

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

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

STATE OF CALIFORNIA, DELAWARE, ILLINOIS, TEXAS AND DISTRICT OF COLUMBIA'S AMICI CURIAE BRIEF IN OPPOSITION TO MERCK'S MOTION TO DISMISS

I. INTRODUCTION

Nevada sued Merck in Nevada State Court alleging Merck implemented Zocor and Vioxx marketing schemes to conceal price discounts otherwise required for Best Price reporting and rebate calculations under the Medicaid Rebate Act, 42 U.S.C. §1396r-8. Nevada alleges it was thereby harmed by overpaying for necessary Zocor and Vioxx products and by paying for too many Zocor and Vioxx prescriptions where hospitals participating in Merck's SAVE and VIP schemes were induced to prescribe Vioxx and Zocor to reap the full profits available under the Zocor SAVE "Simvastatin Acute-Care **Value Enhancement**" and Vioxx VIP "**Value Incentive Program**."

Merck removed that state court action to this court and filed a Rule 12 Motion to Dismiss. Nevada next filed a response including its proposed First Amended Complaint. This Amici brief addresses Merck's Motion to Dismiss, and Nevada's response to same, in light of the First Amended Complaint. California, Delaware, Illinois, Texas and the District of Columbia

join Nevada's Opposition and also contend that the facts, as alleged in Nevada's First Amended Complaint, state viable claims. Thus we support denial of Merck's Motion to Dismiss.

Amici further wish to emphasize two reasons that the Medicaid Rebate Act, and applicable laws in each of the Amici's respective jurisdictions, prohibit Merck's marketing schemes at issue. Specifically, 1) Merck's unreported SAVE ("Value Enhancement") and VIP ("Incentive Program") contingent discounts, are actually volume discounts off of the customer's contracted price and specifically required to be included in the calculation and reporting of Best Price; and 2) Merck's unreported SAVE ("Value Enhancement") and VIP ("Incentive Program") contingent discounts up to 92% off of list price are not "merely nominal prices" because the "*quid pro quo*" conditions precedent to hospitals receiving the sliding scale discounts up to 92% off of contracted List Price constituted valuable consideration – hospitals were required to give more than merely 8% of list price in order to receive the Vioxx and Zocor discounts off of the otherwise guaranteed price – so these sales do not qualify for the "merely nominal price" exception to Best Price.

II. BRIEF IN SUPPORT

A. Volume Discounts Are Expressly Included in Best Price

Merck's SAVE and VIP price discounts (up to 92% off of list price) were conditioned on the hospital either purchasing and prescribing a certain volume of Zocor or Vioxx to achieve the market share threshold Merck required, or taking other steps to increase sales volume and profits - such as agreeing to push Merck's drugs by officially endorsing Zocor and Vioxx (over cheaper and equally effective alternative products offered by Merck's competitors) for the hospital's formulary.

Congress expressly requires Best Price “shall be inclusive of . . . volume discounts . . .” 42 U.S.C. § 1396r-8(c)(1)(C)(ii). Congress’s mandate that volume discounts must be included in Best Price further undermines Merck’s premise that contingent volume discounts can be characterized as “merely nominal prices” and thereby excluded from Best Price. Congress intended Medicaid to obtain the benefit of volume discounts, and Merck is not allowed to hide its profit-motivated retail-sales “spill-over” volume discounts under the guise of a “merely nominal price.” A “merely nominal price” is a price that has no strings attached and is “merely nominal” without regard to any other conditions of performance or consideration beyond simple payment of the “merely nominal” price. A “volume discount” is a discount off of the contracted price and is only available if certain precedent conditions – such as meeting sales market-share volume targets or endorsing a product to increase sales volume – are met.

Otherwise, the State Medicaid programs could be required to foot the venture capital bill (by giving Merck a free ride on true Best Price calculation) for implementing Merck’s SAVE and VIP schemes on the front side – by ignoring the “spill-over” volume discount promotions in Best Price calculation. Further, Merck’s position would force Medicaid to reimburse an even higher volume of long-term Zocor and Vioxx prescriptions for Medicaid Recipients guided to Vioxx and Zocor while a patient at the hospital – again at inflated prices that do not give Medicaid the benefits of the true Best Price.

Under the facts alleged, there is a direct correlation between Medicaid’s overpayments, Merck’s funding of the SAVE and VIP incentive programs and Merck’s ability to reap millions in windfall “spill-over” profits from the unreported discounts and inducements Merck offered to hospitals under these programs. Therefore, Nevada has properly alleged facts stating a claim

because Merck's SAVE and VIP discounts constitute volume discounts specifically required for Best Price reporting and calculation.

B. SAVE ("Value Enhancement") and VIP ("Incentive Program") Contingent Discounts and Inducements are not "Merely Nominal Prices" under the Rebate Statute

Congress expressly required that discounts be reported for Best Price and only granted a limited exclusion from Best Price providing that manufacturers such as Merck need not include "prices that are merely nominal in amount." 42 U.S.C. § 1396r-8(c)(1)(C)(ii). Here, Merck is not excluding a "price" that is "merely nominal in amount." Instead, Merck seeks to exclude an entire promotional scheme (including contingent price discounts) aimed at inducing hospitals to prescribe Merck drugs for cheap on the front end, and adopt formulary endorsements of Merck drugs, so Merck can gain millions of dollars in "spill-over" profits from months and years of patient refill prescriptions after hospital discharge.

Prices that are properly "merely nominal" in amount do not include other valuable consideration or "*quid pro quo*" conditions precedent – such as meeting volume targets or agreeing to make a clinical judgment endorsement such as a formulary endorsement. The SAVE and VIP discount, pricing and marketing schemes alleged by Nevada require additional valuable, quantifiable consideration and "*quid pro quo*" conditions precedent that is more than a "merely nominal" price and should have been reported and included in Best Price.

Further, Merck cannot shield marketing inducements and volume discounts from Best Price obligations by moving the discounts from 89% off of list price to 92% off of list price and waving the "nominal" magic wand. Merck's interpretation would encourage the impossible situation where all drug manufacturers offer all drug products to all hospitals at 92% discounts and all hospital sales would be exempt from Best Price and all manufacturers would get the

benefit of using huge volume discounts, at taxpayer (Medicaid and Medicare) expense, to fund marketing ventures aimed at gaining millions of dollars of post-discharge spill-over prescription profits - profits that result when Medicaid programs throughout the country overpay falsely inflated prices because the manufacturers have skirted the States' individual Medicaid Fraud Prevention statutes, Best Price and state-specific rebates the States and District of Columbia would otherwise be entitled to. Merck's interpretation would further allow this 92% volume discount to be offered in "*quid pro quo*" exchange for a hospital agreeing to push the manufacturer's drug over competitor drugs based on the potential profit to the hospital rather than medical necessity for the individual patient.

The plain language of the Medicaid Rebate statute does not support Merck's interpretation – Merck's interpretation is contrary to the plain language, Congress's intent and public policy. Nevada has alleged facts sufficient to state a claim and Merck's Motion to Dismiss should be denied. Merck's Motion to Dismiss should be denied as set forth in Nevada's Opposition and herein.

Respectfully submitted,

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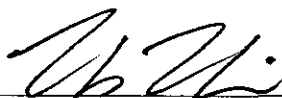
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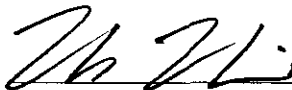
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CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of this Amici Curiae Brief was delivered by facsimile to all attorneys of record below on this 6th day of March, 2006.



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