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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.* STEFAN KRUSZEWSKI; the DISTRICT of COLUMBIA *ex rel.* STEFAN KRUSZEWSKI, CALIFORNIA *ex rel.* STEFAN KRUSZEWSKI, DELAWARE *ex rel.* STEFAN KRUSZEWSKI, FLORIDA *ex rel.* STEFAN KRUSZEWSKI, GEORGIA *ex rel.* STEFAN KRUSZEWSKI, HAWAII *ex rel.* STEFAN KRUSZEWSKI, ILLINOIS *ex rel.* STEFAN KRUSZEWSKI, INDIANA *ex rel.* STEFAN KRUSZEWSKI, LOUISIANA *ex rel.* STEFAN KRUSZEWSKI, MASSACHUSETTS *ex rel.* STEFAN KRUSZEWSKI, MICHIGAN *ex rel.* STEFAN KRUSZEWSKI, MONTANA *ex rel.* STEFAN KRUSZEWSKI, NEVADA *ex rel.* STEFAN KRUSZEWSKI, NEW HAMPSHIRE *ex rel.* STEFAN KRUSZEWSKI, NEW JERSEY *ex rel.* STEFAN KRUSZEWSKI, NEW MEXICO *ex rel.* STEFAN KRUSZEWSKI, NEW YORK *ex rel.* STEFAN KRUSZEWSKI, OKLAHOMA *ex rel.* STEFAN KRUSZEWSKI, RHODE ISLAND *ex rel.* STEFAN KRUSZEWSKI, TENNESSEE *ex rel.* STEFAN KRUSZEWSKI, TEXAS *ex rel.* STEFAN KRUSZEWSKI, VIRGINIA *ex rel.* STEFAN KRUSZEWSKI, WISCONSIN *ex rel.* STEFAN KRUSZEWSKI, and STEFAN KRUSZEWSKI, individually,

Plaintiffs,

v.

PFIZER, INC.,

Defendant.

CASE No.: 07-CV-4106

FILED *IN CAMERA* UNDER SEAL

JURY TRIAL DEMANDED

FIRST AMENDED COMPLAINT

Plaintiff-Relator Stefan Kruszewski, M.D., by and through his undersigned attorneys, on behalf of the United States of America (the "United States") and the State of California, the State of Delaware, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Louisiana, the Commonwealth of Massachusetts, the State of Michigan, the State of Montana, the State of Nevada, the State of New Hampshire, the State of New Jersey, the State of New Mexico, the State of New York, the State of Oklahoma; the State of Rhode Island; the State of Tennessee, the State of Texas, the State of Wisconsin; the Commonwealth of Virginia and the District of Columbia (collectively "Plaintiff States") for his Complaint against Defendant Pfizer, Inc. ("Pfizer" or "Defendant") alleges based upon personal knowledge and relevant documents, as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America and the Plaintiff States arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by Defendant Pfizer and/or its agents, employees and co-conspirators in violation of the Federal Civil False Claims Act, 31 U.S.C. §3729 *et seq.*, as amended ("the FCA" or "the Act") and its state-law counterparts: the California False Claims Act, Cal. Govt Code §12650 *et seq.*; the Delaware False Claims and False Reporting Act, 6 Del. C. §1201 *et seq.*; the Florida False Claims Act, Fla. Stat. Ann. §68.081 *et seq.*; the Georgia State False Medicaid Claims Act, Ga. Code 49-4-168 *et seq.*; the Hawaii False Claims Act, Haw. Rev. Stat. §661-21 *et seq.*; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175/1-8; the Indiana False Claims and Whistleblower Protection Act, Indiana Code

5-11-5.5 *et seq.*; the Louisiana False Claims Act, La. Rev. Stat. Ann. § 46:439.1 *et seq.*; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §5 *et seq.*; the Michigan Medicaid False Claim Act, MCL 400.611 § 10a *et seq.*; Michigan Public Acts, 1977 PA 72, as amended by 1984 PA 333, as amended by 2005 PA 337, as amended by 2008 PA 421; the Montana False Claims Act. 2005 Mont. Code, Ch. 465; the Nevada False Claims Act, Nev. Rev. Stat. Ann. §§357.010 *et seq.*; the New Hampshire False Claims Act, § 167:61-h *et seq.*; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann.§ 27-2F-1 *et seq.*; New Mexico Fraud Against Taxpayers Act , N.M. Stat. § 44-9-1 *et seq.*; the New York False Claims Act, State Finance Law. §187 *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-181 *et seq.*; Tennessee False Claims Act Tenn. Code Ann. § 4-18-101 *et seq.*; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§36.001 *et seq.*; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§8.01-216.1 *et seq.*; and the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §§1-1188.13 *et seq.*; New Jersey False Claims Act, N.J. STAT. § 2A:32C-1; Oklahoma Medicaid False Claims Act, 63 Okla. Stat. § 5053, *et seq.*; Wisconsin False Claims for Medical Assistance Act, WIS. STAT. § 20.931, *et seq.*; and the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1, *et seq.*

2. The instant matter arises in principal part from Defendant Pfizer's nationwide, coordinated deceptive off-label marketing and promotional practices for its potent atypical antipsychotic Geodon. Specifically, Pfizer devised and successfully implemented through its Roerig division and Geodon sales representatives a marketing campaign calculated to increase primary care physicians' and physiatrists' off-label use of Geodon, in various doses, to treat symptoms, mood disorders and patients within age demographics for which

the drug has not received FDA approval (the elderly and pediatrics), nor which has been supported by the medical compendia DRUGDEX, the American Hospital Formulary Service Drug Information or the United States Pharmacopeia-Drug Information. Pfizer's illegal conduct has been ongoing since 2001.

3. A key component of Pfizer's unlawful marketing of Geodon has been that the drug is as safe as or more effective than other antipsychotics and/or more tolerable and because of Geodon's comparatively "safe" metabolic profile, as such patients on other atypical antipsychotics should be switched to Geodon. However, Pfizer's marketing of Geodon as comparatively safe and effective is deceptive and misleading and has materially minimized and/or conceal Geodon's dangerous side effects, in particular cardiovascular side effects such as the risks of heart attack and death from treatment-emergent QT prolongation.

4. As a direct result of Pfizer's improper off-label and misleading marketing practices for Geodon, health insurance programs funded by the United States and the Plaintiff States (collectively the "Government Plaintiffs") including, but not limited to Medicaid, Medicare, Medicare Part D, the Railroad Retirement Medicare Program, Federal Employees Health Benefit Programs, Tri-Care (formerly CHAMPUS), CHAMPVA, State Legal Immigrant Assistance Grants and the Indian Health Service (collectively the "Programs") paid false or fraudulent Geodon reimbursement claims for prescriptions written to the Programs' beneficiaries for off-label, non-medically accepted indications. The United States and the Plaintiff States would not have paid such false claims but for Pfizer's illegal and fraudulent conduct.

5. Moreover Pfizer's conduct endangered the health of the Programs' beneficiaries by

placing them at great risk of harm of developing serious, irreversible and even life-threatening side effects that were known to Pfizer at all times relevant to this Amended Complaint, but which Pfizer intentionally concealed to protect its windfall of Geodon sales revenues.

6. The FCA provides that any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the U.S. Government for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. Liability attaches when a defendant knowingly seeks payment, or causes others to seek payment, from the Government that is unwarranted.

7. The Act allows any person having information about a false or fraudulent claim against the Government to bring an action for himself and the Government, and to share in any recovery.

8. Based on these provisions, Plaintiff-Relator Stefan Kruszewski seeks through this action to recover on behalf of the United States and the Plaintiff States (which have laws authorizing similar *qui tam* actions) damages and civil penalties arising from Pfizer's making or causing to be made false or fraudulent records, statements and/or claims for reimbursement for ineligible Geodon prescriptions as the direct and foreseeable consequence of its national off-label marketing of Geodon for use by pediatrics and the elderly, and off-label marketing to primary care physicians and psychiatrists to treat symptoms and conditions such as depression, insomnia, anxiety, attention deficit disorder, insomnia lack of concentration, and other mood, behavioral and conduct disorders, among other off-label uses.

9. Pfizer did not directly submit claims for prescription drugs to federal and state health insurance programs, however, Pfizer knew -- and in fact it was Pfizer's goal -- that its illegal off-label and misleading marketing practices would cause the submission of thousands of claims to government-funded health programs for prescriptions that were not eligible for program reimbursement.

10. Pfizer's unlawful off-label marketing campaign and its efforts to minimize and distort the side effect and safety profile of Geodon were used by, and are continued to be used by, the company and its sales representatives to market the drug. As a result, Geodon sales in the United States alone have skyrocketed from $146 million in 2001 to $822 million in 2008.

II. PARTIES

11. Plaintiff-Relator Stefan Kruszewski, MD brings this action on behalf the United States and the Plaintiff States to recover the hundreds of millions of dollars Medicaid, Medicare, Medicare Part D, the Railroad Retirement Medicare Program, Federal Employees Health Benefit Programs, Tri-Care (formerly CHAMPUS), CHAMPVA, State Legal Immigrant Assistance Grants and the Indian Health Service have been fraudulently induced to pay as a result of false and/or fraudulent Geodon reimbursement claims submitted by, and caused to be submitted by, Defendant Pfizer.

12. Plaintiff-Relator Stefan Kruszewski, M.D., is a resident of Harrisburg, Pennsylvania. Plaintiff-Relator Kruszewski has filed the instant *qui tam* suit seeking redress for Geodon written off-label and/or for non-medically accepted indications that were unlawfully induced by Pfizer as a result of its deceptive marketing practices, specifically, the company's off-label marketing and misrepresentation of Geodon's safety

and efficacy. Plaintiff-Relator Kruszewski is a recognized Board Certified expert in psychopharmacology who has over 28 years of clinical experience during which time he has treated thousands of patients with a wide variety of psychiatric and neuropsychiatric conditions and to whom he prescribed numerous drugs for psychiatric and neuropsychiatric indications. During the time period in question, Plaintiff-Relator has witnessed and monitored the effects of Geodon in patients prescribed Geodon. Pfizer Geodon sales representatives have also pitched Geodon off-label to Plaintiff-Relator, as described herein.

13. Defendant Pfizer, Inc. ("Pfizer" or "Defendant") is a publicly traded company that engages in the development, manufacturing, and marketing of prescription medicines for humans in the United States, Europe, Canada, Asia, and Latin America. The company was founded in 1849 and is headquartered in New York, New York. One of its primary business activities in the United States relates to the company's manufacture and/or sale of Geodon, a widely distributed psychotropic medication.

III. JURISDICTION AND VENUE

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, 28 U.S.C. §1367 and 31 U.S.C. §3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. Under 31 U.S.C. §3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint. Plaintiff-Relator Kruszewski, moreover, qualifies under that section of False Claims Act as an "original source" of the allegations in this Complaint even had such a public disclosure occurred.

12. At the time he filed his original complaint in this action, Relator Kruszewski

concurrently served upon the Attorney General of the United States, the United States Attorney for the District Eastern District of Pennsylvania and the Plaintiff States Attorney Generals' offices the complaint and a statement summarizing known material evidence and information related to Plaintiff-Relator's original Complaint (and this Amended Complaint), in accordance with the provisions of 31 U.S.C. §3730(b)(2). The disclosure statement is supported by material evidence. The initial disclosure's statement and all supplements thereto and documents provided therewith are incorporated herein by reference.

13. This Court has personal jurisdiction and venue over the Pfizer pursuant to 28 U.S.C. §§1391(b) and 31 U.S.C. §3732(a) because those sections authorize nationwide service of process and because Pfizer has minimum contacts with the United States. Moreover, Pfizer can be found in, resides, and transacts business in this District.

14. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) because Defendant Pfizer transacts business in this judicial district, and acts proscribed by 31 U.S.C. §3729 have been committed by Defendant Pfizer in this District. Therefore, venue is proper within the meaning of 28 U.S.C. §1391(b) & (c) and 31 U.S.C. §3732(a).

IV. BACKGROUND

15. Among the numerous prescription drugs manufactured and/or distributed by Defendant Pfizer in the United States is Geodon ("ziprasidone"), a widely distributed atypical antipsychotic prescription drug.

16. There are two types of such antipsychotic drugs, the first-generation of "conventional" or "typical" drugs, which includes, but is not limited to, chlorpromazine (Thorazine), thioridazine (Mellaril), haloperidol (Haldol), thiothixene (Navane), and

pimozide (Orap), and newer "atypical" drugs, which include clozapine (Clorazil), risperidone (Risperdal), olanzapine (Zyprexa), quetiapine (Seroquel), ziprasidone (Geodon), paliperidone (Invega), and aripiprazole (Abilify).

A. Geodon's Indicated Uses

17. Geodon received initial approval by the United States Food and Drug Administration ("FDA") on February 5, 2001 for the treatment of acute manifestations of schizophrenia. (*See* FDA New Drug Application ("NDA") 020825).

18. Geodon was subsequently approved for the following limited uses as well:

i. *June 21st, 2002*: Approved for acute agitation in schizophrenic patients for whom treatment with ziprasidone is appropriate and who need intramuscular antipsychotic medication for rapid control of the agitation (NDA 020919).

ii. *August 19th, 2004*: Approved for acute manic or mixed episodes in Bipolar I disorder, with or without psychotic features (NDA 020825).

iii. *March 29th, 2006*: Approval of Geodon (ziprasidone HCL). Oral suspension for the treatment of schizophrenia and for the treatment of acute manic or mixed episodes associated with bipolar disorder, with or without psychotic features. (NDA 021483).

B. Geodon's FDA Approval

19. When Geodon received initial FDA approval on February 5, 2001, it marked the end of a long, hard fought battle to get the FDA to permit Pfizer to market the drug. Pfizer had originally applied for approval of the drug under the name Zeldox in March, 1997. However, the FDA, because of concerns regarding Zeldox initiating serious arrhythmias, issued a "non-approvable" letter in June 1998.

20. In 1998, when the FDA advisory committee rejected Zeldox (ziprasidone) because of safety concerns, they asked Pfizer to conduct additional studies to assess the

problems with QTc prolongation and the arrhythmogenic potential of the drug. Two years later, Pfizer brought back the same drug to the FDA committee for re- evaluation and hoped-for approval.

21. Pfizer re-applied to the FDA for approval of Zeldox (ziprasidone) in 2000. The FDA directed Pfizer to change the drug's name in order to avoid confusion between Zeldox and Zyvox (linezolid), an antibiotic medication. Pfizer renamed the drug Geodon and resubmitted an NDA for the drug without changing its chemical components in any way.

22. The second time, the FDA Advisory Committee approved Geodon over the strong objections by FDA staff that feared its effects on the heart, including causing QT prolongation. Pfizer conceded the QT interval problem, but argued it should be approved because it does not cause weight gain, an argument rejected by FDA staff. In fact, the NDA documents indicated that weight gain of >7% was observed in 10% of subjects taking Geodon in the short term placebo controlled phase II/III studies, and this was shown to be statistically significant when compared to placebo.

23. As Pfizer is aware, the clinical research used by Pfizer in support of Geodon's pre-approval and post-approval status is flawed. The data from the clinical trials that supported Geodon's new drug application to the FDA and work used to subsequently support post-approval marketing included the work of scientific researchers who have been variously sanctioned by regulatory authorities as follows:

- Dr. Richard Borison: received notice of debarment by the FDA in November 2002. Borison is not allowed to participate in or supervise any clinical drug trials for a minimum period of ten years. Borison, a psychiatrist who previously worked

at the Medical College of Georgia and conducted a huge number of clinical trials for ziprasidone, was indicted for embezzlement and research fraud and is currently serving a minimum 15 year jail sentence in Hancock State Prison, Sparta, Georgia.

- Dr. Bruce Diamond, a psychologist and pharmacologist, was indicted for research misconduct and embezzlement. Like Borison, he was found guilty and served time in Georgia state prison system. He received a notice from the FDA on or about November 26th, 2002, to debar him from participation in or provision of any services to any clinical drug trial for ten years.
- Dr. Louis Fabre, a psychiatrist from Houston, Texas who conducted and supervised several hundred clinical drug trials, including those for Geodon, was sanctioned by the Texas Board of Medical Examiners in October 2006 for research misconduct.

24. Pfizer's reliance on clinical researchers with a known history of professional misconduct (information known as early as 1996 in the cases of Drs. Borison and Diamond) demonstrates the lengths to which the company is willing to go to facilitate its "positive" clinical trials' reporting and its subsequent scheme to market off-label Geodon as safe and effective while downplaying its known and dangerous side-effects.

25. For example, the data presented by Pfizer to the FDA Advisory Committee in June 2000 incorrectly and misleadingly identified the adverse events associated with Geodon. A Pfizer employee reported that ziprasidone clinical trial data of adverse events reports (AERs) with a frequency greater than 5% only included somnolence, respiratory infections, and possibly asthenia and insomnia. The Pfizer representative omitted important increases in neurologically-associated adverse events including EPS/akathisia

from his discussion---information that would have been known to him from Pfizer-sponsored short-term clinical trials.

26. This Pfizer representative also misleadingly brought forth information suggesting that Geodon had favorable effects on serum cholesterol, LDL cholesterol and "especially triglycerides."

27. In fact, Pfizer went so far as to claim that "[Geodon] is an effective and well tolerated treatment for a severe illness, and in contrast with the adverse effects of many other approved treatments, [Geodon] has *"favorable effects" on well documented cardiovascular risk factors."* This statement is intentionally misleading. It is, in part, a byproduct of clinical trial manipulation in which individuals "switched" from other antipsychotics to Geodon may experience a decline in certain lipid levels because there was a heightened increase with other drugs -- not because there were any inherently "favorable" effects on cardiovascular risk factors without that design artifact. The statement is also misleading because it implies that taking Geodon may favorably improve cardiovascular risk factors simply by taking the drug, a statement which does not have reliable and reproducible scientific underpinnings and is contradicted by Pfizer's clinical trials submitted to the FDA for initial approval of the drug.

C. Pfizer's Aggressive Marketing to Grow Geodon's Off-Label Market Share.

28. Upon securing FDA approval for Geodon, in violation of the FDA's prohibition on marketing a prescription drug for unapproved uses, Defendant Pfizer embarked on a concerted campaign to increase Geodon "off label" prescriptions to increase Geodon's share of the atypical antipsychotic market and to increase Geodon's profits.

29. Specifically, Defendant Pfizer employed a marketing scheme aimed at persuading

prescribing physicians who treat the Programs' beneficiaries, including psychiatrists, primary care physicians and doctors of internal medicine to use Geodon to treat the following conditions and symptoms, none of which were or are FDA approved uses and none of which are medically accepted indications, as that term of defined by the Medicaid Act: agitation, depression, anxiety, personality disorders, psychotic symptoms not part of schizophrenia or Bipolar I, sundowning, mood instability, impaired concentration, impaired attention, impulsivity, oppositional behaviors, irritability, delirium, dementias, sleeplessness, explosiveness and, finally, drug-induced excitement or withdrawal.

30. On multiple occasions between 2001 and the filing of the initial Complaint, Pfizer representatives have made marketing presentations to Plaintiff-Relator and encouraged him to prescribe Geodon for many off-label and uses that are not medically accepted indications, including for many of the unapproved uses set forth in detail above.

31. In addition to being an eyewitness to Geodon off-label promotional marketing by Pfizer representatives, the Plaintiff-Relator, a widely recognized, Board Certified scientist and psyehiatrist, has reviewed promotional materials from Pfizer, including Pfizer-sponsored advertisements, lecture slides and educational materials. After careful review, Plaintiff-Relator found the scientific content that underscored the data put forth by Pfizer's promotional materials inconsistent, unbalanced and misleading. This data reviewed by the Plaintiff-Relator includes information that preceded the FDA's original approval for Geodon in February 2001 and continues through May 2007.

D. Geodon's Undisclosed Side Effects

32. In an effort to generate Geodon revenues, Pfizer knowingly misrepresented the

drug's safety profile concomitantly with Pfizer's complained of off-label marketing scheme.

33. Since its FDA-approval, Pfizer has falsely marketed and promoted Geodon as a safer alternative to other atypical antipsychotics. In particular, Pfizer-sponsored advertisements have misleadingly represented that Geodon has minimal ability to cause neurological side-effects, despite evidence to the contrary and evidence that was known to them prior to, at the time of, and after the re-submission of the NDA in 2000. In fact, Geodon produces neurological disorders known as extrapyramidal symptoms (EPS) in a dose-dependent manner. EPS are anticipated in a substantial percentage of patients -- perhaps as many as 30% -- who take Geodon at the higher doses needed to produce reliable antipsychotic effects.

34. As set forth in more detail below, at least two Pfizer pharmaceutical representatives told Plaintiff-Relator in April 2007 that they believe that Pfizer knowingly misrepresents the risk of neurological side-effects caused by Geodon. The names of these Pfizer sales representatives are Sean D. Kelly, Senior Professional Healthcare Consultant, Roerig Division of Pfizer and Chris Jobson, CMR, Professional Healthcare Representative, Pfizer Division of Arthritis, Pain & Musculoskeletal.

35. Pfizer has also materially misrepresented the clinical significance of Geodon's link to QT prolongation. Pfizer is known to have ignored the restrictions placed on them at the time of the 2001 FDA approval, representing the drug as having low risk of clinically significant prolongation of QT.

36. Pfizer has been cited by the FDA for its manipulation of information about Geodon to prescribers. In September 2002, Pfizer received a "Warning Letter" from the

FDA directed at false and misleading promotional activities regarding safety claims for Geodon as well as non-approved indication for depression. The 2002 warning letter from the FDA's Lisa Stockbridge to Pfizer's Rita A. Wittich, Vice President of World-Wide Regulatory Strategy, provided that: "Pfizer Inc. (Pfizer) has promoted Geodon in a manner that is misleading and lacking fair balance because it minimizes the important risk information regarding the greater capacity of Geodon to cause QT prolongation, and the potential to cause *torsade de pointes*-type arrhythmia and sudden death."

37. Skyrocketing sales resulting from Pfizer's marketing and promotional misconduct involving Geodon have had the adverse effect of hurting individuals because certain serious problems like substantial weight gain, adverse neurological side effects and conditions including extrapyramidal side-effects (EPS) and increased risk of infection were misleadingly denied as significant or otherwise misidentified, minimized or omitted completely.

38. In his capacity as a clinical psychiatrist, Plaintiff-Relator has witnessed and been apprised of Geodon's ill-effects on unsuspecting patients, including children and adolescents, who have not been adequately informed about the drug's dangerous side-effects and limited approved uses.

V. APPLICABLE LAW

A. The FDA Regulatory Scheme

39. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the Food and Drug Administration ("FDA") that the drug is safe and effective for each of its intended uses. 21 U.S.C. §355 (a) & (d).

Approval of the drug by the FDA is the final stage of a multi-year process of study and testing.

40. The FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved for treatment of a specific condition, for which the drug has been tested in patients. The specific approved use is called the "indication" for which the drug may he prescribed. The FDA will specify particular dosages determined to be safe and effective for each indication.

41. The indication and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also reviewed and approved by the FDA. 21 U.S.C. §§352, 355(d). An example of the drug's labeling is the printed insert in the drug's packaging. The FDA will only approve the new drug application if the labeling conforms to the uses and dosages that the FDA has approved. 21 U.S.C. §355(d).

42. Under the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), if a manufacturer wishes to market or promote an approved drug for alternative uses - i.e., uses not listed on the approved label - the manufacturer must resubmit the drug for another series of clinical trials similar to those for the initial approval. 21 U.S.C. §360aaa(b) & (c). Until subsequent approval of the new use has been granted, the unapproved use is considered to be "off-label." "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or treating a different patient population (e g., treating a child when the drug is approved to treat adults).

43. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit doctors from prescribing the drug for uses that are different from those approved by the FDA.

44. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved. Specifically, under the Food and Drug laws, (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose, and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§331, 352.

45. An off-label use of a drug can cease to be off-label only if the manufacturer submits a supplemental application and demonstrates to the satisfaction of the FDA that the product is safe and effective for the proposed new use. 21 U.S.C. §360aaa(b)&(c).

46. In addition to prohibiting manufacturers from directly marketing and promoting a product's off-label uses, Congress and the FDA have also sought to prevent manufacturers from employing indirect methods to accomplish the same end. For example, Congress and the FDA have attempted to regulate two of the most prevalent indirect promotional strategies: (1) manufacturer dissemination of medical and scientific publications concerning the off-label uses of its products, and (2) manufacturer support for Continuing Medical Education (CME) programs that focus on off-label uses. With regard to the first practice - disseminating written information - the FDAMA only permits a manufacturer to disseminate information regarding off-label usage in response to an

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

47. With regard to manufacturer involvement in CME programs, the FDA's examination of these practices led to publication of an agency enforcement policy in 1997 entitled, "Guidance for Industry: Industry-Supported Scientific and Educational Activities," 62 Fed. Reg. 64,074, 64,093. 1997 WL 740420 (F.R.) (1997). This guidance document states that CME programs must be truly independent of the drug companies, and sets forth a number of factors that the FDA will consider in determining whether a program is "free from the supporting company's influence and bias." *Id.* These factors include, among others, an examination of the relationship between the program provider and supporting company, the company's control of content and selection of presenters, whether there is a meaningful disclosure of the company's funding and role in the program, whether multiple presentations of the same program are held, whether the audience is selected by the sales and marketing department of the company, and whether information about the supporting company's product is disseminated after the initial program other than in response to an unsolicited request. *Id.* The promotion of off-label drug uses at a CME program which fails this test of "independence" violates Congress' off-label marketing restrictions

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

49. Pfizer, unable to control and bolster Geodon revenues by directly submitting prescription drug reimbursement claims to Medicaid and Medicare and the other government-funded healthcare programs named herein, instead launched a campaign intended to increase Government-funded off-label purchases of Geodon by defrauding geriatric physicians and psyehiatrists, pediatric physicians and psychiatrists, general practice psychiatrists, primary care physicians ("PCPs") and doctors of internal medicine to prescribe Geodon for non-medically accepted indications. The natural, intended and foreseeable effect consequence of such unlawful, premeditated conduct caused such physicians and/or pharmacists to submit claims to publicly-funded health plans that were ineligible for reimbursement pursuant to these programs' regulations.

58. Each such claim Pfizer knowingly caused to be submitted under these false pretenses in derogation of the labeling and misbranding laws, and each false statement it made to cause claims to get claims for Geodon paid, constitutes a false claim for which Pfizer is accountable under the Federal False Claims Act and the analogous laws of the Plaintiff States.

1. Prescription Drug Reimbursement in Federal Health Care Programs

50. Whether a drug is FDA-approved for a particular use will largely determine whether a prescription for that use will be reimbursed under Medicaid and other federal health care programs.

a. The Medicaid Act

51. Title XIX of the Social Security Act is a program that provides medical assistance for certain individuals and families with low incomes and resources. The program, known as Medicaid, became law in 1965 as a jointly funded cooperative venture between the Federal and State governments to assist States in the provision of adequate medical care to eligible needy Americans. Among the groups of people served by Medicaid are eligible low-income parents and children. Among the health benefits funded primarily by Medicaid, up until January 1, 2006, was funding for the prescription drug needs of the Program's beneficiaries.

52. A State must have a plan for medical assistance that has been approved by the Centers for Medicare and Medicaid Services (CMS), which administers the program on behalf of the Secretary of Health and Human Services to participate in the Medicaid program. The state plan must specify, among other things, the specific kinds of medical care and services that will be covered. 42 U.S.C. § 1396a(a)(1 0) and (17). If the plan is approved by the Secretary, the State thereafter is eligible for federal financial participation, *i.e.,* reimbursement by the federal government for a specified percentage of the amounts that qualify as medical assistance under the state plan. *Id.* at §§ 1396b(a)(I), 1396d(b).

53. States are accorded a broad measure of flexibility in tailoring the scope and coverage of their plans to meet the particular needs of their residents and their own budgetary and other circumstances. While the Medicaid Act requires States to provide certain basic services, the Act permits, but does not require, States to cover prescription drugs, although most States choose to do so. 42 U.S.C. § 1396d(a)(12).

54. In 1990, Congress enacted the Medicaid Drug Rebate Statute, codified at 42 U.S.C. §1396r-8, to "establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser." H.R. Rep. No. 881, 101st Cong., 2d Sess. 96 (1990). That statute prohibits federal financial participation for covered outpatient drugs unless there is a rebate agreement in effect under section 1396r-8. See 42 U.S.C. §§ 1396b(i)(10)(A) and 1396r-8(a)(1). Once a drug manufacturer has entered into a rebate agreement for a covered outpatient drug, a State is generally required to cover that drug under the state plan.

55. However, there are several provisions of the Medicaid Act that permit a State to exclude or restrict coverage. 42 U.S.C. § 1396a(a)(54); H.R. Rep. No. 881 at 97,98. A State may restrict from coverage or exclude altogether certain drugs or classes of drugs, or certain medical uses, such as drugs used for, among other things, cosmetic purposes. 42 U.S.C. § 1396r-8(d)(1)(B)(ii). Relevant hereto is the provision which permits a State to exclude or restrict coverage of a drug where "the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(i).

56. Under the statute, a "covered outpatient drug" includes a drug dispensed by prescription and approved as safe and effective under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 355 & 357. It does not include "a drug or biological used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(2), (3).

57. The statute defines "medically accepted indication" as: any use for a covered outpatient drug which is approved [by the FDA, *i.e.* an on-label use], or the use

of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section. *Id.* at § 1396r-8(k)(6).

58. The three compendia identified in subsection (g)(1)(B)(i) are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, and the Drugdex Information System. *Id.* at § 1396r-8(g)(1)(B)(i).

59. During the time period relevant to this Amended Complaint, many of the off-label uses of drugs promoted by Pfizer were not eligible for reimbursement from Medicaid because such off-label uses were neither listed in the labeling approved by the FDA nor otherwise supported as safe and effective by any of the drug compendia specified by the Medicaid Act.

60. Although Pfizer has promoted Geodon as medically safe and effective for the following conditions, diagnoses and symptomatic complaints listed below, Geodon's use in these conditions have not been supported by the 'compendia' as medically safe and effective, *i.e.*, these uses are not medically accepted indications. Examples include treating agitation in conditions unrelated to schizophrenia and bipolar disorder; the depressive phase of bipolar disorder, maintenance treatment for bipolar disorder; depression; atypical psychosis; bipolar disorder II with atypical features; psychoses not associated with schizophrenia or bipolar I disorder; multi-infarct dementia; Alzheimer's type dementia; Pick's dementia; dementia not otherwise specified; delirium; acute confusional states; sundowning; insomnia or inability to fall asleep quickly; drug-induced intoxication or withdrawal, including alcohol intoxication, cocaine intoxication, ecstasy intoxication, amphetamine-induced intoxication; and

drug-induced intoxicated and withdrawal states secondary to hallucinogenic or inhalant abuse; severe anxiety; eating disorders; Borderline personality disorder; conduct disturbance; oppositional and defiant behavior; sexual acting-out behaviors; attention deficit disorder with or without hyperactivity; disorders of impulse control; Intermittent explosive disorder; Pervasive developmental disorder (autism) and its variants, including Asperger's disease; and post-traumatic stress disorder.

61. For example, Pfizer has aggressively promoted Geodon to primary care physicians, internists, psychiatrists (geriatric, adult and child) for the treatment of depression. Treatment of depression is not a medically accepted indication of Geodon, *i.e.*, it is off-label and not supported by the medical compendia identified in the Medicaid Act.

62. Moreover, according to Pfizer's own website currently in use, Geodon is recommended off-label for depression and Geodon's risks continue to be misrepresented and minimized. The current Geodon information supplied by Pfizer reads, for example: "Geodon significantly improves symptoms of depression associated with manic or mixed episodes" and "Treatment goal: manage symptoms of depression associated with manic or mixed episodes, (egs.) dysphoric mood, worry, loss of interest."

63. Further, there are no current citations in DrugDex for the use of Geodon for any of the following diagnoses or conditions: anxiety disorders, phobias, Post traumatic stress disorder, depressive or mood disorders (other than Bipolar I, mixed or manic), dementia, agitation associated with sundowning in the elderly, delirium, pediatric indications, geriatric indications, psychotic symptoms unrelated to schizophrenia or Bipolar I disorder, oppositional-defiant disorder, ADHD, autism/pervasive developmental

disorder, tic disorders, drug-induced agitation or psychosis or personality disorders. Nonetheless, Pfizer has promoted Geodon for these non-medically accepted uses.

64. Additionally, because Pfizer's unlawful off-label marketing efforts were designed to generate overutilization of Geodon in clinical situations in which it was not proven safe and effective and/or was not medically necessary for treatment of patients' specific medical conditions, Pfizer caused Medicaid/Medicare participating pharmacies and/or physicians to submit claims for reimbursement to Medicaid that were ineligible for reimbursement at the time submitted and therefore false.

h. Other Federal Health Care Programs

65. In addition to Medicaid, the federal government reimburses a portion of the cost of prescription drugs under several other federal health care programs, including but not limited to CHAMPUS/TRICARE, CHAMPVA and the Federal Employees Health Benefit Program ("FEHBP"). These programs, described below, have been harmed by defendant Pfizer's conduct in that they have been caused by Pfizer to pay false and/or fraudulent claims and a direct result of the conduct complained of in this Amended Complaint.

VI. ALLEGATIONS

66. In 2001, Pfizer introduced Geodon on the market. Pfizer knew that there was a small market for Geodon's "on" label uses. Since 2001, Pfizer has wantonly and willfully disregarded legal restrictions on the manner in which it could promote pharmaceuticals that it manufactured and/or distributed, specifically Geodon, in derogation of federal and state statutory law cited herein.

67. Accordingly, as other atypical antipsychotic manufacturers had done before it

(Lilly, AstraZeneca, Janssen) thereby achieving blockbuster sales success, Pfizer focused its marketing and promotional efforts for Geodon on expanding its sales for off-label uses to achieve the blockbuster revenues achieved by companies such as Janssen, AstraZeneca and Lilly.

A. Pfizer Has Illegally Promoted Geodon Off-Label.

68. Until August 19, 2004, Geodon's only approved FDA use was to treat acute agitation in schizophrenic patients and acute manifestations of schizophrenia.

69. Since at least January 2001, however, Pfizer was already aggressively marketing Geodon off-label for conditions other than schizophrenia or its associated agitation, including: non-schizophrenia-related agitation, depression, anxiety, personality disorders, psychotic symptoms not part of schizophrenia or Bipolar I; sundowning; mood instability; impaired concentration; impaired attention; impulsivity; oppositional behaviors; irritability; delirium; dementias, sleeplessness; explosiveness and, finally, drug-induced excitement or withdrawal. None of these uses were approved by the FDA or supported by the compendia. Pfizer's promotion of the treatment of these non-medically accepted indications was targeted towards geriatric and pediatric psychiatrists, geriatric and pediatric physicians, primary care physicians and doctors of internal medicine, among others.

70. For example, Pfizer sales training slide shows used in promotional Geodon lectures and provided to Geodon sales representatives instructed sales representatives to promote Geodon's "positive sedative qualities."

71. Plaintiff-Relator is an eyewitness to Pfizer's off-label marketing scheme. Beginning in early 2001, Pfizer and its sales representatives marketed Geodon to

Plaintiff-Relator for many of these off-label uses. In particular, Plaintiff-Relator was detailed by four (4) Pfizer sales representatives with off-label and misleading information about Geodon between January 2001 and April 2007. During their Geodon detailing of Plaintiff-Relator, the Pfizer representatives encouraged him to prescribe Geodon for unapproved uses including, agitation, delirium, dementia, use in children and adolescents, depression, psychotic states unrelated to schizophrenia and schizoaffective disorder.

72. When making marketing presentations to Plaintiff-Relator and others promoting non-FDA approved "off-label" uses of Geodon, Pfizer sales representatives also misrepresented the drug's safety profile by having provided to Plaintiff-Relator misleading medical literature in 2001-2007 that was funded and/or sponsored by Pfizer. Interestingly, in April 2007, two Pfizer representatives admitted to Plaintiff-Relator that they disagreed with Pfizer's safety promotion of Geodon and explained that Geodon posed a significantly higher risk of extrapyramidal symptoms, including akathisia and dystonias (except for tardive dyskinesia) than Pfizer admitted to in its marketing of the drug.

73. In furtherance of its efforts to inflate Geodon's off-label market share, Pfizer sales representatives called upon primary care physicians and psychiatrists whom Pfizer's research indicated were treating patients likely to suffer the kinds of disorders for which off-label prescriptions could be solicited, including drug and alcohol detoxification, severe personality disturbances with behavioral conduct disorders and agitation unassociated with schizophrenia in the elderly and child populations.

74. Among the primary care physicians detailed by Geodon sales representatives in the Philadelphia area include: *Charles Bolno* – Family Practice, DO; *Matthew Shore* –

Family Practice DO; *Kenneth Hoellein*; *Larry Doroshow* Family Practitioner, DO; *Jonathan Levyn* – Family Practitioner, DO; *Gerald Phelan* – Internal Medicine; *Gary Cohen* – Family Practitioner; and *John Lawson* –Family Practitioner, DO.

75. Further, upon information and belief, Pfizer has promoted the off label use of Geodon for inclusion in hospital standing orders and protocols. Plaintiff-Relator uncovered that an adult inpatient psychiatric unit in Pennsylvania has made the use of Geodon IM injections a standing Order. Specifically, as per this standing Order, if a patient were to refuse a dose of Depakote, Geodon IM was to be administered, even over the patients' objection. The standing order is for an off-label use as Depakote is an anti-convulsant.

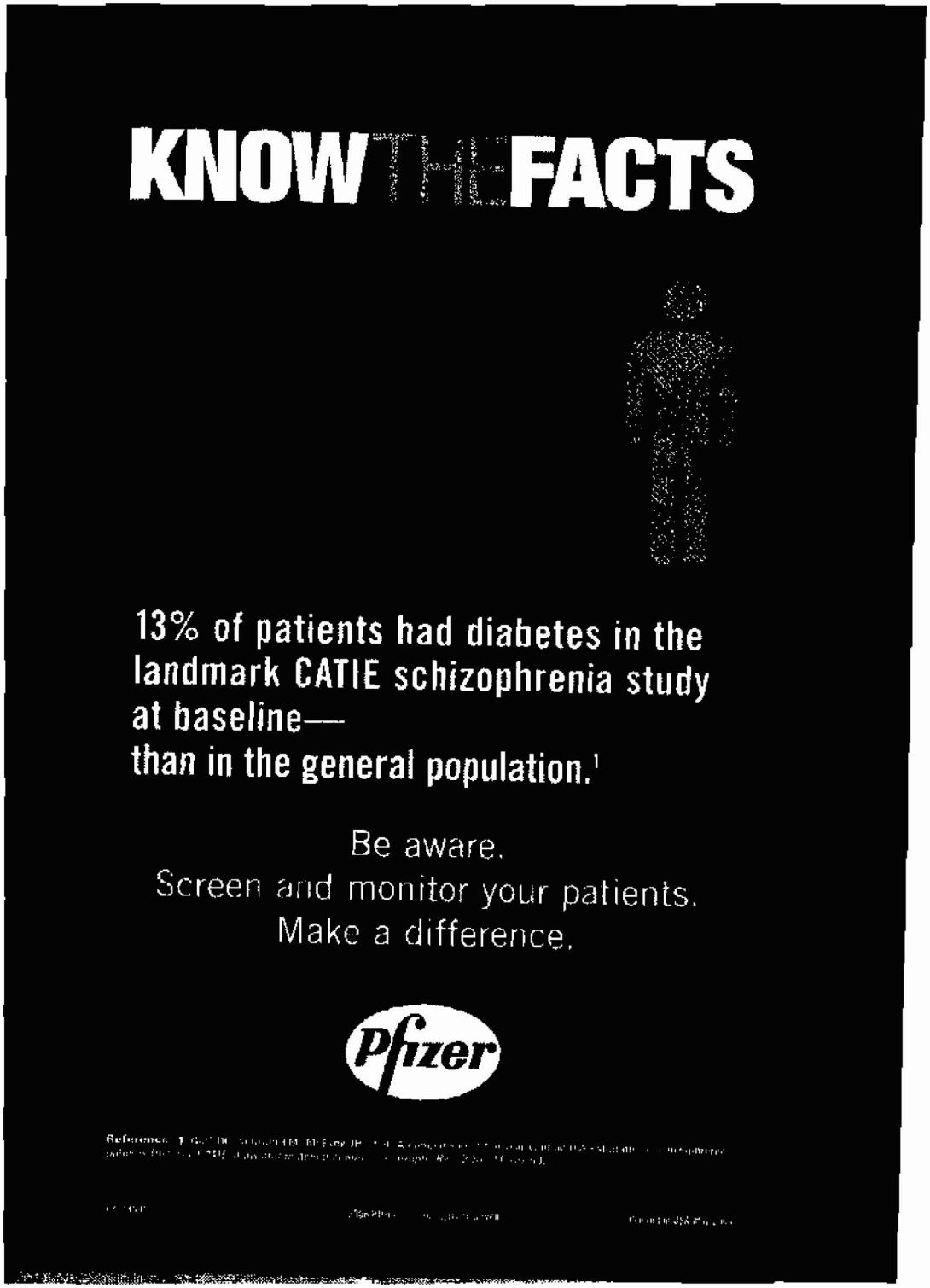
76. Concerning Pfizer's promotion of Geodon for the elderly, Plaintiff-Relator has personal knowledge that Geodon is routinely used off-label for purposes at a Nursing Home facility located in Harrisburg, Pennsylvania. Nearly 50% of the nursing home residents receive injections of Geodon IM at night to prevent nighttime disruptiveness as well as to treat agitation relating to dementia and Alzheimers.

B. Pfizer's Off-Label Promotion and Deceptive Marketing of Geodon is Ongoing.

77. Pfizer continues to expand its off-label market share by claiming that Geodon is safer - in terms of minimal or no weight gain, minimal EPS liability, minimal induction of diabetes and metabolic syndrome - and more effective than rival atypical antipsychotics - particularly olanzapine, risperidone and quetiapine). Pfizer has also mislead as to the safety and efficacy of Geodon by mamking claims that Geodon has significantly lower risk to induce neurological side-effects than conventional

antipsychotics.

78. Pfizer also continues to expand its market share by densely covering the psychiatric and neuropsychiatric/neurologie scientific literature with large scientific ads that are misleading and/or inaccurate.



79. These self-serving and misleading ads such as the one pictured here deceptively suggest that there is a significant underlying risk of diabetes and metabolic syndrome

attendant to the diagnoses of hipolar and schizophrenia. In fact, this is a misstatement of science promoted to serve the marketing efforts of Pfizer and Geodon. By flooding the scientific journals with these ads, Pfizer does three things: (1) They offer Geodon as a positive alternative to drugs like olanzapine (*Zyprexa*-Eli Lilly Company), taking advantage of the fact that Zyprexa has been the target of on-going and repetitive media attention because of its association with weight gain, diabetes, and the metabolic syndrome; (2) erroneously suggest that individuals suffering from schizophrenia are, in and of themselves, four times more likely to have associated diabetes, a statement that is not grounded in generally accepted psychiatric or endocrinological science for individuals unmedicated with antipsychotics; and (3) by mis-advertising that Geodon is safer because it causes little or no weight gain and/or beeause it has a "favorable" cardiovascular side-effect profile and, therefore, may be less likely to cause diabetes and its clinical sequelae, Pfizer suggests that "switching" from previously established and possibly effective antipsychoties, like Zyprexa, may be helpful to individuals. In fact, that "switch" may predispose individuals to more mental and physical problems beeause "switching" upsets clinical stability and is accompanied with the false promise that the patient is receiving a "safer" drug.

80. In fact, there is virtually no credible non-manufacturer-funded scientific evidence to support the fact that diabetes type-2 or metabolic syndrome or significant cardiovascular problems are conditions causally related to un-medicated or drug-naive persons with schizophrenia or bipolar disorder. On the other hand, there is ample evidence, abundantly supported by the scientific literature, that individuals who have serious mental illness (e.g. bipolar disorder 1 or schizophrenic) ***and who consume***

atypical antipsychotics increase the risk of diabetes type-2, hyperlipidemia, obesity, metabolic syndrome and cardiovascular consequences.

81. Pfizer has knowingly engaged in a scheme to mislead the health care community into believing that Geodon is a safe alternative to olanzapine, risperidone and quetiapine with regard to the risk of side-effects including: weight gain, diabetes and metabolic syndrome. In other words, Pfizer promotes Geodon as the preferred drug ***to switch to*** because Pfizer promotes it as equally or more efficacious with a markedly improved side effect profile. However, the scientific evidence does not support that ostensible claim.

82. Moreover, this switching marketing campaign was also a deceptive way to market Geodon off-label. Indeed, as known by Pfizer, the majority of prescriptions for competing antipsychotics such as Zyprexa and Seroquel are written for off-label, non-medically accepted uses. Thus by encouraging switching from a competing antipsychotic to Geodon, Pfizer was able to capture the lucrative off-label market dominance of the competing antipsychotics.

83. The off-label market has been expanded by falsely representing, through the various schemes described in detail herein, that Geodon has a low or minimal risk of extrapyramidal side effects and that patients should be "switched" from other atypical antipsychotics to decrease the risk of metabolic problems (including obesity) and the risk of hyperprolactinemia. Pfizer's representations in this regard are false because the scientific evidence indicates that Geodon (ziprasidone), like olanzapine, risperidone and quetiapine, has its own risk of weight gain, increased prolactin and other serious side effects.

84. Plaintiff-Relator Kruszewski is an eyewitness to this "switching" marketing

message. Specifically, in April 2007, Pfizer Geodon sales representatives directly marketed Geodon to Plaintiff-Relator as the antipsychotic to switch to because of its comparative safety and "favorable" metabolic profile. In particular, two (2) separate Pfizer sales representatives detailed Plaintiff-Relator about Geodon and represented to him that the drug was equally efficacious to any antipsychotic on the market and had the "best" side-effect profile.

85. Specifically, the Pfizer representatives Jobson and Kelly touted Geodon as far better than Zyprexa because Geodon does not have the problems associated with metabolic syndrome, weight gain, obesity, diabetes mellitus or hyperprolactinemia. Both Jobson and Kelly stated that there might be isolated cases when any of these problems could arise, but clearly the risk/benefit ratio in terms of metabolic-associated problems was far better with Geodon than with Zyprexa. They also made the same comparison with Risperdal.

86. Jobson and Kelley also compared Geodon favorably to Abilify. They discussed that Abilify was a partial dopamine agonist and did not appear to be as effective in its control of psychotic symptoms as Geodon, Zyprexa, Risperdal or Seroquel.

87. Additionally, the Pfizer representatives encouraged the use of Geodon as the preferred drug "in the elderly, demented population." While misrepresenting Geodon's side-effect profile, these Pfizer representatives then proceeded to encourage Plaintiff-Relator that patients could be "switched" from other atypical antipsychotics, including olanzapine and risperidone, to Geodon.

88. To "support" these representations, Geodon representative Kelly provided Plaintiff-Relator with a supplement (supported by Pfizer, Inc.) to the Journal of Clinical

Psychiatry in 2003. The issue was completely devoted to ziprasidone (Geodon). This supplement was provided to convince Plaintiff-Relator Kruszewski of the beneficial metabolic effects of ziprasidone compared to older atypical and typical agents, the minimal extrapyramidal side effects and the minimal liability regarding prolactin elevation. He specifically stated that the elevation of prolactin levels was far less than experienced with risperidone or placebo.

89. Plaintiff-Relator's scientific analysis of the supplement revealed that the information contained therein, completely subsidized by Pfizer, was biased in several ways. While the information had been "peer-reviewed," but it was unbalanced and provided nothing more than a huge promotional effort about the benefits of ziprasidone while minimizing the associated risks.

90. Pfizer representatives also encouraged the use of Geodon for the treatment of children and adolescent disorders by offering, without solicitation by Plaintiff-Relator, to set-up and pay for a Pfizer-sponsored one-on-one dinner lecture between the Plaintiff-Relator and an established Pfizer-sponsored child and adolescent psychiatrist.

91. This child psychiatrist routinely gave promotional Geodon talks to VA doctors, internists, family practitioners, pediatricians and child psychiatrists. His presence alone was off-label marketing to pediatricians and child psychiatrists.

92. In fact, as part of its off-label promotional campaign, Pfizer had a large number of child psychiatrists routinely paid substantial honorariums to give purportedly "educational" lectures about Geodon, although these lectures were in fact promotional in nature. Pfizer's intent in hiring pediatric psychiatrists to lecture on Geodon was to expand Geodon's off-label market share among pediatrics.

93. The off-label market share has been promoted through Pfizer-funded scientific studies that misrepresent the evidence supporting the safety of Geodon. This misrepresentation has been carried forth into Pfizer-supported continning medical education (CME) seminars, round table discussions, promotional advertisements, journal supplements, and includes Pfizer's sponsorship of physician meetings, as well as slides made and funded by Pfizer to be used by physicians who are paid to promote Geodon in detailing to other health professionals, most specifically family practitioners.

C. Pfizer Continues to Misrepresent Geodon's Side-Effect Profile to Sustain Geodon Sales.

94. It is now well-established in peer reviewed medical literature that the significant side effects associated with Geodon include, but are not limited to, extrapyramidal side effects including akathisia, tremor, and hypertonic/dystonic reactions. These neurological side effects have been minimized by the company. Also minimized by Pfizer's promotional efforts is Geodon's propensity to cause QT prolongation, hypertension, weight gain, the possibility of diabetes type 2, increased blood lipids, rash, peripheral edema and an increased risk of infection.

95. For example, Geodon prolongs the so-called QT interval on the electrocardiogram (ECG). The QT interval is the time it takes for the muscle-walled lower chambers of the heart (the ventricles) to contract and relax during the normal cardiac cycle. If the QT interval is increased excessively, the conditions are created whereby unstable heart rhythms can intercede and disrupt the normal, regular rhythm essential for heart function. One of the most notorious unstable ventricular rhythms that may result from prolonged QT is *torsades de pointe*, a French term which means "twisting around the point." Not

all episodes of *torsades de pointe* or other ventricular rhythm disturbances are fatal, but these greatly increase the risk of SCD if not promptly corrected.

96. Moreover, contrary to Pfizer's marketing communications, Geodon is similar to risperidone, quetiapine and olanzapine in that it also can induce serious neurological side effects, increase blood lipids, induce weight gain, induce hypertension, and increase the risk of edema, rash and infection.

97. According to the Federal Drug Administration's MedWatch adverse event reporting System ("AERS") and as primarily reported primarily by healthcare practitioners, Geodon has a similar number of adverse events reported when compared to other atypical antipsychotics. In a five-year period between 2001-2006, generated for the sake of comparison by the Plaintiff-Relator, Geodon showed approximately 3,600 adverse events reported compared to a high of 4,830 for Zyprexa, 4,350 for Risperdal, and 2,760 for Seroquel. In other words, in a rough comparison that demonstrates the magnitude of comparability, adverse events were similar for all of the major atypicals.

98. The voluntary reporting that underscores the FDA MedWatch AERS numbers are believed to represent only a small fraction of the actual number of adverse events associated with a drug, assuming that all AERS were reported.

99. As of today, from data in journal articles and review of scientific literature and supported by my review of DrugDex, Geodon has supportive evidence by controlled trials to support a limited claim of efficacy for Geodon in schizophrenia, and Bipolar I, mixed or manic and less so for schizoaffective disorder. There is no other evidence, at this time, to support its use in a myriad of indications where it has been actively promoted by Pfizer, especially in adult depression and anxiety, agitation or pediatric and

geriatric indications. Moreover, Pfizer's tolerability claims for Geodon, especially at *therapeutic* doses (above 120mgs per day), is suspect because the risks of neurological disorders, risks minimized by Pfizer while Geodon is misleadingly promoted as safer than the clinical and academic science support continue.

D. The Financial Consequences of Pfizer's Unlawful Marketing Practices Involving Geodon Are Substantial.

100. Predominantly because of Pfizer's implementation of aggressive off-label marketing efforts as alleged in this Amended Complaint, sales of Geodon in the United States have risen from approximately $141 Million Dollars in 2001 to approximately more than $800 Million Dollars in 2008.

101. The majority of Geodon sales are paid for by state Medicaid programs and the federal government. It is believed, and therefore averred, that Pfizer's sales of Geodon in the United States exceeded $1 Billion in 2006. The high cost and increasing utilization of these psychotropic medications have made them one of the largest cost centers for Medicaid pharmacy programs. Atypical antipsychotics in particular are driving much of the cost, as nationally they comprise more than 90 percent of the national market for antipsychotics, a class that costs Medicaid programs more than $3 billion in 2004.

102. For example, in Wisconsin, for fiscal years 2003, 2004, and 2005, the largest percentage of the Medicaid FFS pharmaceutical budget was spent on atypical antipsychotics. In Florida, the State's Medicaid spending on psychopharmaceuticals increased from $175 million in 1999 to $521 million in FY03-04. These same reimbursement patterns are consistent throughout the country's Medicaid and Medicare

budgets.

103. By way of further example, the New York Medicaid program's expenditures on Geodon prescribed program beneficiaries under the age of 18 increased by 50% from 2004 to 2006. In 2006, Medicaid paid $1,504,510.00 for 7,253 Geodon reimbursement claims for 1,310 children prescribed Geodon.

104. The financial cost of Geodon to the United States and the Plaintiff States through *inter alia* Medicaid, Medicare, Medicare Part D and state Medicaid programs, has been enormous while cheaper and equally effective antipsychotics (examples: perphenazine or thiothixene) with different side-effect profiles could have been prescribed and consumed. In addition, but for Pfizer's off-label marketing of Geodon, these off-label Geodon prescriptions for non medically accepted indications would not have been written and reimbursed by government-funded health care programs.

105. For example, it is believed and, therefore, averred that the cost of Geodon for a single patient alone is paid for by Medicaid at a rate of $250-275 per month.

106. The financial cost of ziprasidone to the United States and the Plaintiff States through Medicaid, Medicare, Medicare Part D, the Railroad Retirement Medicare Program, Federal Employees Health Benefit Programs, Tri-Care (formerly CHAMPUS), CHAMPVA, State Legal Immigrant Assistance Grants and the Indian Health Service has been enormous while cheaper and equally effective antipsychotics (Examples: perphenazine or thiothixene) with different side-effect profiles could have been prescribed and consumed.

VIII. GOVERNMENT FUNDED HEALTHCARE PROGRAMS DAMAGED BY PAYING FALSE GEODON CLAIMS

107. In addition to Medicaid, the federal government reimburses a portion of the cost of prescription drugs under several other health care programs, including but not limited to Medicare, Medicare Part D, the Railroad Retirement Medicare Program, Federal Employees Health Benefit Programs, Tri-Care (formerly CHAMPUS), CHAMPVA, State Legal Immigrant Assistance Grants and the Indian Health Service, as alleged below. As alleged below, these programs operate in similar ways to the Medicare program. For example, the VA and CHAMPUS/Tri-care operate in substantially similar ways to the Medicare and Medicaid programs, but primarily for the benefit of military veterans, their spouses (or widowed spouses) and other beneficiaries.

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

A. Medicaid

109. Title XIX of the Social Security Act is a program which provides medical assistance for certain individuals and families with low incomes and resources. The program, known as Medicaid, became law in 1965 as a jointly funded cooperative venture between the Federal and State governments to assist States in the provision of adequate medical care to eligible needy Americans. Among the groups of people served by Medicaid are eligible low-income parents and children.

110. The Medicaid Program (42 U.S.C. § 1395, *et seq.*) is administered through the Centers for Medicare and Medicaid Services (CMS), which is a division of the Department of Health and Human Services (HHS) of the federal government. Numerous

states statutorily limit Medicaid reimbursement for prescription drugs to those uses approved by the FDA or when the prescribing physician makes a medical necessity certification after the identified patient has failed to respond to treatment with medications indicated for the patient's illness. This prohibition directly implicates Pfizer's off-label marketing scheme because claims for off-label prescriptions were induced to be submitted to the United States and the Plaintiff States for reimbursement without the required certification of medical necessity.

B. Medicare and Medicare Part D

111. Medicare is a government financial health insurance program administered by the Social Security Administration of the United States. The health insurance provided to beneficiaries of the Medicare insurance program is paid in whole or in part by the United States. Medicare was promulgated to provide payment for medical services, durable medical equipment and other related health items for individuals 65 and over. Medicare also makes payment for certain health services provided to additional classes of needy classes of individual healthcare patients pursuant to federal regulation.

112. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"). Title I of the MMA created new outpatient prescription drug coverage under Medicare ("Medicare Part D").

113. Medicare Part D went into effect on January 1, 2006. The Program is administered by the United States Department of Health and Human Services, Centers for Medicare and Medicaid ("CMS"). For "dual eligibles," defined as individuals who received prescription drug coverage under Medicaid in addition to Medicare coverage for other health care in 2005, enrollment in Medicare Part D was compulsory. Such

beneficiaries were automatically switched to Part D plans for 2006 and commenced receiving comprehensive prescription drug coverage under Medicare Part D.

114. Coverage of prescription drugs under Medicare Part D is subject to the same regulations as coverage under the Medicaid Program described above.

115. As a direct, proximate and intended result of the conduct of the Defendants' alleged herein in violation of the federal false claims act and the analogous laws of the Plaintiff States, the Medicare and Medicare Part D programs have been damaged.

C. The Railroad Retirement Medicare Program

116. The Railroad Retirement Medicare program is authorized by the railroad retirement act of 1974, at U.S.C.A. §231 *et seq.* It is administered through the United States Railroad Retirement Board, "RRB," and furnishes Medicare coverage to retired railroad employees.

117. As a direct, proximate and intended result of the conduct of the Defendants' alleged herein in violation of the federal false claims act and the analogous laws of the Plaintiff States, the RRB program has been damaged.

D. Federal Employee Health Benefit Plans

118. The Federal Employees Health Benefits Program ("FEHBP") is administered by the United States Office of Personnel Management ("OPM") pursuant to 5 U.S.C.A §8901 *et seq.* and provides health care coverage to federal employees, retirees and their dependants and survivors.

119. As a direct, proximate and intended result of the conduct of the Defendants' alleged herein in violation of the federal false claims act and the analogous

laws of the Plaintiff States, the FEHBP program has been damaged.

E. Tri-Care

120. The Tri-Care program, formerly, CHAMPUS, is administered by the United States Department of Defense through its component in agency, CHAMPUS, under the authority of 10 U.S.C.A. §§1701-1106. It is a health care program that provides for care in civilian facilities for members of the uniformed services and their dependents.

121. As a direct, proximate and intended result of the conduct of the Defendants' alleged herein in violation of the federal false claims act and the analogous laws of the Plaintiff States, the Tri-care program has been damaged.

F. The Veterans Administration

122. The Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA") is a comprehensive health care program in which the VA shares the cost of covered health care services and supplies with eligible beneficiaries. The program is administered by Health Administration Center and our offices are located in Denver, Colorado. In general, the CHAMPVA program covers most health care services and supplies that are medically and psychologically necessary.

123. Due to the similarity between CHAMPVA and the Department of Defense ("DoD") Tri-Care program, the two are often mistaken for each other. CHAMPVA is a Department of Veterans Affairs program whereas Tri-Care is a regionally managed health care program for active duty and retired members of the uniformed services, their families and survivors. In some cases a veteran may appear to be eligible for both/either program on paper. However, military retirees, or the spouse of a veteran who was killed

in action, are and will always be Tri-Care beneficiaries.

124. Pursuant to 38 U.S.C.A. §8126, and the regulations based thereon, and contracts the Veterans Administration had with manufacturers, drugs furnished to the Veterans' Administration by drug manufacturers must be furnished at the best price.

125. The VA and CHAMPUS/Tri-care operate in substantially similar ways to the Medicare and Medicaid programs, but primarily for the benefit of military veterans, their spouses (or widowed spouses) and other beneficiaries.

126. As a direct, proximate and intended result of the conduct of the Defendants' alleged herein in violation of the federal false claims act and the analogous laws of the Plaintiff States, the CHAMPVA program has been damaged.

G. Indian IIealth Service

127. The Indian health service is responsible for providing comprehensive health services to more than 1,400,000 Americans. It is administered by the department of health and human services pursuant to 42 U.S.C.A. 2002 *et seq*. The statute authorizes the Secretary to enter into contracts with independent providers to furnish health services to Native Americans whenever the Secretary determines that independent providers can better meet the population's need.

II. State Legal Immigrant Assistance Grants

128. Relator is informed and believes and based thereon alleges that the United State also furnishes funds which several States use to pay for sueh drugs pursuant to State Legal Immigrant Assistance Grants ("SLIAG"), 8 U.S.C.A §1255A; 45 C.F.R. §402.10.

129. As a direct, proximate and intended result of the conduct of the Defendants' alleged herein in violation of the federal false claims act and the analogous

laws of the Plaintiff States, the SLIAG program has been damaged.

COUNT ONE

Violations of Federal False Claims Act
31 U.S.C. § 3729(a)(1)

84. Plaintiff incorporates by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the United States under the *qui tam* provisions of 31 U.S.C. §3730 for Defendant's violations of 31 U.S.C. §3729.

85. By virtue of the above-described acts, Defendant Pfizer knowingly caused to be presented false or fraudulent claims for Geodon for payment or approval, and continues to cause to be submitted false or fraudulent claims for Geodon for payment or approval, directly or indirectly, to officers, employees or agents of the United States.

86. Plaintiff United States, unaware of the falsity of the claims and/or statements caused to be made by Defendant Pfizer and in reliance on the accuracy thereof, paid said Defendant for claims that would otherwise not have been allowed.

87. The amounts of the false or fraudulent claims caused by the Defendant to be submitted to the United States for Geodon were material. By reason of Defendant Pfizer's wrongful conduct, the United States has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false claim caused to be submitted by Defendant Pfizer.

88. Relator-Plaintiff believes and avers that he is an original source of the facts and information on which this action is based.

COUNT TWO

Violations of False Claims Act
31 U.S.C. § 3729(a)(2)

89. Plaintiff incorporates by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the United States under the *qui tam* provisions of 31 U.S.C. § 3730 for Defendant's violation of 31 U.S.C. § 3729(a)(2).

90. By virtue of the above-described acts, Defendant Pfizer knowingly caused to be made or used false records or statements to get false or fraudulent claims for payment or approval by the United States, and continues to make, use or cause false records and statements to be made or used to get false or fraudulent claims for Geodon paid or approved by the United States.

91. Plaintiff United States, unaware of the falsity of the records and/or statements caused to be made and used by Defendant Pfizer, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for Geodon that were ineligible for reimbursement and would not have been paid or approved if any part of the truth were known.

92. The amounts of the false or fraudulent claims caused by the Defendant to be submitted to the United States for Geodon were material. By reason of Defendant Pfizer's wrongful conduct, the United States has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false statement caused to be made or used by Defendant Pfizer.

93. Plaintiff-Relator believes and avers that he is an original source of the facts and

information on which this action is based.

COUNT THREE

Violations of the False Claims Act, 31 U.S.C. §3729(a)(3)

94. Plaintiff re-alleges and incorporates by reference all of the foregoing paragraphs as if fully set forth herein. Defendant Pfizer entered into conspiracies with paid consultants and public officials for the purpose of defrauding the Plaintiff United States.

95. By the foregoing acts and omissions, Defendant Pfizer took actions in furtherance of its conspiracies, including but not limited to the payment of substantial sums of monies to its co-conspirators in exchange for casting favorable light upon Geodon and for choosing Geodon to become a first line treatment, thereby exponentially increasing the number of Geodon prescriptions submitted to the United States for payment.

96. By the foregoing acts and omissions, Defendant Pfizer entered into these unlawful marketing conspiracies to defraud the United States by causing false and fraudulent claims to be paid and approved in violation of the False Claims Act, 31 U.S.C. §3729(a)(3).

97. At all times relevant to the complaint, Pfizer acted with the requisite knowledge.

98. As a direct and proximate consequence of Defendant Pfizer's conspiratorial conduct, the United States has suffered significant, material financial damages in an amount to be proved at trial. The United States *ex rel.* Plaintiff-Relator is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each ineligible Geodon claims submitted to the United States for payment.

COUNT FOUR

Violations of the Illinois Whistleblower Reward and Protection Act
740 ILCS 175/1 *et seq.*

99. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of Illinois under the *qui tam* provisions of 740 ILCS 175/4 for Defendant's violation of 740 ILCS 175/3.

100. Defendant Pfizer at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Illinois, including Geodon.

101. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175/3 (a)(1)-(3), specifically provide 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;...
> (2) Knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;...
> (3) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid;. . .
>
> (a) is liable to State for civil penalty of not less than $5,500 and not more than $11,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

102. By virtue of the above-described acts, among others, Defendant Pfizer knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Illinois, for Geodon.

103. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Illinois,

- knowingly made, used or caused to be made or nsed false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent elaims allowed or paid; ; and,
- failed to disclose the existence of the false claims it has caused to be presented.

104. The amounts of the false or fraudulent claims to the State of Illinois were material.

105. Plaintiff State of Illinois, being unaware of the falsity of the claims caused to be submitted by the Defendant, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed Geodon.

COUNT FIVE

Violations of the California False Claims Act Ca. Government Code §12650 *et seq.*

106. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein.

107. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of California under the *qui tam* provisions of the California False Claims Act, California Government Code §12651(a) pursuant to which treble damages and civil penalties are sought.

108. Defendant Pfizer at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals, including Geodon, in the State of California.

109. Cal. Gov't Code §12651(a) provides liability for the costs of a civil action, a civil penalty of up to $10,000 and

treble damages for all damages sustained by the state for any person who-

(1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval;

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

(3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision;

(8) is a beneficiary of an inadvertent snbmission of a false claim, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

110. By virtue of the above-described acts, among others, Defendant Pfizer knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of California, for Geodon.

372. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of California,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; ; and,
- failed to disclose the existence of the false claims it has caused to be presented.

111. The amounts of the false or fraudulent claims to the State of California were material.

112. Plaintiff State of California, being unaware of the falsity of the claims caused to be submitted by Defendant Pfizer and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed Geodon.

COUNT SIX

Violations of the Delaware False Claims Act
Del. Stat. Tit. VI. §1201

113. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of Delaware under the *qui tam* provisions of the Delaware False Claims and Reporting Act, Delaware Statute Title VI, Section 1201.

114. Defendant Pfizer at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Delaware, including Geodon.

115. The Delaware False Claims and Reporting Act, 6 Del Code Ann. §1201(a)(1) provides for liability for any person who:

> knowingly presents or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval; . . . 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 the actual damages which the Government sustains because of the act of that person.

116. The Delaware False Claims and Reporting Act, 6 Del. C. §1201(a)(2) provides for liability for any person who:

> 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 the actual damages which the Government sustains because of the act of that person.

117. The Delaware False Claims and Reporting Act, 6 Del. C. §1201(a)(3),

provides for liability for any person who:

> 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 the actual damages which the Government sustains because of the act of that person.

118. By virtue of the above-described acts, among others, Defendant Pfizer knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Delaware, for Geodon.

372. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Delaware.
- knowingly made, used or caused to be made or used false records to get false claims paid.
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; ; and,
- failed to disclose the existence of the false claims it has caused to be presented.

119. The amounts of the false or fraudulent claims to the State of Delaware were material.

120. Plaintiff State of Delaware, being unaware of the falsity of the claims caused to be submitted by the Defendant, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed Geodon.

COUNT SEVEN

Violations of the District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(1)

121. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein.

122. This Count is brought by Plaintiff-Relator Kruszewski in the name of the District of Columbia under the *qui tam* provisions of D.C. Stat. §2-308.03 *et seq.*

123. Defendant Pfizer at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the District of Columbia, including Geodon.

124. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(1)-(3), specifically provide 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.
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the District.
>
> (3) Conspires to defraud the District of Columbia by getting a false claim allowed or paid by the District.

125. By virtue of the above-described acts, among others, Defendant Pfizer knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the District of Columbia, for Geodon.

126. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the District of Columbia,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; ; and,
- failed to disclose the existenee of the false claims it has caused to be presented.

127. The amounts of the false or fraudulent claims to the District of Columbia were material.

128. Plaintiff District of Columbia, being unaware of the falsity of the claims caused to be submitted by the Defendant, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed Geodon.

COUNT EIGHT

Violations of the Florida False Claims Act FI. Stat. §§68.081-68.09

129. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein.

130. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of Florida under the *qui tam* provisions of Florida False Claims Act, Fl. Stat. §§68.081-68.09.

131. Defendant Pfizer at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Florida, including Geodon.

132. Fla. Stat § 68.082(2)(a)-(c) provide liability for any person who-

(a) Knowingly presents, or

causes to be presented, to an officer or employee of an agency, a false or fraudulent claim for payment or approval; ... 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 $5,500 and not more than $11,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

(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 $5,500 and not more than $11,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

(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 $5,500 and not more than $11,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

* * *

is liable to the state for a civil penalty of not less than $5,500 and not more than $11,000 and for treble the amount of damages the agency sustains beeause of the act or omission of that person;

133. By virtue of the above-described acts, among others, Defendant Pfizer caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be suhmitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Florida, for Geodon.

134. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Florida,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- eonspired to defraud the state by getting false and fraudulent claims allowed or paid; ; and,
- failed to disclose the existence of the false elaims it has caused to be presented.

135. The amounts of the false or fraudulent claims to the State of Florida were material.

136. Plaintiff State of Florida, being unaware of the falsity of the claims caused to be submitted by the defendant, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed Geodon.

COUNT NINE

Violations of the Georgia State False Medicaid Claims Act, O.C.G.A. § 49-4-168 *et seq.*

137. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein.

138. This is a *qui tam* action brought by brought by Relator Kruszewski and the State of Georgia to recover treble damages, civil penalties and the cost of this action, under the Georgia State False Medicaid Claims Act, O.C.G.A. § 49-4-168 *et. seq.*

139. Defendant Pfizer at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Georgia, including Geodon.

140. Georgia State False Medicaid Claims Act, O.C.G.A. § 49-4-168.1(a), specifically provides in part:

(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;

...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.

141. By virtue of the acts described above, Defendant knowingly presented, or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

142. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Georgia,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; ; and,
- failed to disclose the existence of the false claims it has caused to be presented.

143. For example, Geodon prescriptions for the purposes of non-medically accepted uses would not have been presented but for the illegal incentives and unlawful promotional activities made by Defendant. As a result of this illegal scheme, these claims were improper in whole pursuant to the Georgia State False Medicaid Claims Act.

144. By virtue of the acts described above, Pfizer knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

145. Each prescription that was written as a result of Defendant's illegal marketing practices represents a false or fraudulent record or statement. Each claim for reimbursement for such preseriptions for non-medically accepted uses submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

146. Plaintiff cannot at this time identify all of the false claims for payment that

were caused by Pfizer's conduct. The false claims were presented by thousands of separate entities, and over many years.

147. The Georgia State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Pfizer, paid and continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

148. By reason of Pfizer's acts, the Georgia State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

149. Georgia is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Pfizer.

150. Defendant did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

151. Relator is a private person with direct and independent knowledge of the allegations in this Complaint, who have brought this action pursuant to Georgia State False Medicaid Claims Act on behalf of himself and the State of Georgia.

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

COUNT TEN

Violations of the Hawaii False Claims Act
Haw. Rev. Stat. §661-21 *et seq.*

153. Plaintiff incorporates by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of Hawaii under the *qui tam* provisions of Hawaii False Claims Act, Haw. Rev. Stat. §661-21 *et seq.*

154. Defendant Pfizer at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Hawaii, including Geodon. The Hawaii False Claims Act, Haw. Rev. Stat § 661-21(a)(1)-(3) specifically provides 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;...
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;...
> (3) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid;...
>
> * * *
>
> Shall be liable to the State for a civil peualty 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.

155. By virtue of the above-described acts, among others, Defendant Pfizer knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Hawaii, for Geodon.

156. Specifically, Defendant has:

- caused hundreds of thousands of false claims to he presented to the State of Hawaii,
- knowingly made, used or caused to be made or used false records to get false claims paid,

- conspired to defraud the state by getting false and fraudulent claims allowed or paid; ; and,

- failed to disclose the existence of the false claims it has caused to be presented.

157. The amounts of the false or fraudulent claims to the State of Hawaii were material.

158. Plaintiff State of Hawaii, being unaware of the falsity of the claims caused to be submitted by Defendant, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed Geodon.

COUNT ELEVEN

Violations of the Louisiana Medical Assistance Programs Integrity Law Louisiana Rev. Stat. §437 *et seq.*

159. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of Louisiana under the *qui tam* provisions of the Louisiana Medical Assistance Programs Integrity Law, Louisiana Rev. Stat. §437 *et seq.*

160. Defendant Pfizer at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Louisiana, including Geodon.

161. The Louisiana False Claims Act/Medical Assistance Programs Integrity Law, La. Rev. Stat. § 46-438.3 provides:

> (A) No person shall knowingly present or cause to be presented a false or fraudulent claim.
> (B) No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance program funds;
> (C) No person

> shall 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 medical assistance programs.

162. By virtue of the above-described acts, among others, Defendant Pfizer knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Louisiana, for Geodon.

163. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Louisiana,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

164. The amounts of the false or fraudulent claims to the State of Louisiana were material.

165. Plaintiff State of Louisiana, being unaware of the falsity of the claims caused to be submitted by the Defendant, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed Geodon.

COUNT TWELVE

Violations of the Massachusetts False Claims Act
Massachusetts Gen. Laws c.12 §5(A)

166. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of Massachusetts under the *qui tam* provisions of the Massachusetts False Claims Act, Massachusetts Gen. Laws c.12 §5(A).

167. Defendant Pfizer at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the Commonwealth of Massachusetts, including Geodon.

168. The Massachusetts False Claims Act, Mass. Gen. Laws Ann. chap. 12, §5(B)(1)-(3), provides in part, that any person who:

> (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment; ...
> (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; ...
> (3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim; ...
>
> * * *
>
> shall 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.

169. By virtue of the above-described acts, among others, Defendant Pfizer knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the Commonwealth of Massachusetts, for Geodon.

170. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the Commonwealth of Massachusetts,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

171. The amounts of the false or fraudulent claims to the State of Massachusetts were material.

172. Plaintiff Commonwealth of Massachusetts, being unaware of the falsity of the claims caused to be submitted by the Defendant's conspiracies and in reliance on the accuracy thereof, paid and continues to pay for improperly preseribed Geodon.

COUNT THIRTEEN

Violations of the Montana False Claims Act 2005 Mont. Code, CH. 465, HB 146, *et seq.*

173. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of Montana under the *qui tam* provisions of the Montana False Claims Act, 2005 Mont. Code, CH. 465, HB 146, *et seq.*

174. Defendant Pfizer at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals, including Geodon, in the State of Montana.

175. The Montana False Claims Act, Mont. Code Ann., § 17-8-403 provides for liability for *inter alia* any person who engages in any or all of the following conduct:

(a) knowingly

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

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

(c) conspiring to defraud the governmental entity by getting a false claim allowed or paid by the governmental entity; . . .or

(h) as a beneficiary of an inadvertent submission of a false claim to the governmental entity, subsequently discovering the falsity of the claim and failing to disclose the false claim to the governmental entity within a reasonable time after discovery of the false claim.

176. By virtue of the above-described acts, among others, Defendant Pfizer knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Montana, for Geodon.

177. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Montana,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

178. The amounts of the false or fraudulent claims Defendant caused to be made to the State of Montana were material.

179. Plaintiff State of Montana, being unaware of the falsity of the claims caused to be submitted by the Defendant and in reliance on the accuracy thereof paid and

may continue to pay for improperly prescribed Geodon.

180. At all times relevant to the complaint, Pfizer acted with the requisite knowledge.

181. By virtue of the above-described acts, among others, Defendant Pfizer knowingly engaged in conspiracies to defraud the Government of Montana by getting a false claim allowed or paid by the government for Geodon.

182. As a direct and proximate consequence of Defendant Pfizer's conspiratorial conduct, the State of Montana has suffered significant, material financial damages in an amount to be proved at trial.

183. The State of Montana would not have suffered these devastating losses had the truth about Defendant's marketing conspiracies been known.

COUNT FOURTEEN

Violations of the Tennessee Medicaid False Claims Act Tenn. Stat. §§75-1-181 *et seq.*

184. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein.

185. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of Tennessee under the *qui tam* provisions of the Tennessee Medicaid False Claims Act, Tenn. Stat. §§75-1-181 *et seq.*

186. Defendant Pfizer at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Tennessee, including Geodon.

187. By virtue of the above-described acts, among others, Defendant Pfizer

knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Tennessee, for Geodon.

188. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Tennessee,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

189. The amounts of the false or fraudulent claims to the State of Tennessee were material.

190. Plaintiff State of Tennessee, being unaware of the falsity of the claims and/or statements caused to be made by the Defendant, and in reliance on the accuracy thereof paid and may continue to pay for Defendant's improperly prescribed drug Geodon.

COUNT FIFTEEN

Violations of the Tennessee False Claims Act Tenn. Code Ann. § 4-18-101 *et seq.*

191. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein.

192. This is a qui tam action brought by Plaintiff Kruszewski on behalf of the State of Tennessee to recover treble

damages, civil penalties and the cost of the civil action under the *qui tam* provisions of the Tennessee False Claims Act, Tenn. Code Ann. § 4-18-101 *et seq.*

193. Tenn. Code Ann. §4-18-103, titled "Liability for violations," provides:

> (a) Any person who commits any of the following acts shall be liable to the state or to the political subdivision for three (3) times the amount of damages which the state or the political subdivision sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state or to the political subdivision for the costs of a civil action brought to recover any of those penalties or damages, and shall be liable to the state or political subdivision for a civil penalty of not less than two thousand five hundred dollars ($ 2,500) and not more than ten thousand dollars ($ 10,000) for each false claim:
>
> (1) Knowingly presents or causes to be presented to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
>
> (3) Conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision;
>
> (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 or to any political subdivision;

194. Defendant violated §4-18-103(a)(1), (2), and (3) and knowingly presented or caused to be presented hundreds of thousands of false claims from at least 2001 to the present by their violation of state and federal laws, including the Anti-Kickback Statute and Best Price Statute, as described herein.

195. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Tennessee,

- knowingly made, used or caused to be made or used false records to get false claims paid,

- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,

- failed to disclose the existence of the false claims it has caused to be presented.

196. The State of Tennessee, by and through Tennessee-funded health plans, and unaware of Defendants' illegal practices, paid the claims submitted by health care providers and third party payors in connection therewith.

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

198. As a result of Defendant's violations of Tenn. Code Ann. §§4-18-103, the State of Tennessee has been damaged in an amount far in excess of millions of dollars exclusive on interest.

199. Kruszewski is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Tenn. Code Ann. §§4-18-103 on behalf of himself and the State of Tennessee.

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

COUNT SIXTEEN

Violations of the Texas Medicaid Fraud Prevention Act
Tx. Human Resources Code, Ch. 36, §36.101 *et seq.*

201. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of Texas under the *qui tam* provisions of the Texas Medicaid Fraud Prevention Act, Tx. Human Resources Code, Ch. 36, §36.101 *et seq.*

202. Defendant Pfizer at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Texas, including Geodon.

203. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Texas,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

204. By virtue of the above-described acts, among others, Defendant Pfizer knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Texas, for Geodon.

205. The amounts of the false or fraudulent claims to the State of Texas were material.

206. Plaintiff State of Texas, being unaware of the falsity of the claims caused to be submitted by the defendant, and in reliance on the accuracy thereof paid and continues to pay for Defendant's improperly prescribed drug, Geodon.

COUNT SEVENTEEN

Violations of the Virginia Fraud Against Taxpayers Act
Va. Stat. Ch. 842, Article 19.1, § 8.01-216.1 *et seq.*

207. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the Commonwealth of Virginia under the *qui tam* provisions of the Virginia Fraud Against Taxpayers Act, Va. Stat. Ch. 842, Article 19.1, § 8.01-216.1 *et seq.*

208. Defendant Pfizer at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the Commonwealth of Virginia, including Geodon.

209. By virtue of the above-described acts, among others, Defendant Pfizer knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the Commonwealth of Virginia, for Geodon.

210. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the Commonwealth of Virginia,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

211. The amounts of the false or fraudulent claims to the Commonwealth of Virginia were material.

212. Plaintiff Commonwealth of Virginia, being unaware of the falsity of the claims caused to be submitted by the Defendant, and in reliance on the accuracy thereof paid and continues to pay for Defendant's improperly prescribed drug Geodon.

COUNT EIGHTEEN
Violations of the Indiana False Claims and Whistleblower Act (IC 5-11-5.5 *et seq.*)

213. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein.

214. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of Indiana under the *qui tam* provisions of IC 5-11-5.5-4, for the Defendant Pfizer's violations of IC 5-11-5.5-2.

215. Defendant Pfizer, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Indiana, including Geodon.

216. The Indiana False Claims and Whistleblower Act, Ind. Code § 5-11-5.5-2(b) (2008), specifically provides that by engaging in certain acts a person commits an unlawful act and shall be liable to the state for civil penalties of at least $5000 and for up to 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; or
> (2) making or using a false record or statement to obtain payment or approval of a false claim from the state; . . . or
> (7) conspiring with another person to perform an act described above; or
> (8) Causing or inducing another person to perform an act described [above].

217. Through the acts described above and otherwise, Defendant Pfizer knowingly caused to be presented for payment and approval to the Indiana Medicaid

program, possibly continues to cause to be presented, directly or indirectly, to officers, employees or agents of the State of Indiana, false and fraudulent claims in order to induce Medicaid reimbursement for Geodon, and Defendant Pfizer's other drugs, that were not eligible for any such reimbursement.

218. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Indiana,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; ; and,
- failed to disclose the existence of the false claims it has caused to be presented.

219. As a result, Plaintiff Indiana reimbursed Medicare and Medicaid participating providers for ineligible claims of Geodon, resulting in material financial losses to the State of Indiana.

220. Plaintiff State of Indiana, unaware of the falsity of the claims caused to be presented by Defendant Pfizer, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for Geodon that would not have been paid or approved in any part if the truth were known.

221. By reason of Defendant Pfizer's wrongful conduct, Indiana has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the State's false claims act in an amount to be determined at trial, plus civil penalties for each such false statement caused to be made or used by Defendant Pfizer.

COUNT NINETEEN

Violations of the Nevada False Claims Act
Nevada Rev. Stat. §357.010 *et seq.*

222. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein.

223. This Count is brought by Plaintiff-Relator Stefan Kruszewski in the name of the State of Nevada under the *qui tam* provisions of Nevada Rev. Stat. §357.010 *et seq.*, "Submission of False Claims to State or Local Government."

224. Defendant Pfizer, at all times relevant to this action, sold and continue to sell pharmaceuticals in the State of Nevada, including Geodon.

225. Through the acts described above and otherwise, Defendant Pfizer knowingly caused to be presented for payment and approval to the Nevada Medicaid program, possibly continues to cause to be presented, directly or indirectly, to officers, employees or agents of the State of Nevada, false and fraudulent claims in order to induce Medicaid reimbursement for Geodon.

226. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Nevada,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; ; and,
- failed to disclose the existence of the false claims it has caused to be presented.

227. At all times relevant and material to this Complaint, Defendant Pfizer knowingly caused false claims for payment or approval for Geodon to be presented to

officers and employees of the federal and state governments. As a result, the federal and state governments reimbursed Medicare and Medicaid provider pharmacies for ineligible claims for Geodon, resulting in great financial loss to the Nevada government.

228. By virtue of the above-described acts, among others, Defendant Pfizer knowingly caused to be made or used and continues to cause to be made or used false or fraudulent statements to get claims allowed or paid for Geodon by the State of Nevada, for Geodon.

229. The amounts of the false or fraudulent claims and statements caused to be made by Pfizer to the State of Nevada were material.

230. Plaintiff State of Nevada, being unaware of the falsity of the claims and/or statements caused to be made or used by Defendant, and in reliance on the accuracy thereof paid and continues to pay for Defendant's improperly prescribed drug Geodon.

COUNT TWENTY

Violations of the New Hampshire False Claims Act 167:61-b *et. seq.*

231. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of New Hampshire under the *qui tam* provisions of New Hampshire False Claims Act, 167:61-b *et. seq.*

232. Defendant Pfizer at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of New Hampshire.

233. Through the acts described above and otherwise, Defendant Pfizer knowingly caused to be presented for

payment and approval to the New Hampshire Medicaid and Medicare programs, and continues to cause to be presented, false and fraudulent claims, directly or indirectly, to officers, employees or agents of the State of New Hampshire, to induce Medicaid and/or Medicare reimbursement for claims for Geodon that were not and are not eligible for any such reimbursement.

234. Through the acts described above and otherwise, Defendant Pfizer knowingly caused to be made or used, and continues to cause to be made or used, false and fraudulent records and/or statements, in order to get claims for Geodon allowed or paid by Medicaid and/or Medicare, that were not eligible for any such reimbursement.

235. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of New Hampshire,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

236. The amounts of the false or fraudulent claims to the State of New Hampshire were material.

237. Plaintiff State of New Hampshire, unaware of the falsity of the claims presented or caused to be presented by Defendant Pfizer, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for Defendant Pfizer's drugs that would not have been paid or approved in any part if the truth were known.

238. By reason of Defendant Pfizer's wrongful conduct, New Hampshire has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus the maximum penalties for each such false statement caused to be made or used by Defendant Pfizer and each such false claim caused to be submitted by Defendant Pfizer.

COUNT TWENTY ONE

Violations of the New Mexico Medicaid False Claims Act, N.M. Stat ANN. §27-14-1 et *seq.*

239. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of New Mexico under the *qui tam* provisions of the New Mexico Medicaid False Claims Act §27-14-1 *et seq.*

240. Defendant Pfizer at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of New Mexico, including Geodon.

241. Through the acts described above and otherwise, Defendant Pfizer knowingly caused to be presented for payment and approval to the New Mexico Medicaid and/or Medicare programs, and continues to cause to be presented, false and fraudulent claims directly or indirectly, to officers, employees or agents of the State of New Mexico, in order to induce Medicaid and/or Medicare reimbursement for claims for Geodon that were not eligible for any such reimbursement.

242. Through the acts described above and otherwise, Defendant Pfizer knowingly caused to be made or used, and continues to cause to be made or used, false

and fraudulent records and/or statements, in order to get claims for Geodon allowed or paid by Medicaid and Medicare that were not eligible for any such reimbursement.

243. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Nevada,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; ; and,
- failed to disclose the existence of the false claims it has caused to be presented.

244. The amounts of the false or fraudulent claims caused to be made to the State of New Mexico were material.

245. Plaintiff State of New Mexico, unaware of the falsity of the claims presented or caused to be presented by Defendant Pfizer, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for Geodon that would not have been paid or approved in any part if the truth were known.

246. By reason of Defendant Pfizer's wrongful conduct, New Mexico has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus the maximum civil penalty allowed under the state law for each such false claim caused to be submitted by Defendant Pfizer and each such false statement caused to be made or used by Defendant Pfizer.

COUNT TWENTY TWO

Violations of the New Mexico Fraud Against Taxpayers Act
N.M. Stat. § 44-9-1 *et seq.*

247. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein.

248. This is a *qui tam* action brought by Plaintiff Kruszewski on behalf of the State of New Mexico to recover treble damages, civil penalties and the cost of the civil action under the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. § 44-9-1.

249. N.M. Stat. Ann. § 44-9-3 (A) of the New Mexico Fraud Against Taxpayers Act provides that [a] person shall not:

> (1) knowingly present, or cause to be presented, to an employee, officer or agent of the state or to a contractor, grantee or other recipient of state funds a false or fraudulent claim for payment or approval;
>
> (2) knowingly make or use, or cause to be made or used, a false record or statement to obtain approval or payment on a false or fraudulent claim;
>
> (3) conspire to defraud the state by obtaining approval or payment on a false claim;
>
> (9) as a beneficiary of an inadvertent submission of a false claim and having subsequently discovered the falsity of the claim, fail to disclose the false claim to the state agency within a reasonable time after discovery.

250. Pursuant to N.M. Stat. Ann. § 44-9-3(B) of the New Mexico Fraud Against Taxpayers Act, proof of specific intent is not required for a violation of subsection A of Section 3.

251. Defendant at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of New Mexico.

252. By virtue of the illegal conduct and the other misconduct alleged herein, including causing the submissions of non-reimbursable claims for prescription drugs described above and using or causing to be used false or fraudulent records to accomplish

this purpose, Defendants violated N.M. Stat. Ann. § 44-9-3(A) of the New Mexico Fraud Against Taxpayers Act with the requisite intent.

253. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Nw Mexico,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

254. For example, claims for reimbursement for off-label prescriptions of Pfizer's drug Geodon prescribed to government-funded health care program beneficiaries for non-medically accepted indications would not have been submitted to the State of New Mexico but for the illegal practices of Defendant described in this Complaint.

255. The New Mexico Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

256. By reason of these improper payments, the New Mexico Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

257. Defendant did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

258. Plaintiff is private persons with direct and independent knowledge of the allegations in this Complaint, who have brought this action pursuant to N.M. Stat. Ann. § 44-9-5 of the New Mexico Fraud Against Taxpayers Act on behalf of himself and the State of New Mexico.

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

COUNT TWENTY THREE

Violations of the Michigan Medicaid False Claims Act (M.C.L.A. 400.601 *et seq.*)

260. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of Michigan under the *qui tam* provisions of the Michigan False Claims Act, M.C.L.A. 4000.601 *et seq.*

261. Defendant Pfizer at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Michigan, including Geodon.

262. Through the acts described above and otherwise, Defendant Pfizer knowingly caused to be presented for payment and approval to the Michigan Medicaid and/or Medicare programs, and continues to cause to be presented, false and fraudulent claims, directly or indirectly, to officers, employees or agents of the State of Michigan, in order to induce Medicaid and or Medicare to reimburse Medicaid or Medicare

participating pharmaceutical providers for Geodon when those claims were not and are not eligible for any such reimbursement.

263. Through the acts described above and otherwise, Defendant Pfizer knowingly caused to be made or used, and continues to cause to be used or made, false and fraudulent records and/or statements, in order to get claims for Geodon allowed or paid by Medicaid and/or Medicare that were not eligible for any such reimbursement.

264. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Michigan,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; ; and,
- failed to disclose the existence of the false claims it has caused to be presented.

265. The amounts of the false or fraudulent claims caused to be made to the State of Michigan were material.

266. Plaintiff State of Michigan, unaware of the falsity of the claims caused to be presented by Defendant Pfizer, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for Geodon that would not have been paid or approved in any part if the truth were known.

267. By reason of Defendant Pfizer's wrongful conduct, Michigan has suffered substantial financial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus the maximum allowable civil penalties for each such false statement caused to made or used

by Defendant Pfizer and each such false claim caused to be made by Defendant Pfizer.

COUNT TWENTY FOUR

Violations of Michigan Public Acts, 1977 PA 72, as amended by 1984 PA 333, as amended by 2005 PA 337, as amended by 2008 PA 421

268. Plaintiff realleges and incorporates by reference each and every of the foregoing paragraphs as if fully set forth herein.

269. This is a claim for treble damages and penalties under the Michigan Medicaid False Claims Act brought by Plaintiff Kruszewski on behalf of himself and the State of Michigan.

270. By virtue of the acts described above, Defendant has violated the the Michigan Medicaid False Claims Act.

271. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Michigan,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

272. For example, prescriptions for the purposes of non-medically accepted 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 State of Michigan's False Medicaid Claims Act.

273. By virtue of the acts described above, Pfizer knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

274. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. Each claim for reimbursement for such off-label prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

275. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Pfizer's conduct. The false claims were presented by thousands of separate entities, and over many years.

276. The Michigan State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Pfizer, paid and continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

277. By reason of Pfizer's acts, the Michigan State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

278. The State of Michigan is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Pfizer.

279. Defendants did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to

the State regarding the claims for reimbursement at issue.

280. Plaintiff are private persons with direct and independent knowledge of the allegations in this Complaint, who have brought this action pursuant to Michigan's False Claims Act on behalf of themselves and the State of Michigan.

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

COUNT TWENTY FIVE

Violations of the New York False Claims Act State Finance Law, §187 *et seq.*

282. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Kruszewski in the name of the State of New York under the *qui tam* provisions of the New York False Claims Act, N.Y. St. Fin. §187 *et seq.*

283. Defendant Pfizer at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of New York, including Geodon.

284. The New York False Claims Act, State Fin. Law § 189 specifically provides, in part, that a person commits an unlawful act if the person:

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

a local government;

(c) conspires to defraud the state or a local government by getting a false or fraudulent claim allowed or paid;

285. Through the acts described above and otherwise, Defendant Pfizer knowingly caused to be presented for payment and approval to the New York Medicaid and/or Medicare programs, and continues to cause to be presented, false and fraudulent claims, directly or indirectly, to officers, employees or agents of the State of New York, in order to induce Medicaid and or Medicare to reimburse Medicaid or Medicare participating pharmaceutical providers for Geodon when those claims were not and are not eligible for any such reimbursement.

286. Through the acts described above and otherwise, Defendant Pfizer knowingly caused to be made or used, and continues to cause to be used or made, false and fraudulent records and/or statements, in order to get claims for Geodon allowed or paid by Medicaid and/or Medicare that were not eligible for any such reimbursement.

287. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of New York,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

288. The amounts of the false or fraudulent claims to the State of New York were material.

289. Plaintiff State of New York, unaware of the falsity of the claims caused to be presented by Defendant Pfizer, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for Geodon that would not have been paid or approved in any part if the truth were known.

290. By reason of Defendant Pfizer's wrongful conduct, New York has suffered substantial financial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus the maximum allowable civil penalties for each such false statement caused to made or used by Defendant Pfizer and each such false claim caused to be made by Defendant Pfizer.

COUNT TWENTY SIX

Violations of the Oklahoma Medicaid False Claims Act, 63 Okla. Stat. § 5053, *et seq.*

291. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein.

292. This is a *qui tam* action brought by brought by Kruszewski and the State of Oklahoma to recover treble damages, civil penalties and the cost of this action, under the Oklahoma Medicaid False Claims Act, 63 Okla. Stat. § 5053, *et. seq.*

293. Defendant, from at least 2001 to the present, has engaged in a continuous practice of using and concealing unlawful marketing practices to promote the off-label use of Geodon, with the result that they have: (a) knowingly presented and caused to be presented, to an officer and employee of the State of Oklahoma, false and fraudulent claims for payment and approval; and (b) have 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 Oklahoma.

294. The Oklahoma Medicaid False Claims Act, 63 Okla. Stat. § 5053.1 (B), specifically provides in part:

> (B) Any person who:
>
> (1) knowingly presenting or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the state; and,
>
> (3) conspires to defraud the state by getting a false claim allowed or paid by the governmental entity; ...
>
> Is liable to the State of Oklahoma for a civil penalty of not less than $ 5,000.00 and not more than $10,000.00, ... plus three times the amount of damages which the state sustains because of the act of that person.

295. Defendant knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the Oklahoma Medicaid program, claims which failed to disclose the material violations of the Oklahoma Medicaid False Claims Act.

296. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Oklahoma,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

297. For example, prescriptions for the purposes of non-medically accepted uses would not have been presented but for the illegal incentives and unlawful promotional activities made by Defendant. As a result of this illegal scheme, these claims were improper in whole pursuant to the State of Oklahoma State False Medicaid Claims Act.

298. By virtue of the acts described above, Pfizer knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

299. Each prescription that was written as a result of Defendant' illegal marketing practices represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions for non-medically accepted uses submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

300. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Pfizer's conduct. The false claims were presented by thousands of separate entities, and over many years.

301. The Oklahoma State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Pfizer, paid and continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

302. By reason of Pfizer's acts, the Oklahoma State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

303. Oklahoma is entitled to the maximum penalty for each and every false or

fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Pfizer.

304. Defendant did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

305. Relators are private persons with direct and independent knowledge of the allegations in this Complaint, who have brought this action pursuant to Oklahoma False Medicaid Claims Act on behalf of himself and the State of Oklahoma.

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

COUNT TWENTY SEVEN

Violations of the Wisconsin False Claims for Medical Assistance Act, WIS. STAT. § 20.931, *et seq.*

307. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein.

308. This is a *qui tam* action brought by brought by Kruszewski and the State of Wisconsin to recover treble damages, civil penalties and the cost of this action, under the Wisconsin False Claims for Medical Assistance Act, WIS. STAT. § 20.931, *et. seq.*

309. Defendant, from at least 2001 to the present, have engaged in a continuous

practice of using and concealing unlawful marketing practices to promote the off-label use of Geodon, with the result that they have: (a) knowingly presented and caused to be presented, to an officer and employee of the State of Wisconsin, false and fraudulent claims for payment and approval; and (b) have 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 Wisconsin.

310. The Wisconsin False Claims for Medical Assistance Act, WIS. STAT. § 20.931(2), specifically provides in part:

> (2) Except as provided in sub. (3), any person who does any of the following is liable to this state for 3 times the amount of the damages sustained by this state because of the actions of the person, and shall forfeit not less than 5,000 nor more than 10,000 for each violation:
>
> (a) Knowingly presents or causes to be presented to any officer, employee, or agent of this state a false claim for medical assistance.
>
> (b) Knowingly makes, uses, or causes to be made or used a false record or statement to obtain approval or payment of a false claim for medical assistance.
>
> (c) Conspires to defraud this state by obtaining allowance or payment of a false claim for medical assistance, or by knowingly making or using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance program.

311. Defendant knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the Wisconsin Medicaid program, claims which failed to disclose the material violations of the Wisconsin False Claims for Medical Assistanee Aet.

312. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Wisconsin,

- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

313. For example, prescriptions for the purposes of non-medically accepted uses would not have been presented but for the illegal incentives and unlawful promotional activities made by Defendant. As a result of this illegal scheme, these claims were improper in whole pursuant to the State of Wisconsin State False Medicaid Claims Act.

314. By virtue of the acts described above, Pfizer knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

315. Each prescription that was written as a result of Defendaut' illegal marketing practices represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions for non-medically accepted uses submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

316. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Pfizer's conduct. The false claims were presented by thousands of separate entities, and over many years.

317. The Wisconsin State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Pfizer, paid and continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing

practices.

318. By reason of Pfizer's acts, the Wisconsin State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

319. Wisconsin is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Pfizer.

320. Defendant did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

321. Relators are private persons with direct and independent knowledge of the allegations in this Complaint, who have brought this action pursuant to the Wisconsin False Claims for Medical Assistance Act on behalf of himself and the State of Wisconsin.

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

COUNT TWENTY EIGHT

Violations of the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1, *et seq.*

323. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein.

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

325. Defendant, from at least 2001 to the present, have engaged in a continuous practice of using and concealing unlawful marketing practices to promote the off-label use of Geodon, with the result that they have: (a) knowingly presented and caused to be presented, to an officer and employee of the State of Rhode Island, false and fraudulent claims for payment and approval; and (b) have 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 Rhode Island.

326. The Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-3(a), specifically provides in part:

> (a) Any person who:
>
> (1) Knowingly presents, or causes to be presented, to an officer or employee of the state or a member of the guard a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;
>
> (3) Conspires to defraud the state by getting a false or fraudulent claim allowed or paid; ... 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. A person violating this subsection (a) shall also be liable to the state for the costs of a civil action brought to recover any such penalty or damages.

327. Defendant knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the Rhode

Island Medicaid program, claims which failed to disclose the material violations of the Rhode Island False Claims Act.

328. Defendant knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the Rhode Island Medicaid program, claims which failed to disclose the material violations of the Rhode Island False Claims Act.

329. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of Rhode Island,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

330. For example, prescriptions for the purposes of non-medically accepted uses would not have been presented but for the illegal incentives and unlawful promotional activities made by Defendant. As a result of this illegal scheme, these claims were improper in whole pursuant to the State of Rhode Island False Claims Act.

331. By virtue of the acts described above, Pfizer knowingly made, used, or caused to he made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

332. Each prescription that was written as a result of Defendant' illegal marketing practices represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions for non-medically accepted uses submitted to a

State-funded health insurance program represents a false or fraudulent claim for payment.

333. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Pfizer's conduct. The false claims were presented by thousands of separate entities, and over many years.

334. The Rhode Island State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Pfizer, paid and continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

335. By reason of Pfizer's acts, the Rhode Island State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

336. Rhode Island is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Pfizer.

337. Defendant did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

338. Relators are private persons with direct and independent knowledge of the allegations in this Complaint, who have brought this action pursuant to the Rhode Island False Claims Act on behalf of himself and the State of Rhode Island.

339. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely

asserts separate damage to the State of Rhode Island in the operation of its Medicaid program.

COUNT TWENTY NINE

Violations of the New Jersey False Claims Act, N.J. STAT. § 2A:32C-1

340. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein.

341. This is a *qui tam* action brought by brought by Kruszewski and the State of New Jersey to recover treble damages, civil penalties and the cost of this action, under the New Jersey False Claims Act.

342. Defendant, from at least 2001 to the present, has engaged in a continuous practice of using and concealing unlawful marketing practices to promote the off-label use of Geodon, with the result that they have: (a) knowingly presented and caused to be presented, to an officer and employee of the State of Rhode Island, false and fraudulent claims for payment and approval; and (h) have 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 New Jersey.

343. The New Jersey False Claim Act prohibits any person from:

> (1) Knowingly presenting, or causing to be presented, to an officer or employee of the state or a member of the guard a false or fraudulent claim for payment or approval;
>
> (2) Knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;
>
> (3) Conspiring to defraud the state by getting a false or fraudulent claim allowed or paid;

344. Defendant knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the New Jersey Medicaid program, claims which failed to disclose the material violations of the New Jersey False Claims Act.

345. Defendant knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the New Jersey Medicaid program, claims which failed to disclose the material violations of the New Jersey False Claims Act.

346. Specifically, Defendant has:

- caused hundreds of thousands of false claims to be presented to the State of New Jersey,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

347. For example, prescriptions for the purposes of non-medically accepted uses would not have been presented but for the illegal incentives and unlawful promotional activities made by Defendant. As a result of this illegal scheme, these claims were improper in whole pursuant to the State of New Jersey False Claims Act.

348. By virtue of the acts described above, Pfizer knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

349. Each prescription that was written as a result of Defendant' illegal

marketing practices represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions for non-medically accepted uses submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

350. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Pfizer's conduct. The false claims were presented by thousands of separate entities, and over many years.

351. The New Jersey State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Pfizer, paid and continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

352. By reason of Pfizer's acts, the New Jersey Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

353. New Jersey is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Pfizer.

354. Defendant did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

355. Relators are private persons with direct and independent knowledge of the allegations in this Complaint, who have brought this action pursuant to the New Jersey False Claims Act on behalf of himself and the State of New Jersey.

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

JURY DEMAND

357. Plaintiff demands trial by jury on all claims.

PRAYER

WHEREFORE, Plaintiff-Relator Stefan Kruszewski, on behalf of himself, the United States of America and the Plaintiff States, demands and prays that judgment be entered as follows against the Defendant Pfizer under the Federal FCA Counts and under supplemental FCA counts of the Plaintiff States as follows:

(a) In favor of the United States against Defendant Pfizer for treble the amount of damages to Government health Care Programs (Medicaid, Medicare, Medicare Part D, the Railroad Retirement Medicare Program, Federal Employees Health Benefit Programs, Tri-Care (formerly CHAMPUS), CHAMPVA, State Legal Immigrant Assistance Grants and the Indian Health Service) from the illegal marketing, selling, prescribing, pricing and billing alleged herein, plus the maximum civil penalties of $11,000 (plus interest) for each false claim caused to be submitted, for each false record submitted or caused to be submitted and each false claim caused to be submitted by Defendant Pfizer's conspiracy to submit false claims;

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

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

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

(e) In favor of the Plaintiff- Relator Kruszewski and the United States for such other relief as this Court deems just and equitable;

(f) In favor of the Plaintiff-Relator Kruszewski and the named State Plaintiffs against Defendant Pfizer in an amount equal to three times the amount of damages that the named Plaintiff States havesustained as a result of the Defendants' actions, as well as the statutory maximum penality against the Defendant Pfizer for each violation of each State's FCA;

(g) In favor of Plaintiff- Relator Kruszewski for the maximum amount allowed as Relator's share pursuant to the Plaintiff State FCAs as follows: the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175, *et seq.*, the California False Claims Act, Cal. Gov. Code §12651(a), the Delaware False Claims and Reporting Act, Del. Stat. Tit. VI. §1201, *et seq.*, the District of Columbia False Claims Act, D.C. Stat. §2-308.03 *et seq.*, the Florida False Claims Act, Fl. Stat. §§68.081-68.09, *et seq.*, the Hawaii False Claims Act, Haw. Rev. Stat. §661-21 *et seq.*, the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §439, *et seq.*, Massachusetts False Claims Act, Mass. Gen. Laws c.12 §5(A), *et seq.*, the Michigan Medicaid False Claims Act, M.C.L.A. 400.601 *et seq.*; Michigan Public Acts, 1977 PA 72, as amended by 1984 PA 333, as amended by 2005 PA 337, as amended by 2008 PA 421; the Montana False Claims Act, 2005 Mont. Code, CH. 465, HB 146, *et seq.*, the Nevada False Claims Act, Nevada Rev. Stat.

§357.010 *et seq.*, the New Hampshire False Claims Act, 167:61-b *et seq.*, the New Mexico False Claims Act, N.M. Stat ANN. §27-14-1 *et seq.*; New Mexico Fraud Against Taxpayers Act , N.M. Stat. § 44-9-1 *et seq.*; the New York False Claims Act, State Finance Law, §187 *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Stat. §§75-1-181 *et seq.*; the Tennessee False Claims Act Tenn. Code Ann. § 4-18-101 *et seq.*; the Texas Medicaid Fraud Prevention Act, Tx. Human Resources Code, Ch. 36, §36.101 *et seq.*, Indiana False Claims and Whistleblower Act, IC 5-11-5.5 *et seq.*, Georgia State False Medicaid Claims Act, Ga. Code 49-4-168 *et seq.*, and the Virginia Fraud Against Taxpayers Act, Va. Stat. Ch. 842, Article 19.1, §8.01-216.1 *et seq.*; New Jersey False Claims Act, N.J. STAT. § 2A:32C-1; Oklahoma Medicaid False Claims Act, 63 Okla. Stat. § 5053, *et seq.*; Wisconsin False Claims for Medical Assistance Act, WIS. STAT. § 20.931, *et seq.*; and the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1, *et seq.*; plus interest;

(h) In favor of Plaintiff- Relator Kruszewski for all costs and expenses associated with the supplemental claims of the Plaintiff States, including attorney's fees and costs;

(i) In favor of the Plaintiff States and Plaintiff- Relator Kruszewski for all such other relief as the Court deems just and proper; and,

(j) In the event that the United States or Plaintiff States proceed with this action, Plaintiff-Relator Kruszewski, be awarded an appropriate amount for disclosing evidence or information that the United States and/or the Plaintiff States did not possess when this action was brought to the government. The appropriate amount is not greater than twenty-five percent (25%) of the proceeds of the action or settlement of a claim. The amount awarded to Plaintiff-Relator also includes the results of government actions or

settlement of claims resulting from the expansion of claims through the government's further investigation directly generated from or attributable to Plaintiff-Relator's information; and

(k) Such other relief as this Court deems just and appropriate.

Respectfully Submitted,

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