MORRIS, PICKERING & PETERSON
William E. Peterson, #1528
6100 Neil Road, Suite 555
Reno, NV 89511
Telephone: (775) 829-6000
Facsimile: (775) 829-6001

MORGAN, LEWIS & BOCKIUS LLP
Michael J. Holston (admitted *pro hac vice)*
Lisa C. Dykstra (admitted *pro hac vice)*
1701 Market Street
Philadelphia, PA 19103-2921
Telephone: (215) 963-5000
Facsimile: (215) 963-5001

Attorneys for Defendant
Merck & Co., Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

STATE OF NEVADA EX REL. H. DEAN STEINKE,	)	**3:05-cv-322**
Plaintiff-Relator	)	
V.	)	**DEFENDANT'S MOTION TO DISMISS PLAINTIFF'S AMENDED COMPLAINT**
MERCK & CO., INC.,	)	
Defendant	)	**(ORAL ARGUMENT REQUESTED)**

DEFENDANT'S MOTION TO DISMISS PLAINTIFFS' AMENDED COMPLAINT

Pursuant to Federal Rules of Civil Procedure 12(b)(6), Defendant Merck & Co., Inc. ("Merck") respectfully requests the Court to dismiss the amended complaint ("the Amended Complaint")[1] of the State of Nevada ("Nevada") and Relator Dean H. Steinke ("Relator") (collectively, "Plaintiffs") in its entirety for failure to state a claim upon which relief may be granted. Merck also contends that Count IV of the Amended Complaint should be dismissed under Federal Rule of Civil Procedure 9(b) for failure to plead with particularity the circumstances constituting alleged fraud under Nevada law. This motion is supported by the accompanying Defendant's Memorandum of Points and Authorities In Support of Defendant's Motion To Dismiss Plaintiffs' Amended Complaint.

Merck respectfully requests that the Court grant the parties an opportunity to present oral argument at a time convenient to the Court and parties.

Respectfully submitted,

William E. Peterson, #1528
MORRIS, PICKERING & PETERSON
6100 Neil Road, Suite 555
Reno, Nevada 89511
Telephone: (775) 829-6000

Michael J. Holston (admitted *pro hac vice)*
Lisa C. Dykstra(admitted *pro hac vice)*
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921

Attorneys for Defendant
Merck & Co., Inc.

Dated: January 20, 2006

[1] Relator filed his original complaint in Nevada state court on April 19, 2005, and Nevada intervened on April 25, 2005. Merck subsequently removed the original complaint to this Court, and filed a motion to dismiss the complaint in its entirety. Plaintiffs incorporated a proposed amended complaint in their opposition to Merck's motion, withdrawing Counts I and III of the original complaint and alleging revised Counts II and IV. On December 14, 2005, the Court accepted the proposed complaint as an amended complaint, denied Merck's pending motion as moot, and directed Merck to file a renewed motion to dismiss the amended complaint by January 20, 2006.

CERTIFICATE OF SERVICE

I, Holly W. Longe, hereby certify that a true and correct copy of Defendant's Motion To Dismiss Plaintiffs' Amended Complaint and accompanying Defendant's Memorandum of Points and Authorities In Support Of Defendant's Motion To Dismiss Plaintiffs' Amended Complaint was served on January 20, 2006 upon the following by using the ECF system and that the following is an ECF user:

L. Timothy Terry
Chief Deputy Attorney General
Office of Attorney General
100 North Carson Street
Carson City, Nevada 89701-4717
ATTORNEY FOR STATE OF NEVADA

In addition, I certify that a true and correct copy of the Motion and Memorandum of Points and Authorities was deposited with an overnight delivery service for overnight delivery to:

Mark A. Winter
801 N. Division Street
Carson City, Nevada 89703
ATTORNEY FOR RELATOR

Holly W. Longe

Holly W. Longe
MORRIS, PICKERING & PETERSON
6100 Neil Road, Suite 555
Reno, Nevada 89511
Telephone: (775) 829-6000

MORRIS, PICKERING & PETERSON
William E. Peterson, #1528
6100 Neil Road, Suite 555
Reno, NV 89511
Telephone: (775) 829-6000
Facsimile: (775) 829-6001

MORGAN, LEWIS & BOCKIUS LLP
Michael J. Holston (admitted *pro hac vice)*
Lisa C. Dykstra (admitted *pro hac vice)*
1701 Market Street
Philadelphia, PA 19103-2921
Telephone: (215) 963-5000
Facsimile: (215) 963-5001

Attorneys for Defendant
Merck & Co., Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

STATE OF NEVADA, EX REL. H. DEAN STEINKE,	)	
Plaintiff-Plaintiffs	)	**3:05-cv-322**
V.	)	
MERCK & CO., INC., et al.,	)	
Defendants	)	

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS PLAINTIFFS' AMENDED COMPLAINT

January 20, 2006

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RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 655
RENO, NEVADA 8951
775/829-6000
FAX 775/829-6001

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FEDERAL CASES

RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD SUITE 555
RENO, NEVADA 8951
775/823-6000
FAX 775/823-6001

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RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 555
RENO, NEVADA 89511
775/828-6000
FAX 775/828-6001

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RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 555
RENO, NEVADA 89511
775/823-6000
FAX 775/823 6001

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RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 555
RENO, NEVADA 89511
775/829-6000
FAX 775/829-6001

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RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 555
RENO, NEVADA 89511
775/829-6000
FAX 775/829-6001

I. INTRODUCTION

In this *qui tam* action under Nevada's False Claims Act, N.R.S. § 357.010 *et seq.*, brought by Relator H. Dean Steinke ("Relator") and assumed by the State of Nevada ("Nevada") (collectively, "Plaintiffs"), Plaintiffs allege that Merck is liable under Nevada's False Claims Act for failing to include certain discounted prices charged by Merck for its Zocor and Vioxx products, as well as complimentary Zocor and Vioxx allegedly given away by Merck, in the "Best Price" reports Merck submitted to the federal government pursuant to the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8 ("Rebate Statute" or "§ 1396r-8") and the federal contract between Merck and the Secretary of the United States Department of Health and Human Services ("HHS") (the "Rebate Agreement").

According to Plaintiffs' amended complaint (the "Amended Complaint"),[1] the discounts and free goods at issue are the following:

- For Zocor, starting in April 1998, Merck offered a 92% discount from the catalog price if a hospital maintained a 70% market share or, starting in May 1999, if the hospital increased the market share for Zocor by 10 points over the prior quarter or established Zocor as the exclusive statin drug on its formulary. Amended Complaint at ¶ 33. These discounts, which were part of Merck's Simvastatin Acute Care Value Enhancement, or "SAVE," program, are referred to as the Zocor "nominal price" discounts by Plaintiffs.

- For Zocor, also pursuant to the SAVE Program, Merck offered second and third tier discounts of 30% and 20% respectively for hospitals that achieved Zocor market shares of 55% and 45% respectively. Amended Complaint at ¶ 34. Plaintiffs refer to these prices as the "non-nominal price" discounts.

- For Vioxx, Merck offered a 92% discount from the catalog price if a hospital committed to maintain an 80% market share. Amended Complaint at ¶ 45. Plaintiffs also refer to those discounts, which were part of Merck's Vioxx Incentive Program or "VIP," as the Vioxx "nominal price" discount.

[1] Relator filed his original complaint in Nevada state court on April 19, 2005, and Nevada intervened on April 25, 2005. Merck subsequently removed the original complaint to this Court, and filed a motion to dismiss the complaint in its entirety. Plaintiffs incorporated a proposed amended complaint in their opposition to Merck's motion, and, on December 14, 2005, the Court accepted the proposed complaint as an amended complaint, denied Merck's pending motion as moot, and directed Merck to file a renewed motion to dismiss the amended complaint by January 20, 2006.

RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 555
RENO, NEVADA 89511
775/823-6000
FAX 775/823-6001

- For both Zocor and Vioxx, Merck gave away free goods in the form of "stock bottles" or "trade complimentary product" to "effectively lower" the prices Merck charged providers for these drugs. Amended Complaint at ¶ 52-53.

As alleged in the Amended Complaint, Merck's SAVE and VIP discount programs were offered to hospitals for in-patient use. Amended Complaint at ¶¶ 32, 48. Following the filing of Merck's motion to dismiss the original complaint, Plaintiffs voluntarily withdrew Counts I and III related to Merck's reporting of Average Manufacturer's Price ("AMP") and allegations that Merck submitted false claims to Nevada under Section 357.040(1)(a) and (b) of the Nevada False Claims Act, recognizing that these counts were insufficient and lacked merit as a matter of law. The Amended Complaint proceeds on Counts II and IV, but fares no better than the initial complaint.

Count II of the Amended Complaint (the "Nominal Price Allegations") alleges that Merck violated Nevada law by improperly excluding the Zocor and Vioxx nominal prices from its Best Price reported to the federal government. Amended Complaint at ¶¶ 85-96. Plaintiffs contend that, while certain nominal prices are properly excluded from Best Price, this exclusion is intended "for not-for-profit, charitable entities and for researchers using the drugs for experimental or non-standard purposes," and Merck, therefore, acted improperly by excluding nominal prices for other customers. Amended Complaint at ¶ 25. The remaining count of the Amended Complaint, Count IV (the "Non-Nominal Price Allegations"), alleges that Merck was required to include non-nominal discounts on Zocor sold for inpatient hospital care as well as account for free goods in its Best Price reported to the federal government, and that Merck failed to do so in violation of Nevada law. Amended Complaint at ¶¶ 112-122.

Plaintiffs' Amended Complaint should be dismissed as a matter of law for several reasons. First, with respect to the Nominal Price Allegations, Plaintiffs have fundamentally misread the relevant provisions of the Rebate Statute and the Rebate Agreement. The statutory definition of

RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 655
RENO, NEVADA 89511
775/828-6000
FAX 775/825-8001

Best Price expressly excludes ***"prices that are merely nominal in amount"*** from Best Price. § 1396r-8(c)(3)(C). Consistent with this provision of the Rebate Statute, the Rebate Agreement between Merck and the Secretary expressly provides that nominal price "for purposes of excluding prices from the Best Price calculation" means "***any price less than 10%*** of the [Average Manufacturer Price, or "AMP"] in the same quarter for which the AMP is computed." Rebate Agreement, § I(s) (emphasis added). The term "any price" in Merck's federal contract does not mean "any price to charitable institutions," or "any price, except for prices to customers excluded by a State"; rather, it means "all" prices less than 10% of AMP. *Cf. Hertzberg v. Dignity Partners, Inc.*, 191 F.3d 1076, 1080 (9th Cir. 1999) (explaining that ordinary meaning of "any" includes "all"). Accordingly, Merck's exclusion of all nominal prices from Best Price, consistent with the plain meaning of its contract with the Secretary and current law, could not result in the submission of a "false" record or statement under Nevada law.

Second, Merck's Best Price reports as a matter of law are not "knowingly" false, as required by Nevada law. The Amended Complaint at most establishes that Merck interpreted the Rebate Statute in the same way that the Secretary interpreted it, and under such circumstances, Plaintiffs have not pled facts to support that Merck acted with the requisite scienter. Furthermore, Merck acted in accordance with the obligations the Secretary mandated in the Rebate Agreement and emphasized in guidance to Merck and other manufacturers. Even assuming Merck somehow acted "knowingly" for purposes of this motion, Plaintiffs' claims still fail because Merck's Best Price reports were consistent with the express terms of Merck's Rebate Agreement with the Secretary and therefore cannot be false as a matter of law.

Third, Plaintiffs' Nominal Price Allegations must be dismissed under the doctrine of conflict preemption. In the early 1990s, Congress and HHS defined Best Price in the Rebate Statute and Rebate Agreement respectively. Nothing in the Rebate Statute – let alone the separate Rebate

RRIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 555
RENO, NEVADA 89511
775/829-6000
FAX 775/829-6001

Agreement between Merck and HHS, to which Nevada and other States are not parties – suggests that Congress intended to permit Plaintiffs to sue a drug manufacturer based on an alleged violation of that statute or agreement. If Plaintiffs' suit is permitted to proceed, and its interpretation of nominal price adopted, Merck's nationwide Best Price reports to HHS for each of its reimbursed drugs could be accurate and proper under federal law and simultaneously inaccurate or false in Nevada for the purposes of its False Claims Act. Merck would be placed in a position where, under the doctrine of conflict preemption, compliance with both federal and Nevada state regulations is impossible, thus requiring that Plaintiffs be precluded from bringing the instant suit. Additionally, Plaintiffs' Nominal Price Allegations and Non-Nominal Price Allegations are also preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001) ("*Buckman*"), in which the United States Supreme Court rejected state-law claims based upon alleged fraudulent submissions to a federal agency.

Fourth, the Non-Nominal Price claims fail because they do not state a claim as a matter of law, and Plaintiffs have not satisfied the stringent pleading requirements for allegations of fraud under Fed. R. Civ. P. 9(b). The Rebate Statute provides that free goods, which are *not* "contingent on any purchase requirement," are *not* to be included in Best Price reports. Yet, despite including numerous allegations regarding the provision of free goods to different institutions, Plaintiffs provide no factual details showing that Merck, acting with scienter, failed to include *any* product *contingent* on a purchase requirement in a Best Price report. And, with respect to other allegations regarding non-nominal price discounts, Plaintiffs fail to identify any specific sale that Merck should have included in Best Price. Such generalized, unsubstantiated allegations are insufficient to withstand dismissal.

BIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 556
ENO, NEVADA 89511
775/829-6000
FAX 775/825-6001

Finally, both the Nominal and Non-Nominal Price claims allege fraudulent submissions by Merck dating back to "at least 1994." Complaint, ¶¶ 91 (Count II); 117 (Count IV). Under the governing statute of limitations, at a minimum, any assertedly false reports made prior to April 19, 2000 (five years prior to the filing of Plaintiffs' original complaint), are time barred and must be dismissed. N.R.S. § 357.170(1). If the Court determines that any part of Plaintiffs' claims survive this Motion and does not dismiss this action in its entirety, the Court should dismiss all allegations based upon any claim arising from a Best Price report prior to April 19, 2000.

II. BACKGROUND

A. The Federal Medicaid Drug Rebate Program

In 1990, as part of the Omnibus Budget and Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388 (1990), Congress enacted the Medicaid Drug Rebate Statute, codified at § 1396r-8. As the United States Supreme Court has explained:

> The new program had two basic parts. First, it imposed a general requirement that, in order to qualify for Medicaid payments, drug companies must enter into agreements either with the Secretary [of HHS] or, if authorized by the Secretary, with individual States, to provide rebates on their Medicaid sales of outpatient prescription drugs. The rebate on a "single source drug" or an "innovator multiple source drug" is the difference between the manufacturer's average price and its "best price," or 15.1% of the average manufacturer price, whichever is greater. 42 U. S. C. §§ 1396r-8(c)(1), (2). The rebate for other drugs is 11.1% of the average manufacturer price. *See* 42 U.S.C. § 1396r-8(c)(3).
>
> Second, once a drug manufacturer enters into a rebate agreement, the law requires the State to provide coverage for that drug under its plan unless the State complies with one of the exclusion or restriction provisions in the Medicaid Act. *See* 42 U.S.C. § 1396r-8(d).

Pharm. Research & Mfrs. Of Am. v. Walsh, 538 U.S. 644, 652 (2003).

In order to implement the Rebate Statute, the Secretary developed and issued a model agreement, the Rebate Agreement, for execution by the Secretary and each participating drug

RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 555
RENO, NEVADA 89511
775/629-6000
FAX 775/824-6001

manufacturer. *See Medicaid Program, Drug Rebate Agreement*, 56 Fed. Reg. 7049 (February 21, 1991). The Rebate Agreement, drafted by the Secretary, is entered into only by the drug manufacturer and the Secretary; the States are not parties to the Agreement. The Rebate Agreement is construed in accordance with federal common law. Rebate Agreement, § IX(e).

The Rebate Statute and the Rebate Agreement establish the responsibilities and obligations of manufacturers participating in the Medicaid drug rebate program. Under the Rebate Statute and the Rebate Agreement, each manufacturer (including Merck) reports Best Price data to the Secretary on a quarterly basis. § 1396r-8(b)(3); Rebate Agreement, § II(e). The Secretary maintains this data in confidence and the data are not provided to the States. § 1396r-8(b)(3)(D); Rebate Agreement, § VII; *Medicaid Program; Payment for Covered Outpatient Drugs Under Drug Rebate*, 60 Fed. Reg. 48442, 48466 (September 19, 1995) ("*1995 Proposed Rebate Rules*"). As required by the Rebate Statute, participating States report Medicaid Utilization Information – the total number of units of each dosage form, strength and package size for each covered outpatient drug dispensed under its state Medicaid plan – to each manufacturer and to the Secretary. § 1396r-8(b)(2)(A); *see also* Rebate Agreement, § III(a) (providing that Secretary will use "best efforts" to ensure that state agencies report Medicaid utilization information to manufacturers). A particular drug may have multiple Medicaid Utilization Information and Best Price reports, since both Medicaid Utilization Information and Best Price are specific to each individual strength and formulation of each drug.

Based upon the information received from manufacturers, the Secretary calculates a "Unit Rebate Amount" ("URA"). The exact type of calculation performed by the Secretary varies depending upon the nature of the drug (e.g., whether brand name or generic) and other detailed provisions of the Rebate Statute. *See generally* § 1396r-8(c). The Secretary also applies certain "minimum rebate percentages" as well as a factor for increases in AMP over time. *See id.*

After receiving the URAs, States apply them to the Medicaid Utilization Information for

RIS PICKERING & PETERSON
ATTORNEYS AT LAW
NEIL ROAD, SUITE 555
ENO, NEVADA 89511
775/829-6000
FAX 775/829-6001

each drug to invoice manufacturers for rebates. As provided in the Rebate Statute and Rebate Agreement, however, manufacturers have an explicit obligation to calculate and pay the rebates independent of any State invoicing. § 1396r-8(b)(1)(A); Rebate Agreement, §§ I(p), I(dd), & II(a). Federal payments to each state Medicaid plan are reduced by the amount of the rebates the State receives from manufacturers. § 1396r-8(b)(1)(B).[2]

The Rebate Statute and the Rebate Agreement include comprehensive federal enforcement mechanisms. The Secretary is empowered to survey drug manufacturers to verify manufacturer prices, to audit manufacturer AMP and Best Price data, and to impose civil monetary penalties if a manufacturer "provides false information" or refuses a request for information in connection with such a survey. § 1396r-8(b)(3)(B); *see also* Rebate Agreement, §§ III & IV. Manufacturers are generally subject to civil penalties of up to $100,000.00 for provision of false information. *Id.*; § 1396r-8(b)(3)(C). The Secretary has the power to terminate a Rebate Agreement with a manufacturer. *See* § 1396r-8(b)(4)(B) & Rebate Agreement, §§ VIII(c).

The Secretary promulgates regulations for the program, including interpretations of the Rebate Agreement. *See, e.g., Medicaid Program; Time Limitation on Price Recalculations and Recordkeeping*, 68 Fed. Reg. 51912 (August 29, 2003); *1995 Proposed Rebate Rules.* Through the Center for Medicare and Medicaid Services ("CMS"), the Secretary also issues additional requirements and instruction to States and manufacturers participating in the program in the form of "CMS releases." To date, the Secretary has issued seventy-one separate releases.[3]

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[2] Plaintiffs concede that the amount Nevada actually pays to the pharmacists and other entities for each covered prescription under Medicaid is unrelated to the URAs derived from Best Price data at issue in this proceeding. *See* Amended Complaint at ¶ 28.

[3] Each release is available on-line at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp#TopOfPage.

RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 555
RENO, NEVADA 89511
775/823-6000
FAX 775/823-6001

The Rebate Statute and Rebate Agreement also provide additional rights to the manufacturers with respect to the States. Although States do not have a right to audit manufacturer pricing data, manufacturers may audit state Medicaid Utilization Information. § 1396r-8(b)(2)(B); Rebate Agreement, § V(d). States also are obligated to provide a hearing mechanism to a manufacturer where the manufacturer believes state Medicaid Utilization Information is erroneous, but the results of such proceedings are not binding upon the Secretary with respect to any of the false information penalties the Secretary may impose upon a manufacturer. Rebate Agreement, § V. The Secretary also has the right to initiate compliance actions against States or manufacturers relating to the provision and use of state Medicaid Utilization Information. Rebate Agreement, § VI.

B. Best Price

In the Rebate Statute, Congress included a detailed definition of Best Price:

> The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer during the rebate period **to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States.**

§ 1396r-8(c)(1)(C)(i) (emphasis added). The statute has certain specific limited exclusions, including, for example, sales to the Department of Veterans Affairs ("VA"). *See* § 1396r-8(c)(1)(C)(I). The statute includes several "special rules" and provides that the term "best price":

> (I) shall be inclusive of cash discounts, free goods that are *contingent* on any purchase requirement, volume discounts, and rebates (other than rebates under this section);
>
> * * *
>
> (III) shall *not* take into account prices that are *merely nominal in amount.*

§ 1396r-8(c)(1)(C)(ii) (emphasis added).

RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 555
RENO, NEVADA 89511
775/825-6000
FAX 775/825-6001

After consultations with States, drug manufacturers, and other interested parties, the Secretary of HHS included a definition of Best Price in the Rebate Agreement. *See* Rebate Agreement, § I(d); *see also* 56 Fed. Reg. 7049 (referencing HHS consultations). Consistent with the Rebate Statute, the Rebate Agreement provides that nominal prices are not to be included in Best Price data and defined nominal price as follows:

> (s) Nominal Price, for purposes of excluding prices from the Best Price calculation, means ***any*** price less than 10% of the AMP in the same quarter for which the AMP is computed.

Rebate Agreement, § I(s) (emphasis added). The Secretary later issued a CMS Release on December 14, 1994, which emphasized:

> Please remember that ***any*** prices which are nominal in amount, that is, less than 10% of the AMP in the same quarter which the AMP is computed, are excluded from the best price calculation. Therefore, ***if any arrangement results in prices which are nominal,*** those sales and prices do not affect best price and must be excluded by the manufacturer.

CMS Release No. 14, at 2 (emphasis added).

Subsequently, the Secretary issued a proposed rule for approval of rebate agreements which included the Secretary's response to comments received on the model Rebate Agreement. *See generally 1995 Proposed Rebate Rules.* In its proposed rule, the Secretary concluded there was no basis to change the model Rebate Agreement, and, among other determinations, confirmed that all prices less than 10% of AMP were to be excluded from Best Price as nominal prices:

> Q. Definition of Nominal Price
>
> Comment: One commenter contended that the definition of "nominal price" should not be predicated on a fixed percentage of 10 percent since this definition is not authorized by law and ignores the unique marketing and pricing practices of each drug manufacturer. This commenter believed that the company that claims a nominal price for a drug should have the burden of demonstrating to HCFA that the facts and circumstances concerning the drug render the price

RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 555
ENO, NEVADA 89511
775/858-6000
FAX 775/329-6001

> as nominal. The commenter stated that the standards and procedures to demonstrate a nominal price should be specified in the regulations. Another commenter agreed with the nominal price definition in the rebate agreement of "any price less than 10 percent of the AMP."
>
> Response: We originally gave consideration to a definition that a nominal price be less than 1 percent of AMP. However, after discussions with manufacturers, States, and other parties, we believe the current definition of "less than 10 percent of AMP" to be sufficient to encompass the nominal prices offered by manufacturers. Prices greater than this appear to be for sales of the type meeting the definition for inclusion of AMP or best price.
>
> **We believe the administrative costs and burdens are too great to justify a policy that would require HCFA to review each manufacturer's case of why a nominal price for a drug is warranted and would offer no greater assurance of more accurately defining nominal price.**

1995 Proposed Rebate Rules, at 48478 (emphasis added).[4]

III. ARGUMENT

A. Standard Of Review

In considering a motion to dismiss for failure to state a claim under Fed. R. Civ. P. 12(b)(6), a court must accept a plaintiff's allegations as true and construe them in the light most favorable to plaintiffs. *Seinfeld v. Bartz*, 322 F.3d 693, 696 (9th Cir. 2003). However, "[c]onclusory allegations of law and unwarranted inferences are insufficient to defeat a motion to dismiss for failure to state a claim." *In re VeriFone Sec. Litig.*, 11 F.3d 865, 868 (9th Cir. 1993).

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[4] In December, 2005, the United States Senate and the House of Representatives approved new legislation limiting "sales at a nominal price or merely nominal in amount" under the Rebate Statute to Public Health Service hospitals, facilities providing care to the mentally retarded, nursing homes owned by state governments, and other facilities that may be determined by the Secretary to be a "safety net provider." *See* Deficit Reduction Act of 2005, S. 1932, 109th Cong., § 6001(d) (excerpt attached as Exhibit A); *see also* H. R. Conf. Rep. No. 109-362, at 259-60 (excerpt attached as Exhibit B). This provision would have an effective date of January 1, 2007. *See id.* at § 6001(f). For the reasons explained in Section III.B below, the fact that both Houses of Congress have determined that this new legislation is necessary confirms the correctness of Merck's construction of the definition of "nominal price" under existing law.

RRIS PICKERING & PETERSON
ATTORNEYS AT LAW
OO NEIL ROAD, SUITE 555
RENO, NEVADA 89511
775/329-6000
FAX 775/329-6001

Rule 9(b) of the Federal Rules of Civil Procedure requires that in all averments of fraud, a plaintiff must plead with particularity the circumstances constituting fraud. "Averments of fraud must be accompanied by 'the who, what, when, where, and how' of the misconduct charged." *Vess v. CIBA-GEIGY Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2002) (*quoting Cooper v. Pickett*, 137 F.3d 616, 627 (9th Cir. 1997)). Failure to satisfy this pleading requirement is grounds for dismissal. *Id.* at 1107.

B. The Court Should Dismiss Plaintiffs' "Nominal Price Allegations" Because The Rebate Statute And The Rebate Agreement Expressly Exclude All Nominal Prices From Best Price

Count II of the Amended Complaint alleges that Merck's SAVE and VIP Programs offered nominally priced Zocor and Vioxx to hospitals for inpatient use, and that Merck's programs were not limited to not-for profit institutions. Count II further alleges that Merck submitted false Best Price data to HHS because Merck excluded all nominal prices for Zocor and Vioxx from its Best Price when it should have excluded only those nominal prices provided to charitable or not-for-profit institutions. Amended Complaint at ¶¶ 25, 42 & 85.

Count II must be dismissed because Merck's exclusion of these nominal prices from Best Price was consistent with the Rebate Statute and Rebate Agreement, and Plaintiffs' theory that Merck's Best Price reporting was "false" because the exclusion of nominal prices from Best Price was "intended" only for certain purchasers, such as charitable and non-profit institutions, is wrong as a matter of law. Under well-established principles of statutory and contract construction, "[t]he starting point in discerning congressional intent is the existing statutory text . . . . It is well established that 'when the statute's language is plain, the sole function of the courts – at least where the disposition required by the text is not absurd – is to enforce [the statute] according to its terms.'" *Lamie v. United States*, 540 U.S. 526, 536 (2004) (*quoting Hartford Underwriters Ins. Co. v. Union Planters Bank, N. A.*, 530 U.S. 1, 6 (2000)). Similarly, with respect to the Rebate Agreement, which is to be

RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 555
ENO, NEVADA 89511
775/829-6000
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construed under federal common law (Rebate Agreement, § IX(e)), "[c]ontract terms are to be given their ordinary meaning, and when the terms of a contract are clear, the intent of the parties must be ascertained from the contract itself." *Klamath Water Users Protective Ass'n v. Patterson*, 204 F.3d 1206, 1210 (9th Cir. 1999) (applying federal common law).

Here, the Rebate Statute includes "an express and lengthy definition of 'Best Price.'" *In re Pharmaceutical Ind. Average Wholesale Price*, 321 F. Supp. 2d 187, 196 (D. Mass. 2004) ("*Pharm IV*").[5] The Rebate Statute is applicable to "***any*** wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States." § 1396r-8(c)(1)(C)(i) (emphasis added). The Rebate Statute then provides, without any qualification or limitation, that the term Best Price shall not "take into account prices that are merely nominal in amount." § 1396r8(c)(1)(C)(ii)(III). Consistent with this statutory definition, the Secretary, after consultation with States and manufacturers, defined "Nominal Price" for purposes of Best Price as "***any*** price less than 10% of the AMP in the same quarter which the AMP is computed." Rebate Agreement, § I(s) (emphasis added).

Subsequent to execution of the Rebate Agreement, the Secretary, after notice and comment, including additional consultations with the States and manufacturers, reiterated that the "any price less than 10% of the AMP" nominal price definition was proper. *See 1995 Proposed Rebate* Rules, at 48478; *see also* Omnibus Budget and Reconciliation Act of 1990, § 4207(j), Pub. L. No. 101-508, 104 Stat. 1388, 1388-124 (1990) (authorizing the Secretary to issue regulations, on an interim or other basis, as may be necessary to implement Medicaid amendments, including the Rebate Statute). The Secretary also issued CMS Release No. 14, which further reinforced that "***any*** prices which are nominal in amount, that is less than 10% of the AMP in the same quarter which the AMP is

[5] The court's decision in *Pharm IV* relating to preemption issues is addressed in further detail below. *See* Section III.D *supra*.

RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 855
RENO, NEVADA 8951
775/825-6000
FAX 775/829-600

computed, are excluded from the best price calculation." CMS Release No. 14, at 2 (emphasis added).

As a matter of law, the word "any" means "all." *Hertzberg v. Dignity Partners, Inc.*, 191 F.3d 1076, 1080 (9th Cir. 1999) (explaining that the meaning of "any" includes "all" and "[t]his broad meaning of 'any' has "been recognized by this circuit"); *see also United States v. Rucker*, 535 U.S. 125, 131 (2002) ("As we have explained, 'the word 'any' has an expansive meaning, that is, 'one or some indiscriminately of whatever kind.'") (*quoting United States v. Gonzales*, 520 U.S. 1, 5 (1997)); *TRW Envtl. Safety Sys., Inc. v. United States*, 18 Cl. Ct. 33, 48 (1989) ("[t]he manner in which the word 'any' is included in this definition, wherein it precedes, modifies, and expands every word in the definition, clearly serves to broaden the meaning of each. In this context, therefore, we construe the word 'any' to mean 'without limitation as to which,' that is to say, 'every.'"); *cf. Small v. United States*, 125 S. Ct. 1732, 1754-55 (2005) (holding that the phrase "any court" as used in an unlawful gun possession statute means "all domestic courts" but not foreign courts). The nominal price exclusion is therefore not limited to certain classes of customers; rather, the exclusion applies to all customers, both for-profit and not-for-profit entities.[6]

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[6] Indeed, even "[w]here there is a conflict between an agency's interpretation and the contract terms" – which is not the case here – "'[i]t is the unambiguous terms of the contract, not the unilateral beliefs of one of the parties, that define the parties' respective obligations.'" *Commonwealth Edison Co. v. United States*, 56 Fed. Cl. 652, 661 (2003) (quoting *Park Village Apartments v. United States*, 25 Cl. Ct. 729, 733 (1992)).

Notably, Plaintiffs' claims do not rely on any language in the Rebate Agreement or the Rebate Statute. Instead, Plaintiffs cite only a single report by the U.S. Senate Special Committee On Aging issued several months *after* the enactment of the Rebate Statute. *See* Amended Complaint at ¶ 25. But even that report does not support the Plaintiffs' proposition that *only* nominal prices offered to charitable groups or organizations would be excluded from Best Price. *See* S. Rep. 102-28(I), Developments in Aging: 1990 Volume 1, 102nd Cong., 1st Sess. 1991 (March 22, 1991), at 254, 1991 WL 52579. In any event, in the absence of any kind of textual ambiguity in the statute – which is the case here – any reliance upon legislative history is improper. *Cf. Rucker*, 535 U.S. at 133-34 (noting that Court of Appeals "correctly recognized that reference to legislative history is inappropriate when the text of the statute is unambiguous" but reversing where court improperly found textual ambiguity and considered legislative history).

RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 555
RENO, NEVADA 89511
775/829-6000
FAX 775/829-6001

In addition, the recent amendments to the definition of nominal price that both the United States Senate and the House of Representatives approved in the Deficit Reduction Act of 2005 (the "2005 Amendments"): (a) confirm that the Secretary's implementation of the existing Rebate Statute and Merck's exclusion of all nominal prices are proper under existing law; and (b) contradict Plaintiffs' position that the current nominal price exception is limited to only certain sales and certain customers. In the new legislation, which requires an additional House vote as a result of the Senate's decision to strike three unrelated provisions due to a failure to conform to Senate budget rules, Congress has expressed its intent to modify the existing definition of nominal price by expressly limiting "sales at a nominal price or merely nominal in amount" to sales to Public Health Service hospitals, facilities providing care to the mentally retarded, nursing homes owned by state governments, and other facilities that may be determined by the Secretary to be a "safety net provider." *See* Deficit Reduction Act of 2005, S. 1932, 109th Cong., § 6001; *see also* H. R. Conf. Rep. No. 109-362, at 259-60; *supra* Section II.B., n.4 If the Rebate Statute and the Rebate Agreement *already* restricted nominally priced sales to certain charitable or non-profit organizations, as Plaintiffs claim, there would be no basis for Congress to enact the 2005 Amendments.

Thus, the plain text of the Rebate Statute and the Rebate Agreement, as well as the Secretary's interpretation of the Rebate Agreement after notice and comment and recent Congressional action, all conclusively demonstrate that Plaintiffs are wrong in contending that only *some*, as opposed to all, of Merck's nominal prices to hospitals should be excluded from Best Price under current law. Nothing in the definition of nominal price in either the Rebate Statute or the Rebate Agreement supports the interpretation proffered by Plaintiffs that the nominal price exclusion is limited to only those nominal prices offered to certain purchasers, such as charitable

RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 555
RENO, NEVADA 89511
775/828-6000
FAX 775/828-6001

institutions. Because Plaintiffs' Nominal Price Allegations are precluded by the Rebate Statute and Agreement, they must be dismissed.[7]

C. The Court Should Dismiss Plaintiffs' Nominal Price Allegations Because Plaintiffs' Cannot Plead That Merck "Knowingly" Submitted False Best Price Reports

As a matter of law, Plaintiffs' Nominal Price Allegations also fail to satisfy the requirement of the Nevada False Claims Act that a person must *knowingly* have made or used a *false* record or statement to decrease an obligation to pay money to Nevada. *See* N.R.S. 357.040(1)(g). In effect, Plaintiffs are asserting their *legal* contentions regarding how the Rebate Statute and Rebate Agreement should be interpreted as *factual* allegations (which must be read as true for purposes of Merck's motion) supporting that Merck acted with the requisite scienter. But simply because the rebates Merck paid to Nevada would be higher if Plaintiffs' misinterpretations of the Rebate Statute and Rebate Agreement were correct does not render Merck's Best Price reports "knowingly" false.

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[7] Plaintiffs' argument (first tried in their opposition to Merck's motion to dismiss the initial complaint) that the general legislative purpose of lowering Medicaid costs should trump the plain, unambiguous text of the Rebate Statute and Rebate Agreement concerning the meaning of "nominal price" cannot be countenanced. *Kimberly Assocs. v. United States*, 261 F.3d 864, 870 (9th Cir. 2001) (quoting *Alaska Pulp Corp., Inc. v. United States*, 48 Fed. Cl. 655, 659 (2001) (holding that a party to a contract cannot "unilaterally alter the contract or . . . condition his performance on terms that were not part of the bargain" and that "[t]he result is no different where the government [is] a party to the contract")); *Standard Oil Co. of Calif. v. United States*, 685 F.2d 1322, 1333 (Ct. Cl. 1982) (concluding that the "invocation of the basic policy of the Unit Plan Contract and the authorizing legislation cannot overcome or justify a departure from the unequivocal language of the particular provision of the contract . . . here involved"); *Reservation Ranch v. United States*, 39 Fed. Cl. 696, 708-09 (1997) (according deference to contract term addressing a specific issue "[w]here a statute is silent on" that issue, and noting that "[t]his is not a case where Congress has limited the discretion of an agency to contract"); *Arakaki v. United States*, 62 Fed. Cl. 244, 263 (2004) ("The Secretary could not enter into any transactions unless the Secretary gave up some options in order to pursue a particular end. A contract is a choice among options. While Congress can set standards and take away the authority to make certain kinds of contracts, the statutory scheme here does not prevent the Secretary from making deals, or delegating authority to make deals."). Congress enacted specific exclusions in the definition of Best Price, and there is no basis in the text, structure, or context of the Rebate Statute to conclude that Congress foreclosed the Secretary from adopting the definition of nominal price found in the Rebate Agreement. *See, e.g.*, § 1396r-8(c)(i) (excluding from "Best Price" the prices of drugs under various federal programs).

RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 555
PENO, NEVADA 89511
775/829-6000
FAX 775/829-6001

The most that the Amended Complaint supports is that Merck interpreted the Rebate Statute in the same way that CMS interpreted that statute and acted in accordance with the obligations CMS mandated in the Rebate Agreement. Moreover, in light of the 2005 Amendments, which reflect the determination by both Houses of Congress that new legislation is required in order to restrict sales that are nominal or merely nominal in amount to sales to certain charitable or nonprofit organizations, Merck clearly could not have "knowingly" submitted false claims in excluding all nominal price sales under existing law.

Even accepting as true Plaintiffs' conclusory allegations that Merck acted *knowingly* for purposes of the scienter requirement of the Nevada False Claims Act, Plaintiffs' claims still fail because Merck's Best Price reports, consistent with the express terms of the Rebate Agreement, are not *false* as a matter of law. *See, e.g., United States ex rel. Lindenthal v. General Dynamics Corp.*, 61 F.3d 1402, 1412 (9th Cir. 1995) (concluding that claims for payment consistent with contractual obligations "could not have been 'false or fraudulent'" within the meaning of the federal False Claims Act). Furthermore, if the Court were to conclude that the Rebate Statute, the Rebate Agreement, and CMS releases do not provide specific guidance on the scope of nominal prices, the Rebate Agreement expressly provides that a manufacturer "may make reasonable assumptions in its calculations of AMP and Best Price, consistent with the intent of section 1927 of the Act, Federal regulations, and the terms of this agreement." *See* Rebate Agreement, § II(i); *cf. United States ex rel. Oliver v. The Parsons Co.*, 195 F.3d 457, 463-64 (9th Cir. 1999) (citing *Lindenthal* and distinguishing parties' interpretation of federal contracts and federal regulations in determining falsity under the False Claims Act). Given Congress' conclusion that the Best Price definition must be changed to limit sales that are "merely nominal in amount" to certain types of providers, Merck at a minimum acted reasonably in excluding all prices for Zocor and Vioxx that were less than ten percent of AMP from its Best Price calculations.

RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 555
RENO, NEVADA 89511
775/829-6000
FAX 775/829-6001

For these reasons, Plaintiffs have not pled, and cannot plead, that Merck either submitted a "false" claim or that Merck acted with the requisite scienter. These failings are another reason for dismissal of Plaintiffs' Nominal Price Allegations.

D. The Court Should Dismiss Plaintiffs' Amended Complaint In Its Entirety Because Plaintiffs' Claims Are Preempted By The Federal Medicaid Rebate Statute

In addition to its conflict with both the Rebate Statute and Rebate Agreement, Plaintiffs' Nominal Price claims are preempted as a matter of law because Plaintiffs' state law claims directly conflict with the Rebate Statute and federal guidance on the definition of nominal price. Likewise, both Plaintiffs' Nominal and Non-Nominal Price claims also constitute state-law "fraud-on-the-agency" claims which are preempted under the Supreme Court's analysis in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2000).

"A fundamental principle of the Constitution is that Congress has the power to preempt state law." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000) (citing U.S. CONST. ART. VI, cl. 2). "Pre-emption may be either expressed or implied, and 'is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose.'" *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992) (*quoting Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)). In the absence of express preemption language, there are two types of implied preemption. In the first, referred to as field preemption, Congress might implicitly withdraw the States' power to regulate "where the scheme of federal regulation is 'so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it' . . . ." *Id.* at 98 (*quoting Jones*, 430 U.S. at 525). In the second, referred to as conflict preemption, either "compliance with both federal and state regulations is a physical impossibility," *see id.* (*quoting Fla. Lime & Avocado Growers v. Paul*, 373 U.S. 132, 142-143 (1963)), or the state law "'stands as an

RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 555
ENO, NEVADA 89511
775/329-6000
FAX 775/329-6001

obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Id.* *(quoting Hines v. Davidowitz*, 314 U.S. 52, 67 (1941)).

In the case of implied preemption, there is a presumption that Congress did not intend to preempt the historic police powers of the States "unless that was the clear and manifest purpose of Congress." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (*quoting Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). However, when the state law claims involve a fraud against a federal agency, there is no presumption against preemption, since "the relationship between a federal agency and the entity it regulates is inherently federal in character," and "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied.'" *Buckman*, at 347 (*quoting Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

As set forth below, Plaintiffs' Amended Complaint is preempted because Plaintiffs' state law claims directly conflict with the Rebate Statute and federal regulations and also constitute state-law "fraud-on-the-agency" claims which are precluded under *Buckman*.

1. Plaintiffs' Nominal Price Allegations Present a Direct Conflict and are Preempted.

As alleged, Plaintiffs contend Merck's Best Price reports to the federal government violated Nevada law because the nominal price exclusion under the Rebate Statute and the Rebate Agreement was "intended for not-for-profit, charitable entities and for researchers using the drugs for experimental or non-standard purposes," not nominal prices offered by Merck through its SAVE and VIP programs. Amended Complaint at ¶¶ 25, 42, & 85. For the same reasons that Plaintiffs' claims are inconsistent with the Rebate Statute and the Rebate Agreement, Plaintiffs' Nominal Price Allegations under Nevada's False Claims Act, if accepted, would create a direct conflict with the express language in the federal Rebate Statute and the Rebate Agreement, and therefore must be preempted.

LIS PICKERING & PETERSON
ATTORNEYS AT LAW
NEIL ROAD, SUITE 555
ENO, NEVADA 89511
775/823-6000
FAX 775/823-6001

If Congress had intended the current nominal price exclusion to be limited to only certain sales transactions or certain purchasers, such as charitable and research entities, it certainly could have included such limitations. *See, e.g.*, 15 U.S.C. § 13c (excluding purchase of supplies by charitable institutions from the Robinson-Patman Antidiscrimination Act); *see also* 2005 Amendments (providing limitations on nominal price sales). Instead, Congress provided that the Best Price provision applies to sales to **any** wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States except for those transactions which Congress expressly excluded, such as sales to the Department of Veterans Affairs. § 1396r-8(c)(1)(C)(i)(I). Within the broad context of these sales to **any** wholesalers, retailers, providers, health maintenance organizations, nonprofit and governmental entities, Congress directed that sales which are "merely nominal in amount" shall be excluded from Best Price, without qualification or limitation. Consistently, the Rebate Agreement further defines "nominal price" as "***any*** price less than 10% of the AMP," and, as explained in Section III.B *supra*, the word "any" means "all."

The obligations that would arise if Plaintiffs' interpretation of the Rebate Statute and Rebate Agreement were accepted are in direct conflict with the Rebate Statute, the Rebate Agreement, and federal guidance. Merck could not submit one set of data to HHS under existing federal requirements for states other than Nevada and at the same time comply with the different standards asserted by Plaintiffs for the State of Nevada. Simply put, without preemption, application of Nevada law to the federal statutory scheme would create a situation in which compliance with federal law would violate state law.

Recognizing this factor as critical to any preemption analysis of state-law claims and the federal Medicaid program, the Department of Justice in *Pharm IV* filed an amicus brief on behalf of the Secretary of HHS in which it argued against preemption of state-law claims under Nevada's Medicaid Fraud Act relating to Best Price reporting obligations. In its argument, however, the DOJ

RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 555
RENO, NEVADA 89511
775/823-6000
FAX 775/823-6001

expressly carved out the circumstance where a state law claim attempted to redefine nominal price discounts:

> [T]he Defendants have not identified any state-imposed obligation that directly conflicts with their best price obligations as defined in the rebate statute or agreement. Neither Montana nor Nevada is asking, for example, the Defendants to include nominal prices, or exclude cash discounts, in their best price calculations in conflict with 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(I) & (II).

Brief of the United States as Amici Curiae, at 10; (excerpts attached as Exhibit C) (*citing Boyle v. United Tech. Corp.*, 487 U.S. 500, 508-509 (1988)) (emphasis added); *see also id.* at 17 (contrasting state claims seeking to impose obligations contrary to Rebate Agreement or CMS guidance). The district court in *Pharm IV* agreed with the DOJ's position, yet here, Plaintiffs are seeking to impose exactly the type of state-imposed conflicting obligations that DOJ distinguished in *Pharm IV*.

Notably, in response to Merck's motion to dismiss Plaintiffs' original complaint in this litigation (in which Merck also explained that Plaintiffs' state-law claims were preempted and cited the DOJ's position in *Pharm IV*), the Department of Justice submitted a letter to this Court, which provided:

> The issue of preemption was raised in the defendant's motion to dismiss filed in [this proceeding.] Should the Court reach that issue in ruling on the motion, the Department of Justice submits that the holding in [*Pharm IV*] is correct with respect to that issue.

See Letter to the Honorable Howard D. McKibben from Viveca D. Parker, Assistant United States Attorney, Eastern District of Pennsylvania, dated October 31, 2005 (attached as Exhibit D). That the DOJ agrees with the position it advocated successfully in *Pharm IV* is not notable. But since the DOJ clearly was aware of Merck's specific arguments in Merck's original motion, the DOJ's letter is far more notable for what it does *not* say. It does not, for example, suggest in any way that Merck's interpretation of the Rebate Statute, the Rebate Agreement, or the CMS guidance with respect to

LIS PICKERING & PETERSON
ATTORNEYS AT LAW
NEIL ROAD, SUITE 555
ENO, NEVADA 89511
775/823-6000
AX 775/823-6001

Best Price and nominal price is incorrect. Nor does the DOJ disavow the position it took in *Pharm IV* with respect to nominal pricing – that a state-law claim seeking to require Merck to report nominal prices in conflict with the Rebate Statute, the Rebate Agreement, and CMS guidance is a direct conflict for purposes of preemption.

Even if Merck (and all other drug manufacturers with national rebate agreements) could deduce the specific prices with certain purchasers that Plaintiffs believe should be allowed as "nominal" prices, Merck is still required to exclude any nominal price (*i.e.*, less than ten percent of AMP) from its Best Price reports under the express terms of its Rebate Agreement and present CMS guidance. Merck could thus report its Best Price to CMS and then be accused of filing a false claim by Plaintiffs because its Best Price included one of the prices Nevada believes should be included. Or Merck could report its Best Price to Nevada, including nominal prices Nevada believes should be reported, and then be out of compliance with its federal and contractual obligations that are applicable with respect to other states. This is exactly the type of direct conflict which the doctrine of federal preemption resolves, and, accordingly, Plaintiffs' state-law claims with respect to Merck's nominal price reporting should be dismissed as preempted under federal law.[8]

[8] In contrast to Nevada's approach, the 2005 Amendments provide a single, federal standard, identifying specific non-profit entities whose purchase of drugs at nominal prices should be excluded from Best Price and permitting the Secretary to explicitly identify other entities consistent with factors enumerated in the 2005 Amendments. *See* 2005 Amendments, at § 6001(d)(2)(i)(IV). The 2005 Amendments clearly do not envision a role for States in establishing separate standards for nominal price sales, nor do they suggest that Congress envisioned a State role in enforcing federal limitations on nominal price sales.

(continued . . .)

RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 555
RENO, NEVADA 8951
775/825-6000
FAX 775/825-6001

2. Plaintiffs' Entire Amended Complaint is Preempted under *Buckman's* Fraud on the Agency Analysis.

In addition, both Plaintiffs' Nominal Price Allegations and Non-Nominal Price Allegations are state law "fraud-on-the-agency" claims that are preempted under the Supreme Court's decision in *Buckman*. In *Buckman,* the Supreme Court analyzed a claim alleging fraud on the FDA in the context of statements made to the FDA pursuant to a FDA regulatory approval process. Specifically, the petitioner, a manufacturer of bone screws, was required under FDA regulation to submit to the FDA proposed labeling and a statement that its device was similar to other products of comparable type accompanied by data to support the statement. *Id.* The respondents in *Buckman* alleged that the statements made to the FDA were fraudulent under state law. *Buckman*, at 345.

After first determining that no "presumption against preemption" was available because the relationship between a federal agency and the entity it regulates was "inherently federal" and policing fraud against federal agencies was not a traditional activity of States, the Court found "plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted by, federal law." *Id.* In discussing the nature of this conflict, the Court explained that "petitioner's dealings with the FDA were prompted by the [FDA's regulations], and the very subject matter of petitioner's statements was dictated by the statute's provisions." *Id.* at 347-8. The Court reasoned that the FDA possesses ample power to punish and deter fraud, and that permitting state tort law claims would skew the "delicate balance" of Congress' statutory objectives. *Id.* In addition, the Court recognized that there was real potential for an actual conflict by permitting state-law fraud claims to reach

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Even if the Court were to conclude that Plaintiffs' interpretation of existing law were correct, and for the reasons described herein it should not, Plaintiffs' claims should still be preempted. Permitting individual States effectively to determine *federal* Best Price requirements through *state* law would inevitably result in conflicting obligations for manufacturers, undermining "the full purposes and objectives" of the Rebate Act. *Cf. Geier, et al. v. American Honda Motor Co., Inc.*, 529 U.S. 861, 873 & 881 (2000) (*citing Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)) (preempting state law claims where state tort claim based upon "minimum airbag standard" not reflected in federal regulations would create obstacle to federal objectives).

LIS PICKERING & PETTERSON
ATTORNEYS AT LAW
NEIL ROAD, SUITE 555
ENO, NEVADA 89511
775/829-6000
AX 775/829-6001

statements made to the FDA because statements deemed appropriate by the FDA could later be judged insufficient by a state court. *Id.* at 351.

Similar to the FDA regulatory process in *Buckman*, the Rebate Statute "provides an express and lengthy definition of Best Price."[2] *Pharm IV*, 321 F. Supp. 2d at 195. Best Price is further defined and governed by the national contract between each manufacturer and the federal government, and pharmaceutical manufacturers are required to comply with the Rebate Statute and the Rebate Agreement by submitting Best Price data to HHS. As in *Buckman*, each of Plaintiffs' claims is fundamentally only an assertion that Merck submitted false information to HHS by reporting inaccurate Best Price data, and each of Plaintiffs' fraud claims, as in *Buckman*, "exist solely by virtue of [federal] requirements." *Buckman*, at 353. There is nothing in the Rebate Statute to suggest that Congress intended to permit Nevada (or other states) to adopt state-specific interpretations of such fundamental contract terms as "nominal price." *Cf. Boyle v. United Tech. Corp.*, 487 U.S. 500, 504-05 (explaining that the obligations and rights of the United States under its contracts are one of the "uniquely few" areas of federal law where conflicting state law is preempted and replaced by federal common law); *see also* Rebate Agreement, § IX (e) (explaining that the Rebate Agreement is to be construed in accordance with federal common law).[10]

Moreover, the Rebate Statute has a variety of provisions that "amply empower" the Secretary in "detecting, deterring and punishing false statements" by manufacturers. *Compare Buckman* at 349. The Secretary can survey drug manufacturers to verify manufacturer prices, audit

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[2] *See supra* Section II.B.

[10] Notably, the law that forms the basis of Plaintiffs' claims – Nevada's False Claims Act – was not even enacted until 1999 and therefore did not exist until *eight years after* Merck entered into the Rebate Agreement with the Secretary. In these circumstances, Plaintiffs hardly can contend that their claims of fraud arising from Merck's submission of data to the Secretary (which Nevada does not itself receive from Merck) grew "in a field which the States have traditionally occupied." *Buckman*, at 347 (finding state fraud claims preempted where state statute predated federal statute but "existence [of] federal enactments is a critical element" in state fraud case).

RIS PICKERING & PETERSON
ATTORNEYS AT LAW
NEIL ROAD, SUITE 555
ENO, NEVADA 89511
775/829-6000
FAX 775/829-6001

manufacturer Best Price data, and impose civil monetary penalties "if a manufacturer provides false information" or refuses a request for information in connection with such a survey. § 1396r-8(b)(3)(B); *see also* Rebate Agreement, §§ III & IV. Manufacturers generally are subject to civil penalties of up to $100,000 for provision of false information. *Id.*; § 1396r-8(b)(3)(C). The Secretary also has the power to terminate a rebate agreement with a manufacturer. § 1396r-8(b)(4)(B). And it is the Secretary who promulgated the Rebate Agreement, in accordance with federal law, and who must approve any separate rebate agreement a state may enter into with a manufacturer. § 1396r-8(a).

States have no such enforcement and supervision powers under the Rebate Statute or Rebate Agreement. Congress' decision not to provide a mechanism for States to enforce accurate Best Price reporting is not surprising, since the Rebate Statute requires manufacturers to submit Best Price data directly to the Secretary. *See* § 1396r-8(b)(3)(A) (requiring manufacturers to provide Best Price data to the Secretary of HHS). What the Secretary has done is provide that States must make available a dispute resolution mechanism *to the manufacturer* in the event of a dispute between a manufacturer and a state relating to utilization numbers, not Best Price. *See* Rebate Agreement, § IV. But even then, results of such state proceedings are not binding on the Secretary for purposes of the penalty provisions of the Rebate Statute. *See id.*

Permitting state-law "fraud on the agency" claims under the Rebate Statute could lead to multiple state-by-state definitions of Best Price that are contrary to federal definitions. These differing state law definitions would frustrate the Congressional intent behind the Rebate Statute, undermine the Rebate Statute's "delicate balance" of statutory objectives and require manufacturers to attempt to comply with their single, nationwide Rebate Agreement with the Secretary "in the shadow of 50 states' tort regimes . . . ." *Buckman*, at 347 & 350. Establishing conflicting state-by-state definitions for manufacturers under a national contract with HHS could not have been

S PICKERING & PETERSON
ATTORNEYS AT LAW
NEIL ROAD, SUITE 555
ENO, NEVADA 89511
775/626-6000
AX 775/626-6001

contemplated by Congress, which made it plain that the Medicaid Drug Rebate Program would be based upon a detailed, uniform, federal definition of Best Price, without any provision for state-specific variations. *See* §§ 1396r-8(c)(1)(C) & 1396r-8(k); Rebate Agreement, § I. Consistent with *Buckman*, Plaintiffs are not entitled to any "presumption against preemption," and Plaintiffs' "fraud on the agency" claims should be preempted by the Rebate Statute and dismissed in their entirety.

E. The Court Should Dismiss Plaintiffs' "Non-Nominal Price" Allegations Concerning "Free Goods" Because Plaintiffs Fail To State A Claim Upon Which Relief Can Be Granted.

As part of their Non-Nominal Price Allegations, Plaintiffs allege that Merck "induced hospitals (as well as HMOs and health systems) to purchase its drugs to prescribe to their patients" by giving "away large amounts of free drug to hospitals in order to reduce the total cost of the drugs the hospital purchased from Merck." Amended Complaint at ¶ 52. Plaintiffs allege "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." *Id.* at ¶ 55. As a result, Plaintiffs allege that Merck violated the Nevada False Claims Act by effectively "decreasing the total rebate amount paid by Merck to Nevada." *Id.* at ¶ 71; *see also id.* at ¶¶ 111-122 (incorporating *id.* at ¶¶ 52-71).[11] Plaintiffs' free goods allegations should be dismissed for two distinct reasons: (1) Plaintiffs fail to allege that any specific give away of free goods "contingent on a purchase requirement," *see* 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(I), was excluded from a Best Price report with the required scienter and therefore do not state a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure; and (2) Plaintiffs do not allege necessary factual details required by Fed. R. Civ. P. 9(b).

Under both Fed. R. Civ. P.. 9(b) and 12(b)(6), Plaintiffs must plead with particularity, and with respect to a specific transaction, that: (a) Merck distributed free drugs to a customer contingent

[11] Count II of the Amended Complaint likewise incorporates ¶¶ 52-71, but the allegations in those paragraphs are relevant only to Count IV.

IS PICKERING & PETERSON
ATTORNEYS AT LAW
NEIL ROAD, SUITE 555
ENO, NEVADA 89511
775/829-6000
775/829-6001

on a purchase requirement; (b) Merck, acting with scienter, excluded free goods that were contingent on a purchase requirement when calculating the net price paid by the customer for all purchases of that particular drug; and (c) had Merck accounted for the free goods contingent on a purchase requirement in the net price calculation for the specific customer, the resulting price would have been lower than the Best Price that Merck actually reported for that drug for the reporting period in question. Because Plaintiffs have not satisfied these elements here, their Complaint must be dismissed.

1. Plaintiffs' allegations concerning "free goods" should be dismissed because Plaintiffs have not alleged that Merck, acting with scienter, excluded drugs given away "contingent on any purchase requirement" from a best price calculation.

Plaintiffs concede, as they must, that not all distributions of "free goods" must be accounted for in "Best Price" calculations. Referencing the Rebate Statute, Plaintiffs acknowledge that only "[f]ree goods that are given away *contingent on any purchase requirement* . . . must be taken into account in calculating Best Price." Amended Complaint at ¶ 52 (emphasis added) (citing 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(I)).[12] However, Plaintiffs' Amended Complaint asks this Court effectively to excise the

[12] The Department of Health and Human Services ("HHS") recently confirmed that "free drugs given to the Hurricane Katrina relief effort are not a discount, for best price purposes, to each of the recipients to whom they are shipped[,]" despite the fact that "other shipments" were made "to the same entity." *See* Letter from M. McClellan, CMS Administrator, to W. Tauzin, President and Chief Executive Officer, Pharmaceutical Research and Manufacturers of America, dated September 3, 2005 (Attached as Exhibit E). Indeed, as HHS noted, "simply the bulk transfer of product . . . not for resale by the recipient, are not included in the best price or Average Manufacturer Price (AMP) computations." *Id.* In no uncertain terms, HHS reported that "[u]nder the plain terms of the Medicaid statute" only free goods "'that are contingent on any purchase requirement' must be included in the calculation of the best price." Id.; *see also* 60 Fed. Reg. at 48445 ("free goods that are not contingent on any purchase requirements may be excluded from best price").

RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 555
RENO, NEVADA 89511
775/829-6000
FAX 775/829-6001

phrase "contingent on any purchase requirement" from 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(I),[13] and to interpret the Rebate Statute as requiring manufacturers to include all free goods in their Best Price.

Plaintiffs' sole allegation regarding "contingency on any purchase requirement" is not connected in any way to specific transactions, conduct, or statements. Rather, Plaintiffs simply allege, with respect to Merck's "Special Promotion Program" ("SPP"), that "Merck did not give away free drugs unless it was tied to a purchase – past, present or future," Amended Complaint at ¶ 57. The sole basis Plaintiffs identify for this generalized allegation is one reference to unspecified "[e]mails between Merck sales representatives and their managers" that "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." *Id.* Without any more factual details, Plaintiffs then simply recite a handful of occasions in which Merck allegedly provided free goods to hospitals or other institutions. Amended Complaint at ¶¶ 58-69.

Even accepting Plaintiffs' extraordinarily vague allegations as true for purposes of this motion, the plain language of § 1396r-8(c)(1)(C)(ii)(I) makes Merck's mere "expectations" irrelevant. Rather, as noted, Plaintiffs must allege that, for a specific, identifiable transaction, Merck, acting with scienter, offered free goods to a customer contingent on a purchase requirement and did not account for those sales in a particular Best Price calculation. Furthermore, the Plaintiffs must allege that the failure to account for the specific free goods transaction in a Best Price calculation resulted in Merck reporting a higher Best Price for the goods at issue than it would otherwise have reported. This Plaintiffs have not done. Indeed, the Amended Complaint does not identify a single, specific

[13] As noted by the American Medical Association, "[m]any gifts given to physicians by companies in the pharmaceutical, device, and medical equipment industries serve an important and socially beneficial function." *See* AMA Code of Ethics, http://www.ama-assn.org/ama/pub/category/8484.html. Free pharmaceuticals programs allow physicians and institutions to evaluate the therapeutic advantages and disadvantages of selected drugs without regard to cost.

S PICKERING & PETERSON
ATTORNEYS AT LAW
NEIL ROAD, SUITE 555
NO, NEVADA 8951
775/829-6000
AX 775/829-5001

reported Best Price that it alleges was too high as a result of any distribution of free goods contingent on a purchase requirement.

Moreover, Plaintiffs' allegations are defective for the additional reason that a good faith interpretation of a statute or contract, as a matter of law, cannot satisfy the scienter requirement of the Nevada False Claims Act (*i.e.*, that Merck knowingly made or used, or caused to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to Nevada). *See, e.g., United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1267 (9th Cir. 1996) ("The [Federal] FCA…requires a false claim. Thus, some request for payment containing falsities made with scienter…must exist. This does not mean that other types of violations of regulations, or contracts…are not remediable; it merely means that such are not remediable under the FCA . . . ."); *United States ex rel. Butler v. Hughes Helicopter*, 71 F.3d 321, 326 (9th Cir. 1995) (rejecting plaintiff's argument as "rais[ing] questions of contract interpretation rather than false claims").[14] Because Plaintiffs in these circumstances cannot plead facts establishing required elements of a false claim, the Non-Nominal Price Allegations in Count IV of the Amended Complaint concerning free goods are patently deficient and should be dismissed.

[14] The Ninth Circuit's decision in *United States ex rel. Oliver v. The Parsons Co.*, 195 F.3d 457 (9th Cir. 1999) is consistent with its prior decisions in *Anton* and *Hughes* in this respect. In *Oliver*, the court, while rejecting the defendant's argument that a reasonable interpretation of an ambiguous regulation cannot be the basis for establishing falsity under the False Claims Act, held that "a contractor relying on a good faith interpretation of a regulation is not subject to liability [under the FCA] . . . because the good faith nature of his or her action forecloses the possibility that the scienter requirement is met." Here, consistent with *Oliver*, the most that the pleadings establish is that Merck complied with a good faith interpretation of the phrase "contingent on any purchase requirement." The Amended Complaint does not contain any facts which, if taken as true, would support that Merck *knowingly* submitted a false best price report or that Merck *knowingly* paid a lower rebate to Nevada than is required by law. Under these circumstances, Plaintiffs have not – and cannot – plead scienter as required by the Nevada False Claims Act.

RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 555
PENO, NEVADA 89511
775/829-6000
FAX 775/829-6001

2. Plaintiffs' "free goods" allegations should be dismissed because they have not pled fraud with particularity as required under Fed. R. Civ. P. 9(b).

Plaintiffs' free goods allegations and Count IV of the Amended Complaint also fail to comply with Fed. R. Civ. P. 9(b), which requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." *See United States ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1051 (9th Cir. 2001) ("Complaints brought under the [FCA] must fulfill the requirements of Rule 9(b)."). Rule 9(b) mandates that the Amended Complaint must be "'specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong.'" *Id.* at 1052 (quoting *Neubronner v. Milken*, 6 F.3d 666, 671 (9th Cir. 1993)); *United States ex rel. Riley v. Alpha Therapeutic Corp.*, 1997 WL 818593, *3 (N.D. Cal. 1997) (concluding that "[p]laintiff's amended complaint . . . still fails to identify a specific false claim made by any of the named persons").[15]

Plaintiffs' free goods allegations are insufficient under Fed. R. Civ. P. 9(b) not only because they fail to allege details regarding how, or in what manner, specific "give-aways" were "contingent" on a "purchase requirement," but also because Plaintiffs have failed to include *any* details of free "give-aways," and have failed to plead with particularity factual elements necessary to maintain a cause of action. While Count IV of the Amended Complaint generally alleges that the "free drug give-away schemes" identified in the Amended Complaint "have the effect of decreasing the total

[15] *See also Arroyo v. Wheat*, 591 F. Supp. 136, 139 (D. Nev. 1984) ("Rule 9(b) is designed to thwart charges of fraud from arising out of contractual relations that merely don't work out as well as the parties had anticipated. The particularity with which the circumstances must be alleged in the complaint provides some assurance that the plaintiffs, and their counsel, have investigated the facts to such an extent that their claim of having been defrauded by the defendants is reasonable."); *see Graziose v. American Home Prods. Corp.*, 202 F.R.D. 638, 642 (D. Nev. 2001) ("The specificity of fraud claims is a necessary requirement to preclude the filing of baseless claims and avoid general, unsubstantiated charges of fraud that can do damage to a defendant's reputation, but not afford it the opportunity to defend against the allegations.").

SPICKERING & PETERSON
ATTORNEYS AT LAW
NEIL ROAD, SUITE 555
NO, NEVADA 8951
775/825-6000
AX 775/829-600

amount of rebates paid by Merck to Nevada in violation of N.R.S. § 357.040(1)(g)," *see* Amended Complaint at ¶ 115, the descriptions of such "give-aways" in paragraphs 52-71 of the Amended Complaint are not pled with sufficient factual particularity as required by Fed. R. Civ. P. 9(b). For example, the list of alleged "give-aways" (*see* "Table A," Amended Complaint at ¶ 54) does not contain any corresponding facts constituting an allegation of a contingent relationship between the "give away" and a purchase requirement, a subsequent effect on any Best Price reported by Merck, or that Merck acted with scienter. Instead, Plaintiffs allege facts which, if taken as true, are sufficient to conclude only that Merck gave away free product. Plaintiffs offer nothing but conclusory assertions that the free product should have been taken into account in calculating Best Price or that Merck's Best Price would have been affected. As explained below, such blanket allegations – devoid of a specific factual predicate – are insufficient under Rule 9(b):

- Paragraphs 56-57; SPP. Plaintiffs' statement concerning SPP that "Merck did not give away free drugs unless it was tied to a purchase" (Amended Complaint at ¶ 57) contains no more facts than classically deficient complaints that merely parrot statutory language or that contain conclusory allegations of fraud. *See, e.g., Semegen v. Weidner*, 780 F.2d 727, 731 (9th Cir. 1985) (Plaintiffs cannot simply "set forth conclusory allegations of fraud ... punctuated by a handful of neutral facts"); *accord, United States ex rel. Phillips v. Permian Residential Care Ctr.*, 386 F. Supp. 2d 879, 883 (W.D. Tex. 2005) (dismissing complaint for failing to comply with Rule 9(b) where "the Relators' Complaint contains general and conclusory allegations that Defendant submitted false claims to Medicare/Medicaid, but . . . fails to provide the requisite particulars"). It does not allege any particulars as to how any specific SPP transaction adversely affected a best price that Merck reported to CMS or a rebate that Merck paid to Nevada.

- Paragraphs 58-61; South Nassau Community Hospital and Christ Hospital: With respect to South Nassau Community Hospital, Plaintiffs allege that "Merck gave South Nassau Community Hospital in Oceanside, New York, 720 tablets of Vioxx in or around the second quarter of 2001. Plaintiffs believe that, around this same time, the hospital

SPICKERING & PETERSON
ATTORNEYS AT LAW
NEIL ROAD, SUITE 555
NO, NEVADA 89511
775/829-6000
AX 775/829-6001

purchased about 1729 tablets at about $2.34 [per] tablet, for a total of $4,047." Amended Complaint at ¶¶ 60-61. Plaintiffs fail to allege, however, that the distribution of the 720 tablets was contingent upon the purchase of the 1729 tablets. Moreover, Plaintiffs do not identify the dosage of either the Vioxx tablets that comprised the alleged "give away" to South Nassau Community Hospital or the Vioxx tablets that the hospital allegedly purchased. This failure is important because, as Plaintiffs acknowledge (*see* Amended Complaint at ¶¶ 59, 60), Merck reports a different Best Price for each different dosage level of each drug. If the dosage levels are different, then a free distribution of one dosage level would not affect the best price for a different dosage of the drug (i.e., it is not an apples-to-apples comparison). Because Plaintiffs have not pled the dosage of either the purchased Vioxx tablets or those allegedly provided via "give-aways," Plaintiffs have not pled that any of Merck's Best Price figures was overstated – a necessary element of their claim. The same defects undermine Plaintiffs' allegations at paragraphs 60 and 61 regarding Christ Hospital.

- Paragraphs 62-64; Outpatient clinics: As with the allegations concerning hospitals, Plaintiffs also fail to plead necessary facts concerning the dosage of the "give-aways" to clinics and that the alleged "give-aways" were "contingent on any purchase requirement." Amended Complaint at ¶ 62-64. Additionally, Plaintiffs do not identify a single clinic to which free drugs were allegedly provided under this "initiative." *Id.* As a result, Plaintiffs have not alleged that a transaction with a clinic would have yielded a lower Best Price than Merck reported.

- Paragraphs 65-69; Hospitals and HMOs Outside SPP: With respect to free product assertedly provided to hospitals and HMOs outside of the SPP program, Plaintiffs allege that: "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 ("BCN") in Michigan." Amended Complaint at ¶ 65. With respect to the Blue Care Network, however, Plaintiffs do not allege that, in fact, Merck gave free tablets to BCN; the allegation is only that Merck "planned" to provide free tablets to BCN. *See* Amended

LIS PICKERING & PETERSON
ATTORNEYS AT LAW
NEIL ROAD, SUITE 555
ENO, NEVADA 89511
775/823-6000
AX 775/823-6001

> Complaint ¶¶ 65, 66, 68. A "planned" distribution of free product cannot form the basis of a false claim. *See United States v. Kitsap Physicians Serv.*, 314 F.3d 995, 1002 (9th Cir. 2002) (plaintiff "must show 'an actual false claim for payment being made to the Government.' Evidence of an actual false claim is 'the *sine qua non* of a False Claims Act violation.'") (citations omitted) (emphasis in original).

Not only do Plaintiffs fail to provide any facts regarding any other "give away" to any other hospital, HMO, or similar institution, allegations made on "information and belief," without more, are insufficient under Fed. R. Civ. P. 9(b). *See California ex rel. Mueller v. Walgreen Corp.*, 175 F.R.D. 631, 635 (N.D. Cal. 1997) (holding that "even where allegations are based upon information and belief, a plaintiff still must: (1) specifically allege that the necessary information lies within the defendant's control; and (2) include a statement of the facts upon which plaintiff's information and belief is based" (citing Ninth Circuit cases)).[16] In *Walgreen Corp.*, the court concluded that plaintiff's complaint failed to satisfy Rule 9(b), because "plaintiff does not allege in his complaint that any of the necessary facts are exclusively within defendant Walgreen's control." 175 F.R.D. at 635; *accord, id.* at 635-36 ("given the vast number of alleged 'short-filled' prescriptions and subsequent billings to Medi-Cal, . . . it may be difficult for plaintiff to make such an allegation. If the nature and scope of plaintiff's allegations are true, one would assume that numerous California Walgreen customers possess personal knowledge of Walgreen's alleged practice[s] [and] . . . for each 'short-filled' prescription, there should be corresponding Medi-Cal records evidencing an overcharge").

As in *Walgreen Corp.*, Plaintiffs' "information and belief" allegations in the instant case fail to allege that "any of the necessary facts are exclusively within [Merck's] control" and thus are

[16] Other courts have made clear that pleading on "information and belief" "must not be mistaken for license to base claims of fraud on speculation and conclusory allegations." *United States ex rel. Willard v. Humana Health Plan of Tex., Inc.* 336 F.3d 375, 388 (5th Cir. 2003) (internal quotations omitted); *see also United States ex rel. Clausen v. Lab. Corp.*, 198 F.R.D. 560 (N.D. Ga. 2000), *aff'd*, 290 F.3d 1301 (11th Cir. 2002) (concluding that in False Claims Act cases, under Rule 9(b), "pleadings generally cannot be based on information and belief" (citing cases)).

IS PICKERING & PETERSON
ATTORNEYS AT LAW
NEIL ROAD, SUITE 555
ENO, NEVADA 89511
775/829-6000
AX 775/829-6001

insufficient. In addition, Plaintiffs admit that they intend to use the discovery process to find support for their Complaint. *See* Amended Complaint at ¶ 55 ("discovery should reveal more cases of Merck not reporting the Best Price"). As this remarkable allegation demonstrates, Plaintiffs' claims must be seen for what they are – an attempt to manufacture "a ticket to the discovery process." *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 198 F.R.D. 560, 564 (N.D. Ga. 2000). However,

> [i]f given such a ticket, the next stage of this litigation is clear. [Plaintiffs] will request production of every . . . claim submitted by the Defendant over the last ten years. . . . In that case, the Court will be presented with the dilemma of allowing an unlimited fishing expedition or no discovery at all because of the difficulty in fashioning logical and principled limits on what has to be produced. The particularity requirement of Rule 9(b), if enforced, will not only protect defendants against strike suits, but will result in claims with discernable boundaries and manageable discovery limits.

Id.

F. The Court Should Dismiss Plaintiffs' Allegations That Merck Failed To Report Other "Non-Nominal" Discounts Because Plaintiffs' Claims Do Not Satisfy The Requirements Of Fed. R. Civ. P. 12(b)(6) and 9(b)

As the other part of their Non-Nominal Price claims, Plaintiffs generally allege that Merck failed to include certain "non-nominal" prices in its Best Price reports for Zocor. Plaintiffs assert that, on information and belief, Merck "periodically . . . refused" to report non-nominal discounts to the Secretary, and make an equally conclusory allegation that Merck knowingly concealed these discounts. Amended Complaint at ¶ 43. The only "facts" Plaintiffs allege are based upon one comment in an unidentified document which Merck allegedly provided to its sales force which states that the non-nominal discount "on Zocor in 1999 amounted to, as an *average over the dosages, about* $1.80 per tablet." Amended Complaint at ¶ 45 (emphasis added). Plaintiffs then allege that because Merck's "reported Best Price for its most popular dosage (20 mg) *ranged* from $1.80 to almost $1.83 per tablet," Merck's Best Price reports must be false. Amended Complaint at ¶ 45 (emphasis added).

RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 555
RENO, NEVADA 89511
775/689-6000
FAX 775/689-6001

Plaintiffs' claim is based on at least two incorrect premises. First, Plaintiffs assume that the average price of a drug across dosages is relevant to Best Price. As noted above, however, Best Price is measured on a particular dosage level, not based on an average of Best Prices for multiple dosages of a drug. Second, Plaintiffs assume that an annual average price is relevant to Best Price. However, Best Price is reported on a quarterly basis, not on an annual basis. Based on these two incorrect assumptions, Plaintiffs then proceed to compare the average annual non-nominal price discount for all dosage forms of Zocor (which they contend was $1.80 for the year in question) to the Best Price for one particular dosage of Zocor (which they contend was between $1.80 to $1.83 for the year in question) and on the basis of that comparison conclude that the reported Best Price must have been too high. The facts alleged do not support the conclusion reached. Rather, to state a claim, Plaintiffs must allege specific facts which, if true, would demonstrate that Merck's knowing failure to account for a non-nominal price for a specific dosage of Zocor in a Best Price report resulted in Merck reporting a Best Price for that particular dosage of Zocor that was too high. For the reasons described, Plaintiffs' allegations do not meet this pleading burden, and the Amended Complaint must be dismissed under Fed. R. Civ. P. 12(b)(6).

Plaintiffs' allegations concerning non-nominal price discounts also do not satisfy the pleading requirements of Fed. R. Civ. P. 9(b). As discussed *supra* in Section III.D, Plaintiffs' speculative, general allegations of fraud on information and belief cannot be used as a license to surmount Fed. R. Civ. P. 9(b)'s requirements and undertake a fishing expedition for some example of misreporting by Merck. Furthermore, Plaintiffs' assertion that it cannot compare Merck's discount prices for Zocor and Merck's reported Best Prices because Nevada "does not have access to Merck's catalog pricing" and "cannot determine the discount's impact on Best Price reports," Amended Complaint at ¶ 46, simply underscores that Plaintiffs' abstract claims in this proceeding should be preempted in light of federal law. Congress empowered the Secretary, not the States, to

S PICKERING & PETERSON
ATTORNEYS AT LAW
NEIL ROAD, SUITE 555
ENO, NEVADA 89511
775/823-6000
AX 775/823-6001

audit manufacturer and Best Price information and to impose substantial penalties for any fraud, and those powers are also incorporated in the Rebate Agreement. *See* § 1396r-8(b)(3)(B); Rebate Agreement, §§ III & IV; Section II.B, *supra.* The information Plaintiffs seek is not unavailable. Rather, Congress delegated the power to obtain such information to the Secretary, not the States, and Plaintiffs should hardly be excused from complying with Fed. R. Civ. P. 9(b) because they do not have the same powers Congress granted to the Secretary. *Cf. United States ex rel. Russell v. Epic Healthcare Mgmt. Group*, 193 F.3d 304, 308 (5th Cir. 1999) (affirming district court conclusion that relator was not entitled to relaxed Fed. R. Civ. P. 9(b) standard where documents were possessed by other entities, including the Healthcare Financing Administration (now CMS)). Since Plaintiffs clearly have not satisfied Fed. R. Civ. P. 9(b), the Court should dismiss all of Plaintiffs' Non-Nominal Price Allegations based upon the vague and nondescript allegations that Merck violated Nevada law by failing to report non-nominal prices to the Secretary.

G. All Claims Based On Allegedly Fraudulent Reports Submitted Prior To April 19, 2000 Must Be Dismissed As Time Barred

While not specifically identifying the fraudulent activity, both the Nominal and Non-Nominal Price claims allege that Merck's allegedly fraudulent and illegal practices occurred "from at least 1994 to the present." Amended Complaint at ¶¶ 91, 117. Under Nevada law, any action under the False Claims Act:

> may not be commenced more than 3 years after the date of discovery of the fraudulent activity by the attorney general or more than 5 years after the fraudulent activity occurred, whichever is earlier. Within those limits, an action may be based on fraudulent activity that occurred before October 1, 1999.

N.R.S. § 357.170(1).

Under the plain language of this provision, actions based on fraudulent activity that occurred more than 5 years before the filing of the complaint in this proceeding are time barred. Courts that

RIS PICKERING & PETERSON
ATTORNEYS AT LAW
O NEIL ROAD, SUITE 555
PENO, NEVADA 89511
775/829-6000
FAX 775/829-6001

have considered the interaction between statutes of limitations and the timing of alleged fraudulent claims have determined that causes of action based on allegedly fraudulent activity occurring before the limitations period specified in the false claims act are time barred.[17] *See, e.g., United States ex rel. Fisher v. Network Software Assoc., Inc.*, 180 F. Supp. 2d 192 (D.C. 2002) (barring all counts based on actions occurring more than six years before the complaint was filed); *United States v. Buckley*, No. 00-11632, 2005 WL 164287 (D. Mass. Jan. 25, 2005) (government admitted that since the complaint was filed on August 14, 2000, it could not recover for misconduct occurring before August 14, 1994); *Moore v. Navarro*, No. C 00-03213, 2004 WL 783104 (N.D. Cal. Mar. 31, 2004) (plaintiff's allegations that defendant presented its allegedly false claims in 1993, more than six years before the action was filed, were time barred). And the law is clear that a false claim will not be actionable until presentation of the claim. *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996) (explaining that the False Claims Act offense is the knowing presentation of a fraudulent claim). Accordingly, Plaintiffs' allegations based on allegedly fraudulent conduct that occurred prior to April 19, 2000, five years before the Complaint was filed, must be dismissed.

[17] No court has issued an opinion considering the applicability of the limitations period set forth in section 357.170(1) of the Nevada False Claims Act. However, the federal False Claims Act, on which the Nevada statute was modeled, includes an analogous limitations provision. *See* Minutes of the Assembly Committee on Government Affairs, Seventieth Session, May 5, 1999 (in discussing proposed Senate Bill 418, Tim Terry, Senior Deputy Attorney General, Medicaid Fraud Control Unit, explains that the bill was modeled after the federal False Claims Act.) Section 3730(b) of the federal False Claims Act provides that "a civil action under section 3730 may not be brought (1) more than 6 years after the date on which the violation of section 3729 is committed, or (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed, whichever occurs last." 31 U.S.C. § 3730(b).

S PICKERING & PETERSON
ATTORNEYS AT LAW
NEIL ROAD, SUITE 556
ENO, NEVADA 89511
775/829-6000
AX 775/829-6001

IV. CONCLUSION

For the reasons set forth above, the Court should grant the Motion to Dismiss Plaintiffs' Amended Complaint by Defendant Merck & Co., Inc.

Respectfully submitted,

William E. Peterson, #1528
MORRIS, PICKERING & PETERSON
6100 Neil Road, Suite 555
Reno, NV 89511
Telephone: (775) 829-6000
Facsimile: (775) 829-6001

Michael J. Holston (admitted *pro hac vice)*
Lisa C. Dykstra (admitted *pro hac vice)*
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921
Telephone: (215) 963-5000
Facsimile: (215) 963-5001

Attorneys for Defendant
Merck & Co., Inc.

Dated: January 20, 2006

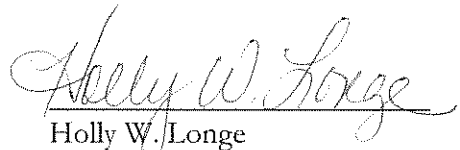
CERTIFICATE OF SERVICE

I, Holly W. Longe, hereby certify that a true and correct copy of Defendant's Memorandum of Points and Authorities In Support Of Defendant's Motion To Dismiss Plaintiffs' Amended Complaint was served on January 20, 2006 upon the following by using the ECF system and that the following is an ECF user:

L. Timothy Terry
Chief Deputy Attorney General
Office of Attorney General
100 North Carson Street
Carson City, Nevada 89701-4717
ATTORNEY FOR STATE OF NEVADA

In addition, I certify that a true and correct copy of the Motion and Memorandum of Points and Authorities was deposited with an overnight delivery service for overnight delivery to:

Mark A. Winter
801 N. Division Street
Carson City, Nevada 89703
ATTORNEY FOR RELATOR



Holly W. Longe
MORRIS, PICKERING & PETERSON
6100 Neil Road, Suite 555
Reno, Nevada 89511
Telephone: (775) 829-6000

EXHIBIT A

In the Senate of the United States,

December 21, 2005.

Resolved, That the Senate agree to the amendment of the House of Representatives to the bill (S. 1932) entitled "An Act to provide for reconciliation pursuant to section 202(a) of the concurrent resolution on the budget for fiscal year 2006 (H. Con. Res. 95)." with the following

SENATE AMENDMENT TO HOUSE AMENDMENT:

In lieu of the matter proposed to be inserted by the House amendment to the text of the bill, insert:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Deficit Reduction Act of 2005".

SEC. 2. TABLE OF TITLES.

The table of titles is as follows:

1934 of the Social Security Act (42 U.S.C. 1395eee; 1396u–4).

TITLE VI—MEDICAID AND SCHIP

Subtitle A—Medicaid

CHAPTER 1—PAYMENT FOR PRESCRIPTION DRUGS

SEC. 6001. FEDERAL UPPER PAYMENT LIMIT FOR MULTIPLE SOURCE DRUGS AND OTHER DRUG PAYMENT PROVISIONS.

(a) MODIFICATION OF FEDERAL UPPER PAYMENT LIMIT FOR MULTIPLE SOURCE DRUGS; DEFINITION OF MULTIPLE SOURCE DRUGS.—Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is amended—

(1) in subsection (e)(4)—

(A) by striking "The Secretary" and inserting "Subject to paragraph (5), the Secretary"; and

(B) by inserting "(or, effective January 1, 2007, two or more)" after "three or more";

(2) by adding at the end of subsection (e) the following new paragraph:

"(5) USE OF AMP IN UPPER PAYMENT LIMITS.—Effective January 1, 2007, in applying the Federal upper reimbursement limit under paragraph (4) and section 447.332(b) of title 42 of the Code of Federal

requirements or manner as the Inspector General determines to be appropriate.

(B) DEADLINE FOR PROMULGATION.—Not later than July 1, 2007, the Secretary of Health and Human Services shall promulgate a regulation that clarifies the requirements for, and manner in which, average manufacturer prices are determined under section 1927 of the Social Security Act, taking into consideration the recommendations submitted to the Secretary in accordance with subparagraph (A)(ii).

(d) EXCLUSION OF SALES AT A NOMINAL PRICE FROM DETERMINATION OF BEST PRICE.—

(1) MANUFACTURER REPORTING OF SALES.—Subsection (b)(3)(A)(iii) of such section is amended by inserting before the period at the end the following: ", and, for calendar quarters beginning on or after January 1, 2007 and only with respect to the information described in subclause (III), for covered outpatient drugs".

(2) LIMITATION ON SALES AT A NOMINAL PRICE.—Subsection (c)(1) of such section is amended by adding at the end the following new subparagraph:

"(D) LIMITATION ON SALES AT A NOMINAL PRICE.—

"(i) IN GENERAL.—For purposes of subparagraph (C)(ii)(III) and subsection (b)(3)(A)(iii)(III), only sales by a manufacturer of covered outpatient drugs at nominal prices to the following shall be considered to be sales at a nominal price or merely nominal in amount:

"(I) A covered entity described in section 340B(a)(4) of the Public Health Service Act.

"(II) An intermediate care facility for the mentally retarded.

"(III) A State-owned or operated nursing facility.

"(IV) Any other facility or entity that the Secretary determines is a safety net provider to which sales of such drugs at a nominal price would be appropriate based on the factors described in clause (ii).

"(ii) FACTORS.—The factors described in this clause with respect to a facility or entity are the following:

"(I) The type of facility or entity.

"(II) The services provided by the facility or entity.

"(III) The patient population served by the facility or entity.

"(IV) The number of other facilities or entities eligible to purchase at nominal prices in the same service area.

"(iii) NONAPPLICATION.—Clause (i) shall not apply with respect to sales by a manufacturer at a nominal price of covered outpatient drugs pursuant to a master agreement under section 8126 of title 38, United States Code.".

(e) RETAIL SURVEY PRICES; STATE PAYMENT AND UTILIZATION RATES; AND PERFORMANCE RANKINGS.—Such section is further amended by inserting after subsection (e) the following new subsection:

"(f) SURVEY OF RETAIL PRICES; STATE PAYMENT AND UTILIZATION RATES; AND PERFORMANCE RANKINGS.—

"(1) SURVEY OF RETAIL PRICES.—

"(A) USE OF VENDOR.—The Secretary may contract services for—

"(i) the determination on a monthly basis of retail survey prices for covered out-

"(C) utilization rates for noninnovator multiple source drugs under such plan.

"(3) ANNUAL STATE PERFORMANCE RANKINGS.—

"(A) COMPARATIVE ANALYSIS.—The Secretary annually shall compare, for the 50 most widely prescribed drugs identified by the Secretary, the national retail sales price data (collected under paragraph (1)) for such drugs with data on prices under this title for each such drug for each State.

"(B) AVAILABILITY OF INFORMATION.—The Secretary shall submit to Congress and the States full information regarding the annual rankings made under subparagraph (A).

"(4) APPROPRIATION.—Out of any funds in the Treasury not otherwise appropriated, there is appropriated to the Secretary of Health and Human Services $5,000,000 for each of fiscal years 2006 through 2010 to carry out this subsection.".

(f) MISCELLANEOUS AMENDMENTS.—

(1) IN GENERAL.—Sections 1927(g)(1)(B)(i)(II) and 1861(t)(2)(B)(ii)(I) of such Act are each amended by inserting "(or its successor publications)" after "United States Pharmacopoeia-Drug Information".

(2) PAPERWORK REDUCTION.—The last sentence of section 1927(g)(2)(A)(ii) of such Act (42 U.S.C. 1396r–8(g)(2)(A)(ii)) is amended by inserting before the period at the end the following: ", or to require verification of the offer to provide consultation or a refusal of such offer".

(3) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the date of the enactment of this Act.

(g) EFFECTIVE DATE.—Except as otherwise provided, the amendments made by this section shall take effect on January 1, 2007, without regard to whether or not final regulations to carry out such amendments have been promulgated by such date.

SEC. 6002. COLLECTION AND SUBMISSION OF UTILIZATION DATA FOR CERTAIN PHYSICIAN ADMINISTERED DRUGS.

(a) IN GENERAL.—Section 1927(a) of the Social Security Act (42 U.S.C. 1396r–8(a)) is amended by adding at the end the following new paragraph:

"(7) REQUIREMENT FOR SUBMISSION OF UTILIZATION DATA FOR CERTAIN PHYSICIAN ADMINISTERED DRUGS.—

"(A) SINGLE SOURCE DRUGS.—In order for payment to be available under section 1903(a)

EXHIBIT B

109TH CONGRESS, 1st Session | HOUSE OF REPRESENTATIVES | REPORT 109–362

DEFICIT REDUCTION ACT OF 2005

DECEMBER 19 (legislative day, DECEMBER 18), 2005.—Ordered to be printed

Mr. NUSSLE, from the committee of conference, submitted the following

CONFERENCE REPORT

[To accompany S. 1932]

The committee of conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S. 1932), to provide for reconciliation pursuant to section 202(a) of the concurrent resolution on the budget for fiscal year 2006 (H. Con. Res. 95), having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its disagreement to the amendment of the House and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the House amendment, insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Deficit Reduction Act of 2005".

SEC. 2. TABLE OF TITLES.

The table of titles is as follows:

Congress any recommendations for changes as determined to be appropriate.

The agreement also requires the Secretary of HHS to promulgate a regulation clarifying the requirements for and the manner in which AMPs are to be determined, taking into consideration the recommendations of the Inspector General.

d. Exclusion of sales at a nominal price from determination of best price

Current Law

In addition to the AMP, pharmaceutical manufacturers are required to report to the Secretary of HHS the "best price" at which the manufacturer sells each of its drug products to certain purchasers for the purpose of calculating the rebate amounts. Prices that are nominal in amount are excluded from best price reporting. Nominal prices are defined by CMS to be those that are below 10 percent of the average manufacturer's price.

Senate Bill

The Senate bill would exclude, for the purposes of computing the AMP, sales by a manufacturer of covered outpatient drugs that are single source, innovator multiple source drugs, or are authorized generics that are made available at nominal prices to the following listed entities: (a) entities eligible for discounted prescription drug prices under Section 340(B) of the Public Health Service Act; (b) intermediate care facilities for the mentally retarded, (c) stateowned or operated nursing facilities, (d) any other facility or entity that the Secretary determines is a safety net provider to which sales of such drugs at nominal prices would be appropriate based on the type of facility, the services it provides, the patients served and the number of other such facilities eligible for nominal pricing in the area. The nominal price limitations would not apply to nominal drug purchases pursuant to a master agreement for procurement of drugs on the Federal Supply Schedule. In addition, the bill would modify manufacturers' price reporting requirements to include, for calendar quarters beginning on or after January 1, 2006 information on sales made at a nominal price.

House Bill

The House bill would exclude, for the purpose of computing the RAMP, sales as the Secretary identifies, that are nominal in amount. In addition, the bill would modify manufacturers' price reporting requirements to include, for calendar quarters beginning on or after July 1, 2006 information on sales made at a nominal price.

Conference Agreement

The conference agreement modifies the manufacturer price reporting requirements so that for calendar quarters beginning on or after January 1, 2007, manufacturers would be required to report information on sales of Medicaid covered drugs that are made at a nominal price.

In addition, the agreement defines the sales are to be considered nominal for the purpose of reporting nominal price sales and

for computing and reporting the best price. (The agreement does not amend the AMP vis-a-vis nominal prices.) Nominal sales are those made by a manufacturer of covered drugs at nominal prices to (a) entities eligible for discounted prescription drug prices under Section 340(B) of the Public Health Service Act; (b) intermediate care facilities for the mentally retarded, (c) state-owned or operated nursing facilities, (d) any other facility or entity that the Secretary determines is a safety net provider to which sales of such drugs at nominal prices would be appropriate based on the type of facility, the services it provides, the patients served and the number of other such facilities eligible for nominal pricing in the area. The nominal price limitations do not apply to nominal drug purchases pursuant to a master agreement for procurement of drugs on the Federal Supply Schedule.

e. Retail survey prices; state payment and utilization rates; and performance rankings

Current Law

No provision.

Senate Bill

No provision.

House Bill

The House bill would allow the Secretary to contract with a vendor to obtain retail survey prices for Medicaid covered outpatient drugs that represent a nationwide average of pharmacy sales costs for such drugs, net of all discounts and rebates. Such a contract would be awarded for a term of 2 years.

The Secretary would be required to competitively bid for an outside vendor with a demonstrated history in surveying and determining on a representative nationwide basis, retail prices for ingredient costs of prescription drugs; working with retail pharmacies, commercial payers, and states in obtaining and disseminating price information; and collecting and reporting price information on at least a monthly basis. The contract would include the terms and conditions specified by the Secretary and would include a requirement that the vendor monitor the marketplace and report to the Secretary each time there is a new covered outpatient drug available nationwide; update the Secretary no less often than monthly on the retail survey prices for multiple source drugs and on the computed upper payment limit for those drugs; to independently confirm retail survey prices. Information on the retail survey prices obtained through this process, including information on single source drugs would be required to be provided to states on an ongoing and timely basis.

Conference Agreement

The conference agreement includes a provision similar to the House provision. The agreement allows the Secretary to contract for services for the determination of retail survey prices for covered outpatient drugs that represent a nationwide average of consumer purchase prices for such drugs. The conference agreement adds a

EXHIBIT C

UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO: State of Montana v. Abbott Labs., Inc., et al., 02-CV-12084-PBS State of Nevada v. American Home Products Corp., et al., 02-CV-12086-PBS County of Suffolk v. Abbott Laboratories, Inc., et al., 01-CV-12257-PBS	

BRIEF OF THE UNITED STATES AS AMICUS CURIAE

reasonable measures to ascertain the legal liability of third parties" and to pursue reimbursement.[7] Finally, to the extent that states identify and prosecute a manufacturer that violates its best price reporting obligations as alleged in this case, such actions would presumably advance, not hinder, the congressional objectives of reducing Medicaid drug costs and ensuring that state Medicaid programs are given the full benefit obtained by other high volume purchasers of prescription drugs. See PhRMA v. Thompson, 235 F.3d 219, 225 (D.C. Cir. 2001) (noting that Congress imposed the rebate requirement to reduce the costs of Medicaid and to prevent pharmaceutical manufacturers from charging the government and taxpayers above-market prices for Medicaid drugs). Given that Montana and Nevada are, in this instance, "pursuing common purposes" with the federal government through their best price claims, see Walsh, 123 S.Ct. at 1869, Dublino, 413 U.S. at 421, the case for preemption is particularly weak.

A. Allowing Montana And Nevada To Pursue State Law Best Price Claims Does Not Create A "Phyisical Impossibility" For The Defendants

As discussed above, federal law may impliedly preempt state law where "compliance with both federal and state regulations is a physical impossibility." Florida Lime, 373 U.S. at 142-43. An example of such a "physical impossibility" arose in Boyle v. United Technologies Corp., 487 U.S. 500 (1988), where the state-imposed duty of care asserted by the private plaintiffs (to equip helicopters with an escape hatch door that opened inwards) was precisely

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[7] The statutory charge of MFCUs is broader than suggested by the Defendants. Pursuant to 42 U.S.C. §1396b(q)(3), MFCUs are charged with investigating and prosecuting "violations of all applicable State laws regarding any and all aspects of fraud in connection with . . . any aspect of the provision of medical assistance and the activities of providers of such assistance under the State plan under this subchapter[.]" Given the direct impact that best price fraud has on a state's Medicaid funding, and consequently its ability to provide assistance to beneficiaries, it is within their statutory authority to investigate and prosecute Medicaid best price violations as alleged in this case.

contrary to the duty imposed by the federal government contract (to manufacture and deliver helicopters with an escape-hatch mechanism that opened outwards). 487 U.S. at 509.

At least based on the present record, the Defendants have not identified any state-imposed obligation that directly conflicts with their best price obligations as defined in the rebate statute or agreement. Neither Montana nor Nevada is asking, for example, the Defendants to include nominal prices, or exclude cash discounts, in their best price calculations in conflict with 42 U.S.C. §1396r-8(c)(1)(C)(ii)(I) & (II). Instead, these states' best price allegations, at least as currently pled, merely require the Defendants to properly account for all relevant discounts (i.e., free goods, volume discounts, educational grants, discounts to HMO's) that may have effectively lowered their best prices. Requiring the Defendants to comply with their already existing statutory and rebate agreement obligations hardly creates an actual conflict, much less a "physical impossibility," that would warrant preemption. Cf. Boyle, 487 U.S. 508-509 (observing how private plaintiffs in Miree v. DeKalb County, 433 U.S. 25 (1977), were "not seeking to impose upon the person contracting with the Government a duty contrary to the duty imposed by the Government contract . . . [but] [r]ather, it was the contractual duty *itself* that the private plaintiff (as third-party beneficiary) sought to enforce.") (emphasis in original).[8]

Thus, because Montana and Nevada's state law best price allegations do not require the Defendants to do anything different from (much less contrary to) their obligations under the

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[8] In Miree, survivors of deceased aircraft passengers filed state law claims against the county where the aircraft crashed. 433 U.S. at 25-6. In addition to negligence and nuisance claims, the private plaintiffs alleged that the county had breached its grant contract with the Federal Aviation Administration by failing to restrict the use of land adjacent to the airport. Id. at 25. The plaintiffs alleged that the county breached the contract by operating a garbage dump near the airport and that the crash was caused by the ingestion of birds swarming from the dump into the aircraft's jet engine shortly after takeoff. Id.

impact an applicant's behavior to the detriment of the FDA approval process. 531 U.S. 350-52. In this case, while referring to the "insuperable compliance obstacles" and "dramatically increas[ed] burdens" that would result from state regulation in this arena, see Consolidated Memorandum in Support of the Defendants' Motion To Dismiss the State of Montana's Second Amended Complaint and the State of Nevada's Amended Complaint, at 9, the only concrete example articulated is having to file a state specific quarterly report instead of a single uniform report to CMS. Id. at 9-10. This is hardly enough, if relevant at all, given that the net result is to "produce savings for the Medicaid program." Walsh, 123 S.Ct. at 1870. Manufacturers participating in the rebate program already contend with some state rebate variation with regard to prior authorization programs, formularies, or supplemental rebate agreements. Against this backdrop, we are not persuaded that requiring manufacturers to report state-specific best prices to CMS– after a court has found that manufacturer to have fraudulently miscalculated or misreported its best price– would be so burdensome as to fatally disrupt the rebate program.

Third, the Defendants overstate the likelihood of a "patchwork of liability." As this Court previously noted, "state courts frequently construe terms in federal laws in order to adjudicate causes of action based in state law" and the Supreme Court is the "ultimate decision-maker on federal questions arising out of state court." Abbott, 266 F.Supp.2d at 253. To the extent that a state sues a drug manufacturer that failed to calculate its best price obligations in accordance with the rebate agreement or CMS guidance-- but does not seek to impose any additional or contrary obligations– the state is merely enforcing the existing rebate program responsibilities and does not inject any more variation than if the Department of Justice brought suit. Moreover, to the extent a state alleges a best price violation (like Nevada or Montana)

EXHIBIT D

U.S. Department of Justice

United States Attorney

Eastern District of Pennsylvania

Viveca D. Parker
Direct Dial: (215) 861-8443
Facsimile: (215) 861- 8349
E-mail Address: viveca.parker@usdoj.gov

615 Chestnut Street
Suite 1250
Philadelphia, Pennsylvania 19106-4476
(215) 861-8200

October 31, 2005

Honorable Howard D. McKibben
Bruce R. Thompson U.S. Courthouse & Federal Bldg.
400 S. Virginia Street, suite 804
Reno, NV 89501

RE: State of Nevada ex rel. Dean Steinke v. Merck & Co., Inc., CV-N-05-0322-HDM-RAM

Dear Judge McKibben:

The issue of preemption was raised in the defendant's motion to dismiss filed in the above referenced matter. Should the Court reach that issue in ruling on the motion, the Department of Justice submits that the holding in In re Pharmaceutical Industry Average Wholesale Price Litigation, 321 F. Supp.2d 187 (D. Mass. 2004) is correct with respect to that issue.

Very truly yours,

PATRICK L. MEEHAN
United States Attorney

Viveca D. Parker
Assistant United States Attorney

cc William E. Peterson
Michael J. Holston
Lisa C. Dykstra
Brian Sandoval
L. Tim Terry
Steven H. Cohen
Mark A. Kleiman
Mark A. Winter

EXHIBIT E

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

SEP - 3 2005

W.J. "Billy" Tauzin
President and Chief Executive Officer
Pharmaceutical Research and Manufacturers of America
1100 15th Street, N.W.
Washington, D.C. 20005

Dear Mr. Tauzin:

I understand that the Pharmaceutical Research and Manufacturers of America is interested in helping its member companies ensure that donations of pharmaceuticals reach those who need help dealing with the aftermath of Hurricane Katrina. We appreciate your assistance during this national emergency. You have asked a question of the Centers for Medicare & Medicaid Services regarding the effect that any such donations might have on the obligations of pharmaceutical manufacturers to pay rebates under Section 1927 of the Social Security Act and the effect of any such donations on the average sales price of drugs and biologicals covered under Part B of the Medicare program.

In particular, you have asked whether manufacturers would need to count the free prescription drugs given to the Hurricane Katrina relief effort as a discount to each of the doctors, hospitals, clinics, pharmacies, and wholesalers to which they are being shipped for best price purposes. Our Medicaid rebate program guidance cautions manufacturers that "free goods" typically must be included in the Medicaid "best price" so that all states' Medicaid programs get the same benefit. You have noted that your member companies are setting up systems for routing orders from doctors and others who have a critical shortage of medicines, and arranging for companies to ship free drugs so that they can be provided to patients at no charge who have been displaced by the disaster and need help to get their medications. Significantly, however, as you have described the program, the provision of those drugs at no charge is not contingent on any purchase requirement.

Under the plain terms of the Medicaid statute, free goods "that are contingent on any purchase requirement" must be included in the calculation of the best price. Here, by contrast, the provision of the free drugs is not contingent on any purchase requirement. Therefore, the free drugs given to the Hurricane Katrina relief effort are not a discount, for best price purposes, to each of the recipients to whom they are shipped. Orders taken in this way that result in shipments of goods can be distinguished from other shipments to the same entity. For example, Hurricane Katrina relief shipments could be considered a single "account" with multiple different shipping addresses and there would be no ambiguity for Medicaid compliance purposes. Donations made to the Hurricane Katrina relief effort, whether through a charity, an order routing center, or simply the bulk

transfer of product designated for use only in providing relief and not for resale by the recipient, are not included in the best price or Average Manufacturer Price (AMP) computations.

In addition, the donation of the drugs at no charge will not affect the Average Sales Price (ASP) of the drugs for purposes of Part B of the Medicare program. Although the definition of ASP includes "sales to all purchasers in the United States", sales that are exempted from the best price calculation are exempted from the ASP calculation. As explained above, free drugs given to the Hurricane Katrina relief effort are not included in the best price calculations. Therefore, those same donations will not affect the ASP of the drug that is donated. It is also quite likely that we would not view donation of these drugs as "sales" in the first place; hence, their donation would not be a "sale to a purchaser in the United States" in any event.

Hurricane Katrina is one of the worst natural disasters in our nation's history, and all of us are working together to help its many victims at this time of urgent need. We appreciate the compassionate and timely response of your members to this crisis.

Sincerely,

Mark B. McClellan, M.D., Ph.D