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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

STATE OF NEVADA, *EX REL.* H. DEAN STEINKE, Relator, PLAINTIFFS, v. MERCK & CO., INC., DEFENDANT.	Case No. CV-N-05-322-HDM (RAM)

[redacted]

FIRST AMENDED COMPLAINT
FOR DAMAGES UNDER NEVADA FALSE CLAIMS ACT
NRS 357.010 et. seq.

The State of Nevada, by the Attorney General for the State of Nevada, for its First Amended Complaint in Intervention against Defendant Merck & Co., Inc. alleges as follows:

1. The State of Nevada brings this action to recover statutory damages and civil penalties under the Nevada False Claims Act, N.R.S. § 357.010, et. seq.

2. The Defendant, Merck & Co., Inc. (Merck) devised a number of marketing schemes to regain or increase its market share in the face of competition. One of these schemes centered on Zocor, which is a drug prescribed for the treatment of cardiac problems, and one scheme centered on Vioxx, which was prescribed for the treatment of chronic pain or joint inflammation. These drugs share a common characteristic because they are both prescribed for chronic conditions. Thus, a patient who is prescribed one of these drugs will generate income for Merck for years after the initial prescription is made. Merck's marketing strategy for these drugs included programs to ensure that hospitals would prescribe Zocor or Vioxx to hospital admittees in order to capture the patient early on and capitalize on the long term spill-over effect of that patient's continued use of the drug after they were released from the hospital.

3. Merck therefore gave selected hospitals tremendous financial incentives, in the form of steep discounts to either start patients on Vioxx or Zocor, or to switch them to these drugs away from competitors' drugs during their hospital stay in expectation that such patients would continue to take Merck's products after they were released from the hospital to achieve a pull-through strategy, as it is known in the pharmaceutical industry.

4. Merck was required under the Medicaid Rebate Act, 42 U.S.C.§ 1396r-8, to report these discounts as Best Prices for calculating Merck's rebates to the States, including Nevada. Merck, however, concealed these discounts from the Centers for Medicare and Medicaid Services (CMS) which relies on truthful reporting of Best Price information so that rebates due to the States may be properly calculated. Merck knowingly, deliberately, and purposefully concealed the discounted prices; because if it had reported the true discounted prices, Merck would have had to pay far greater rebates to the States.

5. Merck's conduct damaged Nevada's Medicaid program in four ways: (1) Nevada did not receive the rebates to which it was entitled; (2) Nevada had to pay for outpatient prescriptions which were more expensive prescriptions than the old prescriptions; (3) switching patients to Zocor required Medicaid beneficiaries to undergo expensive liver function tests; and (4) a measurable percentage of Medicaid beneficiaries who were switched to Vioxx developed cardiac problems as a result of the switch, necessitating more treatment.

6. This complaint details Merck's fraudulent and illegal conduct and is based

upon non-public information Mr. Steinke obtained while employed by Merck.

7 In connection with the filing of the original Complaint, and prior to, Relator furnished the State of Nevada with documents evidencing and supporting the fraudulent and illegal practices described herein.

THE PARTIES

8. The State of Nevada brings this action on behalf of itself and its agencies.

9. Relator H. Dean Steinke (Steinke) is a citizen of the United States and a resident of the State of Michigan. Steinke was employed by Merck from March of 1995 to April 2001. Merck initially hired Steinke as a sales representative, and then promoted him 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 illegal practices.

10. Defendant Merck is a global pharmaceutical company, comprised of several reportable segments, including Merck Pharmaceuticals and Merck Human Health Division. 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. According to its internet website, in 2001 Merck experienced total sales of over $47 billion and income of over $7 billion. Prescription products sold by Merck include those at issue here, Zocor and Vioxx.

JURISDICTION

11. This court has personal jurisdiction over the Defendant as the Defendant transacts business in the State of Nevada and has engaged in wrongdoing in Nevada. Defendant Merck sells the drugs it manufacturers to hospitals in Nevada, such as St. Mary's Regional Medical Center in Reno, Nevada and University Medical Center of Southern Nevada, Sunrise Hospital and Medical Center, and Valley Hospital Medical Center, all in Las Vegas, Nevada.

12. There has been no statutorily relevant public disclosure of the allegations or transactions in this Complaint. Relator, moreover, would qualify under the Act as an original source even if such a public disclosure were found to exist because he has direct and independent knowledge of the wrongdoing alleged in this Complaint and because he voluntarily provided this information relating to such misconduct to State prior to initiating this qui tam lawsuit.

BACKGROUND

A. The Nevada False Claims Act

13. The pertinent provisions of the Nevada False Claims Act provides liability for any person who:

> (a) knowingly presents or causes to be presented a 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 false claim; and/or ...

(g) knowingly makes or uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state or a political subdivision. N.R.S. § 357.040(1).

14. The Nevada False Claims Act violations here involve the knowing and deliberate submission of false records and/or statements to CMS (formally, HCFA) regarding the Best Price, i.e. the lowest price, that Merck sold the drugs known as Zocor and Vioxx, in abuse of the Medicaid Program.

B. The Federal Medicaid Program

15. In 1965, Congress enacted Title XIX of the Social Security Act to expand the nation's medical assistance program for the needy, the medically needy aged, blind, disabled, and families with dependent children. 42 U.S.C. §§ 1396-1396v. This became known as the Medicaid Program. The Medicaid Program is funded by both Federal and State monies, collectively referred to as Medicaid Funds, with the federal contribution computed separately for each state. 42 U.S.C. §§ 11396b; 1396d(b).

16. Each State is permitted, within certain parameters, to design its own medical assistance plan, subject to approval by the Department of Health and Human Services (HHS). Among other forms of medical assistance, the States are permitted to provide medical assistance from the Medicaid Funds to eligible persons for outpatient prescription drugs. 42 U.S.C. § 1396a(10)(A); 1396d(a)(12).

17. HHS is an agency of the United States and is responsible for the

administration, supervision and funding of the federal Medicaid Program. CMS is the division of HHS that is directly responsible for administering the federal Medicaid Program. Prior to 2001, CMS was known as the Health Care Finance Administration, or HCFA.

18. In 1990, Congress enacted the Medicaid Rebate Program, 4 U.S.C. §1396r-8, as part of the Omnibus Budget Reconciliation Act of 1990. The Medicaid Rebate Program, also known as the Medicaid Rebate Act and the Medicaid Rebate Statute, is a cost-savings measure that Congress passed in response to increasing Medicaid expenditures for prescription drugs (and) requires drug companies to pay rebates to states on their Medicaid purchases. Pharmaceutical Research & Mfrs. Of America v. Walsh, 538 U.S. 644, 649, 123 S. Ct. 1855, 1860 (2003).

19. Pursuant to the Medicaid Rebate Act participating manufacturers who want their drugs covered by Medicaid must contract with the federal government in a manner that is consistent with Congressional intent in passing the Medicaid Rebate Act.

20. Drug manufacturers must enter into a Rebate Agreement with the Secretary of HHS in order for federal matching funds to be made available for that manufacturer's covered outpatient drugs, 42 U.S.C. § 1396r-8(a)(1). Each participating manufacturer must sign, indicating agreement and compliance with all provisions therein, including that The Rebate Agreement shall be construed in accordance with federal common law and ambiguities shall be interpreted in the manner which effectuates the statutory scheme.

21. The Rebate Agreement provides that the Secretary enters the agreement on behalf of the Department of Health and Human Services and all States and the District of Columbia (except to the extent they have in force an Individual State Agreement). Upon entering a Rebate Agreement with the Secretary, the manufacturer must pay a quarterly rebate directly to each participating State based on all of the manufacturer's drugs purchased by that State pursuant to its Medicaid plan during that quarter.

22. For single source or innovator multiple source drugs, the basic rebate due on each unit paid for under the State plan is calculated as the greater of either (a) a flat 15.1% off of the average manufacturers' price (AMP) or (b) the difference between the AMP and the Best Price, or the lowest price available from the manufacturer during the previous quarter rebate period to *any* wholesaler, retailer, provider, health maintenance organization, non-profit entity or non-excluded government entity. 42 U.S.C. § 1396r-8(c)(1),(2).

23. The term 'average manufacturer price' means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts. 42 U.S.C. § 1936r-8(k)(1).

24. The Best Price, or lowest price charged must take into account cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates, other than the rebate paid to the States under the Medicaid Rebate Program.

The Best Price also is determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package. And, the best price does not take into account prices that are merely nominal in amount. 42 U.S.C. § 1396r-8(C)(1).

25. Nominally-priced discounts are intended for not-for-profit, charitable entities and for researchers using the drugs for experimental or non-standard purposes. See S. Rep. 102-28(I), Developments in Aging: 1990-Volume 1, 102nd Cong., 1st Sess. 1991 (March 22, 1991), WL 52579 (Leg.Hist.). Such discounts are not intended for marketing purposes. The Rebate Agreement defines nominal price as any price less than 10% of the AMP in the same quarter for which the AMP is computed. Rebate Agreement at I. Definitions,(s). Any rebate amounts received by the State must be offset against the State's Medicaid expenditures that quarter for purposes of calculating the matching federal financial participation. 42 U.S.C. § 1396r-8(b)(1)(B).

26. Drug manufacturers are required under the Medicaid Rebate Statute and Rebate Agreement to calculate and report their AMPs and Best Prices to the Secretary on a quarterly basis. 42 U.S.C. § 1396r-8(3)(A)(i); Rebate Agreement at § II(e). Any information provided by a manufacturer or wholesaler under the rebate statute is confidential and shall not be disclosed by the Secretary...or a State agency. . .except as the Secretary determines to be necessary to carry out this section. 42 U.S.C. § 1396r-8(b)(3)(D); Rebate Agreement at § VII.

27. States are required to report their total Medicaid drug utilization to each

manufacturer and the Secretary sixty days after the end of the rebate quarter. 42 U.S.C. § 13964-8(b)(2)(A). Using the manufacturer pricing date, CMS computes the unit rebate amount (URA) to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due. Rebate Agreement at § I(dd). Using the Medicaid drug utilization data, manufacturers calculate and pay the States the rebates they believe are due and owing to each State.

C. The Nevada Medicaid Program

28. The Division of Health Care Financing and Policy is Nevada's state agency which, working with CMS, administers the Nevada State Medical Assistance Plan, or Medicaid. Nevada Medicaid pays for certain prescription drugs provided to eligible low-income individuals, including people with disabilities, children and elderly citizens. Pursuant to federal and state regulations, reimbursement for prescription drugs dispensed to participants in the Nevada Medicaid program is limited in accordance with formulas that are based on the provider's estimated acquisition cost of the drug or other regulatory limitations. In Nevada, the reimbursement rate is the lowest of: (a) the Maximum Allowable Cost (MAC) established by CMS for multiple source drugs that meet certain criteria, plus the professional/dispensing fee; (b) the Estimated Acquisition Cost (EAC), defined as the Average Wholesale Price (AWP) less 15%, plus the professional/dispensing fee (presently $4.76); or (c) the pharmacy's usual charge to the general public.

29. Nevada pays a portion of Medicaid the cost for goods and services given

to the State's Medicaid beneficiaries. The current portion is approximately 55.9%. In the 2004 fiscal year, Nevada spent well over $900 million in Medicaid, over $125 million of which consisted of payments to pharmacies. See http://shcfp.state.nv.us/pdf%20forms/Info/Fact%20Book%201-21-05%Final.pdf.

30. The State of Nevada relied and continues to rely upon the benefits conferred by the Medicaid Rebate program, and on the performance of Merck of the obligations imposed by the Rebate Agreements, to ensure that the Nevada Medicaid program reimburses payors, e.g. pharmacies, based on the Best Price available for Merck's pharmaceutical products.

D. Defendant's Reported Best Price Was False and Fraudulent.

31. Merck faces a continuous battle for market share of its prescription drugs. In response to the competition, Merck employs a variety of illegal marketing strategies to maintain and/or increase its market share by inducing doctors and hospitals to prescribe Merck products over those of competitors. Two such marketing strategies were the SAVE and VIP programs; another was Merck's free drug give-away.

1. The Zocor SAVE Program

32. Merck launched the SAVE (Simvastatin Acute-Care Value Enhancement) Program for Zocor (simvastatin) in April 1998 to counter Pfizer's introduction into the marketplace of its lower priced statin, Lipitor. This national program was intended to have coronary heart disease (CHD) patients in the hospital either initially put on Zocor, or

switched from Lipitor to Zocor so that when they were discharged, they would continue the prescription, thus creating a spill-over market.

33. So long as the hospital or hospital system maintains a market share of 70% for Merck HMG's (Zocor and Mevacor (a lovastatin)), the hospital is entitled to nominal price discounts or a 92% discount off the catalog price of Zocor. In May 1999, Merck expanded SAVE to allow hospitals to get in on the 92% discount even if they could not maintain the 70% market share of the HMGs so long as they increased market share for Zocor by 10 points over the previous quarter or established Zocor as the exclusive or sole-preferred HMG on the formulary for the first time.

34. Merck also offers second and third-tier, non-nominal price discounts for hospitals which could not meet any of these three standards to be given nominal price discounts. SAVE offers a 30% discount off of catalog price of Zocor for hospitals maintaining a 55% market share of Zocor and a 20% discount for a 45% market share.

35. By May of 1999, Merck was already seeing the desired results from SAVE. Internal reports stated that in-patient market share for ZOCOR at SAVE hospitals continued to climb. Further, spill-over analysis shows that SAVE was blunting the growth of Lipitor leading to more scripts for ZOCOR in the communities surrounding SAVE hospitals. As of the beginning of December 1999, Merck reported that Market share for ZOCOR for targeted SAVE hospitals had grown from 42% to 55% since SAVE was launched and SAVE had generated over $55 million in retail sales spill-over for ZOCOR nationally.

36. Merck used the SAVE program to create a package of financial incentives to induce hospitals to achieve Merck's sought-after increased market share. For example, from the launch in April 1998 until October 1999, participating hospitals, regardless of the market share maintained, were allowed to take advantage of the nominal price discounts.

37. For those hospitals that had not yet signed on to the SAVE program, Merck directed its pharmaceutical sales representatives to offer hospitals the following monetary incentives to induce them to join:

a. Over one year of up-front nominal pricing for ZOCOR, a benefit not typically seen in the industry.

b. A two month rebate at the start of the contract until wholesaler notification.

c. Multiple enhancements and extensions to SAVE designed to help hospitals achieve and maintain nominal pricing.

38. Merck also used SAVE to fend off the effects that favorable studies regarding Lipitor were having on Zocor's market share. As stated in an internal Merck memorandum: "One of the key objectives for Zocor for the remainder of 2000 is to blunt the potential impact of MIRACL, an outcomes trial utilizing Lipitor 80mg...(T)he SAVE contract is the key resource you can use to pre-empt the possible effects of MIRACL". The point was to keep Zocor in the hospitals to achieve the increased market share which would result from hospital prescriptions spilling over into outpatient retail scripts being paid by Medicaid. "By actively reinforcing the value of ZOCOR through the SAVE

program in these accounts, you can stay on the offense and continue to strengthen the position of ZOCOR on the hospital's formulary."

39. SAVE's "nominal pricing" is indisputably an incentive-based marketing program. Merck admits that the 20% and 30% discounts off of Zocor were "highly competitive versus competitive statins"! Merck is virtually giving away Zocor to hospitals so that they would exclusively prescribe Zocor to their CHD patients. Merck makes no bones about it: the purpose of SAVE was to induce the hospitals into using Zocor exclusively or at least primarily and to thereby induce the CHD patients into doing the same.

40. Merck permitted SAVE hospitals to purchase Zocor at nominal pricing, *regardless* of the market share the hospital maintained notwithstanding the parameters of the program until October 1999. Then, Merck identified those hospitals at risk of losing the nominal price or other discounts and pressured them to meet the market share requirements and warning that they would lose the SAVE discounts if they did not comply.

41. Merck continues to employ the SAVE program as a key marketing strategy for Zocor.

42. Were Merck to use nominal pricing, as it is intended, to benefit non-profits or financially disadvantaged institutions, the SAVE hospitals would be predominantly "DSH" or Disadvantaged Share Hospitals which have 11.75% indigent population and qualify for nominal pricing. Yet, only a few of the hospitals of those listed who were being

tracked for falling off the SAVE program are designated as DSHs. Instead, Merck offers these terms only to hospitals which achieve Merck's goals of market control.

43. Merck knows, and knew that the nominal price it charged to hospitals must be reported to CMS. Even so, Merck purposefully did not report both the nominal-price discounts and the non-nominal pricing discounts hospitals were given under SAVE as required under the Medicaid Rebate Act. Merck knowingly and deliberately concealed these discounts for the purposes of calculating Best Price. Had Merck truthfully reported these prices, they would have affected the Best Price calculations and Merck would have paid the State of Nevada much greater rebates.

44. Since the launch of SAVE in 1998, Merck has tracked those hospitals eligible for the nominal price discount for Zocor, and for the non-nominal discounts of 20% and 30% off of catalog price. Those hospitals that receive the 20% and 30% discounts are located throughout the nation, and number in the many hundreds since 1999.

45. According to internal documents Merck distributed to its sales force the 30% discount on Zocor in 1999 amounted to, as an average over the dosages, about $1.80 per tablet. However, during 1999, Merck's reported best price for its most popular dosage (20 mg) ranged from $1.80 to almost $1.83 per tablet, indicating that the 30% discount off of catalog price often fell below Merck's reported Best Price.

46. Nevada is informed and believes that periodically from the time the SAVE program was launched until the present, Merck refused to report SAVE's 30% discount

as the Best Price. Because Nevada does not have access to Merck's confidential pricing information which would show the catalog price for each dosage of Zocor it cannot compare the 30% discount off that price with Merck's reported best price for each dosage in each quarterly reporting period.

47. Merck knowingly and deliberately concealed these discounts and knowingly did not account for the steep discounts offered under the SAVE program in calculating its quarterly report of Best Price to CMS.

2. The Vioxx VIP Program

48. Merck used a nominal pricing discount scheme similar to SAVE to promote its cornerstone COX-2 inhibitor drug, Vioxx. Merck marketed Vioxx through the Vioxx Incentive Program or VIP. The VIP Program gave hospitals "up front discounts for Vioxx commensurate with a Hospital/System's agreement to achieve a (greater than or equal to) 80% Market Share for Vioxx...and designating Vioxx as the Exclusive NSAID that selectively inhibits COX-2 on Formulary". The discount amounted to a nominal price of 92% off of the Merck Catalog Price.

49. Merck knows that the nominal price it charges to hospitals must be reported. Even so, Merck purposefully did not report the nominal-price discount hospitals were given under VIP as required under the Medicaid Rebate Act. Merck knowingly and deliberately concealed these discounts for the purposes of calculating Best Price. Had Merck truthfully reported these prices, they would have affected the Best Price calculations

and Merck would have paid the State of Nevada much greater rebates.

50. Merck knowingly did not disclose the nominal price discount and knowingly did not account for the steep discount offered under the VIP program in calculating its quarterly report of Best Price to CMS.

51. Both the VIP and SAVE programs misused and abused nominal pricing to lure hospitals into purchasing and maintaining a high market share of Vioxx and Zocor. The nominal pricing offered by Merck should have been reported as the Best Price on which rebates should have been calculated and issued to the States.

3. Free Drug Give-Aways via Stock Bottle Distribution

52. In furtherance of its marketing plan of using hospitals as the capture point for the retail spill-over market, Merck further induced hospitals (as well as HMOs and health systems) to purchase its drugs to prescribe to their patients. One method Merck employed was to give away large amounts of free drug to hospitals in order to reduce the total cost of the drugs the hospital purchased from Merck. Free goods that are given away contingent on any purchase requirement, as well as volume discounts, must be taken into account in calculating Best Price. 42 U.S.C § 1396r-8(c)(1)(C)(ii)(I).

53. The free drugs at issue, Zocor and Vioxx, that Merck distributed were not patient samples for physicians to give to patients. Rather, the free drugs were distributed in significant amounts, via stock bottles, also known as trade-complimentary product.

54. Nevada's investigation has revealed that Merck gave a number of free stock

bottles of Zocor and Vioxx starting at least in 1998. Nevada has estimated the "street value" or the monetary value of some of these give-aways to hospitals and HMOs by calculating how much the hospital or HMO would have had to pay for the quantity of drugs that Merck gave them. These estimates, illustrated in Table A below, have been calculated by multiplying the amounts given, in tablets, by the Average Wholesale Price (AWP) of the most commonly used dosage of that drug: for Zocor, 20 mg, and for Vioxx, 25 mg. The AWP was calculated by the standard method of multiplying AMP by 1.25 since it is widely accepted that AWP is 25% more than AMP.

TABLE A: EXAMPLES OF THE MONETARY VALUE OF MERCK'S FREE DRUG GIVE-AWAY PROGRAM

DATE	HOSPITAL or HMO AND CITY	ST.	DRUG	# OF TABLETS	VALUE (IN $)
04/25/01	Bay Med. Ctr., Bay City	MI	Zocor	2160	$10,260.00
02/06/98	Botsford Hosp., Farmington Hills	MI	Zocor	900	3,161.25
03/20/01	Stanford Univ. Hospital, Palo Alto	CA	Zocor	1200	4,620.00
08/25/99	White Memorial, LA	CA	Vioxx	600	1,236.00
05/21/01	Duke Univ. Hospital, Durham	NC	Vioxx	720	1,827.00
04/12/00	Duke Univ. Hospital, Durham	NC	Vioxx	1080	2,646.00
03/16/00	U of North Carolina Hosp., Chapel Hill	NC	Zocor	21000	79,170.00
04/02/98	Jacobi Medical Center, Bronx	NY	Zocor	4320	15,336.00
06/03/98	Jacobi Medical Center, Bronx	NY	Zocor	4320	15,336.00
08/10/99	Metropolitan Hospital, NYC	NY	Vioxx	1770	3,646.20
07/23/99	Coney Island Hospital, Brooklyn	NY	Zocor	5940	21,755.25
10/29/97	Coney Island Hospital, Brooklyn	NY	Zocor	600	2,055.00
04/23/01	South Nassau Comm Hosp.Oceanside	NY	Vioxx	720	1,821.60
01/20/98	Franklin Med. Ctr., Valley Stream	NY	Zocor	360	1,264.50
10/02/98	Bellevue Hospital, NYC	NY	Zocor	6780	24,069.00
06/09/00	Bellevue Hospital, NYC	NY	Zocor	1500	5,625.00
08/28/01	Harlem Hospital, NYC	NY	Vioxx	660	1,683.00
11/04/99	U. of New Mexico Hosp., Albuquerque	NM	Vioxx	720	1,773.00
01/07/99	U. of New Mexico Hosp., Albuquerque	NM	Zocor	3600	13,230.00
08/10/99	Columbia St. Mary's Mke.	WI	Vioxx	1440	2,966.40
12/02/99	Bluemound Med. Ctr., Wauwatosa	WI	Zocor	720	2,637.00
12/02/99	Bluemound Med Ctr, Wauwatosa	WI	Vioxx	720	1,771.20
01/05/98	BCBS, Chicopee	MA	Zocor	12600	44,226.00
03/16/98	MA Instit of Tech (MIT) Hosp., Boston	MA	Zocor	720	2,527.25

07/22/99	Ruskin Health Ctr., Ruskin	FL	Zocor	26160	95,745.60
07/21/99	Columbia Brandon Hosp., Brandon	FL	Vioxx	720	1,483.20
08/27/99	Shadyside Hospital, Pittsburgh	PA	Vioxx	2520	5,191.20
09/27/99	Univ. of Pittsburg Med. Ctr., Pittsburgh	PA	Vioxx	2520	5,191.20
01/31/00	Westmoreland Hospital, Greenburg	PA	Vioxx	720	1,764.00
02/24/98	Cooper Univ. Medical Ctr., Camden	NJ	Zocor	1800	6,318.00
10/05/99	St. Joseph's, Omaha	KY	Vioxx	720	1,771.20
10/13/00	LDS Hospital, SLC	UT	Zocor	1440	5,328.00
10/14/99	St. John's Mercy Med. Ctr., St. Louis	MO	Vioxx	600	1,476.00
12/03/99	Grady Health System, Atlanta	GA	Vioxx	1440	3,542.4 0
12/01/99	Cook County, Chicago	IL	Vioxx	2970	7,306.20
08/04/99	Advocate Health, Frankfort	IL	Vioxx	2880	5,932.80
01/05/01	Christ Hospital, Oak Lawn	IL	Zocor	720	2,781.00
04/05/00	Touchette Reg. Hospital., Centrenville	IL	Vioxx	450	1,102.50
10/20/00	Univ. of Chicago Hosp., Chicago	IL	Vioxx	2160	5,319.00
11/23/99	Rush Prudential HMO, Chicago	IL	Vioxx	720	1,771.20
01/05/01	Palos Comm. Hospital, Orland Park	IL	Zocor	3600	13,896.00

55. Since Nevada does not have access to Merck's confidential sales information, but only had limited data of Vioxx and Zocor sales obtained through its investigation, Nevada has only limited examples of how these give-aways impacted Best Price. However, Nevada's investigation is continuing. Moreover, discovery should reveal more cases of Merck not reporting the Best Price, as calculated by taking into account free goods.

56. Pursuant to this continuing investigation, Nevada is informed and believes that there were numerous incidents where Merck did not calculate Best Price by taking into account free goods in violation of the Medicaid Rebate Act. Nevada uncovered during its investigation examples of this. Some of these examples are evident from Merck's distribution of free drugs through Merck's Special Promotion Program (SPP).

57. SPP was and is a nationwide program to give to hospitals large amounts of

free drugs. SPP is a marketing program that tied free give-aways to purchases of drugs by hospitals, even though Merck's stated policy was that SPP give-aways were not to be tied to purchases but were to be used only for a "reasonable and necessary for evaluation of a Merck product." Emails between Merck sales representatives and their managers reveal that free drugs would only be given to hospitals or HMOs that made the kind of purchases that met Merck's return-on-investment expectations. Merck did not give away free drugs unless it was tied to a purchase—past, present or future.

58. Nevada discovered that Merck gave South Nassau Community Hospital in Oceanside, New York 720 tablets of Vioxx in or around the second quarter of 2001. See Table A, above. Based upon Merck documents regarding the hospital's purchase record, Nevada believes that around this same time, the hospital purchased about 1729 tablets at about $2.34 tablet, for a total of $4,047. However, since the hospital received a total of 2449 tablets, the actual cost, taking into account the free goods, was reduced to about $1.65 per tablet, i.e., the purchase of $4,047 divided by the number of tablets received, 2449.

59. Merck's Best Price report for the second quarter, however, was about $1.78, for the most common dosage, 25 mg. The difference between the actual cost, taking into account free goods, of $1.65 and the reported $1.78 is $0.13 per tablet. Since Vioxx, like Zocor is used once a day, this differential is an increased cost to Nevada in the amount of $47.45 per Medicaid beneficiary annually.

60. Merck also gave away Zocor, and these free goods lowered the price, but

Merck did not report the resulting lower price as the best price. For example, Nevada learned that during or around the first quarter of 2001, Merck gave Christ Hospital and Medical Center in Oak Lawn, Illinois at least 720 tablets of Zocor. See Table A, above. According to Merck's documentation of the hospital's purchase record, the hospital likely purchased about 2460 tablets during this same time period. Giving Merck the benefit of the doubt that the hospital paid no more than Merck's best reported price during that time of about $1.99—the Best Price for the most common dosage of Zocor 20 mg—the hospital paid about $4,895 for the 2460 tablets.

61. However, the hospital received 3180 tablets (the 2460 purchased plus the free 720 tablets) for that amount. Taking into account the free tablets, the cost of each tablet was reduced to $1.54, which is $0.45 less than the reported Best Price of $1.99. That difference over a year amounts to $164.25 per Medicaid patient.

62. Also, in early 2002, Merck launched a new stock bottle initiative to promote Vioxx. This promotional program required that targeted sales representatives give out large amounts of Vioxx—2880 tablets to be given out by each representative—in stock bottles to outpatient clinics.

63. Even a small amount of free drugs may set a new Best Price that Merck should have reported if the hospital or HMO or clinic did not purchase a significant amount and the free goods reduced the cost of the amount purchased.

64. Merck gave away free drugs in such volumes as to effectively lower the

price Merck was charging health care providers for these drugs. Merck knew that it had to take into account the free drugs it gave to hospitals, health care systems and HMOs in the form of stock bottles in calculating and reporting Medicaid Best Prices.

65. Merck also gave away free drugs to hospitals and HMOs in violation of the Medicaid Act that were not calculated into Merck's reported Best Price through means other than the SPP. Through its continuing investigation, Nevada is informed and believes that there were several incidents of such give-aways. One specific example Nevada uncovered concerned Merck's planned give-away to Blue Care Network in Michigan.

66. While at Merck, Mr. Steinke learned about a stock-bottle give-away of free Zocor, 20 mg dosage to BCN. The give-away was planned for late 1999 or early 2000. Mr. Steinke knew that such drug give-aways were one of Merck's ways of facilitating a switch from a competitor's drug to a Merck product, or obtaining the price parity between a competitor's drug and a Merck drug.

67. The purpose of Merck's give-away to BCN was to switch BCN patients from Zocor's competitor, Pravachol 40mg, to Zocor 20mg, so that BCN would continue its contract to purchase Zocor and other Merck drugs. The amount to be given away was 123,840 tablets of Zocor 20 mg, the amount BCN and Merck determined was needed to switch over the patients taking Pravachol 40 mg.

68. At the time of the planned give-away, BCN's purchase record in 1999 indicates that BCN was purchasing about 125,052 tablets of Zocor 20 mg per quarter.

Based upon this same record, the value of these 125,052 tablets to BCN was approximately $3.18 each, for a total of $397,862.41. Adding the 123,840 tablets Merck planned to give to BCN to the approximate 125,052 tablets purchased, the sum is 248,892 tablets. However, because of BCN's receipt of free tablets, its cost is reduced to about $1.59 per tablet.

69. Merck reported Best Price per tablet for Zocor 20 mg during this same time was about $1.79, a differential of $0.20 per pill. Had Merck reported the accurate Best Price, Nevada would have saved $73.00 per Medicaid beneficiary annually.

70. Merck deliberately and knowingly submitted false records and/or statements of quarterly Best Price reports to CMS for Zocor and Vioxx which did not take into account the net reduction in the prices paid by the hospitals, et al. due to Merck's free drug give-aways via stock bottles. Merck did this to avoid paying a rebate based upon the much larger difference between AMP and the Best Price for Zocor and Vioxx that would have resulted had Merck taken into account the stock bottle give-aways.

71. Merck's free stock bottle drug give-away scheme detailed herein has and had the effect of decreasing the total rebate amount paid by Merck to Nevada.

COUNT I
VIOLATION OF NEVADA FALSE CLAIMS ACT
FOR NOMINAL PRICE DISCOUNTS

(PROPOSED TO BE WITHDRAWN)

72. Plaintiff repeats and realleges each allegation contained in paragraphs 1

through 48 above as if fully set forth herein.

73. Merck's products Zocor and Vioxx are prescribed to Nevada public aid recipients and Nevada's Division of Health Care Financing and Policy makes payment to pharmacies that sell these drugs to Nevada public aid recipients.

74. Merck knowingly and willfully makes or made and/or causes or caused to be made false statements and/or representations of material facts, directly and indirectly to Nevada's Division of Health Care Financing and Policy, to obtain reimbursement to pharmacies from the Nevada Medicaid program for its pharmaceutical products in violation of N.R.S. § 357.040(1)(a) and/or (b). Specifically, Merck causes the Secretary to make false statements to Nevada regarding URAs which are used to invoice Merck with the amount that Merck rebates to Nevada.

75. Merck uses the schemes detailed herein that have the effect of increasing the total amount the Nevada Medicaid program pays for pharmaceutical products beyond the maximum amount payable for such products under the applicable rate or fee schedule in violation N.R.S. § 357.040(1)(a) and/or(b).

76. Merck's deliberate and purposeful concealment from Nevada of the marketing, promotional and pricing inducements it offers to hospital purchasers participating in the SAVE and VIP programs, and Merck's deliberate and purposeful failure to report the net reduction in the prices paid by the hospitals constitute violations of N.R.S. § 357.040(1)(a) and/or (b).

77. Accordingly, Merck violated N.R.S. § 357.040(1)(a) and/or (b) from at least 1994 to the present by engaging in the fraudulent and illegal practices described herein, including its deliberate and knowing submission of false records and/or statements of quarterly reports to CMS of AMP and best price for Zocor and Vioxx which did not take into account the nominal-price discounts offered under the SAVE and VIP programs.

78. Merck violated N.R.S § 357.040(1) (a) and/or (b) and knowingly causes or caused thousands of false claims to be made, used and presented to the State of Nevada from at least 1994 to the present.

79. Compliance with applicable Medicaid laws, regulations, and provisions was and continues to be an express condition of payment of claims submitted to the State of Nevada, and an express condition of Merck's participation in the Nevada Medicaid program.

80. Had the State of Nevada known that Merck was violating the Medicaid Rebate Act and the state laws cited herein, it would not have paid the claims submitted by health care providers and third party papers in connection with Merck's fraudulent and illegal practices. More importantly, Nevada would have disallowed Merck's participation in the Nevada Medicaid Program.

81. 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 for outpatient prescriptions for Zocor and Vioxx in connection

therewith. As a result of Merck's false statements and/or representations of material facts, Nevada has paid sums in excess of the amounts which should have been charged for pharmaceutical products.

82. As a result of Merck's violations of N.R.S. § 357.040(1) (a) and/or (b) the State of Nevada has been damaged in the millions of dollars.

83. 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.

84. WHEREFORE, Relator H. Dean Steinke respectfully demands judgment against Merck as prayed for below.

COUNT II
VIOLATION OF NEVADA FALSE CLAIMS ACT
FOR NOMINAL PRICE DISCOUNTS

85. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 71 above as if fully set forth herein.

86. Merck's product Zocor and Vioxx are prescribed to Nevada public aid recipients and Nevada makes payments to pharmacies that sell these drugs to Nevada public aid recipients.

87. Merck knowingly and willfully makes or made and/or causes or caused to be made false statements and/or representations of material facts, directly and indirectly to Nevada to avoid paying a sum certain of a rebate based upon the difference between AMP

and the nominal price which should have been reported as the best price, in violation of N.R.S. § 357.040(1)(g).

88. Merck uses the schemes detailed herein that have the effect of decreasing the total amount paid by Merck to Nevada, in violation of N.R.S. § 357.040(1)(g).

89. Merck's deliberate and purposeful concealment from Nevada of the marketing, promotional and pricing inducements it offers to hospital purchasers participating in the SAVE and VIP program, and Merck's deliberate and purposeful failure to report the net reduction in the prices paid by the hospitals constitute violations of N.R.S. § 357.040(1)(g).

90. Accordingly, Merck violated N.R.S. § 357.040(1)(g) from at least 1994 to the present by engaging in the fraudulent and illegal practices described herein, including its deliberate and knowing submission of false records and/or statements of quarterly reports to CMS of best price for Zocor and Vioxx which did not take into account the nominal-price discounts offered under the SAVE and VIP programs.

91. Merck violated N.R.S. § 357.040(1)(g) and knowingly causes or caused thousands of false claims to be made, used and presented to the CMS and the State of Nevada from at least 1994 to the present.

92. Compliance with applicable Medicaid laws, regulations, and provisions was and continues to be an express condition of Merck's participation in the Nevada Medicaid program.

93. Had the State of Nevada known that Merck was violating the Medicaid Rebate Act and the state laws cited herein, it would not have paid the claims submitted by pharmacies arising from Merck's fraudulent and illegal practices. More importantly, Nevada would have disallowed Merck's participation in the Nevada Medicaid Program.

94. 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 for outpatient prescriptions for Zocor and Vioxx in connection therewith. As a result of Merck's false statements and/or representations of material facts, Nevada has paid out excessive amounts in Medicaid reimbursements for Merck's pharmaceutical products to pharmacies throughout the state of Nevada.

95. As a result of Merck's violations of N.R.S. § 357.040(1)(g) the State of Nevada has been damaged in the millions of dollars.

96. WHEREFORE, the State of Nevada respectfully demands judgment against Merck as prayed for below.

COUNT III
VIOLATION OF NEVADA FALSE CLAIMS ACT
FOR OTHER THAN NOMINAL PRICE DISCOUNTS

(PROPOSED TO BE WITHDRAWN)

97. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 48 above as if fully set forth herein.

98. Merck's products Zocor and Vioxx are prescribed to Nevada public aid

recipients and Nevada's Division of Health Care Financing and Policy makes payment to pharmacies that sell these drugs to Nevada public aid recipients.

99. Merck knowingly and willfully makes or made and/or causes or caused to be made false statements and/or representations of material facts, directly and indirectly to Nevada's Division of Health Care Financing and Policy, to obtain reimbursement to pharmacies from the Nevada Medicaid program for its pharmaceutical products in violation of N.R.S. § 357.040(1) (a) and/or (b). Specifically, Merck causes the Secretary to make false statements to Nevada regarding URAs which are used to invoice Merck with the amount that Merck rebates to Nevada.

100. Merck uses the schemes detailed herein that have the effect of increasing the total amount the Nevada Medicaid program pays for pharmaceutical products beyond the maximum amount payable for such products under the applicable rate or fee schedule in violation of N.R.S. § 357.040(1) (a) and/or (b).

101. Merck's deliberate and purposeful concealment from Nevada of the marketing, promotional and pricing inducements it offers to hospital purchasers participating in the SAVE program, and Merck's deliberate and purposeful failure to report the net reduction in the prices paid by the hospitals constitute violations of N.R.S. § 357.040(1) (a) and/or (b).

102. Merck violated N.R.S. § 357.040(1) (a) and/or (b) from at least 1994 to the present by engaging in the fraudulent and illegal practices described herein, including its

deliberate and knowing submission of false records and/or statements of quarterly reports to CMS of AMP and best price for Zocor which did not take into account the first and second-tier discounts (other than nominal-price discounts) offered under the SAVE program.

103. Merck furthermore violated N.R.S. § 357.040(1) and/or (b) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Nevada from at least 1994.

104. Compliance with applicable Medicaid laws, regulations, and provisions was and continues to be an express condition of payment of claims submitted to the State of Nevada, and an express condition of Merck's participation in the Nevada Medicaid program.

105. Had the State of Nevada known that Merck was violating the Medicaid Rebate Act and the 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. More importantly, Nevada would have disallowed Merck's participation in the Nevada Medicaid Program.

106. Relator is informed and believes and based thereon alleges that Merck further violated N.R.S. § 357.040(1) (a) and/or (b) by delivering to some Nevada health care providers free samples, in the form of stock bottles, in such volumes as to effectively lower the price Merck was charging these providers for these drugs.

107. 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. As a result of Merck's false statements and/or representations of material facts, Nevada has paid sums in excess of the amounts which should have been charged for pharmaceutical products.

108. As a result of Merck's violations of N.R.S. § 357.040(1) (a) and/or (b) the State of Nevada has been damaged in the millions of dollars.

109. 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.

110. WHEREFORE, Relator H. Dean Steinke respectfully demands judgment against Merck as prayed for below.

COUNT IV
VIOLATION OF NEVADA FALSE CLAIMS ACT
FOR OTHER THAN NOMINAL PRICE DISCOUNTS

111. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 71 above as if fully set forth herein.

112. Merck's products Zocor and Vioxx are prescribed to Nevada public aid recipients and Nevada makes payment to pharmacies that sell these drugs to Nevada public aid recipients.

113. Merck knowingly and willfully makes or made and/or causes or caused to be made false statements and/or representations of material facts, directly and indirectly to Nevada to avoid paying a sum certain of a rebate based upon the difference between AMP and the Best Price for Zocor which did not take into account the first and second-tier discounts (other than nominal-price discounts) offered under the SAVE program, in violation of N.R.S. § 357.040(1)(g).

114. Merck further violated N.R.S. § 357.040I1)(g) by delivering to hospitals, health care systems and HMOs free drugs, in the form of stock bottles, in such volumes as to effectively lower the price Merck was charging these providers for these drugs. Merck knowingly and willfully makes or made and/or causes or caused to be made false statements and/or representations of material facts, directly and indirectly to Nevada, to avoid paying a rebate based upon the difference between AMP and the best price for Zocor which accounted for the discounts resulting from the free stock bottle give-aways, in violation N.R.S. § 357.040(1)(g).

115. The non-nominal discounts and free drug give-away schemes detailed herein have the effect of decreasing the total amount of rebates paid by Merck to Nevada, in violation of N.R.S. § 357.040(1)(g).

116. Merck's deliberate and purposeful concealment from Nevada of the non-nominal marketing, promotional and pricing inducements it extends to hospital purchasers participating in the SAVE program, and Merck's deliberate and purposeful failure to report

the reduced prices paid by the hospitals et al. due to Merck's free stock bottle drug give-aways constitute violations of N.R.S. § 357.040(1)(g).

117. Accordingly, Merck violated N.R.S. § 357.040(1)(g) from at least 1994 to the present by engaging in the fraudulent and illegal practices described herein, including its deliberate and knowing submission of false records and/or statements of quarterly reports to CMS of Best Price for Zocor and Vioxx which did not take into account the non-nominal price discounts offered under the SAVE program and the net reduction in the prices paid by the hospitals et al. due to Merck's free drug give-aways via stock bottles.

118. Compliance with applicable Medicaid laws, regulations, and provisions was and continues to be an express condition of payment of claims submitted to the State of Nevada, and an express condition of Merck's participation in the Nevada Medicaid program.

119. Had the State of Nevada known that Merck was violating the Medicaid Rebate Act and the 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. More importantly, Nevada would have disallowed Merck's participation in the Nevada Medicaid Program.

120. 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 for outpatient prescriptions for Zocor and Vioxx in connection

therewith. As a result of Merck's false statements and/or representations of material facts, Nevada has paid sums in excess of the amounts which should have been charged for pharmaceutical products.

121. As a result of Merck's violations of N.R.S. § 357.040(1)(g) the State of Nevada has been damaged in the millions of dollars.

122. WHEREFORE, the State of Nevada respectfully demands judgment against Merck as prayed for below.

PRAYER FOR RELIEF

WHEREFORE, the State of Nevada 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) All costs incurred in bringing this action; and

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

To RELATOR, H. DEAN STEINKE:

(1) An appropriate 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.

Dated: September 30th, 2005

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