



(2) its systematic payment of kickbacks to doctors across the country in the form of sham “consultant” and “speaking” arrangements to induce the doctors who receive these payments to favor Novartis’ products over that of its competitors. Novartis deliberately concealed its fraudulent schemes from the government-funded health care programs who pay for prescription drug coverage, and as a result, these programs unknowingly paid, and continue to pay, millions of dollars per year in connection with those schemes.

2. With respect to its off-label promotion campaign, Novartis flouted the FDA requirements and decided not even to seek FDA approval of Trileptal as a treatment for bipolar disorder but instead to aggressively market the drug for this use in the absence of the necessary safety and efficacy studies required by the FDA. As part of this strategy, Novartis concealed critical negative studies and data concerning Trileptal’s use in psychiatry and particularly, unflattering comparisons of the drug to lithium, the FDA-approved and undisputed “first-line” treatment for bipolar disorder. All of these actions were undertaken for the sole purpose of Novartis’ own financial gain, at the expense of government-funded health care programs and the patients who are reliant on those programs.

3. As a result of Novartis’ off-label promotion and kickback schemes, the company caused the submission of hundreds of thousands of false claims to government-funded health care programs across the country that pay for prescription drug coverage for their recipients. These schemes cost the Medicaid programs alone at least one-hundred million dollars during the time period of 2000 through 2003, and with respect to Trileptal only. This complaint, which details Novartis’ off-label promotion and kickback schemes, is based upon non-public information Relator obtained during the course of his thirteen years of employment by Novartis, and his personal observation of the acts and conduct described herein.

4. In connection with the filing of this Complaint, Relator also furnished the United States and state governments with the disclosure statement required by 31 U.S.C. § 3730(b)(2) and like provisions of the state false claims acts, including thousands of pages of documents evidencing and supporting the fraudulent schemes described herein. Relator is the original source of all of the facts and information contained in this complaint and voluntarily provided that information to the government prior to filing his complaint.

### **THE PARTIES**

5. Relator, Steve M. McKee (“McKee”), is a citizen of the United States and a resident of the state of North Carolina. McKee was employed by Novartis (formerly Ciba-Geigy Pharmaceuticals) as a pharmaceutical sales representative from August 1990 until September 2003. Throughout his career with the company, McKee worked with a wide range of pharmaceutical products and disease states. McKee regularly received performance-based bonuses, raises and promotions.

6. In January 2002, McKee was promoted to the Neuroscience Specialty Division, with responsibility for the sale of prescription drug products Exelon, Comtan and Trileptal. McKee’s excellent employment record at Novartis changed only after he joined this new division, where he soon learned Novartis required the sales representatives in that division to promote off-label uses of Trileptal to psychiatrists and other physicians. McKee voiced concerns over the off-label promotion requirements to his supervisor and senior sales representatives in his region throughout the summer of 2002. In response, McKee was told simply that he would “get used to it” and that targeting psychiatrists was the fastest way to gain market share.

7. In mid-2002 and because of the off-label promotion requirements, McKee requested a transfer out of the neuroscience division. McKee’s transfer was denied due to a company policy

requiring a sales representative to remain in a division for at least two years before seeking a transfer. McKee remained in the division and in the fall of 2002, he again told his supervisor he was uncomfortable with promoting Trileptal off-label to psychiatrists, that there was no real data to support the use of the drug in psychiatry. McKee advised his supervisor he refused to initiate any off-label sales discussions with psychiatrists or otherwise promote the product off-label as required by the company. By June 2003, McKee was placed on a Performance Improvement Plan and in September 2003, was terminated for allegedly failing to make his sales goals.

8. Novartis Pharmaceuticals Corporation (hereinafter “Novartis” or “the company”) is a division of Novartis AG, a global pharmaceutical company created in 1996 from the merger of Swiss companies, CIBA-Geigy AG and Sandoz AG. In 2003, Novartis AG achieved sales of nearly \$30 billion and a net income of \$5 billion. Novartis AG is headquartered in Basel, Switzerland, operates in over 140 countries around the world and employs about 78,500 people.

9. According to its internet website, Novartis is a “world leader in the discovery, development, manufacture and marketing of prescription medicine.” *See* [www.novartis.com](http://www.novartis.com). Headquartered in East Hanover, New Jersey, Novartis consists of five business units: primary care, oncology, transplantation, ophthalmics and mature products. Of relevance here, the primary care unit includes products to treat central nervous system disorders such as schizophrenia, epilepsy, Parkinson’s disease, Alzheimer’s disease, attention deficit hyperactivity disorder and migraine headaches. Within the primary care unit, the key products of the neuroscience division include Comtan, Exelon, Focalin, Clozaril/Leponex, Ritalin, Tegretol, and Trileptal.

### **JURISDICTION AND VENUE**

10. This is a civil action arising under the laws of the United States, and specifically, 31 U.S.C. § 3730, the “False Claims Act.” Therefore, this Court has jurisdiction over this action pursuant to 31 U.S.C. § 3732 (a) and (b).

11. Venue is proper in this district pursuant to 31 U.S.C. § 3732 (a) because Defendant Novartis transacts substantial business in this district and also maintains permanent employees and corporate offices in this district. Defendant also committed numerous acts proscribed by 31 U.S.C. § 3729 in this district..

12. This Court has supplemental jurisdiction over the state law claims contained in this action pursuant to 28 U.S.C. § 1367(a), as such claims form part of the same case or controversy as the federal claims.

### **FACTUAL BACKGROUND**

#### **THE REGULATION OF PRESCRIPTION DRUG SALES AND MARKETING ACTIVITIES IN THE UNITED STATES**

13. The Food, Drug and Cosmetic Act (FDCA or the Act) governs the sales and marketing activities of pharmaceutical manufacturers in the United States, including the introduction of new drugs into interstate commerce. Under the FDCA, new drugs cannot be distributed in interstate commerce unless and until the manufacturer demonstrates to the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355 (a) and (d). While pursuant to the “medical practice exception,” an individual physician may prescribe a drug for a use other than one for which it is approved, the FDA prohibits a drug manufacturer from marketing or promoting a drug for non-approved uses. 21 U.S.C. § 331(d) and § 355(a). Likewise, a drug manufacturer’s sales representatives are prohibited from initiating discussions with physicians regarding any off-label uses

of a drug. The dissemination of information or materials by a pharmaceutical manufacturer on any unapproved or off-label uses constitutes unlawful promotional advertising or “misbranding” of the drug and violates the FDCA (this activity is referred to as “off label” marketing or promotion).

14. A limited exception to the prohibition on off-label promotion (not applicable here) is provided for in the FDA Modernization Act of 1997. The limited exception comes into play where a pharmaceutical manufacturer has committed to seeking FDA approval for the new use and has notified the FDA of its intent. 21 U.S.C. § 355 (codified at Pub. L. No. 105-115). Even in that circumstance, the manufacturer must comply with strict requirements, including that it must submit any off-label use materials it plans to disseminate to physicians to the FDA for pre-approval.

15. The reason for the prohibition on off-label promotion by drug manufacturers is many-fold: (1) this activity diminishes or eliminates the drug manufacturer’s incentive to study the use and obtain definitive safety and efficacy data; (2) off-label promotion could result in harm to patients from unstudied uses that actually lead to bad results, or that are merely ineffective; (3) it diminishes the use of evidence-based medicine; and (4) could ultimately erode the efficacy standard in medicine. *See* Presentation by Janet Woodcock, MD (Director of the FDA’s Center for Drug Evaluation and Research), June 23, 1997 available at [www.fda.gov/cder/present/diamontreal/regappr/sld001.htm](http://www.fda.gov/cder/present/diamontreal/regappr/sld001.htm).

#### **THE ANTI-KICKBACK ACT’S PROHIBITIONS**

16. Under the federal Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b), it is illegal to knowingly and willfully offer or pay any remuneration in cash or in kind in exchange for the referral of any product (including a prescription drug product) that is payable in whole or in part by any federally-funded health care programs, including Medicare and Medicaid. These federal health care programs require that providers seeking payment by these programs certify compliance with the

provisions of the Anti-Kickback Act and other federal laws governing the provision of health care services in America.

17. The Anti-Kickback Act prohibits pharmaceutical manufacturers from making any payments, in cash or in kind, to any health care provider where a purpose of such payment is to influence the provider's prescribing habits or, to put it another way, to gain favor for its product over that of a competitor. Activities that have come under attack under this statute include payments by pharmaceutical manufacturers to physicians for sham "consulting" services, illusory "training" sessions, bogus research and "educational" grants, lavish meals, entertainment and other gifts and discounts. These activities are particularly suspect where a drug manufacturer selects physicians for these payments, based not on their professional resume or services actually provided to the company, but rather, on their ability or potential to prescribe the company's products. The Anti-Kickback Act's prohibitions are designed to ensure patient care will not be improperly influenced by the deep pockets of the pharmaceutical industry.

**THE REIMBURSEMENT CRITERIA USED BY  
GOVERNMENT-FUNDED HEALTH CARE PROGRAMS**

18. The federal and state governments pay for prescription drug benefits under a variety of health care programs. The most well known of these programs is Medicaid, which provides health care coverage, including prescription drug benefits, for the poor and disabled. The Medicaid program, administered by the Center for Medicare and Medicaid Services (CMS), is jointly funded by the federal and state governments. Other government-funded health care programs that pay for prescription drug coverage for their members or recipients include CHAMPUS/Tricare, the Veteran's Health Administration and Federal Employees' Health Benefits Program (FEHB), among others (all of these programs, including Medicaid are collectively referred to herein as the

“government-funded health care programs”).

19. While each of the government-funded health care programs varies slightly in its reimbursement criteria, none of these programs pay for medications that are not FDA approved or that are not for “medically accepted indications” (a “medically accepted indication” is a use that is supported by the medical compendia set forth in § 1396r-8(g)(1)(B)(i) of the FDCA). Bipolar disorder is not a “medically accepted indication” for Trileptal and therefore is not eligible for reimbursement for this use. Likewise, the government-funded health care programs do not pay for prescriptions resulting from false or misleading information disseminated by a pharmaceutical manufacturer or connected to illegal kickbacks paid by a pharmaceutical manufacturer.

#### **NOVARTIS’ FRAUDULENT OFF-LABEL PROMOTION SCHEME**

20. In January 2000, Novartis announced that its prescription drug product Trileptal (clinically known as oxcarbazepine) had received FDA approval for use in the treatment of epilepsy. Specifically, the FDA approved Trileptal for the treatment of partial seizures as mono or single drug therapy in adults or adjunctive therapy in adults and children ages four and up. In August, 2003, the FDA also approved Trileptal for use as a mono therapy in children with epilepsy. To date, Trileptal has not received FDA approval for any other use.

21. Nevertheless, almost immediately after launching Trileptal in February 2000, Novartis began an aggressive marketing scheme to promote uses of Trileptal other than the limited use approved by the FDA. Novartis, with very little in the way of medical or scientific data to support that Trileptal was safe and effective for any use other than in the treatment of epileptic seizures (and actually holding information to the contrary), and without the necessary safety trials being completed or even contemplated by the company, began touting Trileptal as a safe and effective treatment for bipolar disorder, a serious, chronic mental illness. Recent data suggests bipolar symptoms may

affect nearly eight million American adults, or one in thirty people. In contrast, the market for epilepsy is only a fraction of that (the condition affects approximately two million Americans). Among psychiatric illnesses, bipolar disorder carries one of the highest rates of suicide completion (as high as 10-15%) and up to 40% of patients with bipolar disorder also have problems with alcohol and drug use during their illness. Many patients with bipolar disorder require institutionalization at some point in their lives. There is presently no cure for the disease.

22. Novartis targeted psychiatrists in its promotion of Trileptal who, as a group, have no reason to prescribe the drug other than for off-label uses. Neurologists, on the other hand, are the most common prescribers of FDA-approved uses of Trileptal. In setting up the off-label promotion scheme, Novartis devoted sales representatives in three of its four neuroscience divisions to the task and required them to promote Trileptal to the psychiatrists on the “target” lists it generated and distributed to its sales force. *See* representative Novartis Target lists for 2002 and 2003, attached as Exh. A. Since psychiatrists do not prescribe Trileptal for any FDA-approved indications, the only discussions that could possibly take place on these sales calls were off-label discussions. Failure of the Novartis sales representatives to make the off-label sales calls to psychiatrists led to negative employment reviews and discipline and negatively impacted any potential merit pay increases they might otherwise receive.

23. To further encourage the off-label promotion activities of its sales force, Novartis paid bonuses for upward shifts in Trileptal market share generated by psychiatrists. The bonus plan continued through 2000, 2001, 2002 and mid-way through 2003. Novartis sales representatives were instructed that psychiatrists were “low hanging fruit” and easy targets for the off-label promotion activities and bonus opportunity.

24. Also beginning as early as the first quarter of 2000, Novartis dedicated a distinct

marketing or promotional budget for the off-label use of Trileptal. According to records kept by the company and distributed to newly hired sales representatives during their training, by early 2001, Novartis was pouring \$250,000 - \$500,000 per month into the off-label promotion scheme. *See* Exh. B (Excerpt from Novartis' 2002 Neuroscience Division New Hire Training Manual).

**THE FALSE AND MISLEADING INFORMATION NOVARTIS PROVIDES TO PSYCHIATRISTS  
AND ITS INITIATION OF OFF-LABEL USE DISCUSSIONS**

25. While off-label promotion under these circumstances is, in and of itself, strictly illegal, Novartis also began disseminating false and misleading information to the psychiatrists it targeted. As a general matter, information concerning safety and efficacy contained in Novartis' general promotional materials for Trileptal, when given to doctors in the field of psychiatry, are false and misleading in that none of the required safety and efficacy tests have been done (or here, even planned) for these patients and disease states. Nonetheless, Novartis sales representatives were told to leave these promotional materials, along with samples of the product on all of their sales calls to psychiatrists. None of these items contained any warning or notice that the FDA had not approved Trileptal for psychiatric indications.

26. Novartis also instructed its sales representatives to carry "Medical Request Forms" on their sales calls to psychiatrists and use them to "prompt" the psychiatrists to "ask" for information on Trileptal's off-label uses. While a physician is free to inquire about off-label uses of a drug, a sales representative may not initiate that communication or use a Medical Request Form for such a purpose (an example of a Medical Request Form is attached as Exh. C). In many cases, the Novartis sales representative even filled out the Medical Request Form in advance of the sales call. They then explained to the psychiatrist that in response to the doctor's "request," the company would provide him or her with all the medical data and studies regarding the off-label use.

27. As it turns out, decision-makers at Novartis' corporate headquarters decided to select out certain positive information in response to the purported requests (consisting mostly of "chart reviews" and single patient or small group studies) and to conceal the negative data and studies suggesting Trileptal is neither safe, nor effective in the treatment of bipolar disorder. The critical studies and data Novartis conceals from psychiatrists includes, but is not limited to:

- A three-year randomized study (Wildebrube 1990) comparing oxcarbazepine to lithium, the generic and "first line" FDA-approved treatment for bipolar disorder and other psychiatric conditions. This study showed "no clear responders" in the group treated with Trileptal.
- A double-blind multi-center trial (Grant & Faulds, 1992) comparing oxcarbazepine to lithium in acutely manic patients where the oxcarbazepine group displayed slower onset and a higher incidence of side effects.

28. Critically, these two studies compare Trileptal (oxcarbazepine) to lithium, the "first-line," *and* FDA- approved treatment for bipolar disorder. Lithium also is, and has been, available in generic form for well over a decade now. The studies concealed by Novartis conclude Trileptal *doesn't even work* for the treatment of bipolar disorder and in the case of the Grant & Faulds study, that Trileptal is *less effective* than Lithium and *less safe* for patients. All of this wholly unflattering information would be material to any doctor's decision-making and is nonetheless absent in the thousands of Medical Information Requests Novartis distributes to psychiatrists across the country in response to their purported "requests" for information. As only one example, Novartis failed to disclose this negative information in materials distributed by Novartis' Medical Information Specialist to Dr. Rigardy Munoz on February 25, 2003 (attached as Exh. D). This information is also not disclosed during any of the off-label sales calls Novartis requires its sales representative to make.

29. The names of additional psychiatrists whom Novartis disseminated false information

as described herein are contained in the “target lists” attached as Exh. A. Novartis sales representatives disseminated the false and misleading information during sales calls to these and other psychiatrists from February 2000 through at least September 2003 when Relator left the company, and likely beyond. A complete listing of psychiatrists who received false and misleading information from Novartis concerning the off-label use of Trileptal in the treatment of bipolar disorder, including each exact date upon which such misrepresentations were made lies solely in the possession of defendant Novartis and is easily obtainable by review of its own records. These records consists of all of the Medical Information Request letters described above and the records of each and every sales call a Novartis sales representatives made to a psychiatrist for Trileptal, which were recorded by the sales representatives and tracked and maintained by the company (except for the calls Novartis instructed its sales force to deliberately keep out of its computer records after January 2003, as further described in paragraph 36 below).

30. Another common ploy Novartis employed in furtherance of its off-label promotion scheme was to illegally use CME materials in its sales activities. CME courses that include off-label use discussion are appropriate (and even valuable) so long as they are independent of a pharmaceutical manufacturer’s influence and are not provided in connection with sales and marketing activity. Nevertheless, Novartis sales representatives systematically distributed CME tapes and other materials involving bipolar disorder during their sales calls to psychiatrists, sometimes sitting through the presentation with the doctor in his or her office and even “queuing” the tape to the segment on Trileptal. These CME materials were sometimes shipped in bulk to Novartis sales representatives.

31. To date, no clinical studies of any validity or magnitude have been performed that demonstrate Trileptal is a safe and effective treatment for bipolar disorder. While a recent summary

known as the “Texas Algorithm” (first published in mid-2002 and already years into the off-label promotion scheme) suggests Trileptal as an alternate choice in the treatment of certain types of bipolar disorder where “first line” treatment does not work, and as a combination therapy, Novartis itself declined to expend its resources to conduct any clinical studies or research to support this use of the drug or even to ensure its safety in patients suffering from the disorder. When the Texas Algorithm became available, Novartis sales representatives began distributing it to psychiatrists on their sales calls but continued to conceal the negative information also failed to inform psychiatrists the company was not going to even seek FDA approval for Trileptal’s use in psychiatry.

32. As another element of its effort to illegally tout the benefits of off-label uses of Trileptal while concealing the negative data, Novartis downplays the potential side effects of the drug, and in particular, the serious risk of hyponatremia. Left untreated, hyponatremia may cause sodium levels to drop to the point of coma or even death. Novartis claims the incidence of hyponatremia for Trileptal patients is 2.5%, already a clinically significant number, but bases its claim on outdated, European studies. Individual physicians have experienced hyponatremia rates in their patients as high as 25-40%. The risk of hyponatremia (or any other of Trileptal’s known side effects) may be of even greater concern to psychiatric patients who are taking more than one medication or who have alcohol or drug-related problems (both common in patients with bipolar disorder). Since the necessary patient safety testing has not been done in the context of psychiatry, the real risk to these vulnerable patients remains unknown. As researchers at Novartis’ Basel, Switzerland headquarters report:

CBZ [carbazepine] has led to hyponatremia in patients with epilepsy, neuralgia, mental retardation, and psychiatric disorders with a frequency varying from 4.8 to 40%. Oxcarbazepine (OCBZ), which is structurally related to CBZ, has shown similar hyponatremic effects, but whether hyponatremia occurs more often than with CBZ

is not yet clear. Experience with OCBZ is still limited, and there is no definite explanation for a possible difference in antidiuretic potency.

Van Amelsvoort, Devaus and Schwabe (1994). Thus, according to Novartis' own researchers, the risk of hyponatremia is potentially as great as 40% or higher. The serious and substantial risk of hyponatremia (coupled with the substantial expense involved in conducting the necessary efficacy and safety trials) was a key factor in Novartis' decision not to seek FDA approval for any psychiatric indications of Trileptal. Additional adverse events associated with the use of Trileptal include dizziness, somnolence (prolonged sleepiness), diplopia (double vision), fatigue, nausea, vomiting, ataxia (muscle coordination problems), abnormal vision, abdominal pain, tremor (involuntary quivering or convulsing), dyspepsia and abnormal gait.

#### **NOVARTIS' DECISION TO FLOUT THE FDA REQUIREMENTS**

33. Novartis instituted its fraudulent off-label promotion scheme even though it never intended to expend the resources to conduct patient safety and efficacy trials or to ever seek FDA approval for psychiatric indications and uses. At a January 2003 national meeting (already three years into the off-label promotion scheme), Novartis management formally announced to its sales force that it was not "economically viable" to conduct the necessary medical trials for psychiatric indications for Trileptal and therefore it would not be doing so. Rather, the company was going to wait and produce a new drug that would have fewer hyponatremia and other problems. The company's patent for Trileptal was set to expire in approximately 2008, just in time for this new drug to be launched, thereby effectuating a transition with no financial "downtime" for Novartis.

#### **THE SUCCESS OF THE OFF-LABEL PROMOTION SCHEME**

34. Novartis' off-label promotion scheme was so successful that as early as December 2001, psychiatrists nearly overtook neurologists in regard to Trileptal sales volume. *See* Exh. E

(Excerpt from PowerPoint presentation from Novartis' T2 2002 national sales meeting). As further illustration, at the end of 2000, the field of psychiatry accounted for only 14% of all Trileptal prescriptions, but less than a year later, by November 2001, this number had jumped to 38% and the proportion of prescriptions written for the approved use of epileptic seizure control plummeted from 71% to 42%. *See* Exh. B. Trileptal's market share for psychiatry now dominates over the approved-use market:

**TRILEPTAL PRESCRIPTIONS (TRX) BY YEAR\***

|                                    |                                              |
|------------------------------------|----------------------------------------------|
| 2001 -                             | <b>42%</b> of TRx attributable to psychiatry |
| 2002 -                             | <b>56%</b> of TRx attributable to psychiatry |
| (1 <sup>st</sup> trimester) 2003 - | <b>62%</b> of TRx attributable to psychiatry |

*\*Source: Novartis Customer Segment Trend Reports (Exh. F).*

35. With the substantial and ever increasing boost from psychiatry, Trileptal became the most successful anti-epileptic drug launch, beating out Neurontin, Lamictal, Topamax, among others. Novartis' forecasted net sales for Trileptal of \$575 million by the year 2006. *See* Exh. E.

**NOVARTIS STARTS TO COVER ITS TRACKS**

36. Around January 2003, Novartis decided it was time to start covering its tracks. As its first step, Novartis removed several thousand psychiatrists from its sales "target" database. The off-label nature of sales calls to these physicians would be the most obvious to government regulators and prosecutors should they ever learn of Novartis' scheme. While these physicians were removed from the target database, Novartis continued to instruct its sales force to call on them, just not to record the calls in their computer system.

37. In May 2003, Novartis took the additional step of removing all psychiatrists from the "bonus" universe for Trileptal. This action was also a distinction without a difference because

Novartis continued to require its sales force to call on psychiatrists for Trileptal, it just wasn't going to pay them extra for it. By this point however, sales to psychiatrists already accounted for greater than 62% of Trileptal's market share and sales representative would have to continue to make these sales calls or watch their sales numbers plummet.

**NOVARTIS' USE OF ILLEGAL PAYMENTS OR KICKBACKS  
TO FURTHER BOOST ITS MARKET SHARE**

38. Novartis additionally made outright cash payments to physicians to induce them to prescribe Trileptal, as well as most of its other drug products. Under the guise of "consultant" services or speaker "training," Novartis hand-picked high prescribers to participate in (and receive payments for) what amounted to sales and marketing programs, known as "Advisory Boards," "Forums" or "Faculty Development Meetings." The bogus nature of all of these programs is evidenced by Novartis' tracking of the attendees prescribing habits before and after the programs and by virtue of the fact that at no time, were attendees actually required to provide any services, consulting, speaking, or otherwise, to the company.

**THE SHAM CONSULTANT MEETINGS**

39. Novartis recruited psychiatrists and other physicians to attend so-called consultant meetings or "Advisory Boards" for Trileptal, where attendees received cash payments to the tune of \$200-500 simply for showing up. Speakers (themselves typically high prescribers) were paid \$1,000-1,500. Attendees at these meetings were paid to enjoy a lavish dinner where they would sit and listen to Novartis promotional messages. Novartis picked up tab at all of these dinners. Typically, a paid Novartis speaker would also show up to tout the benefits of Trileptal. If the speaker did not do so, Novartis would gently prompt the discussion into off-label uses of the drug. After dinner and drinks, it was not uncommon for Novartis to send the attending doctors home with free

bottles of wine or other gifts. While the attendees signed a “consultant agreement” with Novartis, they were not required to perform any services for the company. Novartis did provide attendees with an optional “feedback” form that directly asked attendees if they would prescribe more Trileptal as a result of the program.

40. Among the doctors who received the illegal kickbacks in connection with Advisory Board programs for Trileptal include Dr. Adrian Griffin (psychiatrist in Mount Airy, NC), Michael McClure, MD (psychiatrist in High Point, NC), Sarah Bullard, PA (physician’s assistant to Dr. McClure in High Point, NC), Andy Farah, MD (psychiatrist in High Point, NC), Elizabeth Wright, MD (neurologist in Statesville, NC), Frank Crowell, MD (neurologist in Winston-Salem, NC), Edward Weaver, MD (psychiatrist in Winston-Salem, NC), and Stephen Kirley, MD (psychiatrist in Clemmons, NC). All of these doctors received illegal payments in 2002, and likely on additional occasions as well. A complete listing of the doctors across the country who received these illegal payments (including exact days on which the payments were made) is available from Advanced Health Media (AHM) in New Jersey, a third party administrator of the programs for Novartis. AHM also sends the honoraria checks to the Novartis sales representatives who distribute them to the doctors.

41. After completion of the Advisory Board programs, Novartis tracked the prescribing habits of the attendees to determine its “return on investment” and whether these programs were successful in getting physicians to change their prescribing habits. Such an activity would not have been necessary if the purpose of the meetings was legitimate. These illegal payments were made with respect to Trileptal from February 2000 through at least August 2002, and possibly beyond and were nation-wide in scope. Advisory Boards were, and are, conducted with respect to additional prescription drug products including Diovan. Advisory Boards were conducted from 1997 to at least

August 2002.

42. Similar to the Advisory Boards, Novartis also conducted “Clinical Forums” that involved \$750 per doctor pay-outs and the Novartis “Consultant Network.” As an additional perk to participate in Consultant Network, the doctors were offered “Sample Solutions,” whereby Novartis would pay for supplies and send out its sales force to organize the doctor’s sample closets.

**BOGUS SPEAKER “TRAINING”**

43. Novartis also recruited “high prescribers” for participation in its national speaker “training” program, referred to as “Faculty Development” meetings. For Trileptal, the attendees included psychiatrists and other doctors who, because of their specialty, would not have reason to prescribe the FDA-approved use of the drug. Novartis hand-picked the physicians for these programs, based not on their medical knowledge, reputation or skills, but rather, by review of their ability and tendency to prescribe Novartis products. Novartis sales representatives who recruited the attendees explained that these physicians were under no obligation to speak for the company. The purported training sessions took place at five star or other lavish resorts in Florida or other attractive locations, and included presentations by paid Novartis speakers and the company itself. Attendees of these programs received \$750 honoraria plus an all expense paid trip, including airfare, lodging, meals and entertainment.

44. Among the doctors who received the illegal kickbacks in connection with Faculty Development Meetings for Trileptal include: David Meyers, MD (neurologist in Winston-Salem, NC), Christine Dean, MD (neurologist in Winston-Salem, NC), Cormac O’Donovan (neurologist in Winston-Salem, NC), Cesar Santos, MD (neurologist in Winston-Salem, NC), James Parrott (neurologist in Hickory, NC), John Porter (neurologist in Winston-Salem, NC), Beverly Jones, MD (psychiatrist in Winston-Salem, NC), Joseph Miller, MD (neurologist in High-Point, NC). On

information and belief, the following psychiatrists were among the paid speakers for the Trileptal Faculty Development programs: Eugene Dagon (Tampa, FL), Reddy Pasem (Ocala, FL), F. Cleveland Kinney (Birmingham, AL), Gary Newsom (Northport, AL), John Taylor (Greenville, SC), Ramesh Giwala (Gastonia, NC), and Borja Benedicto (Portsmouth, OH). All of these speakers, as well as the additional names on the Novartis speaker list designated as a “psych” or “P” speciality, attached as Exh. G -- are psychiatrists in private practice that would only have reason to speak about Trileptal’s off-label uses. The above physicians received the illegal kickbacks in 2002-2003 and possibly other occasions as well. A complete listing of the doctors across the country who received these illegal payments (including exact days on which the payments were made) is available from AHM.

45. The Faculty Development Meetings are nation-wide in scope, and with respect to Trileptal, began in January 2000 and continue to this day. The Faculty Development Meetings were, and are, conducted with respect to additional prescription drug products including Diovan. The Faculty Development Meetings date back to at least 1997, were in existence when Relator left the company in September 2003 and on information and belief, continue to this day.

46. Additional gratuities provided by Novartis to its favored physicians include payments for CME programs and medical certification classes. On information and belief, Novartis also supplied “grants” to physicians and institutions for the purpose of influencing prescribing habits in favor of its products.

47. All of the above programs, including the Advisory Boards, Clinical Forums, Faculty Development Meetings, Consultant Network, Sample Solutions, CME programs and grants are thinly disguised means to effectuate payment to physicians for the purpose of influencing their prescribing habits, in violation of the Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b), and the various

state counterparts prohibiting payment of money or other value to induce a referral that will be paid by a government-funded health care program.

**HOW NOVARTIS' FRAUDULENT OFF-LABEL PROMOTION AND KICKBACK SCHEMES  
HARM GOVERNMENT-FUNDED PROGRAMS AND PATIENTS**

48. Novartis' fraudulent schemes drain government-funded health care programs of millions of dollars each year. By virtue of its intentional and deliberate conduct, Novartis caused hundreds of thousands of false claims to be submitted to these government-funded health care programs by doctors and pharmacists across the country who received the false and misleading information provided by Novartis concerning the off-label uses of Trileptal and/or who were the recipients of the kickbacks paid by the company to induce the doctors to write prescriptions for Trileptal and its other drugs. The government-funded health care programs described herein would not have paid for Trileptal prescriptions if these programs knew the prescriptions were the direct result of Novartis' dissemination of false and misleading information concerning the drug's safety and effectiveness for psychiatric patients and/or outright cash payments to the doctors who wrote the prescriptions. Specifically, false claims were submitted for reimbursement to the government-funded health care programs in connection with claims for reimbursement for Trileptal submitted by all of the doctors and pharmacists described in paragraphs 25-29, above, including all doctors who received the false and misleading Medical Information Requests and who were, and are, listed on Novartis' "target lists." False claims were also submitted in connection with all of the doctors who received and continue to receive the illegal kickbacks, including those listed in paragraphs 40 and 44, above. But for Novartis' conduct, the false claims for Trileptal or its other products would not have been submitted for reimbursement to the government-funded health care programs, nor paid by any these programs.

49. Trileptal has no generic equivalent and comes with a price tag of approximately \$150 a month. Lithium, one of at least three FDA-approved treatments for bipolar disorder, and recommended as a “first line” treatment by the American Psychiatric Association, among others, has been generically available since the mid-1970s. Additional FDA-approved treatments for bipolar disorder now include GlaxoSmithKline’s drug Lamictal, and Zyprexa, manufactured by Eli Lilly & Co.

50. National Medicaid reimbursement data shows that since January 2000, the state and federal governments have paid for 1,755,711 total prescriptions for Trileptal, to the tune of over two hundred twenty-five million dollars (\$225,548,983.47). *See* Exh. H. Using the data in paragraph 34 above, at least half of this amount or greater than one hundred million dollars is attributable to off-label prescriptions in psychiatry.

51. Separate and apart from the huge price tag, patients are harmed in that it is unknown whether Trileptal is safe and effective for the serious and chronic mental illness they suffer from.

**COUNT I**  
**FALSE CLAIMS ACT**

52. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

53. This is a *qui tam* action brought by Steve M. McKee and the United States Government to recover treble damages and civil penalties under 31 U.S.C.A. § 3729(a) of the False Claims Act.

54. 31 U.S.C.A. § 3729(a) provides, in relevant part, liability for any person who-

(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

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

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

55. Novartis violated 31 U.S.C.A. § 3729(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the United States Government from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA and Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

56. The United States Government, by and through CMS, CHAMPUS/Tricare, the VA and FEHB, and possibly other federal agencies, and unaware of Novartis' fraudulent off-label promotion and kickback schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

57. Compliance with applicable Medicare and Medicaid, and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of the payment of claims submitted to the United States Government by health care providers and third party payors in connection with Novartis' fraudulent schemes.

58. Had the United States Government known Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by

health care providers and third party payors for the drug products, in connection with those schemes.

59. As a result of Novartis' violations of 31 U.S.C.A. § 3729(a), the United States Government has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

60. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 31 U.S.C.A § 3730(b) on behalf of himself and the United States Government.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the UNITED STATES GOVERNMENT:

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

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to 31 U.S.C.A. § 3730(d) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

**COUNT II**  
**ILLINOIS WHISTLEBLOWER REWARD & PROTECTION ACT**

61. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

62. This is a *qui tam* action brought by Steve M. McKee and the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175 *et seq.*

63. 740 ILCS 175/3(a) provides liability for any person who-

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

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

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

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

65. Novartis violated 305 ILCS 5/8A-3(b) from at least 1997 to the present by engaging in the fraudulent schemes described herein.

66. Novartis furthermore violated 740 ILCS 175/3(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Illinois from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the

FDCA, federal Anti-Kickback Act, and the Illinois Vendor Fraud and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

67. The State of Illinois, by and through the Illinois Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

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

69. Had the State of Illinois known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

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

71. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 740 ILCS 175/3(b) on behalf of himself and the State of Illinois.

72. This Court is requested to accept pendant jurisdiction of this related state claim as it is

predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF ILLINOIS:

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

To RELATOR, STEVE M. MCKEE:

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

**COUNT III**  
**CALIFORNIA FALSE CLAIMS ACT**

73. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

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

75. Cal. Gov't Code § 12651(a) provides liability for any person who-
- (1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof, a false claim for payment or approval;
  - (2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
  - (3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision.
  - (8) is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

76. In addition, the payment or receipt of bribes or kickbacks is prohibited under Cal. Bus. & Prof. Code § 650 and 650.1, and is also specifically prohibited in treatment of Medi-Cal patients pursuant to Cal. Welf. & Inst. Code §14107.2.

77. Novartis violated Cal. Bus. & Prof. Code §§ 650 and 650.1 and Cal. Welf. & Inst. Code §14107.2 from at least 1997 to the present by engaging in the fraudulent schemes described herein.

78. Novartis furthermore violated Cal. Gov't Code § 12651(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of California from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Cal. Bus. & Prof. Code § 650-650.1 and Cal. Welf, & Inst. Code §14107.2 and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-

funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

79. The State of California, by and through the California Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

80. Compliance with applicable Medicare, Medi-Cal and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of California in connection with Novartis' fraudulent schemes.

81. Had the State of California known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

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

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

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

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF CALIFORNIA:

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

To RELATOR, STEVE M. MCKEE:

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

**COUNT IV**  
**FLORIDA FALSE CLAIMS ACT**

85. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

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

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

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

approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency;

(c) conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid.

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

(c) knowingly charge, solicit, accept, or receive anything of value, other than an authorized copayment from a Medicaid recipient, from any source in addition to the amount legally payable for an item or service provided to a Medicaid recipient under the Medicaid program or knowingly fail to credit the agency or its fiscal agent for any payment received from a third-party source;

\* \* \* \* \*

(e) knowingly, solicit, offer, pay or receive any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing of any item or service for which payment may be made, in whole or in part, under the Medicaid program, or in return for obtaining, purchasing, leasing, ordering, or arranging, for or recommending, obtaining, purchasing, leasing, or ordering any goods, facility, item, or service, for which payment may be made, in whole or in part, under the Medicaid program.

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

90. Novartis violated Fla. Stat. §§ 409.920(c) and (e) and §456.054(2) from at least 1997 to the present by engaging in the fraudulent schemes described herein.

91. Novartis furthermore violated Fla. Stat. § 68.082(2) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Florida from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including

the FDCA, federal Anti-Kickback Act, Fla. Stat. §§ 409.920(c) and (e) and §456.054(2) and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

92. The State of Florida, by and through the Florida Medicaid program and other state healthcare programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

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

94. Had the State of Florida known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

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

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

97. This Court is requested to accept pendant jurisdiction of this related state claim as it is

predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF FLORIDA:

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

To RELATOR, STEVE M. MCKEE:

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

**COUNT V**  
**TEXAS FALSE CLAIMS ACT**

98. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

99. This is a *qui tam* action brought by Steve M. McKee and the State of Texas to recover double damages and civil penalties under V.T.C.A. Hum. Res. Code § 36.001 *et seq.*

100. V.T.C.A. Hum. Res. Code § 36.002 provides liability for any person who-

(1) knowingly or intentionally makes or causes to be made a false statement or misrepresentation of a material fact:

- (a) on an application for a contract, benefit, or payment under the Medicaid program; or
- (b) that is intended to be used to determine its eligibility for a benefit or payment under the Medicaid program.

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

- (a) that the person knows affects the initial or continued right to a benefit or payment under the Medicaid program of:
  - (i) the person; or
  - (ii) another person on whose behalf the person has applied for a benefit or payment or is receiving a benefit or payment; and

- (b) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized;

(4) knowingly or intentionally makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:

- (b) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;

(5) knowingly or intentionally charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or continued service to a Medicaid recipient if the cost of the service provided to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program.

101. Novartis violated V.T.C.A. Hum. Res. Code § 36.002 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Texas from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act and § 36.002, and by virtue of the fact that none

of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

102. The State of Texas, by and through the Texas Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

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

104. Had the State of Texas known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

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

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

107. McKee is a private person with direct and independent knowledge of the allegations

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

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

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF TEXAS:

- (1) Two times the amount of actual damages which the State of Texas has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$10,000 pursuant to V.T.C.A. Hum. Res. Code § 36.025(a)(3) for each false claim which Novartis cause to be presented to the state of Texas;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to V.T.C.A. Hum. Res. Code § 36.110, and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

**COUNT VI**  
**MASSACHUSETTS CLAIMS ACT**

109. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

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

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

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

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

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

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

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

113. Novartis violated Mass. Gen. Laws Ann. Chap. 118E § 41 from at least 1997 to the present by engaging in the fraudulent schemes described herein.

114. Novartis furthermore violated Mass. Gen. Laws Ann. Chap. 12 § 5B and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Massachusetts from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Mass. Gen. Law Ann.

Chap. 118E § 41 and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

115. The State of Massachusetts, by and through the Massachusetts Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

116. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Massachusetts in connection with Novartis' fraudulent schemes.

117. Had the State of Massachusetts known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

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

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

120. 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 Massachusetts in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF MASSACHUSETTS:

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

To RELATOR, STEVE M. MCKEE:

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

**COUNT VII**  
**TENNESSEE FALSE CLAIMS ACT**

121. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

122. This is a *qui tam* action brought by Steve M. McKee and the State of Tennessee to recover treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 *et seq.*

123. § 71-5-182(a)(1) provides liability for any person who-

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

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

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

124. Novartis violated Tenn. Code Ann. § 71-5-182(a)(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Tennessee from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA and Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

125. The State of Tennessee, by and through the Tennessee Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

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

127. Had the State of Tennessee known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to

meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

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

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

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

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF TENNESSEE:

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

To RELATOR, STEVE M. MCKEE:

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

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

**COUNT VIII**  
**DELAWARE FALSE CLAIMS AND REPORTING ACT**

131. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

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

133. 6 Del. C. § 1201(a) provides liability for any person who-

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

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

135. Novartis violated 31 Del. C. § 1005 from at least 1997 to the present by engaging in the fraudulent schemes described herein.

136. Novartis furthermore violated 6 Del. C. § 1201(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Delaware from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, the Anti-Kickback Act, and 31 Del. C. § 1005 and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

137. The State of Delaware, by and through the Delaware Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

138. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Delaware in connection with Novartis' fraudulent schemes.

139. Had the State of Delaware known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

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

141. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 6 Del. C. § 1203(b) on behalf of

himself and the State of Delaware.

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

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF DELAWARE:

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

To RELATOR, STEVE M. MCKEE:

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

**COUNT IX**  
**NEVADA FALSE CLAIMS ACT**

143. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

144. This is a *qui tam* action brought by Steve M. McKee and the State of Nevada to

recover treble damages and civil penalties under the Nevada False Claims Act, N.R.S. § 357.010, *et. seq.*

145. N.R.S. § 357.040(1) provides liability for any person who-

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

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

(c) conspires to defraud by obtaining allowance or payment of a false claim;

(h) is a beneficiary of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fails to disclose the falsity to the state or political subdivision within a reasonable time.

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

147. Novartis violated N.R.S. § 422.560 from at least 1997 to the present by engaging in the fraudulent schemes described herein.

148. Novartis furthermore violated N.R.S. § 357.040(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Nevada from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act and N.R.S. § 422.560, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

149. The State of Nevada, by and through the Nevada Medicaid program and other state

health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

150. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Nevada in connection with Novartis' fraudulent schemes.

151. Had the State of Nevada known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

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

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

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

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF NEVADA:

(1) Three times the amount of actual damages which the State of Nevada has

sustained as a result of Novartis' fraudulent schemes;

- (2) A civil penalty of not less than \$2,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the State of Nevada;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

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

#### **COUNT X**

#### **LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW**

155. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

156. This is a *qui tam* action brought by Steve M. McKee and the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 437.1 *et seq.*

157. La. Rev. Stat. Ann. § 438.3 provides-

(A) No person shall knowingly present or cause to be presented a false or fraudulent claim;

(B) No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance program funds;

(C) No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent

claim;

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

159. Novartis violated La. Rev. Stat. Ann. § 438.2(A) from at least 1997 to the present by engaging in the fraudulent schemes described herein.

160. Novartis furthermore violated La. Rev. Stat. Ann. §438.3 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Louisiana from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act and La. Rev. Stat. Ann. § 438.2(A), and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

161. The State of Louisiana, by and through the Louisiana Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

162. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Louisiana in connection with Novartis' fraudulent schemes.

163. Had the State of Louisiana known that Novartis was violating the federal and state

laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

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

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

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

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF LOUISIANA:

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

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to La. Rev. Stat. § 439.4(A) and/or

any other applicable provision of law;

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

**COUNT XI**  
**HAWAII FALSE CLAIMS ACT**

167. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

168. This is a *qui tam* action brought by Steve M. McKee and the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*

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

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

170. Novartis violated Haw. Rev. Stat. §661-21(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Hawaii from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the

FDCA and Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

171. The State of Hawaii, by and through the Hawaii Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

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

173. Had the State of Hawaii known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

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

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

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

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

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF HAWAII:

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

To RELATOR, STEVE M. MCKEE:

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

**COUNT XII**  
**INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT**

177. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

178. This is a *qui tam* action brought by Steve M. McKee and the State of Indiana to recover treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5 *et seq.*

179. Ind. Code § 5-11-5.5-2(b) provides liability for any person who knowingly or

intentionally-

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

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

\* \* \* \* \*

(8) cause or induces another person to perform an act described in subs (1) through (6);

180. Novartis violated Ind. Code § 5-11-5.5-2(b)(8) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Indiana from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

181. The State of Indiana, by and through the Indiana Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

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

183. Had the State of Indiana known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on

false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

184. As a result of Novartis' violations of Ind. Code § 5-11-5.5-2(b), the State of Indiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

185. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Ind. Code Ind. Code § 5-11-5.5-4 on behalf of himself and the State of Indiana.

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

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF INDIANA:

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

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to Ind. Code § 5-11-5.5-6 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and

- (4) Such further relief as this Court deems equitable and just.

**COUNT XIII**  
**NEW HAMPSHIRE FALSE CLAIMS ACT**

187. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

188. This is a *qui tam* action brought by Steve M. McKee and the State of New Hampshire to recover treble damages and civil penalties under the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. § 167:61-b *et seq.*

189. N.H. Rev. Stat. Ann. § 167:61-b(1) provides liability for any person who-

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

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

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

190. Novartis violated N.H. Rev. Stat. Ann. § 167:61-b(1)(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of New Hampshire from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

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

and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

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

193. Had the State of Indiana known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

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

195. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.H. Rev. Stat. Ann. § 167:61-c(II)(a) on behalf of himself and the State of New Hampshire.

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

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF NEW HAMPSHIRE:

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

To RELATOR, STEVE M. MCKEE:

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

**COUNT XIV**  
**MICHIGAN MEDICAID FALSE CLAIM ACT**

197. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

198. This is a *qui tam* action brought by Steve M. McKee and the State of Michigan to recover treble damages and civil penalties under the Michigan Medicaid False Claim Act, Mich. Comp. Laws 400.601 *et seq.*

199. Mich. Comp. Laws 400.607 provides in relevant part-

- (1) A person shall not make or present or cause to be made or presented to an employee or officer of this state a claim under the social welfare act [citations omitted] upon or against the state, knowing the claim to be false.

\* \* \* \* \*

200. In addition, Mich. Comp. Laws 400.604 prohibits the solicitation, offer or receipt of any kickback or bribe in connection with the furnishing of goods or services for which payment may be made whole or in part under the Michigan Medicaid program.

201. Novartis violated Mich. Comp. Laws 400.607(1) from at least 1997 to the present by engaging in the fraudulent schemes described herein.

202. Novartis furthermore violated 400.607(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Michigan from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and the anti-kickback provisions of the Michigan Medicaid False Claim Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

203. The State of Michigan, by and through the Michigan Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

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

205. Had the State of Michigan known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to

meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

206. As a result of Novartis' violations of Mich. Comp. Laws 400.607(1), the State of Michigan has been damaged in an amount far in excess of millions of dollars exclusive of interest.

207. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Mich. Comp. Laws 400.610a(1) on behalf of himself and the State of Michigan.

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

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF MICHIGAN

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

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to Mich. Comp. Laws 400.610a(9) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

**COUNT XV**  
**MONTANA FALSE CLAIMS ACT**

209. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

210. This is a *qui tam* action brought by Steve M. McKee and the State of Montana to recover treble damages and civil penalties under the Montana False Claims Act, Mont. Stat. §17-8-401 *et seq.*

211. Mont. Stat. §17-8-403(1) provides liability for any person who-

- (1) knowingly presents or causes to be presented to an officer or employee of the governmental entity 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 governmental entity;
- (3) conspires to defraud the governmental entity by getting a false or fraudulent claim allowed or paid by the governmental entity.

212. Novartis violated Mont. Stat. §17-8-403(1)(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Montana from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, the Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

213. The State of Montana, by and through the Montana Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

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

215. Had the State of Montana known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

216. As a result of Novartis' violations of Mont. Stat. §17-8-403(1), the State of Montana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

217. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Mont. Stat. §17-8-406(1) on behalf of himself and the State of Montana.

218. 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 Montana in the operation of its Medicaid program.

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF MONTANA:

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

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to Mont. Stat. §17-8-410(1) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

**COUNT XVI**  
**NEW MEXICO FRAUD AGAINST TAXPAYERS ACT**

219. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

220. This is a *qui tam* action brought by Steve M. McKee and the State of New Mexico to recover treble damages and civil penalties under the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §44-9-1 *et seq.*

221. N.M. Stat. Ann. §44-9-3(A) makes it unlawful to-

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

approval of or the payment on a false or fraudulent claim;

(3) conspire to defraud the State by obtaining approval or payment on a false or fraudulent claim.

222. Novartis violated N.M. Stat. Ann. §44-9-3(A)(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented by third party payors and others to the State of New Mexico from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, the Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

223. The State of New Mexico, by and through the New Mexico Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

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

225. Had the State of New Mexico known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

226. As a result of Novartis' violations of N.M. Stat. Ann. §44-9-3(A), the State of New

Mexico has been damaged in an amount far in excess of millions of dollars exclusive of interest.

227. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.M. Stat. Ann. §44-9-5(A) on behalf of himself and the State of New Mexico.

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

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF NEW MEXICO:

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

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to N.M. Stat. Ann. §44-9-7 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

**COUNT XVII**  
**NEW YORK FALSE CLAIMS ACT**

229. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

230. This is a *qui tam* action brought by Steve M. McKee and the State of New York to recover treble damages and civil penalties under the New York False Claims Act, New York Fin. Law § 187 *et seq.*

231. New York Fin. Law § 189 provides liability for any person who-

(a) knowingly presents, or causes to be presented, to any employee, officer or agent of the state or 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.

232. Novartis violated New York Fin. Law § 189(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of New York from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

233. The State of New York, by and through the New York Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

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

235. Had the State of New York known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

236. As a result of Novartis' violations of New York Fin. Law § 189(a), the State of New York has been damaged in an amount far in excess of millions of dollars exclusive of interest.

237. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to New York Fin. Law § 190(2) on behalf of himself and the State of New York.

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

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF NEW YORK:

- (1) Three times the amount of actual damages which the State of New York has sustained as a result of Novartis' fraudulent schemes;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the State of New York;

- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to New York Fin. Law § 190 (6) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

**COUNT XVIII**  
**VIRGINIA FRAUD AGAINST TAXPAYERS ACT**

239. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

240. This is a *qui tam* action brought by Steve M. McKee and the Commonwealth of Virginia to recover treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, 842 Virg. Stat. § 8.01-216 *et seq.*

241. 842 Virg. Stat. § 8.01-216.3(A) provides liability for any person who-

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

242. Novartis violated 842 Virg. Stat. § 8.01-216.3(A)(1) and knowingly caused hundreds

of thousands of false claims to be made, used and presented to the Commonwealth of Virginia from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, the federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

243. The Commonwealth of Virginia, by and through the Virginia Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

244. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the Commonwealth of Virginia in connection with Novartis' fraudulent schemes.

245. Had the Commonwealth of Virginia known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

246. As a result of Novartis' violations of 842 Virg. Stat. § 8.01-216.3, the Commonwealth of Virginia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

247. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 842 Virg. Stat. § 8.01-216.5 on behalf

of himself and the Commonwealth of Virginia.

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

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the COMMONWEALTH OF VIRGINIA:

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

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to 842 Virg. Stat. § 8.01-216.7 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

**COUNT XIX**  
**DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT**

249. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

250. This is a *qui tam* action brought by Steve M. McKee and the District of Columbia to

recover treble damages and civil penalties under the District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.13 *et seq.*

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

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

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

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

(8) is the beneficiary of an inadvertent submission of a false claim to the District, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the District.

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

(1) Referring a recipient to a particular provider of any item or service or for which payment may be made under the District of Columbia Medicaid program; or

(2) Recommending the purchase, lease, or order of any good, facility, service, or item for which payment may be made under the District of Columbia Medicaid Program.

253. Novartis violated D.C. Code § 4-802(c) from at least 1997 to the present by engaging in the illegal schemes described herein.

254. Novartis furthermore violated D.C. Code § 2-308.14(a) and knowingly caused thousands of false claims to be made, used and presented to the District of Columbia from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, D.C. Code § 4-802(c), and by virtue of the fact that none of the claims submitted in connection with its illegal schemes were even eligible for

reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

255. The District of Columbia, by and through the District of Columbia Medicaid program and other state health care programs, and unaware of Novartis' illegal schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

256. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the District of Columbia in connection with Novartis' illegal schemes.

257. Had the District of Columbia known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

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

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

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

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the DISTRICT OF COLUMBIA:

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

To RELATOR, STEVE M. MCKEE:

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

**COUNT XX**  
**OKLAHOMA MEDICAID FALSE CLAIMS ACT**

261. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

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

263. Okla. Stat. §5053.1(B) provides liability for any person who-

- (1) knowingly presents, or causes to be presented, to an officer or

employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;

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

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

264. Novartis violated 63 Okla. Stat. §5053.1(B)(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Oklahoma from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, the federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

265. The State of Oklahoma, by and through the Oklahoma Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

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

267. Had the State of Oklahoma known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care

providers and third party payors in connection with those schemes.

268. As a result of Novartis' violations of 63 Okla. Stat. §5053.1(B)(1), the State of Oklahoma has been damaged in an amount far in excess of millions of dollars exclusive of interest.

269. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 63 Okla. Stat. §5053.2(B)(1) on behalf of himself and the State of Oklahoma.

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

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF OKLAHOMA:

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

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to 63 Okla. Stat. §5053.4 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and

- (4) Such further relief as this Court deems equitable and just.

**COUNT XXI**  
**WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT**

271. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

272. This is a *qui tam* action brought by Steve M. McKee and the State of Wisconsin to recover treble damages and civil penalties under the Wisconsin False Claims For Medical Assistance Act, Wis. Stat. §20.931 *et seq.*

273. Wis. Stat. §20.931(2) provides liability for any person who-

- (1) Knowingly presents, or causes to be presented, to any officer, employee, or agent of this state a false claim for medical assistance;
- (2) 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;
- (3) 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.

274. Novartis violated Wis. Stat. § 20.931(2) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Wisconsin from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, the federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

275. The State of Wisconsin, by and through the Wisconsin Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

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

277. Had the State of Wisconsin known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

278. As a result of Novartis' violations of Wis. Stat. §20.931(2), the State of Wisconsin has been damaged in an amount far in excess of millions of dollars exclusive of interest.

279. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Wis. Stat. §20.931(5)(a) on behalf of himself and the State of Wisconsin.

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

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF WISCONSIN:

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

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to Wis. Stat. §20.931(11) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

**COUNT XXII**  
**GEORGIA FALSE MEDICAID CLAIMS ACT**

281. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

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

283. Ga. Code §49-4-168.1(a) provides liability for any person who-

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

by the Georgia Medicaid program;

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

284. Novartis violated Ga. Code § 49-4-168.1(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Georgia from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, the federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

285. The State of Georgia, by and through the Georgia Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

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

287. Had the State of Georgia known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

288. As a result of Novartis' violations of Ga. Code § 49-4-168.1(a), the State of Georgia

has been damaged in an amount far in excess of millions of dollars exclusive of interest.

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

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

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF GEORGIA:

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

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to Ga. Code § 49-4-168.2(i) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

**COUNT XXIII**  
**NEW JERSEY FALSE CLAIMS ACT**

291. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

292. This is a *qui tam* action brought by Steve M. McKee and the State of New Jersey to recover treble damages and civil penalties under the New Jersey False Claims Act, N.J.S.A. §2A:32C-1 *et seq.*

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

(a) Knowingly presents, or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of state funds, a false or fraudulent claim for payment or approval;

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

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

294. Novartis violated N.J.S.A. §2A:32C-3 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of New Jersey from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, the federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

295. The State of New Jersey, by and through the New Jersey Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims

submitted by health care providers and third party payors in connection therewith.

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

297. Had the State of New Jersey known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

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

299. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.J.S.A. §2A:32C-5(b) on behalf of himself and the State of New Jersey.

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

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF NEW JERSEY:

- (1) Three times the amount of actual damages which the State of New Jersey has sustained as a result of Novartis' fraudulent schemes;

- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Novartis caused to be presented to the State of New Jersey;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to N.J.S.A. §2A:32C-7 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

**COUNT XXIV**  
**RHODE ISLAND FALSE CLAIMS ACT**

301. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

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

303. R.I. Gen. Laws § 9-1.1-3(a) provides liability for any person who-

- (a) Knowingly presents, or causes to be presented to an employee, officer or agent of the state or a member of the guard a false or fraudulent claim for payment or approval;
- (b) Knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;
- (c) Conspires to defraud the state by getting a false or fraudulent claim allowed or paid.

304. Novartis violated R.I. Gen. Laws § 9-1.1-3(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Rhode Island from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, the federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

305. The State of Rhode Island, by and through the Rhode Island Medicaid program and other state health care programs, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

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

307. Had the State of Rhode Island known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

308. As a result of Novartis' violations of R.I. Gen. Laws § 9-1.1-3(a), the State of Rhode Island has been damaged in an amount far in excess of millions of dollars exclusive of interest.

309. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to R.I. Gen. Laws § 9-1.1-4(b) on behalf

of himself and the State of Rhode Island.

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

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF RHODE ISLAND:

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

To RELATOR, STEVE M. MCKEE:

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

**COUNT XXV**  
**CONNECTICUT FALSE CLAIMS ACT**

311. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

312. This is a *qui tam* action brought by Steve M. McKee and the State of Connecticut to

recover treble damages and civil penalties under the Connecticut False Claims Act, C.G.S. § 17b-301a *et seq.*

313. C.G.S. § 17b-301b(a) provides liability for any person who-

(a) Knowingly present, or causes to be presented to an officer or employee of the state a false or fraudulent claim for payment or approval under a medical assistance program administered by the Department of Social Services;

(b) Knowingly make, use or cause to be made or used, a false record or statement to secure the payment or approval by the state of a false or fraudulent claim under a medical assistance program administered by the Department of Social Services;

(c) Conspire to defraud the securing the allowance or payment of a false or fraudulent claim under a medical assistance program administered by the Department of Social Services.

314. Novartis violated C.G.S. § 17b-301b(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Connecticut from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, the federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

315. The State of Connecticut, by and through the Connecticut Medicaid Program, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

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

fraudulent schemes.

317. Had the State of Connecticut known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

318. As a result of Novartis' violations of C.G.S. § 17b-301b(a), the State of Connecticut has been damaged in an amount far in excess of millions of dollars exclusive of interest.

319. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to C.G.S. § 17b-301d(a) on behalf of himself and the State of Connecticut.

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

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the following damages to the following parties and against Novartis:

To the STATE OF CONNECTICUT:

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

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to C.G.S. § 17b-301e and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

**COUNT XXVI**  
**NORTH CAROLINA FALSE CLAIMS ACT**

321. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 51 above as if fully set forth herein.

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

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

- (a) Knowingly presents, or causes to be presented 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 material to a false or fraudulent claim;
- (c) Conspires to commit a violation of subdivision (1), (2), (4), (5), (6), or (7) of this section.

324. Novartis violated N.C. Gen. Stat. § 1-607(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of North Carolina from at least 1997 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, the federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement

by the government-funded health care programs. As described herein, Novartis caused the submission of false claims for its prescription drug products Trileptal and Diovan.

325. The State of North Carolina, by and through the North Carolina Medicaid Program, and unaware of Novartis' fraudulent schemes, paid the claims submitted by health care providers and third party payors in connection therewith.

326. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of North Carolina in connection with Novartis' fraudulent schemes.

327. Had the State of North Carolina known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis' schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payors in connection with those schemes.

328. As a result of Novartis' violations of N.C. Gen. Stat. § 1-607(a), the State of North Carolina has been damaged in an amount far in excess of millions of dollars exclusive of interest.

329. McKee is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.C. Gen. Stat. § 1-608(b) on behalf of himself and the State of North Carolina.

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

WHEREFORE, Relator Steve M. McKee respectfully requests this Court to award the

following damages to the following parties and against Novartis:

To the STATE OF NORTH CAROLINA:

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

To RELATOR, STEVE M. MCKEE:

- (1) The maximum amount allowed pursuant to N.C. Gen. Stat. § 1-610 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

Dated: August 9, 2010

**UNITED STATES OF AMERICA et al., ex rel.  
STEVE M. MCKEE**

By: /s/ Tracy L. Steckling  
*One of Relator's Attorneys*

Tracy L. Steckling  
LAW OFFICE OF TRACY L. STECKLING, LLC  
3096 Rose Moon Way  
Neenah, WI 54956  
(920) 843-2180 (phone)  
(920) 486-1234 (fax)  
tsteckling@whistlelaw.com

Louis Agre  
LAW OFFICE OF LOUIS AGRE  
539 Gates Street  
Philadelphia, PA 19128-2510  
(215) 732-2530 (phone)  
(215) 923-1028 (fax)