State of Delaware paid said claims and has sustained damages, to the extent

of its portion of Medicaid losses from Medicaid claims filed in Delaware, because of these acts by the Defendants.

COUNT TEN

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT Del. Code Ann. tit. 6, § 1201(a)(3)

93. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

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

95. Defendants conspired to defraud the State of Delaware by getting false and fraudulent claims allowed and paid, in violation of Del. Code Ann. tit. 6, § 1201(a)(3).

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

COUNT ELEVEN

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT
Del. Code Ann. tit. 6, § 1201(a)(7)

97. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

98. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(7), specifically provides, in part, that any person who:

> (a)(7) Knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, increase, or decrease an obligation to pay or transmit money to or from the government; shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

99. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the correct rebate amounts to Medicaid, in violation of Del. Code Ann. tit. 6, § 1201(a)(7).

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

COUNT TWELVE

VIOLATIONS OF THE DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT D.C. Code § 2-308.14(a)(1)

101. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

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

103. Defendants knowingly caused to be presented to the District of Columbia Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of D.C. Code § 2-308.14(a)(1).

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

COUNT THIRTEEN

VIOLATIONS OF THE DISTRICT OF THE COLUMBIA PROCUREMENT REFORM AMENDMENT ACT D.C. Code § 2-308.14(a)(2)

105. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the District;

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

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

COUNT FOURTEEN

VIOLATIONS OF THE DISTRICT OF THE COLUMBIA PROCUREMENT REFORM AMENDMENT ACT D.C. Code § 2-308.14(a)(3)

109. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

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

111. Defendants conspired to defraud the District of Columbia by getting false and fraudulent claims allowed and paid, in violation of D.C. Code § 2-308.14(a)(3).

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

COUNT FIFTEEN

VIOLATIONS OF THE DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT D.C. Code § 2-308.14(a)(7)

113. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:
>
> (7) Knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, increase, or decrease an obligation to pay or transmit money to or from the government;

115. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the correct rebate amounts to Medicaid, in violation of D.C. Code § 2-308.14(a)(7).

116. The District of Columbia paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in the District of Columbia,

because of these acts by the Defendants.

COUNT SIXTEEN

VIOLATIONS OF THE FLORIDA FCA
Fla. Stat. § 68.082(2)(a)

117. Relator restates and realleges the allegations contained in Paragraphs 1- 68 above as if each were stated herein in their entirety and said allegations are incorporated by reference.

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

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

119. Defendants knowingly presented or caused to be presented to the Florida Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Fla. Stat. § 68.082(2)(a).

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

COUNT SEVENTEEN

VIOLATIONS OF THE FLORIDA FCA
Fla. Stat. § 60.082(2)(b)

121. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

> (b) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by an agency; …
>
> is liable to the state for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

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

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

COUNT EIGHTEEN

VIOLATIONS OF THE FLORIDA FCA
Fla. Stat. § 68.082(2)(c)

125. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

> (c) Conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid;. . .is liable to the state for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of

damages the agency sustains because of the act or omission of that person.

127. Defendants conspired to submit a false claim to Government Health Care Programs and to deceive Federal/Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of Fla. Stat. § 680.82(2)(c).

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

COUNT NINETEEN

VIOLATIONS OF THE FLORIDA FCA
Fla. Stat. § 68.082(2)(g)

130. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

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

132. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the correct rebate amounts to Medicaid, in violation of Fla. Stat. § 680.82(2)(g).

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

COUNT TWENTY

VIOLATIONS OF THE HAWAII FCA
Haw. Rev. Stat. § 661-21(a)(1)

134. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

135. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(1), specifically provides, in part, that any person who:

> (1) Knowingly presents, or causes to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval;
>
> . . .
>
> shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the State sustains due to the act of that person.

136. Defendants knowingly presented or caused to be presented to the Hawaii Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Haw. Rev. Stat. § 661-21(a)(1).

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

COUNT TWENTY-ONE

VIOLATIONS OF THE HAWAII FCA
Haw. Rev. Stat. § 661-21(a)(2)

138. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

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

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

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

COUNT TWENTY-TWO

VIOLATIONS OF THE HAWAII FCA
Haw. Rev. Stat. § 661-21(a)(3)

142. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

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

144. Defendants conspired to defraud the State of Hawaii by getting false and fraudulent claims allowed and paid, in violation of Haw. Rev. Stat. § 661-21(a)(3).

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

COUNT TWENTY-THREE

VIOLATIONS OF THE HAWAII FCA
Haw. Rev. Stat. § 661-21(a)(7)

146. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

147. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(7), specifically provides, in part, that any person who:

> (3) Knowingly makes, uses, or causes 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 state.
>
> . . .
>
> shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the State sustains due to the act of that person.

148. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the correct rebate amounts to Medicaid, in violation of Haw. Rev. Stat. § 661-21(a)(7).

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

COUNT TWENTY-FOUR

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWERREWARD AND PROTECTION ACT 740 Ill. Comp. Stat. § 175/3 (a)(1)

150. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

(1) knowingly presents, or causes to be presented, to an officer or employee of the State or member of the Guard a false or fraudulent claim for payment or approval;

. . .

is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

152. Defendants knowingly caused to be presented to the Illinois Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of 740 Ill. Comp. Stat. § 175/3(a)(1).

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

COUNT TWENTY-FIVE

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT 740 Ill. Comp. Stat. § 175/3(a)(2)

154. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

(2) knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

. . .

is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

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

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

COUNT TWENTY-SIX

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT 740 Ill. Comp. Stat. § 175/3(a)(3)

158. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

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

. . .

is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

160. Defendants conspired to defraud the State of Illinois by getting false and

fraudulent claims allowed and paid, in violation of 740 Ill. Comp. Stat. § 175/3(a)(3).

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

COUNT TWENTY-SEVEN

VIOLATIONS OF THE ILLINOIS
|WHISTLEBLOWER REWARD AND PROTECTION ACT
740 Ill. Comp. Stat. § 175/3(a)(7)

162. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

163. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a)(7), specifically provides, in part, that any person who:

> (7) knowingly makes, uses, or causes 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 State . . .
>
> is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

164. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the correct rebate amounts to Medicaid, in violation of 740 Ill. Comp. Stat. § 175/3(a)(7).

165. The State of Illinois paid said claims and has sustained damages, to the extent of

its portion of Medicaid losses from Medicaid claims filed in Illinois, because of these acts by the Defendants

COUNT TWENTY-EIGHT

VIOLATIONS OF THE STATE OF INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT IC 5-11-5.5

166. Relator restates and realleges the allegations contained in Paragraphs 1- 68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

167. The Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5-2(b) (2005), specifically provides, in part, that by certain acts a person commits an unlawful act and shall be liable to the state for civil penalties and three times the amount of damages that the state sustains because of the act of that person [including]:

> (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 claims from the state;…
> (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 above; or
> (8) causes or induces another person to perform an act described above.

168. Defendants knowingly violated these provisions of law by presenting or causing to be presented to the Indiana Medicaid program false and/or fraudulent claims for payment and approval, claims which failed to disclose the material violations of the law; knowingly made, used or caused to be made or used a false record or statement to support such claims and/or to conceal its actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired to defraud the state Medicaid program, and caused others to violate the Indiana Act, all in violation of IC 5-11-5.5-2.

169. The State of Indiana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-NINE

VIOLATIONS OF THE LOUISIANA FALSE CLAIMS ACT/MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW 46 La. Rev. Stat. c. 3 § 438.3A

170. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

171. The Louisiana False Claims Act/Medical Assistance Programs Integrity Law ("Louisiana FCA"), 46 La. Rev. Stat. c. 3 § 438.3A, specifically provides, in part, that: "No person shall knowingly present or cause to be presented a false or fraudulent claim".

172. Defendants knowingly presented or caused to be presented to the Louisiana Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of 46 La. Rev. Stat. c. 3 § 438.3A.

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

COUNT THIRTY

VIOLATIONS OF THE LOUISIANA FALSE CLAIMS ACT/MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW 46 La. Rev. Stat. c. 3 § 438.3B

174. Relator restates and realleges the allegations contained in Paragraphs 1-68 above

as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

175. The Louisiana FCA, 46 La. Rev. Stat. c. 3 § 438.3B, specifically provides, in part, that:

> No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance programs funds.

176. Defendants knowingly engaged in misrepresentation and made, used and caused to be made and used, false records and statements to obtain or attempt to obtain payment from or get false and fraudulent claims paid and approved by the State of Illinois, in violation of 46 La. Rev. Stat. c. 3 § 438.3B.

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

COUNT THIRTY-ONE

VIOLATIONS OF THE LOUISIANA FALSE CLAIMS ACT/MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW 46 La. Rev. Stat. c. 3 § 438.3C

178. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

179. The Louisiana FCA, 46 La. Rev. Stat. c. 3 § 438.3C, specifically provides, in part, that:

> 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.

180. Defendants conspired to defraud the State of Louisiana by getting false and fraudulent claims allowed and paid, in violation of 46 La. Rev. Stat. c. 3 § 438.3C.

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

COUNT THIRTY-TWO

VIOLATIONS OF THE LOUISIANA FALSE CLAIMS ACT/MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
46 La. Rev. Stat. c. 3 § 438.2A(1)

182. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

183. Louisiana FCA, 46 La. Rev. Stat. c. 3 § 438.2A(1), specifically provides that:

> No person shall solicit, receive, offer or pay any remuneration, including but not limited to kickbacks, bribes, rebates, or … payments, directly or indirectly, overtly or covertly, in cash or in kind, for the following . ..
>
> (1) In return for referring an individual to a health care provider, …for the furnishing or arranging to furnish any good, supply, or service for which payment may be made, in whole or in part, under the medical assistance programs.

184. In addition, the Louisiana FCA, supra, section 438.3 provides that:

"No person shall knowingly present of cause to be presented a false or fraudulent claim…shall knowingly engage in misrepresentation to obtain, or attempt to obtain payment from medical assistance program funds…shall conspire to defraud, or attempt to defraud, the

medical assistance programs… ."

185. Furthermore, the Louisiana FCA, supra, section 438.4 provides that:

"No person shall knowingly make, use or cause to be made or used a false, fictitious, or misleading statement on any form used for the purpose of certifying or qualifying any person for eligibility … to receive any good, service, or supply under the medical assistance programs which that person is not eligible to receive."

186. Defendants solicited, received, offered and/or paid remuneration, including but not limited to kickbacks, bribes, and gifts, directly or indirectly, overtly or covertly, in cash or in kind, in return for prescribing or arranging the prescribing of drugs which are paid for by the Louisiana Medicaid program, in violation of 46 La. Rev. Stat. c. 3 § 438.2A(1).

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

COUNT THIRTY-THREE

VIOLATIONS OF THE MASSACHUSETTS FCA
Mass. Gen. Laws Ch. 12, § 5B(1)

188. Relator restates and realleges the allegations contained in Paragraphs 1- 68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

(1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

. . .

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

190. Defendants knowingly presented or caused to be presented to the Massachusetts Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Mass. Gen. Laws Ch. 12, § 5B(1).

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

COUNT THIRTY-FOUR

VIOLATIONS OF THE MASSACHUSETTS FCA
Mass. Gen. Laws Ch. 12, § 5B(2)

192. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof;

. . .

shall be liable to the commonwealth or political subdivision for a civil penalty of not less

than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person.

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

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

COUNT THIRTY-FIVE

VIOLATIONS OF THE MASSACHUSETTS FCA
Mass. Gen. Laws Ch. 12, § 5B(3)

196. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

(3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;

. . .

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

198. Defendants conspired to defraud the Commonwealth of Massachusetts through the allowance and payment of fraudulent claims in violation of Mass. Gen. Laws Ch. 12, § 5B(3).

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

COUNT THIRTY-SIX

VIOLATIONS OF THE MASSACHUSETTS FCA
Mass. Gen. Laws Ch. 12, § 5B(8)

200. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

201. The Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5B(8), specifically provides, in part, that any person who:

> (8) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or to transmit money or property to the commonwealth;
>
> . . .
>
> shall be liable to the commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person.

202. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the

correct rebate amounts to Medicaid, in violation of Mass. Gen. Laws Ch. 12, § 5B(8).

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

COUNT THIRTY-SEVEN

VIOLATIONS OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT, MI ST Ch. 400

204. Relators restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

205. The Michigan Medicaid False Claims Act, MI ST Ch. 400, provides, *inter alia*: as follows:

(1) In section 400.603, that "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… [or] for use in determining rights to a Medicaid benefit." It further provides that "A person, having knowledge of the occurrence of an event affecting …[the] initial or continued right of any other person on whose behalf he has applied…shall not conceal or fail to disclose that event with intent to obtain a benefit to which the person or any other person is not entitled or in an amount greater than that to which the person or any other person is entitled."

(2) In section 400.606, that "A person shall not enter into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another to obtain the payment or allowance of a false claim… ."

(3) In section 400.607, that "A person shall not make or present or cause to be made or presented to an employee or officer [of the state] a claim…upon or against the state,

knowing the claim to be false… .” and that “ A person shall not make or present or cause to be made or presented a claim …which he or she knows falsely represents that the goods or services for which the claim is made were medically necessary … .”

(4) In section 400.604, that a person is prohibited from soliciting, offering, making or receiving a kickback or bribe or rebate of any kind.

206. Under section 400.612, “A person who receives a benefit which the person is not entitled to receive by reason of fraud or making a fraudulent statement or knowingly concealing a material fact shall forfeit and pay to the state a civil penalty equal to the full amount received plus triple the amount of damages suffered by the state as a result of the conduct by the person”.

207. Defendants have violated these provisions of the Michigan FCA and caused damage to the State of Michigan.

COUNT THIRTY-EIGHT

VIOLATIONS OF THE NEW HAMPSHIRE FCA N.H. RSA §§ 167:61-b *et seq*.

208. Relator restates and realleges the allegations contained in Paragraphs 1- 68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

209. The New Hampshire Medicaid False Claims Act, N.H. RSA §§ 167:61-b *et seq*. (2005), specifically provides, in part, that by certain acts a person commits an unlawful act and shall be liable to the state for a civil penalty and three times the amount of damages that the state sustains because of the act if that 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 claim;
>
> (b) makes, 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 that such claim is false or fraudulent; [and/or]

(e) makes, uses, or causes to be made or used a record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state, relative to the Medicaid program, knowing that such record or statement is false…."

210. Defendants knowingly violated these provisions of law by presenting or causing to be presented to the New Hampshire Medicaid program false and/or fraudulent claims for payment and approval, claims which failed to disclose the material violations of the law; knowingly made, used or caused to be made or used a false record or statement to support such claims and/or to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, and they conspired to defraud the state Medicaid program, all in violation of N.H. RSA § 167:61-b I. (a)-(c) and (e).

211. The State of New Hampshire paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-NINE

VIOLATIONS OF THE NEVADA FCA
Nev. Rev. Stat. § 357.040(1)(a)

212. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

With or without specific intent to defraud, does any of the following listed acts is liable to the state or a political subdivision, whichever is affected, for three times the amount of

damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than $2,000 or more than $10,000 for each act:

(a) Knowingly presents or causes to be presented a false claim for payment or approval.

214. Defendants knowingly presented or caused to be presented to the Nevada Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Nev. Rev. Stat. § 357.040(1)(a).

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

COUNT FORTY

VIOLATIONS OF THE NEVADA FCA
Nev. Rev. Stat. § 357.040(1)(b)

216. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

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

. . .

(b) Knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim.

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

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

COUNT FORTY-ONE

VIOLATIONS OF THE NEVADA FCA
Nev. Rev. Stat. 357.040(1)(c)

220. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

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

222. Defendants conspired to defraud the Commonwealth of Massachusetts by

obtaining allowance and payment of false claims, in violation of Nev. Rev. Stat. 357.040(1)(c).

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

COUNT FORTY-TWO

VIOLATIONS OF THE NEVADA FCA
Nev. Rev. Stat. 357.040(1)(g)

224. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

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

226. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the

correct rebate amounts to Medicaid, in violation of Nev. Rev. Stat. 357.040(1)(g).

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

COUNT FORTY-THREE

VIOLATIONS OF THE NEW MEXICO FCA
N.M. LEGIS 49 (2004) CHAPTER 49

228. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

229. The New Mexico Medicaid False Claims Act, N.M. Legis 49 (2004) Chapter 4, specifically provides, in part, that by certain acts "a person commits an unlawful act and shall be liable to the state for three times the amount of damages that the state sustains because of the act if that person [including]:

4A. presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that such claims is false or fraudulent claim;

4B. 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;

4C. 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;

4D. conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing that such claim is false or fraudulent; [and/or]

4E. makes, uses, or causes to be made or used a record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state, relative to the Medicaid program, knowing that such record or statement is false…."

230. Defendants knowingly violated these provisions of law by presenting or causing to be presented to the New Mexico Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws; it knowingly made, used or caused to be made or used a false record or statement to support such claims and/or to conceal its actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the correct rebate amounts to Medicaid; and it conspired to defraud the state Medicaid program, all in violation of N.M. Legis 49 (2004) Chapter 4A-E.

231. The State of New Mexico paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in New Mexico, because of these acts by the Defendants.

COUNT FORTY-FOUR

VIOLATIONS OF THE TENNESSEE MEDICAID FCA
Tenn. Code Ann. § 71-5-182(a)(1)(A)

232. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

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

. . .

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

234. Defendants knowingly presented or caused to be presented to the Tennessee Medicaid program claims for payment under the Medicaid program knowing such claims were false and fraudulent, claims which failed to disclose the material violations of the AKA and other laws, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(A).

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

COUNT FORTY-FIVE

VIOLATIONS OF THE TENNESSEE MEDICAID FCA
Tenn. Code Ann. § 71-5-182(a)(1)(B)

236. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

(B) Makes, uses, or causes to made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;

. . .

is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and

not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person.

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

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

COUNT FORTY-SIX

VIOLATIONS OF THE TENNESSEE MEDICAID FCA
Tenn. Code Ann. § 71-5-182(a)(1)(C)

240. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

(C) Conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent;

. . .

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

242. Defendants conspired to defraud the State of Tennessee by getting claims allowed

and paid under the Medicaid program knowing such claims were false and fraudulent, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(C).

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

COUNT FORTY-SEVEN

VIOLATIONS OF THE TENNESSEE MEDICAID FCA
Tenn. Code Ann. § 71-5-182(a)(1)(D)

244. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

> (D) Makes, uses, or causes to be made or sued, a record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state, relative to the Medicaid program knowing such record or statement is false;
>
> . . .
>
> is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person.

246. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the correct rebate amounts to Medicaid, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(D).

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

COUNT FORTY-EIGHT

VIOLATIONS OF THE TEXAS MEDICAID FRAUD PREVENTION LAW Tex. Hum. Res. Code § 36.002(1)-(2)

248. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

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

250. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.001(2)(B), specifically provides, in part, that a person commits an unlawful act if the person:

> (2) knowingly or intentionally conceals or fails to disclose an event: (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… ."

251. Defendants knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the Texas Medicaid

program, claims which failed to disclose the material violations of the AKA and other laws, in violation of Tex. Hum. Res. Code § 36.002 (1)-(2).

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

COUNT FORTY-NINE

VIOLATIONS OF THE TEXAS MEDICAID FRAUD PREVENTION LAW Tex. Hum. Res. Code § 36.002(4)(B)

253. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

> (4) knowingly or intentionally makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:
>
> . . .
>
> (B) Information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;

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

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

Defendants.

COUNT FIFTY

VIOLATIONS OF TEXAS MEDICAID FRAUD PREVENTION LAW
Tex. Hum. Res. Code § 36.002(5)

257. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

258. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.002(5), specifically provides, in part, that a person commits an unlawful act if the person:

> (5) except as authorized under the Medicaid program, 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 to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program . . . .

259. Defendants knowingly and intentionally paid and received kickbacks, gifts, money, or other consideration as a condition of service to a Medicaid recipient, in violation of Tex. Hum. Res. Code §.36.002(5).

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

COUNT FIFTY-ONE

VIOLATIONS OF TEXAS MEDICAID FRAUD PREVENTION LAW
Tex. Hum. Res. Code § 36.002(9)

261. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

> (8) knowingly or intentionally enters into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another person in obtaining an unauthorized payment or benefit from the Medicaid program . . . .

263. Defendants knowingly and intentionally conspired to defraud the State of Texas by aiding another person in obtaining an unauthorized payment from the Medicaid program, in violation of Tex. Hum. Res. Code §.36.002(9).

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

COUNT FIFTY-TWO

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT
Va. Code Ann. § 8.01-216.3(A)(1)

265. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

266. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(1),

specifically provides, in part, that any person who:

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

. . .

shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

267. Defendants knowingly presented or caused to be presented, to the Virginia Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Va. Code Ann. § 8.01-216.3(A)(1).

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

COUNT FIFTY-THREE

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT
Va. Code Ann. § 8.01-216.3(A)(2)

269. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

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

. . .

shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

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

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

COUNT FIFTY-FOUR

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT
Va. Code Ann. § 8.01-216.3(A)(3)

273. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

3. Conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid;

. . .

shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

275. Defendants conspired to defraud the Commonwealth of Virginia by getting false and fraudulent claims allowed and paid, in violation of Va. Code Ann.§ 8.01-216.3(A)(3).

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

COUNT FIFTY-FIVE

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT Va. Code Ann. § 8.01-216.3(A)(7)

277. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

278. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(7), specifically provides, in part, that any person who:

> 3. knowingly makes, uses, or causes 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 Commonwealth;
>
> . . .
>
> shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

279. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the correct rebate amounts to Medicaid, in violation of Va. Code Ann.§ 8.01-216.3(A)(7).

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

COUNT FIFTY-SIX

VIOLATIONS OF THE NEW YORK STATE FCA: 2007 NEW YORK LAWS 58, SECTION 39, ARTICLE XIII, §189 (a)(1),(2) and (7)

281. Relator restates and realleges the allegations contained in Paragraphs 1 to 68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

282. The Defendants knowingly presented or caused to be presented false or fraudulent claims to Medicaid and knowingly made, used or caused to be made or used, false statements to get said claims paid by the Medicaid Programs. Zonegran prescriptions for the purposes of off label uses would not have been presented but for the illegal incentives and unlawful promotional activities made by Defendants. As a result of this illegal scheme, these claims were improper in whole pursuant to Art. XIII, §189(a)(1).

283. These claims were also false or fraudulent and the statements and records were false because they were monetarily excessive, in violation of Art. XIII, §189 (a)(1)-(2). Zonegran prescriptions for the purposes of off label uses cost more than comparative drugs with the same or superior efficacy.

284. In particular, these claims were also false or fraudulent and statements and records were false because the cost of Zonegran was inflated due to the Defendants having to cover their illegal expenditures and unlawful promotional activities, thereby inflating the cost of the product.

285. It is illegal to pass the costs of illegal kickbacks and unlawful promotional activities back to any Federal or Government Health Care Program and it is also illegal to falsely

report the true cost of a drug. In addition to violating Art. XIII, §189(a)(1)-(2), Defendants' conduct violated Art. XIII, §189 (a)(7).

COUNT FIFTY-SEVEN

CONSPIRACY TO DEFRAUD: NEW YORK FCA, 2007 NEW YORK LAWS 58, SECTION 39, ARTICLE XIII §189 (a)(3)

286. Relator restates and realleges the allegations contained in Paragraphs 1-68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

287. Defendants knowingly conspired to defraud the State of New York causing increased sales of Zonegran through unlawful promotion in violation of law. Defendants conspired to violate the AKA by unlawfully offering incentives to physicians that were in a position of authority to cause other physicians to prescribe Zonegran. Said actions constitute violations of Art.13, Section 189(a)(3).

288. Defendants knowingly conspired to violate the FCA by causing false or fraudulent claims to be presented and to make or use false statements which damaged the Medicaid Program. Said claims were improper and should not have been made but for the unlawful promotional activities and unlawful incentives which caused the prescriptions of Zonegran to be made. Said claims were also monetarily excessive in cost due to the illegal kickbacks and unlawful promotional activities of the Defendants. Said actions constitute violations of Art. XIII, Section 189(a)(3).

289. The Defendants knowingly conspired to conceal their actions and they failed to alert the state or federal governments of their unlawful promotion of Zonegran. It is illegal to pass the costs incurred in paying illegal kickbacks and unlawful promotional activities back to

any Federal or Government Health Care Program and it is also illegal to falsely report the true cost of a drug. Said actions constitute violations of Art XIII, Section 189(a)(3).

COUNT FIFTY-EIGHT

VIOLATIONS OF THE GEORGIA STATE FALSE MEDICAID CLAIMS ACT

Article 7B, Chapter 4, Title 49 of the Official Code of Georgia Annotated

290. Relator restates and realleges the allegations contained in Paragraphs 1- 68 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

291. The Georgia State False Medicaid Claims Act, Official Code of Georgia Annotated, 49-4-168, *et seq*., specifically provides, in part at 49-4-168.1, that: :

(a) 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;
(4) Has possession, custody, or control of property or money used, or to be used by the Georgia Medicaid program and, intending to defraud the Georgia Medicaid program or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate of receipt…or
(7) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay, repay or transmit money or property to the State of Georgia,
shall be liable to the State of Georgia for a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each false or fraudulent claim, plus three times the amount of damages which the Georgia Medicaid program sustains because of the act of such person.

292. The Defendants knowingly presented or caused to be presented false or fraudulent claims to Medicaid and knowingly made, used or caused to be made or used, false statements to get said claims paid by the Medicaid Programs. Zonegran prescriptions for the purposes of off

label uses would not have been presented but for the illegal incentives and unlawful promotional activities made by Defendants. As a result of this illegal scheme, these claims were improper in whole pursuant to the Georgia FCA, 49-4-168.1(a)(1)-(2).

293. These claims were also false or fraudulent and the statements and records were false because they were monetarily excessive. Zonegran prescriptions for the purposes of off label uses cost more than comparative drugs with the same or superior efficacy.

294. In particular, these claims were also false or fraudulent and statements and records were false because the cost of Zonegran was inflated due to the Defendants having to cover their illegal expenditures and unlawful promotional activities, thereby inflating the cost of the product.

295. It is illegal to pass the costs of illegal kickbacks and unlawful promotional activities back to any Federal or Government Health Care Program and it is also illegal to falsely report the true cost of a drug. In addition to violating 49-4-168.1(a)(1)-(2), Defendants' conduct violated 49-4-168.1(a)(4) and (7).

296. Defendants knowingly conspired to defraud the State of Georgia causing increased sales of Zonegran through unlawful promotion in violation of law. Defendants conspired to violate the AKA by unlawfully offering incentives to physicians that were in a position of authority to cause other physicians to prescribe Zonegran. Said actions constitute violations of 49-4-168.1(a)(3).

297. Defendants knowingly conspired to violate the Georgia FCA by causing false or fraudulent claims to be presented and to make or use false statements which damaged the Medicaid Program. Said claims were improper and should not have been made but for the unlawful promotional activities and unlawful incentives which caused the prescriptions of Zonegran to be made. Said claims were also monetarily excessive in cost due to the illegal

kickbacks and unlawful promotional activities of the Defendants. Said actions constitute violations of 49-4-168.1(a)(3).

298. The Defendants knowingly conspired to conceal their actions and they failed to alert the state or federal governments of their unlawful promotion of Zonegran. It is illegal to pass the costs incurred in paying illegal kickbacks and unlawful promotional activities back to any Federal or Government Health Care Program and it is also illegal to falsely report the true cost of a drug. Said actions constitute violations of 49-4-168.1(a)(3).

299. Defendants knowingly presented or caused to be presented to the Georgia Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of 49-4-168.1(a)(1)-(4) and (7).

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

PRAYERS FOR RELIEF

WHEREFORE, Relator Dr. Chartock, acting on behalf of and in the name of the United States of America and the State Plaintiffs, and on his own behalf, demands and prays that judgment be entered as follows against the Defendants under the Federal FCA Counts and under pendent State FCA Counts as follows:

(a) In favor of the United States against the Defendants for treble the amount of damages to Federal Health Care Programs from the marketing, selling, prescribing, pricing and billing of Zonegran, plus maximum civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

(b) In favor of the United States against the Defendants for disgorgement of the profits earned by Defendants as a result of its illegal scheme;

(c) In favor of the Relator for the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) to include reasonable expenses, attorney fees and costs incurred by Relator;

(d) For all costs of the Federal FCA civil action;

(e) In favor of the Relator and the United States for such other and further relief as this Court deems to be just and equitable;

(f) In favor of the Relator and the named State Plaintiffs against Defendants in an amount equal to three times the amount of damages that California, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, , Nevada, New Mexico, New Hampshire, New York, Tennessee, and Virginia have sustained, respectively, as a result of the Defendants' actions, as well as a civil penalty against the Defendants of a statutory maximum for each violation of each State's FCA;

(g) In favor of the Relator and the Plaintiff State of Texas against Defendants in an amount equal to two times the amount of damages that Texas has sustained as a result of the Defendants' actions, as well as a civil penalty against the Defendants of a statutory maximum for each violation of Tex. Hum. Res. Code § 36.002;

(h) In favor of the Relator and the Plaintiff State of Michigan against the Defendant for a civil penalty equal to one time the loss caused to the Michigan Medicaid program as a result of the Defendant's actions, plus damages equal to three times such loss;

(i) In favor of the Relator for the maximum amount allowed as a Relator's share pursuant to each State's FCA;

(j) In favor of the Relator for all costs and expenses associated with the pendent State claims, including attorney's fees and costs; and

(k) In favor of the State Plaintiffs and the Relator for all such other relief as the Court deems just and proper.

PLAINTIFF/RELATOR DEMANDS A TRIAL BY JURY ON ALL COUNTS

Dated:

Respectfully submitted,

_____

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