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

UNITED STATES OF AMERICA, ex rel. H. DEAN STEINKE, 4667 Kramar Court Bridgman, MI 49106) FILED FEB - 5 2008) No. 00-CV-6158
STATE OF ILLINOIS, <u>ex rel.</u> H. Dean Steinke;)) FILED IN CAMERA) AND UNDER SEAL
STATE OF CALIFORNIA, <u>ex rel.</u> H. Dean Steinke))) [PROPOSED]
STATE OF FLORIDA <u>ex rel</u> . H. Dean Steinke;)) THIRD AMENDED) COMPLAINT
STATE OF TEXAS <u>ex rel</u> . H. Dean Steinke;) FOR VIOLATION OF THE) FEDERAL FALSE CLAIMS) ACT AND VARIOUS STATE
STATE OF MASSACHUSETTS <u>ex rel.</u> H. Dean Steinke;) FALSE CLAIMS ACTS) JURY TRIAL DEMANDED
STATE OF TENNESSEE ex rel. H. Dean Steinke;)))
STATE OF DELAWARE ex rel. H. Dean Steinke;)))
STATE OF NEVADA ex rel. H. Dean Steinke;))
STATE OF LOUISIANA ex rel. H. Dean Steinke;))
STATE OF HAWAII ex rel. H. Dean Steinke; DISTRICT OF COLUMBIA ex rel.)
H. Dean Steinke; STATE OF INDIANA ex rel.	
H. Dean Steinke; STATE OF NEW YORK ex rel.))
H. Dean Steinke; and)))
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v.)
MERCK & CO, INC., a New Jersey)
Corporation, 770 Sumneytown Pike	.) }
West Point, PA 19486)
Defendant.	·)

Relator, H. Dean Steinke, brings this action under the federal False Claims Act, as amended, 31 U.S.C. § 3729 et. seq., as well as various state false claims statutes, alleges as follows:

INTRODUCTION

- 1. This is a *qui tam* action brought by H. Dean Steinke on behalf of the United States and various States to recover penalties and damages arising from fraudulent and illegal practices in which Defendant Merck & Co., Inc. ("Merck") instituted programs throughout the country designed to induce doctors to prescribe Merck products over those of competitors by means of cash payments and other monetary incentives in violation of federal and state anti-kickback, self-referral laws and best pricing requirements (collectively, the "fraudulent and illegal practices"). Merck's fraudulent and illegal practices, often implemented under the guise of a "study protocol," "educational tutorial," or "grant" were for the sole purpose of enabling Merck to regain or increase its market share in the face of competition. Merck similarly sought to induce managed care organizations to maintain Merck drugs on their formularies by means of disguised cash payments. This complaint, which outlines the details of Merck's fraudulent and illegal practices, is based upon non-public information Mr. Steinke obtained while employed by Merck, and his personal observation of the acts and conduct described herein.
- 2. In connection with the filing of the original Complaint, Relator furnished the United States Government with thousands of pages of documents evidencing and supporting the fraudulent and illegal practices described herein. Relator has also provided additional information about Merck's fraudulent and illegal practices to federal investigations both prior to, and since, filing the Complaint.

THE PARTIES

3. Relator, H. Dean Steinke ("Steinke") is a citizen of the United States and a resident

of the state of Michigan. Steinke has been employed by Merck since March of 1995, initially hired as a sales representative, and then promoted to become one of the Business Managers of the Michigan sales region. During the course of his employment with Merck, Steinke acquired direct, personal knowledge of Merck's fraudulent and illegal practices.

4. Defendant Merck is a global pharmaceutical company, comprised of several reportable segments, including Merck Pharmaceuticals. Merck is a New Jersey corporation with its principal executive office in Whitehouse Station, New Jersey. Merck's pharmaceutical business is conducted through divisional headquarters located in West Point, Pennsylvania and Rahway, New Jersey. Principal research facilities are also located in West Point and Rahway.

JURISDICTION AND VENUE

- 5. 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).
- 6. Venue is proper in this district pursuant to 31 U.S.C. § 3732 (a) because Defendant Merck transacts business in this district, has it's divisional headquarters and principal research facilities in this district, and because Defendants committed numerous acts proscribed by 31 U.S.C. § 3729 in this district.

FACTUAL BACKGROUND

MERCK PHARMACEUTICALS - THE COMPANY

7. Merck is a global pharmaceutical company. According to its internet website, in 2001 Merck experienced total sales of over \$47 billion and a net income of over \$7 billion. Prescription products sold by Merck include: Zocor, Cozaar, Fosamax, Vioxx, Maxalt, and Singulair.

- 8. Merck faces a continuous battle for market share of its prescription products. In response to the competition, Merck has implemented and continues to implement a variety of strategies designed to maintain and/or increase its market share by paying doctors and others to prescribe Merck products over those of competitors. Merck's strategies include: fake "focus groups" and "research studies," illusory representative "training" by doctors, and when all else fails, the catch-all strategies of simply writing a "grant" in order to make an entity "whole," providing "nominal pricing" incentives and using its "neutral" PBM to manipulate the market. The commonality of these and other Merck strategies is that they are all a means to pay doctors. The end result is that Merck's financial inducements cause the recipients to switch patients to Merck products, at the expense of federal and state health care programs and patients. The marketing philosophy and strategy at Merck is simply to win *at all costs*.
- 9. Merck's fraudulent and illegal practices are implemented throughout the United States and through its six Regional Business Groups ("RBGs") which comprise the sales arm of Merck Pharmaceuticals. The RBGs are in turn, comprised of sales regions, districts and territories. At all relevant times, Steinke served as one of the Business Managers of the Michigan sales region. The Michigan region is located within the North Central Regional Business Group ("North Central RBG"), which includes the states of Illinois, Indiana, Michigan, Iowa, Wisconsin, Minnesota, and North and South Dakota. The other RBGs are comprised of the Northeast, MidAtlantic, Western, Southeast, and Southcentral.
- 10. Merck's corporate headquarters in West Point, Pennsylvania, is the "hub" for Merck's fraudulent and illegal practices, as all promotional and educational programs are supposed to be submitted to, and approved by, Merck's compliance department ("Medical/Legal") and by the Health Education Liaison Department ("HEL") for approval of funding. Merck policy

guidelines further direct that all payments for educational and promotional programs must be issued directly from HEL to the payee, after approval of the expenditure. Both Medical/Legal and HEL are located in or near West Point.

MERCK'S FRAUDULENT AND ILLEGAL PRACTICES

ILLUSORY "TRAINING" OF SALES REPRESENTATIVES: TUTORIALS AND PRECEPTORSHIPS

- 11. Pursuant to Merck's stated corporate policy, as expressed in HEL's "Rules of the Road," "tutorial" programs are to be used for educational purposes only, not the promotion of Merck products. In a tutorial, doctors are supposed to "train" sales representatives during a two to four hour session in various aspects of disease management and treatment. As Merck's "Rules of the Road" explains, "the tutorial serves to reinforce basic knowledge and provide a training forum to interact with the healthcare professional." Doctors are then to be paid at least \$250 a session for their "services." Merck's "tutorial" programs are strongly utilized throughout the nation despite the fact that Merck maintains staff physicians and dedicated training staff for each RBG for the express purpose of training its sales representatives.
- 12. Also, despite labeling tutorials as "educational" in nature, representatives are taught to use tutorials as a means of product promotion and making payments to "difficult to see" doctors and/or those who prescribe a low percentage of Merck products as opposed to competitors' products. The funding of tutorial programs is consistent with Merck's intent the money comes from Merck's promotional budget, not its training/education budget.
- 13. The true nature of Merck's tutorial program is also demonstrated by the fact that it is not at all unusual for particular sales representatives to be "trained" multiple times on the same day, for the same drug, and with the same doctor, and then apparently "retrained" again, a month

or two later. For example, Elizabeth Hagg, from the Michigan region was trained twenty-one times from January 14, 1999 through April 1, 1999, for Zocor with eight of her training sessions scheduled for the same day (despite the fact that each tutorial is *supposed to* last two to four hours). Additionally, it seems many of Merck's most experienced representatives, including Kimberly Long, Wayne Meech, and Steve Mogdrige (also a Physician's Assistant) required an extraordinary amount of training via the tutorial program. For example, in approximately 8 months in 1999, Kimberly Long was trained a total of 91 times via Merck's tutorial and preceptorship programs ("preceptorships" are "enhanced" versions of tutorials, discussed *infra*

- 14. In addition to the repetitive training of experienced sales representatives, certain doctors, such as Dr. Gamal S. Zaki repeatedly provide their services. Dr. Zaki, and others, enjoy a consistent stream of income working as a part of the Merck tutorial program.
- 15. The *minimum* payments made to doctors pursuant to the tutorial program remain the same (\$250), regardless of actual time spent with the doctor. Often, representatives spend only minutes with the doctors.
- described herein) are electronically processed through HEL, there is no check in place to ensure that the programs are only used for legitimate purposes. In fact, Merck sales representatives are instructed that they should not include any "unnecessary" information in the "Critical Notes" section of the electronic form submitted to West Point, as this may prevent auto-scheduling of the program and auto-payment to the doctor.
- 17. In the Michigan region alone, over 3,400 tutorials were conducted from January, 2000, through September 2000, at a cost of over \$1.2 million in payments to doctors, in addition

to field expenses (including dinner and entertainment) which likely double the total cost.

- 18. At a National Zocor Cross-Functional Team conference in 1999, attended by Merck Senior Sales Directors from around the country, tutorials, especially those held at restaurants and those occurring several times per week were discussed as one of the "BEST PRACTICES" in the Nation. Another of Merck's "BEST PRACTICES" is to conduct a case study review in a foursome, "while enjoying a round of golf."
- 19. Preceptorships are "enhanced" versions of tutorials pursuant to which a sales representative is supposed to spend a half or full day "shadowing" the doctor as he or she treats patients. Merck pays the doctors \$300 to \$500 for each preceptorship, in addition to payment of meals for the doctor and his or her staff.
- 20. Merck widely utilizes tutorials and preceptorships as a means to pay doctors for prescribing virtually all of Merck's drugs, including Zocor, Cozaar, Fosamax, Vioxx, Maxalt and Singulair.

BOGUS RESEARCH STUDIES

21. Similar to tutorials and reported to West Point as such, "Coronary Heart Disease ("CHD") Crossovers," are designed as another means to pay doctors for prescribing Merck products. Pursuant to this national program, a doctor who switches 10 patients to Zocor is paid \$250 to "discuss the results" with a sales representative, usually over lunch or dinner. A stated objective of this project is "owning the CHD patient." The Diabetic Didactic Program (also Zocor), Patient Experience Program (Cozaar), and Goal to Control (Singulair) programs are similar "clinical" experiences, with de minimis data collection, and ending with a paid "educational tutorial" (the Diabetic Didactic, Patient Experience and Goal to Control programs are also national in scope). The bogus nature of these studies is further evidenced by instructions

from Merck executives to the business managers, directing that information about side effects of Zocor be concealed from the professional representatives, out of fear that some of the representatives might reveal this information to the physicians.

22. Bogus research studies are also a key RBG and regional-level activity. Examples are discussed *infra*, ¶50 and 66.

"ADVOCATE DEVELOPMENT"

- 23. Merck targets Department Directors, such as Cardiology, at major institutions, to become Merck "advocates." Advocates are trained (and paid) to "spread the word" about the value of Merck products, while at the same time, recruiting referrals for their institution. When the speaker doesn't provide a strong enough message he or she is "coached" by Merck on ways to strengthen it. If the improvement doesn't happen, the "advocate" is no longer used, thereby losing the \$500 to \$1,500 honorarium for each speaking opportunity. Such "coaching" memos were commonly written by Merck.
- 24. Roundtables are one example of how doctors are paid via "advocate development." In a roundtable, a doctor is paid an honorarium of *at least* \$500 to give a 30-minute lecture to a small group of his or her peers on a Merck product. Merck's purpose behind the roundtable program is that doctors, rather than the Merck representatives, will be better able to convince other doctors to prescribe Merck products. Merck representatives, who remain during the roundtable, pay for lunch or dinner, and also prep the doctors by communicating key sales messages.
- 25. A similar strategy is employed with Merck's Visiting National Consultant ("VNC") and Facilitated Educational Discussion ("FED") programs. A Merck VNC involves use of a paid Merck consultant to draw doctors to a Merck event, which typically takes place at a ball

game, spa, golf course or even a night club. Merck pays for all the expenses and gives free gifts to the doctors just for showing up. Spouses or guests of the doctors are also invited and paid for by Merck.

- 26. A FED is a smaller-scale version of the VNC. Merck FED programs, formerly known at Merck as "Detail, Dine, and Dash," involve free gifts to doctors (including free meals, gift certificates to a liquor store, gasoline, etc.) just for stopping by and listening to a two to three minute sales message communicated by a paid Merck advocate or a Merck sales representative.
 - 27. Merck VNC and FED programs are conducted nationally.

NOMINAL PRICING "INCENTIVES" AND MASSIVE STOCK BOTTLE EFFORTS

- Merck provides nominal pricing incentives to induce certain hospitals to prescribe Merck products. Participating hospitals under one Merck program ("SAVE") can receive up to a 92% discount on Zocor, but only so long as the hospital meets certain performance levels in terms of patients taking Zocor over that of a competitor. Failure to maintain this performance level results in loss of the substantial discount.
- 29. Merck's nominal pricing schemes induce hospitals to switch patients to Merck products, particularly where the patient entered the hospital on a competitor's product. Merck's purpose in offering the nominal pricing incentive is to "market the spread" between the deeply discounted charge to the hospital and the hospital's charge to the patient or to the federal and state health care programs which pay for the patient's care. Merck's nominal pricing schemes are national in scope and involve at approximately seven hundred fifty hospitals around the nation.
- 30. With similar intent as nominal pricing, but on a smaller scale, Merck mass-ships "stock bottles" via its Special Promotion Program ("SPP) as another means of encouraging

clinics, hospitals, and managed care networks to use Merck products over those of competitors.

Merck stock bottles have also been supplied to individual doctors for personal or family use.

31. As with most other Merck programs, sales representatives obtain stock bottles by filling out a standard form. Sales representatives are instructed to write "For Clinical Evaluation" as the reason for the stock bottle request, in all cases.

THE USE OF UNRESTRICTED "GRANTS"

- 32. Another nation-wide strategy employed by Merck to maintain and/or regain market share for its prescription drug products is to simply write out unrestricted grants as a means of direct payment. Merck provides grants to individual doctors and third party payers. For example, if a doctor expresses a need for a new computer system, a Merck representative will simply write a grant for that purchase. Merck grants have also been written for the purpose of "getting a drug moving," or even more directly, to simply "make them whole," i.e., to offset, for key managed care entities, the higher price that Merck charges for its products than competitors charge for theirs.
- 33. In fact, Merck sales representatives are reprimanded for proposing to write grants which will not yield the appropriate "return on investment" for Merck products i.e., grants must only be written to medical groups and doctors that are "supporting or committ[ed] to supporting" Merck products.

FAKE FOCUS GROUPS

34. "Customer Focus Groups" or "Consultant Meetings" are yet another of Merck's nation-wide strategies to pay doctors. Merck's stated purpose of a customer focus group is to gather small groups of local physicians in order to "assess perceptions and attitudes about certain products, diseases, and market trends." In reality, they are just another means to wine and dine "key" doctors (i.e., low prescribers of Merck products).

35. Merck Customer Focus Groups are commonly held at a lavish resort and/or in an exotic location. All expenses for the doctors and their families are paid by Merck.

THE PRODUCT LINES AFFECTED BY MERCK'S ILLEGAL PRACTICES

ZOCOR

- 36. Zocor is a cholesterol-lowering prescription medication. Zocor is included in Merck's "atherosclerosis" products category (its number one seller), which experienced over \$7 billion in combined sales in 2001. In general, cholesterol-lowering medications are designed to lower LDL (low density lipoprotein) cholesterol levels, while raising HDL (high density lipoprotein) cholesterol levels in patients.
- 37. Zocor will likely remain a top selling product for Merck, as currently in the United States, approximately 8 million out of a total of 30 million (slightly less than one out of four) patients with heart disease are prescribed some type of cholesterol-lowering drug. These numbers will likely rise as cholesterol-lowering therapy is becoming the standard of care for patients with heart disease.
- 38. Competition for cholesterol-lowering medications is strong. Zocor was introduced by Merck in the early 1990's. At this time, "Mevacor" was a leading cholesterol-lowering prescription product, also manufactured by Merck.
- 39. In 1996, Merck's 10-K indicated that Zocor and Mevacor jointly held about 40% of the worldwide cholesterol-lowering prescription drug market.
- 40. Already in direct competition with Zocor and Mevacor, was "Pravachol," Bristol Myers Squibb Co.'s ("Bristol Myers") largest selling pharmaceutical product. Bristol Myers' 10-K filings listed Pravachol's 1996 and 1997 sales at approximately \$1.1 and \$1.4 billion,

respectively.

- 41. In February of 1997, Parke-Davis, a Warner-Lambert subsidiary, introduced "Lipitor," a cholesterol-lowering prescription product offered at a considerable savings over Zocor. For example, a 30-tablet prescription of Zocor (20 mg tablets) sold for approximately \$118.29 in 2000, while the same quantity and therapeutic potency of Lipitor sold for approximately fifty dollars, or less then half of the price of Zocor. Pravachol sold for only \$74.49.
- 42. During the remainder of 1997, following its introduction, Warner-Lambert reported sales of approximately \$865 million for Lipitor. Pravachol continued to experience strong sales as well.
- 43. As a result of the introduction of Lipitor, and the continued competition from Pravachol, Merck experienced a decrease in its market share of cholesterol-lowering prescription medications. In response, Merck rallied to implement strategies designed to recapture market share and "regain the crown."
- 44. For example, Merck implemented the following sales and marketing strategies with regard to Zocor, and as shown in Exhibit A:
 - (A) Widespread use of tutorials and preceptorships.
 - (B) Bogus research studies CHD Crossovers and Diabetic Didactic.
 - (C) A bogus research study in the NC RBG the ZTG project: One of the strategies implemented in the NC RBG (covering all of Michigan, Wisconsin, Minnesota, Indiana, Iowa, Illinois and North and South Dakota) designed to "regain the crown" for Zocor was the "Zocor to Goal" project ("ZTG"). Steinke was chosen to participate on this project and was also given the task of developing a database of physicians to target. ZTG was designed under the guise of a "study protocol" pursuant to which Merck paid \$1,500 "honoraria" to participating doctors who agreed to switch fifteen of their patients from lesser-priced prescriptions of Lipitor or Pravachol to

prescriptions for Zocor. Doctors were carefully screened for participation in ZTG by assigning each a "weighted average" and "ranking," based on the volume of Zocor, Lipitor and Pravachol prescriptions each doctor wrote.

Uniquely, funding for ZTG came directly from the Therapeutic Business Group ("TBG"), out of a "slush fund" for "supplemental regional programs, rather than directly from HEL. Similar slush funds existed for Chicago, Illinois, Indianapolis, Indiana, and Minneapolis, Minnesota.

Not surprisingly, the "data" collected from ZTG was never seriously treated. Steinke was informed by Spencer Kubo, M.D., (a Merck Senior Medical Director) that the "results" were collected only to preserve an appearance of legitimacy.

As a complement to ZTG, additional programs, "Regional Training Faculty" ("RTF"), were implemented in the NC RBG in which doctors were each paid \$750-\$1,000 to "evaluate" promotional speeches of Merck sales representatives.

- (D) Supplemental RTF programs in Michigan, Chicago, Indianapolis, and Minneapolis: Due to the success of RTF and ZTG in the NC RBG, additional monies were made available on a regional level to fund supplemental RTF and ZTG programs for "top-rated" doctors. The amount paid to the doctors under the supplemental RTF programs was at the discretion of the Merck sales managers for each district.
- (E) Bogus research studies in Florida: Pursuant to "Project Florida," Merck implemented a variety of fraudulent and illegal practices for the purpose of regaining market share for Zocor. Nearly \$850,000 was allocated for Project Florida. As an example of one of the programs, Merck implemented the "Lescol Failure Initiative" pursuant to which doctors were paid to identify patients receiving Lescol and who were not meeting their treatment goals, and then switch these patients to Zocor.

Another component of "Project Florida" was the HMG Consultant Training Program in which Merck gave doctors sales brochures and research studies and then required the doctors to take a "test" on those materials. Doctors who were fortunate enough to "pass" Merck's test were paid an honorarium of up to \$1,500 to evaluate the ability of Merck sales representatives to articulate sales messages for Zocor. This program provided the impetus for other Merck programs such as RTF in the NC RBG.

Additional components for "Project Florida" are described below under "Advocate Development."

(F) Advocate Development - widespread use of roundtables, VNC and FED programs.

Advocate Development at the VA: A litary of tactics designed to pay Dr. Jane Third at the Hines VA Medical Center (one of the largest VA's in the country) in Merck's effort to achieve its goal of switching all patients at the VA Clinic to Zocor.

More "advocacy" - the "Baranick Project" in Michigan. Pursuant to the Baranick Project, a paid Merck speaker advocate delivered a lecture on Zocor and Cozaar to key doctors (i.e., high prescribers of cholesterol-lowering products, but weak on Zocor) assembled for lunch in hotel rooms paid for by Merck. After their lecture, sales representatives would practice delivering sales messages to the doctors. Doctors participating in this Merck project were each paid \$500 to \$1,000 out of the Michigan Region "slush fund."

Project Florida Advocates – As another component of "Project Florida," Florida implemented the "Advocate Road Show." As part of Merck's Advocate Road Show, doctors including Dr. William Cromwell were selected (and paid) to travel on sales calls with Merck sales representatives and to also conduct evening speaker programs. The presentations for the speaker programs were typically developed by Merck. The Advocate Road Show provided the impetus to Merck's national VNC program.

As a complement to the "Advocate Road Show," Florida implemented the "Disciple Training Program." Here, Merck's "Road Show" Advocates trained new doctors to "spread the word" about Zocor. The goal of the program was to recruit Merck "disciples" who would ultimately become paid Merck speakers (as well as high prescribers of Zocor).

Additional components of "Project Florida" included: the "Zocor Attack Plan," the Managed Care Switch Campaign, and the "Refusal – No See Doctor Blitz." Relator is informed and believes, and based thereon alleges, Merck also paid substantial honoraria to doctors participating in these programs for the purpose of inducing them to switch patients to Zocor.

- (G) A Nominal pricing scheme for nearly 750 hospitals throughout the United States through "SAVE" as long as performance levels for Zocor are maintained. In addition to hospital sales, SAVE generates over \$55 million in annual retail "spillover" (i.e., patients who leave the hospital on Zocor will likely remain on Zocor, at least for a while).
- (H) **Grant writing** to Blue Care Network ("BCN") was ordered in the amount of approximately \$75,000 in order to "make them whole." BCN was threatening to convert its patients to Lipitor, the less-priced alternative.

- (I) Shipments of stock bottles via Merck's Special Promotion Program (SPP) to clinics, hospitals, managed care networks and doctors.
- (J) Mass shipments of stock bottles of Zocor to the BCN staff model medical group at Saginaw, Michigan. The purpose of this effort was to close the price-gap between Zocor and Lipitor.
- K) Fake focus groups at Amelia Island, Florida and Crystal Mountain, Michigan. For example, the approximately 60 doctors attending Merck's Amelia Island excursion received an all-expense paid weekend at the Ritz Carlton (a total cost of \$300,000 for Merck or \$5,000/doctor), which was approved by Jack Rothstein at Merck's West Point headquarters. In addition to their "honoraria," Merck paid for the doctors' travel expenses, rooms, incidentals, meals and entertainment (including live band). Merck also arranged for Merck sales representatives to be present for a meeting at the very same resort on the preceding day, so that they could then mingle with the doctors and create sales opportunities. Certain doctors on the Amelia Island venture also served as "training consultants" for the representative training meeting the previous day, for which they each received another "honorarium."
- Unreported cash rewards Merck's sales representatives were rewarded for successfully recruiting doctors to participate in certain Merck programs, including ZTG, RTF, the Baranick Project, Diabetes Didactic, and CHD Crossovers, by payment of \$100 American Express Gift Cheques. These cash payments were provided directly by Merck's sales managers to the representatives. The cash payments were not authorized by HEL nor were 1099 forms ever produced. Upon information and belief, Merck also did not generate 1099 payment reports for the doctors paid pursuant to ZTG, RTF and other "supplemental" projects, as they bypassed HEL.
- 45. Steinke is informed and believes Merck has instituted similar fraudulent and illegal practices in regard to Zocor throughout the country.
- 46. Merck's fraudulent and illegal practices for Zocor cost the federal and state governments tens of millions of dollars, as federal and state health care programs bear the burden of the paying the higher-priced prescriptions for Zocor that were the result of Merck's illegal financial inducements to doctors and others.

- 47. Moreover, the federal and state health care programs do not obtain the benefit of nominal pricing, kickbacks, disguised rebates, grants, etc., which are, in reality, monetary discounts and economic incentives from Merck in exchange for prescribing its products.
- 48. In addition, switching patients from a competitor's product or treatment to Zocor generally involves additional and otherwise unnecessary medical visits, tests and follow-up care, further increasing the costs to federal and state health care programs. The switch to Zocor also causes unnecessary testing and procedures because Zocor interacts with certain other drugs in highly unique ways. The process of switching patients from one medication to another also often causes side effects in itself, in addition to the particular side effects of Zocor. Upon information and belief, such unnecessary medical visits, testing, follow-up care, and treatment for side effects was required for the patients who were switched to Zocor pursuant to the fraudulent and illegal practices described above.
- 49. Most importantly, patients bear the burden of Merck's fraudulent and illegal practices in regard to Zocor, as financial inducements compromise physician objectivity and the quality of patient care.

COZAAR

- 50. Cozaar is a Merck product used to treat hypertension. Cozaar and Hyzaar have been used in the treatment of over 3 million patients in the United States.
- 51. In response to competition from Diovan and Avapro, Merck implemented fraudulent and illegal practices designed to maintain and/or regain market share.
- 52. For example, Merck implemented the following sales and marketing strategies with regard to Cozaar, as shown in Exhibit A:
 - (A) Widespread use of tutorials and preceptorships.

- (B) More illusory training the "Baranick Project" see description for Zocor.
- (C) Bogus research studies the "Patient Experience Program."
- (D) Advocate Development widespread use of roundtables, VNC and FED programs.
- (E) Grant writing including a grant to the Henry Ford Medical Clinic (Michigan) to "get Cozaar moving."
- (F) Shipments of stock bottles via Merck's Special Promotion Program (SPP) to clinics, hospitals, managed care networks and doctors.
- (G) Fake focus groups at Amelia Island, Florida and Crystal Mountain, Michigan, described above for Zocor.
- (H) Unreported AmEx Gift Cheque rewards to professional representatives.
- 53. Steinke is informed and believes Merck instituted similar fraudulent and illegal practices in regard to Cozaar throughout the country.
- 54. Merck's fraudulent and illegal practices for Cozaar cost the federal and state governments tens of millions of dollars, as federal and state health care programs bear the burden of the paying the higher-priced prescriptions for Cozaar that were the result of Merck's illegal financial inducements to doctors and others.
- 55. Moreover, the federal and state health care programs do not obtain the benefit of nominal pricing, kickbacks, disguised rebates, grants, etc., which are, in reality, monetary discounts and economic incentives from Merck in exchange for prescribing its products.
- 56. In addition, switching patients from a competitor's product or treatment to Cozaar generally involves additional and otherwise unnecessary medical visits, tests and follow-up care, further increasing the costs to federal and state health care programs. The process of switching patients from one prescription to another often causes side effects in itself, in addition to the

particular side effects of Cozaar. Upon information and belief, such unnecessary medical visits, testing, follow-up care, and treatment for side effects was required for the patients who were switched to Cozaar pursuant to the fraudulent and illegal practices described above.

57. Most importantly, patients bear the burden of Merck's fraudulent and illegal practices in regard to Cozaar, as financial inducements compromise physician objectivity and the quality of patient care.

FOSAMAX

- 58. Fosamax is Merck's osteoporosis medication, approved for the treatment and prevention of osteoporosis in postmenopausal women and for Paget's disease. In 1999, Fosamax also became the first medication approved for the treatment of glucocorticoid-induced osteoporosis in men and women and as treatment for men with osteoporosis.
- 59. In response to competition from Miacalcin, Merck implemented fraudulent and illegal practices designed to maintain and/or regain market share.
- 60. For example, Merck implemented the following sales and marketing strategies with regard to Fosamax, as shown in Exhibit A:
 - (A) Widespread use of tutorials and preceptorships.
 - (B) Bogus regional research studies: The March Against Miacalcin in Michigan (consisting of a variety of Merck programs designed to pay doctors including tutorials, focus groups and "advisory boards").
 - (C) Advocate development widespread use of roundtables, VNC and FED programs.
 - (D) Grant writing including grants to individual doctors for the purchase and support of DEXA (densitometry) machines or "bone buses," which the doctors take to seniors' communities to perform osteoporosis screenings. Merck provides this funding so that the doctors will in turn, prescribe Fosamax. Many of these same doctors are also paid Merck speakers. The tie between Merck and the doctors who receive DEXA funding is so tight that

Merck sales representatives have sat in on business meetings with the doctors in order to develop combined marketing strategies.

Additionally, a national Merck initiative, NORA, made DEXA machines available without any lease or rental charge to physicians who were high volume prescribers of osteoclast inhibitors such as Fosamax. Relator is informed and believes and based thereon alleges that the "loan" of DEXA machines also served as a financial incentive to the physicians, who were able to earn significant income from Part B of Medicare for the professional fees for interpreting the densitometry results.

In many case, Merck "followed-up" with doctors participating in NORA by paying them a \$250 tutorial fee to discuss their "results" with Merck sales representatives.

- (E) Shipments of stock bottles via Merck's Special Promotion Program (SPP) to clinics, hospitals, managed care networks and doctors.
- (F) AmEx Gift Cheque rewards to professional representatives and managers.
- 61. Steinke is informed and believes Merck instituted similar fraudulent and illegal practices in regard to Fosamax throughout the country.
- 62. Merck's fraudulent and illegal practices for Fosamax cost the federal and state governments tens of millions of dollars, as federal and state health care programs bear the burden of the paying the higher-priced prescriptions for Fosamax that were the result of Merck's illegal financial inducements to doctors and others.
- 63. Moreover, the federal and state health care programs do not obtain the benefit of kickbacks, disguised rebates, grants, etc., which are, in reality, monetary discounts and economic incentives from Merck in exchange for prescribing its products.
- 64. In addition, switching patients from a competitor's product or treatment to Fosamax generally involves additional and otherwise unnecessary medical visits, tests and follow-up care, further increasing the costs to federal and state health care programs. The process of

switching patients from one medication to another often causes side effects in itself, in addition to the particular side effects of Fosamax. Upon information and belief, such unnecessary medical visits, testing, follow-up care, and treatment for side effects was required for the patients who were switched to Fosamax pursuant to the fraudulent and illegal practices described above.

65. Most importantly, patients bear the burden of Merck's fraudulent and illegal practices in regard to Fosamax, as financial inducements compromise physician objectivity and the quality of patient care.

VIOXX

- 66. Vioxx is Merck's anti-inflammatory drug and Merck's second largest-selling product. Vioxx is used for a variety of purposes, including relief of osteoarthritis, management of short-term acute pain in adults, and treatment of menstrual pain.
- 67. In response to competition from Celebrex, Merck implemented fraudulent and illegal practices designed to maintain and/or regain market share.
- 68. For example, Merck implemented the following sales and marketing strategies with regard to Vioxx, as shown in Exhibit A:
 - (A) Widespread use of tutorials and preceptorships.
 - (B) Advocate Development widespread use of roundtables, VNC and FED programs.
 - (C) Grant writing.
 - (D) Shipments of stock bottles via Merck's Special Promotion Program (SPP) to clinics, hospitals, managed care networks and doctors.
 - (E) Unreported AmEx Gift Cheque rewards to professional representatives.
 - 69. Steinke is informed and believes Merck instituted similar fraudulent and illegal

practices in regard to Vioxx throughout the country.

- 70. Merck's fraudulent and illegal practices for Vioxx cost the federal and state governments tens of millions of dollars, as federal and state health care programs bear the burden of the paying the higher-priced prescriptions for Vioxx that were the result of Merck's illegal financial inducements to doctors and others.
- 71. Moreover, the federal and state health care programs do not obtain the benefit of kickbacks, disguised rebates, grants, etc., which are, in reality, monetary discounts and economic incentives from Merck in exchange for prescribing its products.
- 72. In addition, switching patients from a competitor's product or treatment to Vioxx generally involves additional and otherwise unnecessary medical visits, tests and follow-up care, further increasing the costs to federal and state health care programs. The process of switching patients from one medication to another often causes side effects in itself, in addition to the particular side effects of Vioxx. Upon information and belief, such unnecessary medical visits, testing, follow-up care, and treatment for side effects was required for the patients who were switched to Vioxx pursuant to the fraudulent and illegal practices described above.
- 73. Most importantly, patients bear the burden of Merck's fraudulent and illegal practices in regard to Vioxx, as financial inducements compromise physician objectivity and the quality of patient care.

MAXALT

- 74. Maxalt is used for the treatment of migraines in adults.
- 75. In response to competition from Zomig and Imitrex, Merck implemented fraudulent and illegal practices designed to maintain and/or regain market share.
 - 76. For example, Merck implemented the following sales and marketing strategies

with regard to Maxalt, as shown in Exhibit A:

- (A) Widespread use of tutorials and preceptorships.
- (B) Teleconferences used with Maxalt as a "hook" into the tutorial program (i.e., doctors will listen to a teleconference if they are paid to do a "tutorial" at the end).
- (C) Advocate Development widespread use of roundtables, VNC and FED programs.
- (D) Grant writing.
- (E) Fake focus groups at the Dearborn Ritz in Michigan.
- (F) Shipments of stock bottles via Merck's Special Promotion Program (SPP) to clinics, hospitals, managed care networks and doctors.
- (G) Unreported AmEx Gift Cheque rewards to professional representatives.
- 77. Steinke is informed and believes Merck instituted similar fraudulent and illegal practices in regard to Maxalt throughout the country.
- 78. Merck's fraudulent and illegal practices for Maxalt cost the federal and state governments tens of millions of dollars, as federal and state health care programs bear the burden of the paying the higher-priced prescriptions for Maxalt that were the result of Merck's illegal financial inducements to doctors and others.
- 79. Moreover, the federal and state health care programs do not obtain the benefit of kickbacks, disguised rebates, grants, etc., which are, in reality, monetary discounts and economic incentives from Merck in exchange for prescribing its products.
- 80. In addition, switching patients from a competitor's product or treatment to Maxalt generally involves additional and otherwise unnecessary medical visits, tests and follow-up care, further increasing the costs to federal and state health care programs. The process of switching patients from one medication to another often causes side effects in itself, in addition to the

particular side effects of Maxalt. Upon information and belief, such unnecessary medical visits, testing, follow-up care, and treatment for side effects was required for the patients who were switched to Maxalt pursuant to the fraudulent and illegal practices described above.

81. Most importantly, patients bear the burden of Merck's fraudulent and illegal practices in regard to Maxalt, as financial inducements compromise physician objectivity and the quality of patient care.

SINGULAIR

- 82. Singulair is used to control chronic asthma, helping to decrease the number of asthma attacks.
- 83. In response to competition from Accolate, Flovent, Seravent, Merck implemented fraudulent and illegal practices designed to maintain and/or regain market share.
- 84. For example, Merck implemented the following sales and marketing strategies with regard to Singulair, as shown in Exhibit A:
 - (A) Widespread use of tutorials and preceptorships.
 - (B) Teleconferences used as a "hook" into the tutorial program (i.e., doctors will listen to the teleconference if they are paid to do a "tutorial" at the end).
 - (C) Bogus research studies the "Goal to Control" Program.
 - (D) Advocate Development widespread use of roundtables, VNC and FED programs.
 - (E) Grant writing.
 - (F) Shipments of stock bottles via Merck's Special Promotion Program (SPP) to clinics, hospitals, managed care networks and doctors.
 - (H) Unreported AmEx Gift Cheque rewards to professional representatives.
 - 85. Steinke is informed and believes Merck instituted similar fraudulent and illegal

practices in regard to Singulair throughout the country.

- 86. Merck's fraudulent and illegal practices for Singulair cost the federal and state governments tens of millions of dollars, as federal and state health care programs bear the burden of the paying the higher-priced prescriptions for Singulair that were the result of Merck's illegal financial inducements to doctors and others.
- 87. Moreover, the federal and state health care programs do not obtain the benefit of kickbacks, disguised rebates, grants, etc., which are, in reality, monetary discounts and economic incentives from Merck in exchange for prescribing its products.
- 88. In addition, switching patients from a competitor's product or treatment to Singulair generally involves additional and otherwise unnecessary medical visits, tests and follow-up care, further increasing the costs to federal and state health care programs. The process of switching patients from one medication to another often causes side effects in itself, in addition to the particular side effects of Singulair. As an example, switching leads to increased aggressiveness and attention deficit problems in school-age children. Upon information and belief, such unnecessary medical visits, testing, follow-up care, and treatment for side effects was required for the patients who were switched to Singulair pursuant to the fraudulent and illegal practices described above.
- 89. Most importantly, patients bear the burden of Merck's fraudulent and illegal practices in regard to Singulair, as financial inducements compromise physician objectivity and the quality of patient care.

FEDERAL HEALTH CARE PROGRAMS AFFECTED BY MERCK'S FRAUDULENT AND ILLEGAL PRACTICES

RAILROAD RETIREMENT MEDICARE PROGRAM

90. The Railroad Retirement Medicare program, is authorized by the Railroad Retirement Act of 1974, 45 U.S.C.A. § 231 et seq. It is administered through the United States Railroad Retirement Board, "RRB" and furnishes Medicare coverage to retired railroad employees.

INDIAN HEALTH SERVICE

91. The Indian Health Service is responsible for providing comprehensive health services to more than 1,400,000 Native Americans. It is administered by the Department of Health and Human Services pursuant to 42 U.S.C.A § 2002 et seq. The statute authorizes the Secretary to enter into contracts with independent providers to furnish health services to Native Americans whenever the Secretary determines that independent providers can better meet a population's needs. Pursuant to 38 U.S.C.A. § 8126, and the regulations based thereon, drugs furnished to the Indian Health Service by drug manufacturers must be furnished at the best price.

FEDERAL EMPLOYEE HEALTH BENEFIT PLANS

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

TRI-CARE

Department of Defense through its component agency, CHAMPUS, under the authority of 10 U.S.C.A §§ 1071-1106, and provides for care in civilian facilities for members of the Uniformed Services and their dependents. Pursuant to 38 U.S.C.A. § 8126, and the regulations based thereon, drugs furnished by drug manufacturers to the Department of Defense must be furnished at the best price.

SLIAG

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

VETERAN'S ADMINISTRATION

95. Pursuant to 38 U.S.C.A. § 8126, and the regulations based thereon, and contracts the Veteran's administration had with manufacturers, drugs furnished to the Veterans' Administration ("VA") by drug manufacturers must be furnished at the best price.

MEDICARE AND MEDICAID

- 96. HHS, through its subsidiary entity, the Centers for Medicare and Medicaid Services (CMS) (formerly, HCFA), administers the Medicare program, which is a system of health insurance for the aged (i.e., those over the age of 65 years) and disabled, created under Title XVIII of the Social Security Act, 42 U.S.C.A. § 1395 et seq. The Medicare program is comprised of two "Parts." Part A of the Medicare program authorized payment for institutional care, including hospital, skilled nursing facility and home health care. 42 U.S.C.A. §§ 1395c-1395i-4. Most hospitals derive a substantial portion of their revenue from the Medicare program.
- Under Medicare's Prospective Payment System (PPS), most hospitals are paid on the basis of prospectively determined fixed rates, which vary according to the type and category of hospital treatment received. 42 U.S.C.A. § 1395ww(d). Medicare has been in the process of phasing in PPS reimbursement for hospital capital costs, such as the costs of buildings and equipment, during the 1990's.
- 98. To assist in the administration of Medicare Part A, CMS contracts with "fiscal intermediaries." 42 U.S.C. § 1395h. Fiscal intermediaries typically are insurance companies that

provide a variety of services, including processing and paying Part A claims and auditing cost reports.

- beneficiaries on the basis of a year-end cost report, submitted by the hospital (or "provider"). During the cost report year, upon discharge of Medicare beneficiaries from the hospital's service, the hospital submits claims for interim reimbursement to an assigned fiscal intermediary for items and services delivered to those beneficiaries during their hospital stays. 42 C.F.R. §§ 413.1, 413.60, and 413.64. Hospitals submit claims for interim payments on a CMS form UB-92. Providers receive payments on theses claims, known as "interim payments," from the Medicare Part A trust fund. Within a specified time after the end of the cost report year, the hospital must submit its cost report to its fiscal intermediary so that the fiscal intermediary can make year-end adjustments to the amounts paid to the hospital, as needed. 42 C.F.R. § 413.20(b).
- payment from Medicare, hospitals are required by CMS to submit annually a form CMS-2552, titled the "Hospital and Hospital Health Care Complex Cost Report" (Hospital Cost Report). Every Hospital Cost Report contains a "Certification," which must be signed by the chief administrator of the provider or a responsible designee of the administrator. Providers who file their Hospital Cost Reports electronically are required to submit a paper certification to the fiscal intermediary, which must be signed and dated. 42 C.F.R. § 413.24(f)(4). Thus, the provider must certify that the filed cost report is (1) truthful, i.e., that the cost information contained in the report is true and accurate, (2) correct, i.e., that the provider is entitled to reimbursement for the reported costs in accordance with applicable instructions, and (3) complete, i.e., that the Hospital Cost Report is based upon all of the provider's cost information pertaining to the determination of

reasonable cost.

101. In addition, the certification provision of the Medicare Hospital Cost Reports includes the following sentence:

I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in their cost report were provided in compliance with such laws and regulations.

Moreover, the certification provisions of CMS Form 2252 clearly state the significance of certain of those laws and regulations:

If services identified by this report were provided or procured through the payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.

- 102. Hospital Cost Reports contain specific financial data relating to the provider, most importantly the reimbursable costs it expanded to care for Medicare patients, including, but not limited to, costs for pharmaceutical agents. Hence, the cost report forms the basis for a determination by Medicare of whether the provider is entitled to reimbursement that is in addition to the interim payments it has already received, or whether the provider has been overpaid and must reimburse Medicare. 42 C.F.R. §§ 405.1803, 413.60 and 413.64(f)(1).
- Congressional mandate. In discharging its responsibilities, CMS has contracted with Medicare + Choice HMOs to provide services to Medicare beneficiaries wishing to enroll in private health maintenance organizations. Services may be provided through traditional fee-for-service providers, through Medicare-certified Health Maintenance Organizations, or through Medicare + Choice organizations. A Medicare+Choice organization is a public or private entity organized and licensed by a State as a risk-bearing entity that is certified by CMS as meeting the Medicare+Choice contract requirements. 42 C.F.R. § 422.2. As such, it is closely associated with

and regulated by, the United States. Medicare + Choice organizations frequently offer pharmaceutical benefits as a means of recruiting members. The acts described herein cause the Medicare + Choice organizations to pay far more for drugs than they would otherwise pay, absent the kickback and related schemes, thus imposing an additional cost upon Medicare.

- 104. Claims for reimbursement under Part B of the Medicare Program are submitted on a document known as the CMS form 1500 or the electronic equivalent of such a form.
- 105. Through CMS, HHS also administers the Medicaid Program, which provides health care benefits for certain groups, including the poor and the disabled, and which is funded in part from federal funds and in part by the state where the facility is located. 42 U.S.C.A. § 1396 et seq.

FEDERAL LAWS VIOLATED BY MERCK'S FRAUDULENT AND ILLEGAL PRACTICES

THE ANTI-KICKBACK ACT

- 106. The Medicare & Medicaid Anti-kickback Act, 42 U.S.C.A. § 1320(a)-7(b), prohibits any person from "knowingly and willfully" offering or paying "any remuneration," including any kickback bribe, rebate or anything of value to induce the recipient to refer, arrange for or recommend a health care item or service covered under a federal health care program. Violation of the statute is a felony and can subject the violator to the administrative sanction of exclusion and civil monetary penalties. 42 U.S.C.A. § 1320(a) 7(b)(c).
- 107. The Medicare and Medicaid Anti-Kickback Act also contains civil monetary penalties, which provide in relevant part:
 - (a) Any person that—
 - (1) knowingly presents or causes to be presented to an officer, employee, or agent of the United States, or of any department

- or agency thereof, or of any State agency...a claim that the Secretary determines—
- (B) is for a medical or other item or service and the person knows or should know the claim is false or fraudulent;
- (E) is for a pattern of medical or other items or services that a person knows or should know are not medically necessary;
- (7) commits an act described in paragraph (1) or (2) of section 1320(a)-7(b) of this title [shall be subject to civil monetary penalties as set forth in this section].

42 U.S.C.A. § 1320(a)-7(a).

- 108. Merck violated 42 U.S.C.A. § 1320(a)-7(a) and § 1320(a)-7(b) when it willfully offered and paid doctors and hospitals, among others in exchange for prescribing Merck drugs pursuant to the fraudulent schemes described herein, as the prescriptions for Zocor, Singulair, Vioxx, Maxalt, Cozaar, and Fosamax, and the unnecessary medical visits, testing, follow-up care and treatment for side effects associated therewith are all "items or services for which payment may be made in whole or in part under a Federal health care program."
- 109. When doctors submit bills for services (typically Evaluation and Management, or E/M codes) and those services include writing a prescription, the physicians are implicitly certifying that these services, including the writing of the prescription, were not improperly influenced by illegal financial inducements. The inducements offered by Merck have caused those certifications to be false.
- 110. In addition, hospitals submit annual cost reports to CMS. Those cost reports include certifications that the hospital has neither offered nor accepted financial inducements in violation of the above referenced statutes. By giving hospitals large quantities of drugs at discounts of up to 92%, or at no charge (via mass shipments of "stock bottles"), and suggesting

that the hospitals continue to charge the regular amount for these drugs, Merck caused the hospitals to submit false statements on the certifications accompanying the annual cost reports.

111. Although "safe harbor" regulations exist to protect certain relatively innocuous and even beneficial commercial arrangements, no such provision protects the payments made by Merck pursuant to its fraudulent schemes. The payments by Merck in this case were made for the sole purpose of increasing Merck's profits at the expense of patients, it's competitors, and the federal and state governments. The payments made by Merck were even strategically based on the impact of choosing particular physicians and hospitals over others (in terms of the effect on Merck's market share) and were conditioned on the volume and value of referrals made by participating physicians and hospitals.

THE STARK ACT

- 112. The Social Security Act contains provisions commonly referred to as Stark II (or, the "Stark Act"), which prohibit hospitals from billing Medicare for certain designated services referred, ordered or arranged for, by a physician with whom the hospital has a financial relationship and which do not fall within narrowly defined statutory exceptions. 42 U.S.C.A. § 1395nn.
- 113. The Stark Act contains a civil penalty provision, providing that if a physician has a financial relationship with an entity,
 - (A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and

the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A). 42 U.S.C.A. § 1395nn(a)(1).

- 114. Under Stark II, the term "financial relationship" is broadly defined to include any compensation arrangements between a physician and an entity. 42 U.S.C.A. § 1395nn (a)(2)(B).
- 115. The term "designated health services" under the Stark Act includes clinical laboratory services, outpatient prescription drugs, and inpatient and outpatient hospital services. 42 U.S.C.A. § 1395nn(h)(6).
- 116. Merck violated 42 U.S.C.A. § 1395nn(a) when it knowingly and willfully entered into arrangements in which Merck paid physicians in return for switching patients to Merck products, as the prescriptions for Zocor, Singulair, Vioxx, Maxalt, Cozaar, and Fosamax, and the unnecessary medical visits, testing, follow-up care and treatment for side effects associated therewith are all "designated health services" for which payment otherwise may be made under Medicare.
- 117. Although "safe harbor" regulations exist to protect certain relatively innocuous and even beneficial commercial arrangements, no such provision protects the payments made by Merck pursuant to its fraudulent schemes. The payments by Merck in this case were made for the sole purpose of increasing Merck's profits at the expense of patients, it's competitors, and the federal and state governments. The payments made by Merck were even strategically based on the impact of choosing particular physicians and hospitals over others (in terms of the effect on Merck's market share) and were conditioned on the volume and value of referrals made by participating physicians and hospitals.

BEST PRICING REQUIREMENTS

118. 38 U.S.C.A. § 8126 et seq. and the regulations based thereon, and contracts signed with Merck and the federal programs listed herein, require that when drug manufacturers furnish

their prescription products to Federal agencies, such as the VA, Public Health Service, including the Indian Health Service, and the Department of Defense, they must furnish them at the "best price."

limited to the SAVE and FLEX NP nominal pricing "discounts," the mass-shipments of stock bottles, and the grants to managed care organizations, Merck knowingly failed and refused to furnish its products to the federal agencies at the best price, in violation of 38 U.S.C.A. § 8126, as these same discounts, monetary concessions and rebates were not passed on to the federal health care programs.

COUNT I FEDERAL FALSE CLAIMS ACT

- 120. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 133 above as if fully set forth herein.
- 121. This is a *qui tam* action brought by H. Dean Steinke 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.
 - 122. 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.

- 123. Merck 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 1994 to the present by its violation of federal and state laws, including the Anti-Kickback Act, the Stark Act and Best Pricing Requirements, as described herein.
- 124. The United States Government, by and through CMS, DHHS, RRB, OPM, CHAMPUS, SLIAG and the VA, and possibly other federal agencies, and unaware of Merck's fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.
- 125. Compliance with applicable Medicare, Medicaid, Best Pricing Requirements, 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 United States Government by health care providers and third party payers in connection with Merck's fraudulent and illegal practices.
- 126. Had the United States Government known that Merck was violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Merck's fraudulent and illegal practices.
- 127. As a result of Merck's 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.
- 128. Steinke 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 H. Dean Steinke respectfully requests this Court to award the

following damages to the following parties and against Merck:

To the UNITED STATES GOVERNMENT:

- (1) Three times the amount of actual damages which the United States Government has sustained as a result of Merck's fraudulent and illegal practices;
- (2) A civil penalty of not less than \$5,500 and not more than \$11,000 for each false claim which Merck 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, H. DEAN STEINKE:

- (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 AND PROTECTION ACT

- 129. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 133 above as if fully set forth herein.
- 130. This is a *qui tam* action brought by H. Dean Steinke 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*.
 - 131. 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.
- 132. 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.
- 133. Merck violated 305 ILCS 5/8A-3(b) from at least 1994 to the present by engaging in the fraudulent and illegal practices described herein.
- 134. Merck 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 1994 to the present by its violation of federal and state laws, including 305 ILCS 5/8A-3(b), the Anti-Kickback Act, the Stark Act and Best-Pricing Requirements, as described herein.
- 135. The State of Illinois, by and through the Illinois Medicaid program and other state health care programs, and unaware of Merck's fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.
- 136. 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 Merck's fraudulent and illegal practices.

- 137. Had the State of Illinois known that Merck was violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Merck's fraudulent and illegal practices.
- 138. As a result of Merck's 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.
- 139. Steinke 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.
- 140. 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 H. Dean Steinke respectfully requests this Court to award the following damages to the following parties and against Merck:

To the STATE OF ILLINOIS:

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

To RELATOR, H. DEAN STEINKE:

- (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

- 141. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 133 above as if fully set forth herein.
- 142. This is a *qui tam* action brought by H. Dean Steinke 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*.
 - 143. 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.
- 144. 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.

- 145. Merck violated Cal. Bus. & Prof. Code §§ 650 and 650.1 and Cal. Welf. & Inst. Code §14107.2 from at least 1994 to the present by engaging in the fraudulent and illegal practices described herein.
- 146. Merck 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 1994 to the present by its violation of federal and state laws, including, Cal. Bus. & Prof. Code § 650-650.1 and Cal. Welf, & Inst. Code §14107.2, the Anti-Kickback Act, the Stark Act and Best-Pricing Requirements, as described herein.
- 147. The State of California, by and through the California Medicaid program and other state health care programs, and unaware of Merck's fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.
- 148. 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 Merck's fraudulent and illegal practices.
- 149. Had the State of California known that Merck was violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Merck's fraudulent and illegal practices.
- 150. As a result of Merck's 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.
- 151. Steinke 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.

152. 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 H. Dean Steinke respectfully requests this Court to award the following damages to the following parties and against Merck:

To the STATE OF CALIFORNIA:

- (1) Three times the amount of actual damages which the State of California has sustained as a result of Merck's fraudulent and illegal practices;
- (2) A civil penalty of up to \$10,000 for each false claim which Merck 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, H. DEAN STEINKE:

- (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

- 153. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 133 above as if fully set forth herein.
 - 154. This is a qui tam action brought by H. Dean Steinke and the State of Florida to

recover treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.081 et seq.

- 155. 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.
- 156. 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.
- 157. 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.
- 158. Merck violated Fla. Stat. §§ 409.920(c) and (e) and §456.054(2) from at least 1994 to the present by engaging in the fraudulent and illegal practices described herein.

- 159. Merck 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 1994 to the present by its violation of federal and state laws, including, the Anti-Kickback Act, the Stark Act and Best-Pricing Requirements, as described herein.
- 160. The State of Florida, by and through the Florida Medicaid program and other state healthcare programs, and unaware of Merck's fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.
- 161. 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 Merck's fraudulent and illegal practices.
- 162. Had the State of Florida known that Merck was violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Merck's fraudulent and illegal practices.
- 163. As a result of Merck's 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.
- 164. Steinke 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.
- 165. 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 H. Dean Steinke respectfully requests this Court to award the

following damages to the following parties and against Merck:

To the STATE OF FLORIDA:

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

To RELATOR, H. DEAN STEINKE:

- (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

- 166. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 133 above as if fully set forth herein.
- 167. This is a *qui tam* action brought by H. Dean Steinke and the State of Texas to recover double damages and civil penalties under V.T.C.A. Hum. Res. Code § 36.001 *et seq*.
 - 168. 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.
- 169. Merck 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 1994 to the present by its violation of federal and state laws, including, the Anti-Kickback Act, the Stark Act and Best-Pricing Requirements, as described herein.
- 170. The State of Texas, by and through the Texas Medicaid program and other state health care programs, and unaware of Merck's fraudulent and illegal practices, paid the claims

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

- 171. 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 Merck's fraudulent and illegal practices.
- 172. Had the State of Texas known that Merck was violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Merck's fraudulent and illegal practices.
- 173. As a result of Merck's 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.
- 174. Merck 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.
- 175. Steinke 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.
- 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 Texas in the operation of its Medicaid program.

WHEREFORE, Relator H. Dean Steinke respectfully requests this Court to award the

following damages to the following parties and against Merck:

To the STATE OF TEXAS:

- (1) Two times the amount of actual damages which the State of Texas has sustained as a result of Merck's fraudulent and illegal practices;
- (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 Merck cause to be presented to the state of Texas;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To RELATOR, H. DEAN STEINKE:

- (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

- 177. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 133 above as if fully set forth herein.
- 178. This is a *qui tam* action brought by H. Dean Steinke 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*.
 - 179. 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 common wealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim.
- 180. In addition, Mass. Gen. Laws Ann. Chap.118E § 41 prohibits the solicitation, receipt or offering of any remuneration, including any bribe ore rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any good, service or item for which payment may be made in whole or in part under the Massachusetts Medicaid program.
- 181. Merck violated Mass. Gen. Laws Ann. Chap. 118E § 41 from at least 1994 to the present by engaging in the fraudulent and illegal practices described herein.
- 182. Merck 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 1994 to the present by its violation of federal and state laws, including Mass. Gen. Laws Ann. Chap. 118E § 41, the Anti-Kickback Act, the Stark Act and Best-Pricing Requirements, as described herein.
- 183. The State of Massachusetts, by and through the Massachusetts Medicaid program and other state health care programs, and unaware of Merck's fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.
- 184. 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 Merck's fraudulent and illegal practices.

- 185. Had the State of Massachusetts known that Merck was violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Merck's fraudulent and illegal practices.
- 186. As a result of Merck's 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.
- 187. Steinke 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.
- 188. 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 H. Dean Steinke respectfully requests this Court to award the following damages to the following parties and against Merck:

To the STATE OF MASSACHUSETTS:

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

To RELATOR, H. DEAN STEINKE:

- (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

- 189. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 133 above as if fully set forth herein.
- 190. This is a *qui tam* action brought by H. Dean Steinke 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*.
 - 191. § 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.
- 192. Merck 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 1994 to the present by its violation of federal and state laws, including the Anti-Kickback Act, the

Stark Act and Best-Pricing Requirements, as described herein.

- 193. The State of Tennessee, by and through the Tennessee Medicaid program and other state health care programs, and unaware of Merck's fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.
- 194. 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 Merck's fraudulent and illegal practices.
- 195. Had the State of Tennessee known that Merck violated the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Merck's fraudulent and illegal practices.
- 196. As a result of Merck's 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.
- 197. Steinke 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.
- 198. 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 H. Dean Steinke respectfully requests this Court to award the following damages to the following parties and against Merck:

To the STATE OF TENNESSEE:

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

To RELATOR, H. DEAN STEINKE:

- (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 <u>DELAWARE FALSE CLAIMS AND REPORTING ACT</u>

- 199. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 133 above as if fully set forth herein.
- 200. This is a *qui tam* action brought by H. Dean Steinke 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.
 - 201. 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.
- 202. 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.
- 203. Merck violated 31 Del. C. § 1005 from at least 1994 to the present by engaging in the fraudulent and illegal practices described herein.
- 204. Merck 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 1994 to the present by its violation of federal and state laws, including 31 Del. C. §1005, the Anti-Kickback Act, the Stark Act and Best-Pricing Requirements, as described herein.
- 205. The State of Delaware, by and through the Delaware Medicaid program and other state health care programs, and unaware of Merck's fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.
- 206. 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 Merck's fraudulent and illegal practices.
- 207. Had the State of Delaware known that Merck was violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Merck's fraudulent and illegal practices.
 - 208. As a result of Merck's 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.

- 209. Steinke 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.
- 210. 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 H. Dean Steinke respectfully requests this Court to award the following damages to the following parties and against Merck:

To the STATE OF DELAWARE:

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

To RELATOR, H. DEAN STEINKE:

- (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

- 211. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 133 above as if fully set forth herein.
- 212. This is a *qui tam* action brought by H. Dean Steinke 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.
 - 213. 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.
- 214. 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.
- 215. Merck violated N.R.S. § 422.560 from at least 1994 to the present by engaging in the fraudulent and illegal practices described herein.
- 216. Merck 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 1994 to the present by its violation of federal and state laws, including N.R.S. § 422.560, the Anti-Kickback Act, the Stark Act and Best-Pricing Requirements, as described herein.
 - 217. The State of Nevada, by and through the Nevada Medicaid program and other state

health care programs, and unaware of Merck's fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

- 218. 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 Merck's fraudulent and illegal practices.
- 219. Had the State of Nevada known that Merck was violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Merck's fraudulent and illegal practices.
- 220. As a result of Merck's 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.
- 221. Steinke 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.
- 222. 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 H. Dean Steinke respectfully requests this Court to award the following damages to the following parties and against Merck:

To the STATE OF NEVADA:

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

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

To RELATOR, H. DEAN STEINKE:

- (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

- 223. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 133 above as if fully set forth herein.
- 224. This is a *qui tam* action brought by H. Dean Steinke 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*.
 - 225. 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;
 - 226. 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.

- 227. Merck violated La. Rev. Stat. Ann. § 438.2(A) from at least 1994 to the present by engaging in the fraudulent and illegal practices described herein.
- 228. Merck 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 1994 to the present by its violation of federal and state laws, including La. Rev. Stat. Ann. §438.2(A), the Anti-Kickback Act, the Stark Act and Best-Pricing Requirements, as described herein.
- 229. The State of Louisiana, by and through the Louisiana Medicaid program and other state health care programs, and unaware of Merck's fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.
- 230. 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 Merck's fraudulent and illegal practices.
- 231. Had the State of Louisiana known that Merck was violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Merck's fraudulent and illegal practices.
- 232. As a result of Merck's 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.

- 233. Steinke 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.
- 234. 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 H. Dean Steinke respectfully requests this Court to award the following damages to the following parties and against Merck:

To the STATE OF LOUISIANA:

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

To RELATOR, H. DEAN STEINKE:

- (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

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

133 above as if fully set forth herein.

- 236. This is a *qui tam* action brought by H. Dean Steinke 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*.
 - 237. 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.
- 238. Merck 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 1994 to the present by its violation of federal and state laws, including the Anti-Kickback Act, the Stark Act and Best-Pricing Requirements, as described herein.
- 239. The State of Hawaii, by and through the Hawaii Medicaid program and other state health care programs, and unaware of Merck's fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.
- 240. 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 Merck's fraudulent and

illegal practices.

- 241. Had the State of Hawaii known that Merck was violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Merck's fraudulent and illegal practices.
- 242. As a result of Merck's 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.
- 243. Steinke 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.
- 244. 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 H. Dean Steinke respectfully requests this Court to award the following damages to the following parties and against Merck:

To the STATE OF HAWAII:

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

To RELATOR, H. DEAN STEINKE:

(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 DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

- 245. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through133 above as if fully set forth herein.
- 246. This is a *qui tam* action brought by H. Dean Steinke 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*.
 - 247. 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.
 - 248. 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.

- 249. Merck violated D.C. Code § 4-802(c) from at least 1994 to the present by engaging in the fraudulent and illegal practices described herein.
- 250. Merck 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 1994 to the present by its violation of federal and state laws, including D.C. Code § 4-802(c), the Anti-Kickback Act, the Stark Act and Best-Pricing Requirements, as described herein.
- 251. The District of Columbia, by and through the District of Columbia Medicaid program and other state health care programs, and unaware of Merck's fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.
- 252. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein 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 Merck's fraudulent and illegal practices.
- 253. Had the District of Columbia known that Merck was violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Merck's fraudulent and illegal practices.
- 254. As a result of Merck's 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.
- 255. Steinke 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.

256. 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 H. Dean Steinke respectfully requests this Court to award the following damages to the following parties and against Merck:

To the DISTRICT OF COLUMBIA:

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

To RELATOR, H. DEAN STEINKE:

- (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 XIII INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

- 257. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 262 above as if fully set forth herein.
 - 258. This is a qui tam action brought by H. Dean Steinke and the State of Indiana to

recover treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5.

- 259. IC 5-11-5.5-2(b) provides liability for any person who knowingly and intentionally:
 - (1) presents a false 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;
 - (6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state; or
 - (8) causes or induces another person to perform an act described in subdivisions (1) through (6)§.
- 260. Merck violated IC 5-11-5.5-2(b) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Indiana from at least 1994 to the present by its violation of federal and state laws, including the Anti-Kickback Act, the Stark Act and Best-Pricing Requirements, as described herein.
- 261. The State of Indiana, by and through the Indiana Medicaid program and other state health care programs, and unaware of Merck's fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.
- 262. 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 Merck's fraudulent and illegal practices.
- 263. Had the State of Indiana known that Merck was violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Merck's fraudulent and illegal practices.

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- 264. As a result of Merck's violations of IC 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.
- 265. Steinke is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to IC 5-11-5.5 on behalf of himself and the State of Indiana.
- 266. 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 H. Dean Steinke respectfully requests this Court to award the following damages to the following parties and against Merck:

To the STATE OF INDIANA:

- (5) Three times the amount of actual damages which the State of Indiana has sustained as a result of Merck's fraudulent and illegal practices;
- (6) A civil penalty of not less than \$5,000 for each false claim which Merck caused to be presented to the State of Indiana;
- (7) Prejudgment interest; and
- (8) All costs incurred in bringing this action.

To RELATOR, H. DEAN STEINKE:

- (5) The maximum amount allowed pursuant to IC 5-11-5.5-6 and/or any other applicable provision of law;
- (6) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (7) An award of reasonable attorneys' fees and costs; and
- (8) Such further relief as this Court deems equitable and just.

COUNT XIV NEW YORK FALSE CLAIMS ACT

- 267. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 272 above as if fully set forth herein.
- 268. This is a *qui tam* action brought by H. Dean Steinke and the State of New York to recover treble damages and civil penalties under the New York False Claims Act, McKinney's State Finance Law § 187 et seq.
 - 269. McKinney's State Finance 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;
 - (g) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or a local government.
- 270. Merck violated McKinney's State Finance Law § 189 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of New York from at least 1994 to the present by its violation of federal and state laws, including the Anti-Kickback Act, the Stark Act and Best-Pricing Requirements, as described herein.
- 271. The State of New York, by and through the Hawaii Medicaid program and other state health care programs, and unaware of Merck's fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.
- 272. 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 Merck's fraudulent and illegal practices.

- 273. Had the State of New York known that Merck was violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Merck's fraudulent and illegal practices.
- 274. As a result of Merck's violations of McKinney's State Finance Law § 189 the State of New York has been damaged in an amount far in excess of millions of dollars exclusive of interest.
- 275. Steinke is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to McKinney's State Finance Law § 189 on behalf of himself and the State of Hawaii.
- 276. 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 H. Dean Steinke respectfully requests this Court to award the following damages to the following parties and against Merck:

To the STATE OF NEW YORK:

- (9) Three times the amount of actual damages which the State of New York has sustained as a result of Merck's fraudulent and illegal practices;
- (10) A civil penalty of not less than \$6,000 and not more than \$12,000 for each false claim which Merck caused to be presented to the State of New York;
- (11) Prejudgment interest; and
- (12) All costs incurred in bringing this action.

To RELATOR, H. DEAN STEINKE:

- (9) The maximum amount allowed pursuant to McKinney's State Finance Law § 190 and/or any other applicable provision of law;
- (10) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
- (11) An award of reasonable attorneys' fees and costs; and
- (12) Such further relief as this Court deems equitable and just.

Dated: January 30, 2008

UNITED STATES OF AMERICA, ex rel. H. DEAN STEINKE

One of the attorneys for Relator

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DEMAND FOR JURY TRIAL

Relator hereby demands a jury trial.

UNITED STATES OF AMERICA, ex rel. H. DEAN STEINKE

one of the attorneys for Relator