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DISTRICT OF NEVADA

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| STATE OF NEVADA<br>EX REL. H. DEAN STEINKE,<br><br>Plaintiffs,<br><br>vs.<br><br>MERCK & CO., INC.,<br><br>Defendant. | Case No. 3:05 cv 322 |

**STATE OF NEVADA'S OPPOSITION TO MERCK'S MOTION TO DISMISS**

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## INTRODUCTION AND SUMMARY OF ARGUMENT

"In response to increasing Medicaid expenditures for prescription drugs," Congress enacted the Medicaid Rebate Act, 42 U.S.C. §1396r-8, in 1990 "as a cost-saving measure." *Pharmaceutical Research and Manufacturers of America ("PhRMA") v. Walsh*, 538 U.S. 644, 649 (2003). The Rebate Act "requires drug companies to pay rebates to States on their Medicaid purchases." *Id.* This case involves Merck's violations of the Rebate Act, specifically, Merck's false "Best Price" reports to shortchange its rebates owed to Nevada and all other states.

The Rebate Act sets rebates for drugs as either: (1) the difference between the manufacturer's average price and the Best Price given to other market purchasers, or (2) 15.1% of the Average Manufacturer's Price ("AMP"), whichever is greater. 42 U.S.C. §1396r-8(c)(1), (2). Merck's rebates here were based on the Best Price option. Best Price excludes "prices merely nominal in amount," but must include discounts contingent on purchase requirements. 42 U.S.C. §1396r-8(c)(1)(C)(ii).

Merck's Best Price reports were false because Merck excluded the following discounts to hospitals, which should have been included, to avoid paying a higher rebate: (1) discounts of more than 90% off of AMP, contingent on purchase requirements; (2) discounts in the form of free goods, contingent on purchase requirements; and (3) discounts of more than 30% off of AMP, contingent on purchase requirements. *See* Nevada's First Amended Complaint ("FAC"), Counts II, IV ¶¶85-96, 111-122.[1]

Merck's discounts violated both the letter and the spirit of the Rebate Act and the Rebate Agreement (the contract pharmaceutical manufacturers must enter into to ensure

[1] Nevada amended its complaint in response to Merck's initial motion to dismiss, and withdrew Counts I and III. The court dismissed Merck's motion as moot and scheduled briefing for the pending motion pertaining to Nevada's FAC. Relators join Nevada in this opposition.

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Medicaid reimbursement for beneficiaries' purchase of their drugs).[2] The discounts undermined the Act's purpose to reduce prescription drug costs because Medicaid did not get the benefit of the discounts that the hospitals did. Worse, the discounts also increased drug costs because the discounts provided Merck with a portal—hospitals eager to obtain steep discounts—to increase its retail market share spilled-over from discharge prescriptions of these drugs that were more expensive than Merck's competitors.

Merck concedes that the purpose of the Rebate Act is to reduce Medicaid's prescription drug costs, but complains that the purpose should not "trump the plain, unambiguous text of the Rebate Statute and Rebate Agreement concerning the meaning of 'nominal price'..." Memorandum of Points and Authorities in Support of Defendant's Motion to Dismiss Plaintiffs' Amended Complaint ("Merck's Memo") at 15 n.7. However, the plain, unambiguous text of a statute can only be interpreted to further Congress' purpose. Merck's interpretation trumps that purpose.

According to Merck, its 90%-plus discount, which it named a "nominal price *discount*," did not have to be disclosed because the Rebate Agreement defines nominal prices as "any price less than 10% of AMP." To Merck, this means that exclusion of *all* prices less than 10% of AMP "without limitation is entirely appropriate," even if Merck excluded discounts that increased Medicaid drugs costs. Merck's Memo at 3; Merck's Memorandum of Points and Authorities in Support of [First] Motion to Dismiss ("Merck's Initial Brief") at 2; *see also* Rebate Agreement at I(s), attached hereto as Exhibit A.

However, Merck did not sell its drugs at a "merely nominal" price. Merck discounted

[2] Medicaid is the largest single purchaser of prescription drugs. "Medicaid's purchases constitute over 10 percent of the outpatient prescription drug market, whereas the largest private institutional purchasers together may represent a smaller portion of the market for outpatient drugs." *How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry*, Congressional Budget Office Paper (January 1996), Chapter II, the Medicaid Rebate Program, at 12-13; this document can be found at: http://www.cbo.gov/ftpdocs/47xx/doc4750/1996Doc20.pdf.

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the cost only to hospitals that met its purchase requirements so that the discounted price fell below the nominal price threshold amount set by the Rebate Agreement to evade the purpose of both the Rebate Act and Agreement. The same provision that excludes "merely nominal" prices in the Act required Merck to include discounts tied to purchases; and, all of Merck's discounts were tied to purchase requirements. Neither the Rebate Act nor the Rebate Agreement can be interpreted so broadly as to undermine Congress' purpose.

Whether Merck knowingly violated the Rebate Act, as with all issues of scienter, cannot be decided as a matter of law. Nonetheless, contrary to Merck's contention, Nevada has more than sufficiently alleged that Merck knew or should have known not to exclude the 90%-plus discounts.

Merck also contends that Nevada's claims are preempted by federal law. The same arguments Merck makes here were rejected in *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 321 F.Supp.2d 187, 198 (D. Mass. 2004) ("*Pharm IV*") where Nevada brought state-law fraud claims against a number of pharmaceutical companies for false reporting under the Rebate Act. *Id.* at 198. "Medicaid is the paradigmatic program of cooperative federalism, and the federal and state governments share the common goal of reducing drug costs." *Id.* Nevada, like all other States, has "historically played a significant role in investigating and prosecuting Medicaid fraud," making the presumption against preempting state law particularly difficult to overcome. *Id.* at 198-99. Just as the manufacturers could not overcome that presumption in *Pharm IV*, Merck cannot do so here. *Pharm IV* also rejected Merck's argument that *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), a decision involving the Food and Drug Administration "fraud on the [federal] agency" claims, applies to Nevada's state-law fraud claims based upon violations of the Rebate Act.

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Congress has shown its unconditional support for States using their own False Claims Act to prosecute Medicaid fraud. Congress recently passed Medicaid savings initiatives giving States incentives to more aggressively fight Medicaid fraud by passing their own False Claims Acts with qui tam provisions, as Nevada has already done, and is using here. The sponsor, Senator Chuck Grassley, Chairman of the Senate Committee on Finance, proclaimed that the new law is "designed to address the fraud waste and abuse of the Medicaid program." Press Release from Senator Chuck Grassley, Chairman of the U.S. Senate Committee on Finance, February 2, 2006, attached hereto as Exhibit B; the amendments, part of the Deficit Reduction Act of 2005, S. 1932, 109th Cong., §6031, are attached hereto as Exhibit C.

Merck next complains that Nevada's Count IV, pertaining to Merck's free drug and non-nominal price discounts, is not sufficiently or specifically pled as required by Fed. Rules Civ. Proc. 12(b)(6) and 9(b). Nevada has sufficiently and specifically put Merck on notice as to the time, place and manner of its fraudulent conduct.

Finally, contrary to Merck's last contention, the statute of limitations cuts off only damages and not evidence.

Merck's Motion to Dismiss should be denied in its entirety.

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## ARGUMENT

### I. MERCK'S BEST PRICE REPORTS THAT EXCLUDED SO-CALLED NOMINAL PRICE DISCOUNTS CONTINGENT ON PURCHASE REQUIREMENTS WERE FALSE.

According to Merck, its Best Price reports were not false because they were "consistent" with the Rebate Act and Agreement, implicitly conceding that if the reports were not consistent, they were false.[3] Here, "the question of 'falsity' itself is determined by whether [Merck's] representations were accurate in light of applicable law." *United States ex rel. Oliver v. The Parsons Co.*, 195 F.3d 457, 463 (9th Cir. 1999). Merck's exclusion of its so-called "nominal price discount" is inconsistent with the plain meaning and intent of the Rebate Act, as well as the Rebate Agreement, which must be interpreted "consistent with the intent" of the Rebate Act. Rebate Agreement at II(i). Thus, Merck's Best Price reports were false.

#### A. The Plain Meaning of "Best Price" Includes Merck's Discounts Contingent on Purchase Requirements.

The Rebate Act delineates that discounts are to be included in, and merely nominal prices are to be excluded from, Best Price. 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);
> ... *and*
> (III) shall not take into account prices that are merely nominal in amount. 42 U.S.C § 1396r-8(c)(1)(C)(ii) (emphasis added).

Best Price includes discounts, i.e., a reduction in the cost, where that reduction is contingent upon a purchase requirement. The discount may be for paying by cash, or for purchasing a set volume or amount. The discount may come in the form of free goods or in a rebate after purchase.

From 1998 through the present, Merck excluded from Best Price what it admits were

[3] Merck agrees that interpretations of the Rebate Act and Agreement must be "consistent." *See, e.g.*, Merck's Memo at 3, 9, 12.

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discounts, and so-called "nominal price discounts," all of which were tied to purchase requirements.

Merck devised two "nominal price discount" programs, "SAVE" and "VIP," using hospitals as portals to increase its retail market share through post-discharge prescriptions by increasing the in-hospital market share of its drugs. FAC at ¶2, 3, 32. SAVE (Simvastatin Acute-care Value Enhancement) promotes Zocor prescriptions, a cholesterol-lowering drug known as an HMG. *Id.* at ¶32, 33. To maximize the retail spill-over, Merck targeted hospitals with the highest CHD (coronary heart disease) discharges. *See id.* at ¶32, 35. One such hospital, targeted in the top tier, is St. Mary's Hospital in Reno, Nevada. *See id.* at ¶11. SAVE discounted the price of Zocor to hospitals to nearly free: 92% of AMP, or 8 cents on the dollar. *Id.* at ¶33. To get this discount, Merck required the hospital to purchase enough Zocor to maintain 70% of the hospital's HMG market share for Zocor and Mevacor (another of Merck's HMGs), or increase their quarterly purchases by 10 points over the previous quarter, or make Zocor the exclusive HMG on the hospital's formulary.[4] *Id.*

Merck's other marketing program, VIP (Value Incentive Program) promoted Vioxx, a NSAID[5] used to treat pain and inflammation. *Id.* at ¶48. Again, to maximize the greatest return in the retail spill-over market, Merck targeted key hospital customers based upon their utilization of NSAIDs. VIP also offered a near-free "discount" of 92% of AMP. *Id.* To get this discount, Merck required that the hospital had to purchase enough Vioxx to make this drug at least an 80% market share of the hospital's purchases of arthritis and analgesic agents. *Id.*

Both Zocor and Vioxx are prescribed to treat chronic problems, and each is a considerably more expensive drug than its competitors. *Id.* at ¶¶2, 5, 31, 66.

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[4] Another component of SAVE allowed hospitals that could maintain only a 55% HMG market share to get a 30% discount off of the catalog price. This is known as the "non-nominal price discount," discussed *infra* at IV C - D.

[5] Non-steroidal anti-inflammatory drug.

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Merck claims that because the discounts resulted in a cost to the hospitals of less than 10% of AMP, it rightfully excluded them from Best Price. But Best Price only excludes prices that are "merely nominal" in amount. Congress modified the word nominal by the term "merely." "Merely" means "without admixture or qualification" or "purely without any other quality, reason, purpose, view, etc., only [what is referred to] and nothing more." *Oxford English Dict.*, Oxford Univ. Press (2d ed. 1989) 629. There was no "merely nominal" price given to hospitals. The hospitals got a 90%-plus discount only if the hospital met Merck's purchasing requirements. Merck's discounts came with a qualification, i.e., the hospitals had to purchase Zocor and Vioxx in set amounts in order to get the discounts, or make Zocor exclusive on the formulary. The discounts had a reason and purpose: to get Zocor and Vioxx into the hospitals in significant amounts sufficient to capture the retail spill-over market through discharge prescriptions. Merck was not entitled to exclude all "nominal" prices because to do so renders the qualifier "merely" as surplusage. *Bair v. Pacific Northwest Sugar Co. LLC*, 85 Fed. Appx. 555, 558 (9th Cir. 2004) ("We must give effect to every word in the statute, if possible, so as not to treat words as surplusage").

In this way, the Rebate Act and Agreement are consistent. The Rebate Agreement sets the amount of a nominal price: less than 10% of AMP. The Rebate Act sets the terms: nominally priced sales without qualifications can be excluded, but not discounts, regardless of price, that are tied to purchase requirements. The conjunction "and" between the discounts to be included and the merely nominal prices to be excluded also cannot be rendered as surplusage. This is accomplished by reading Best Price the way Congress intended, by requiring that Best Price include discounts *and* exclude merely nominal prices that are not discounts.

As opposed to Merck's construction, which trumps Congress' intent, reading Best Price to include discounts contingent on purchase requirements fulfills that intent—even if those

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discounts fall below the nominal price amount.

**B. The Rebate Act, As Well As The Rebate Agreement, Must Be Interpreted In Light Of Congressional Intent.**

The words of a remedial statute, such as the Rebate Act and the Rebate Agreement which implements it, have a "meaning imparted to them by the mischief to be remedied," and those words should not be interpreted to cause the very mischief the statute intended to end. *Duparquet Co. v Evans*, 297 U.S. 216, 221 (1936) (Cardozo, J.). The Act was intended to end the mischief of manufacturers giving hospitals substantial discounts that Medicaid was denied, and Merck should not be able to circumvent that by disguising its discounts as "merely nominal" prices—wolves in sheep's clothing.

No court has previously interpreted the inclusions or exclusions of Best Price, the Rebate Act or the Rebate Agreement. However, in interpreting this provision, the Court must follow the undisputed intent of Congress to stem the ever-increasing costs of Medicaid prescription drugs. *PhRMA v. Walsh*, 538 U.S. at 649. The Rebate Act:

> "requires drug manufacturers to offer substantial discounted prices to the Medicaid Program ... [b]ecause there is no logical reason why, in an era of severe budget constraints and social needs, the Medicaid Program should be denied access to [the] same generous discounts" hospitals and HMOs receive...
>
> This legislative history demonstrates that Congress imposed the rebate requirement for two overlapping reasons: to reduce the cost of Medicaid and to prevent pharmaceutical manufacturers from charging the government and taxpayers above-market prices for Medicaid drugs. *Pharmaceutical Research and Manufacturers of American ("PhRMA") v. Thompson*, 251 F.3d 219, 225 (D.C. Cir. 2001) (emphasis added) (citations to legislative history omitted).

Merck would trump this purpose by relying on its construction of the Rebate Agreement's definition of nominal price of "any prices less than 10% of AMP," as "*all* prices less than 10% of AMP." First, contrary to Merck's contention, "any" does not always mean "all" as a matter of law. Merck's Memo at 13. Merck's authority emphasizes that "[G]eneral words, such as the word 'any,' must be limited in their application to those objects to which the

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legislature intended to apply them... '[A]ny' means different things depending upon the setting..." *Small v. U.S.*, ___ U.S. ___, 125 S.Ct. 1752, 1754-55 (2005) (citations and internal quotations omitted).

In order for the Rebate Agreement to be consistent with the Rebate Act, as Merck agrees it must, "any" cannot be limited to "an absolutely literal meaning." *Lewis v. United States*, 523 U.S. 155, 162 (1998). As this Court has observed, "[t]he plain meaning of the statute controls, except in rare cases in which the literal application of the statutory language would compel an odd result or produce a result demonstrably at odds with legislative intent." *Morrow v. Putnam*, 142 F.Supp.2d 1271, 1272 (D. Nev. 2001) (citations omitted). Where Medicaid is denied the same discount hospitals get and Medicaid costs are increased, this is a result demonstrably at odds with the legislative intent.[6]

Although the language may be clear and unambiguous, a literal reading of the words does not end the analysis. As the D.C. Circuit concluded regarding the Rebate Act: "[A] word's 'ordinary understanding' is not always controlling. Words draw meaning from context. ... Indeed...the Supreme Court [has] emphasized that statutory terms can have a narrower meaning in context than the same words have in common usage." *PhRMA v. Thompson*, 251 F.3d at 224. When the nominal price exception is read in context of the Best Price provision, it is far narrower than *all* prices less than 10% of AMP.

The nominal price exception's legislative history underscores this. The same legislative history *PhRMA v. Thompson* relied upon reinforces that Congress intended the States to get the same discounts drug manufacturers give hospitals and that not *all* sales of less than 10%

[6] Even Merck admits that the Court can only enforce a statute according to its terms up until "where the disposition required by the text is not absurd." Merck's Memo at 11. Whatever benefit Merck's steep discounts give hospitals that care for non-Medicaid beneficiaries (*see* Merck's Reply Memorandum in Support of its Initial Motion to Dismiss at 8-9), the benefit can not, and should not, come at the expense of higher Medicaid costs.

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of AMP were to be excluded from Best Price. *See* 251 F.3d at 225.[7]

> To ensure that Medicaid continues to receive the lowest price in the marketplace, the "Best Price" is defined as the lower of the "Best Price" in the marketplace during the calendar quarter in which the drug... . The definition of "Best Price" excludes those prices that are merely nominal in amount that manufacturers offer to special purchasers, such as the sale of birth control pills for a penny a pack to Planned Parenthood. 136 Cong. Rec. 25,145 at S12954-01, *S12962 (1990).

Contrary to Merck's contention, the Court need not decide that Congress intended the nominal price exception to only apply to non-profits, charities and certain researchers. Merck's Memo at 2, 11. The legislative history demonstrates, however, that discounts tied to purchase requirements are not what Congress intended in excluding prices merely nominal in amount from Best Price.

The only issue here is whether or not Congress intended to allow Merck to exclude its so-called nominal price discounts—discounts contingent upon purchase requirements that increased Medicaid costs. FAC at ¶¶5, 25. The legislative history underscores that the answer to that question is a resounding "no": since "[d]rug manufacturers offer, as a matter of business practice, substantial discounts on drug products to many large-volume purchasers," Medicaid was "to receive the best discounts in the market..." 136 Cong. Rec. 25,145 at S12954-01, *S12954, *S129555.

Neither the Rebate Act nor the Rebate Agreement can be interpreted to contravene Congress' purpose. As the D.C. Circuit held in *PhRMA v. Thompson*, 251 F.3d 219, such an interpretation cannot stand. At issue in PhRMA was Vermont's Pharmacy Discount Program. PhRMA, representing Merck and other drug manufacturers, argued that the program violated the provision of the Rebate Act that limited rebates to those drugs "for which payment was

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[7] Merck is well aware of this legislative history, having participated in making it. "If anything less than 'Best Price' is being offered to Medicaid, manufacturers are still providing 'second class treatment.' Both the Merck and Pfizer [alternate] plans recognize that Medicaid is entitled to this 'Best Price.'" 136 Cong. Rec. 25,145 at S12954-01, *S12961 (1990).

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made under the State [Medicaid] plan." *Id.* at 222, citing 42 U.S.C. § 1396r-8(b)(1)(A). PhRMA argued that these payments, although within the literal meaning of the word "payment," were not what Congress meant by "payment" in the Rebate Act. *Id.* at 223.

The D.C. Circuit concluded that it had to look beyond the literal meaning of word "payment" or the purpose of the Rebate Act would be undermined:

> Although…the word "payment" is broad enough to include reimbursed expenditures, consideration of the word's context—the statute's purpose and legislative history—reveals a far narrower meaning. Properly understood, "payment" here means only payments with state or federal funds appropriated for Medicaid expenditures; absent such payments, pharmaceutical rebates would not contribute to reducing the costs of the taxpayer-funded Medicaid, and the legislative history makes quite clear that Congress's purpose in requiring rebates was to do just that. *Id.* at 224-25.

Since Vermont and the Secretary's construction of the term "payment" ran afoul of that purpose, that construction was unacceptable.[8]

Congress's silence regarding the precise scope of the word "payment" did not mean that the court could not strike down Vermont and the Secretary's interpretation, as the pharmaceutical companies argued.

> [B]ecause we think it so obvious that Congress's purpose in requiring manufacturer rebates was to reduce the cost of the Medicaid program, we conclude that Congress's silence cannot provide a basis for allowing the [Secretary] to extend the rebate requirement to situations where, as here, rebates produce no Medicaid savings. *Id.* at 226.

Here, too, Congress's silence as to the precise scope of the nominal price exception does not mean that the Court should not strike down Merck's construction where it plainly produces no

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[8] The court initially analyzed whether the Secretary was entitled to deference in interpreting the term "payment," but determined that Congress had precisely addressed how "payment" should be interpreted—in a manner that doesn't undermine the purpose to reduce Medicaid costs. *PhRMA v. Thompson*, 251 F.3d at 223-24. In the same way, Congress has also shown that the nominal price exception should be interpreted to support the Rebate Act's purpose. Accordingly, the Court need not defer to the Secretary's definition of "nominal price" in the Rebate Agreement. However, since the Rebate Agreement can only be interpreted consistently with the Rebate Act, as opposed to how Merck interprets it, deference it not an issue.

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Medicaid savings. Rather, we have a more compelling situation here because Merck's construction has produced Medicaid losses.

**C. The Rebate Agreement Merely Implements the Rebate Act.**

The Rebate Agreement cannot be construed to contravene or contradict the Rebate Act. This is especially true here where to do so would mean that the Secretary authorized conduct that undermines the very Act s/he has been charged with enforcing. Since the Rebate Agreement must be interpreted to *best* effectuate Medicaid cost-savings (Rebate Agreement at IX(e)), the definition of nominal price in the Agreement can only be reasonably interpreted to be the Secretary's benchmark for what constitutes a "nominal" amount, not the types of sales that are afforded the nominal price exclusion.

The Secretary specifically left it to the manufacturers to determine what types of sales qualify for the nominal price exception. Four years after drafting the Rebate Agreement, the Secretary warned manufacturers that it was not taking on the "administrative costs and burdens ... to review each manufacturer's case of why nominal price for a drug is warranted and would offer no greater assurance of more accurately defining nominal price." 60 Fed. Reg. 48442, *48478 (September 19, 1995). This makes plain that Merck and other drug manufacturers were to police themselves to ensure their use of the nominal price exception complied with the purpose of the Rebate Act. The Rebate Agreement specifically places the same responsibility on the manufacturer: "assumptions in its calculations of AMP and Best Price [have to be] consistent with the intent of section 1927 of the Act," i.e., the Rebate Act. Rebate Agreement at II(i).

Requiring Merck to abide by the purpose of the Rebate Act is hardly a unilateral change to the Rebate Agreement, as Merck complains. Merck's Memo at 15 n.7. Merck concedes that the Rebate Agreement must express the intent of the parties. Merck's Memo at 12. And, Merck concedes that reducing Medicaid costs, especially for the States which are

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third-party beneficiaries of the Agreement, is the intent of the Act. *Massachusetts v. Mylan Labs*, 357 F.Supp.2d 314, 326 et seq. (D. Mass. 2005). Thus, Merck could only expect that the Rebate Agreement expressed that intent. Merck certainly could not unilaterally expect that its discounts which increased Medicaid costs would be covered by a contract intended to decrease them. Contract construction, as well as statutory construction, should not "be pressed to the point of disingenuous evasion." *Moore Ice Cream Co. v. Rose*, 289 U.S. 373, 379 (1933) (Cardozo, J.).

Merck claims that it was merely following the terms of the Rebate Agreement and Rebate Act. "But there is no canon against using common sense in reading a ... law, so that technical constructions do not defeat its purpose by creating exception from or loopholes in it." *Kordel v. U.S.*, 335 U.S. 345, 349 (1948). Merck knowingly circumvented Congressional intent by marketing Zocor and Vioxx via steep discounts that got below the technical 10% of AMP line, but nonetheless increased Medicaid costs.

**D. The Recent Amendments to the Nominal Price Exception Reinforce that Merck's Discounts Should Not Have Been Excluded from Best Price.**

Congress recently amended Best Price, 42 U.S.C. § 1396r-8(c)(1), to add the following:

> (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). ...

Merck contends that this amendment, which becomes effective January 1, 2007, shows that Congress intended to exclude *all* sales less than 10% from Best Price prior to the amendment.

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Merck Memo at 14. First, the amendment does not change the fact that Merck's discounts, although below 10% of AMP, are discounts tied to purchase requirements which Congress originally mandated to be included in Best Price. The discounts were never "merely nominal" sales.

Second, the amendment reinforces that Congress sets the sales or discounts to be included or excluded from Best Price. Consequently, up until January 1, 2007, manufacturers may still make "merely nominal" sales to entities—sales of drugs at a price less than 10% of AMP that are not tied to purchase requirements. However, after January 1, 2007, those sales are limited to only those entities that qualify under the new amendment.

Third, in assessing the effect of an amendment, it is presumed that Congress was aware of *PhRMA v. Thompson*'s holding that all provisions must promote the Act's purpose to reduce Medicaid costs. *United States v. Severino,* 316 F.3d 939, 955 (9th Cir. 2003) ("We ... presume that when Congress amends a statute, it is knowledgeable about judicial decisions interpreting the prior legislation"). Consequently, since the nominal price exception was already limited to that purpose, in order to change that limitation, Congress had to amend the exception, which it did, to create a safe harbor for those nominal price sales where Medicaid would not get the benefit, such as sales to an intermediate care facility for the mentally retarded or safety-net provider that treated only non-Medicaid beneficiaries.[9]

In sum, "[t]he maxim that 'men must turn square corners when they deal with the Government' applies fully in the [False Claims Act] context."[10] *United States ex rel. Augustine v. Century Health Services, Inc.*, 289 F.3d 409, 413 (6th Cir. 2002) (*quoting United States v.*

[9] Arguably, the small portion of Merck's SAVE and VIP discounts that go to Disproportionate Share Hospitals, "a covered entity described in section 340B(a)(4) of the Public Health Service Act" 42 U.S.C. § 1396r-8(c)(1)(D)(i)(I), might qualify for the safe harbor. FAC at ¶42. But that eventuality is not before the Court, nor does it exonerate Merck's conduct to date.

[10] The parties agree that the Nevada FCA is patterned after the federal FCA. Merck's Memo at 36 n.17. Cases interpreting similar provisions should also apply to the Nevada FCA.

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*Midwest Specialties, Inc.*, 142 F.3d 296, 302, n.4 (6th Cir. 1998) and Justice Holmes in *Rock Island, Ark. & La. R.R. v. U.S.*, 254 U.S. 141, 143 (1920)). Merck did not turn square corners, but played fast and loose to exclude its discounts tied to purchases. Merck's conduct led to the absurd result, never intended by Congress, whereby Merck actually cost Medicaid more money. Merck's Best Price reports that did not include its so-called nominal price discounts were false.

## II. MERCK'S DISCOUNTS SO OBVIOUSLY UNDERMINED THE MEDICAID REBATE ACT THAT MERCK KNOWINGLY VIOLATED THE REBATE ACT BY EXCLUDING THEM FROM BEST PRICE.

The Nevada FCA defines knowingly "with respect to information" if the person "(a) has knowledge of the information; (b) acts in deliberate ignorance of whether the information is true or false; or (c) acts in reckless disregard of the truth or falsity of the information." N.R.S. § 357.040(2). The scienter requirement protects only "innocent mistakes" and "negligence." *Oliver*, 195 F.3d at 464-65.

As this Court has stated, "[t]he determination of scienter is normally a question of fact and it need not be plead with great specificity." *Furman v. Sierra Pac. Resources*, Case No. CV-N-92-543-HDM, 1993 WL 331014 at *1 (U.S. Dist. Ct., D. Nev., May 18, 1993) (citation omitted) (a copy of this decision is attached as Exhibit D); *see also* Fed. R. Civ. Pro. 9(b) ("malice, intent, knowledge, and other condition of mind of a person can be averred generally"). The First Amended Complaint more than sufficiently alleges that Merck knowingly and deliberately submitted claims to the Secretary that increased Medicaid costs to avoid paying the full amount of the rebate owed to Nevada and the other states. *See* FAC at ¶¶ 4, 24, 43, 46, and Counts II and IV. Moreover, in light of the Rebate Act's obvious purpose to reduce Medicaid's prescription drug costs, the reasonable inference from Merck's conduct is that Merck acted in deliberate ignorance or reckless disregard of whether its Best Price reports were true or false.

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Merck claims it "acted reasonably" in excluding the SAVE and VIP discounts. Merck's Memo at 16. However, any inquiry as to whether Merck acted reasonably is a question of fact that cannot be decided on a motion to dismiss. *See Oliver*, 195 F.3d at 464-65 (disputed evidence of whether defendant's interpretation was in good faith or reasonable created genuine issue precluding summary judgment; a reasonable interpretation did not render claim "not false" as a matter of law).[11]

## III. FEDERAL LAW DOES NOT PREEMPT NEVADA'S STATE LAW CLAIMS.

Merck also argues that Nevada's state-law claims are preempted per "conflict preemption," i.e., the Rebate Act conflicts with the state-law claims. There is no preemption here. Rather, there is a compelling presumption against preemption. Under Medicaid, the state and federal governments are pursuing "common purposes" and the presumption against preemption has "special force." *Walsh*, 538 U.S. at 666; *Pharm IV*, 321 F.Supp.2d at 198. In fact, Congress recently enacted Medicaid savings incentives to States that pass their own False Claims Acts so that they can fight Medicaid fraud using their own FCAs, as Nevada has done here. *See* Exhibits B, C. This is a clear signal that suits such as the instant one are encouraged by Congress, not preempted.

The same preemption arguments Merck advances here were also made against Nevada and rejected in *Pharm IV*.[12] *Pharm IV* held that "the presumption against federal

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[11] Merck still contends that its Best Price reports were not false as a matter of law because it complied with the Rebate Agreement, relying on *United States ex rel. Lindenthal v. General Dynamics Corp.*, 61 F.3d 1402 (9th Cir. 1995). Merck's Memo at 16. However, in *Lindenthal* the court held that General Dynamics had met the Air Force's "expectations and satisfied GD's contractual obligations." First and foremost, the expectation and obligation of the Rebate Agreement is to administer the purpose of the Rebate Act, which Merck undermined.

[12] Merck provided this Court, as Exhibit A to its Motion, carefully selected portions of the amicus brief of the United States submitted in response to the court's request in *Pharm IV*. Nevada has attached hereto the entire brief as Exhibit E, and incorporates it herein in full as it counters each of Merck's preemption contentions and advocates that there is no preemption for Nevada to pursue pharmaceutical companies for fraudulently submitting Best Price data

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preemption applies to state fraud statutes that are used to reduce the inflated drug costs to the state Medicaid program produced by fraudulent reporting of Best Price information." *Pharm IV*, 321 F.Supp.2d at 198. This same presumption applies here.

To overcome this strong presumption, Merck must show that Nevada's claims are a "severe" impediment "to the accomplishment and execution of the full purposes and objectives of Congress," and "that there manifestly and clearly is an 'actual conflict' between the state claims and the federal statute." *Id.* at 197, 199 (citations omitted). Rather than a severe impediment or actual conflict, Nevada's claims here promote the purpose and objective of the Rebate Act to "produce savings for the Medicaid program," as did Nevada's claims in *Pharm IV*. *Walsh*, 538 U.S. at 668. Merck has not, and can not, overcome the presumption against preemption here.

**A. Nevada's Claims that Merck's Discounts Defrauded Medicaid Further the Rebate Act.**

There is no disagreement that the issue here is whether Merck's Best Price reports are false in light of the Rebate Act and Agreement. As Merck also admits, since the enactment of the Rebate Act, only one Best Price is reported each quarter for each dosage of drug sold, and this Best Price sets the amount of rebates nationwide to every State. Merck's Initial Brief at 5, 26.[13] Thus, it is the Rebate Act, not the Nevada FCA, which requires Merck to correctly report Best Price. There is no conflict between the Nevada FCA and the Rebate Act here. The Rebate Act sets the standard. The Nevada FCA enforces it.

Contrary to Merck's contention, Nevada is not seeking "to include nominal prices or exclude cash discounts in their best price calculations *in conflict* with 42 U.S.C. §1396r-

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via state law claims. Just as the United States concluded in its brief that there is no conflict between Nevada's claims and the Best Price provisions of the Rebate Act, the same is true here.

[13] The recent amendments to nominal price have not changed this fact, contrary to Merck's implication. Merck's Memo at 21 n.8.

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8(c)(1)(C)(ii)(I)&(II)." Merck's Memo at 19-20, quoting the United States' amicus brief filed in *Pharm IV*, attached hereto as Exhibit E. Again, Nevada is seeking to have Merck comply with the Rebate Act. Nevada is not imposing a state law-based obligation on Merck, but rather a federal law-based obligation based upon the Rebate Act. These claims seek to fully enforce the Rebate Act to eliminate Merck's conduct that increases Medicaid costs.

Nevada's fraud claims also enforce its rights as a third-party beneficiary of the Rebate Agreement. *Mylan Labs*, 357 F.Supp.2d at 329 ("[T]he Rebate Agreement instructs the Court to construe it in a manner which 'best effectuates' the statutory scheme. Permitting the states to sue as third-party intended beneficiaries would advance congressional objectives of reducing Medicaid drug costs"). In fact, the States are entitled to pursue state-law claims where manufacturers submit false information to the Secretary. *Pharm IV*, 321 F.Supp.2d at 199 (the Rebate Act "provides that the federal remedies are 'in addition to other penalties as may be prescribed by law,'" quoting 42 U.S.C. § 1396r-8(b)(3)(C)(ii). Merck thus mischaracterizes the Medicaid Rebate program as precluding the States from enforcing manufacturers' abuse of the program.[14] Merck's Memo at 23-24. Although States do not have access to manufacturers' pricing data nor the right to audit the data, which, as shown, hampers their responsibility to ferret out Medicaid fraud (see *infra* at IV B, D), that responsibility remains. Congress has reinforced that responsibility in its recent legislation.

**B. *Buckman* Is Inapposite.**

Merck also contends that Nevada's claims are preempted because they are "fraud-on-

[14] Merck also mischaracterizes the letter submitted by the Department of Justice in response to Merck's initial motion to dismiss presenting its position that *Pharm IV* was decided correctly. Merck claims the letter is telling because it does not tell the Court that Merck's interpretation of the nominal price exception is incorrect. Merck's Memo at 20-21. True, the Department of Justice did not advise this Court on how to interpret the Best Price provisions of the Rebate Act—that is a matter of law, and a matter of first impression. However, the Department did not suggest that the Court should dismiss this case, as Merck presumes. The presumption runs the other way: Nevada's claims should not be found to be preempted, and the case should proceed.

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the-[federal]-agency" claims precluded under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001). Merck's Memo at 22 et seq. *Buckman* concluded that there was no presumption against preemption because of the scope of FDA regulation of the marketing and distribution of medical devices at issue. *Id.* at 347-48. Here, where the claims involved Medicaid fraud, there is a strong presumption, one that Merck has failed to overcome. Indeed, Merck ignores this distinguishing feature of *Buckman*. *Buckman* addressed claims against the FDA. Unlike Medicaid, the FDA is not a cooperative State and Federal venture.

*Pharm IV* rejected the very *Buckman* arguments Merck makes here. Unlike the FDA's sweeping enforcement powers, "the Secretary does not make an independent determination with respect to Best Price, but merely acts as a go-between. ... The Best Price program is one employing cooperative federalism, and so there is no 'uniquely federal' interest." 321 F.Supp.2d at 199 (citation to *Boyle v. United Tech. Corp.*, 487 U.S. 500, 505 (1988) omitted).[15] In *Buckman*, "Congress provided expressly that it was the federal government, not private litigants, that was authorized to file suit for non-compliance." *Pharm IV*, 321 F.Supp.2d at 199.

In contrast, Best Price violations can be pursued, as they are here, by a whistleblower notifying a State of the fraud. "As a practical matter, the confidentiality of the pricing information and the lack of audit powers inhibit the ability of the states to monitor drug fraud, but those who blow whistles can just as easily blow them into the states' ears." *Id.*

Because the Rebate Act contemplates that remedies other than those afforded the

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[15] Merck cites to *Boyle* (Merck's Brief at 23), which holds that government contracts are one of the "uniquely few" areas of federal law, suggesting the Nevada's claims are breach of contract claims that seek to change the terms of the Rebate Agreement. Contrary to Merck's characterization, here, as in *Pharm IV*, this case involves the interpretation of the Rebate Act. 321 F.Supp.2d at 200. And, Nevada does not intend to alter the "nominal price" term of the Rebate Agreement; rather, Nevada seeks to ensure that the interpretation of that term complies with the purpose of the Rebate Act. The Rebate Agreement must comply with the Rebate Act, and cannot reasonably be interpreted otherwise.

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Secretary may be pursued, Nevada is not constrained by those remedies afforded to the Secretary under the Rebate Act. Nevada can pursue its state-law fraud claims, contrary to Merck's contention. Merck's Memo at 23-24. The fact that Nevada did not have an FCA until some time after the enactment of the Rebate Act, *see* Merck's Memo at 23 n.10, does not mean that Nevada is now hamstrung from using its FCA to pursue Medicaid fraud perpetrated under the Rebate Act. Rather, Congress is ensuring that other States follow Nevada's example here.

The Rebate Act also does not present the *Buckman*-like "delicate balance" of statutory objectives.

> The United States considers the Best Price statute to be one of cooperative federalism, and does not seek the right to exclusive rebate enforcement power. Therefore, there is no "uniquely federal" interest, and there is no "delicate balance of objectives" to be upset. *Pharm IV*, 321 F.Supp.2d at 200.

*Buckman* does not apply here, and there is no *Buckman*-preemption.

## IV. PLAINTIFFS HAVE SUFFICIENTLY PLED THAT THE OTHER DISCOUNTS MERCK CONCEALED WERE FALSE CLAIMS.

Merck claims that Nevada's allegations in Count IV, pertaining to Merck's concealment of its free drug and non-nominal discounts, do not state a claim under Fed. Rule Civ. Proc. 12(b)(6) and are not sufficiently specific under Fed. Rule Civ. Proc. 9(b). However, the thrust of Merck's complaints are that Nevada can't prove its case. A motion to dismiss tests the sufficiency of the allegations, not the evidence.

Pursuant to Fed. Rule Civ. Proc. 12(b)(6), the question is whether the facts alleged, *if true,* would entitle Nevada to relief, construing those facts in a light most favorable to Nevada and recognizing that the allegations "embrace whatever specific facts might be necessary to support them." *Peloza v. Capistrano Unified Sch. Dist.*, 37 F.3d 517, 521 (9th Cir. 1994). Because the answer to that question is "yes," Nevada is entitled to proceed against Merck.

Similarly, under Fed. Rule Civ. Proc. 9(b), "[a] pleading is sufficient under [R]ule 9(b) if

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it identifies the circumstances constituting fraud so that a defendant can prepare an adequate answer from the allegations," for example, "statements of the time, place and nature of the alleged fraudulent activities are sufficient." *Moore v. Kayport Package Express, Inc.*, 885 F.2d 531, 540 (9th Cir. 1989). Nevada need not plead evidence. *Arroyo v. Wheat*, 591 F.Supp. 136, 138-39 (D. Nev. 1984). Indeed it is "'not fatal to the complaint that it [does] not describe in detail a single specific transaction,'" so long as Nevada has identified "(i) some of the specific customers defrauded, (ii) the type of conduct at issue, (iii) the general time frame in which the conduct occurred, and (iv) why the conduct was fraudulent." *United States ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1052 (9th Cir. 2001), *quoting Cooper v. Pickett*, 137 F.3d 616, 627 (9th Cir. 1998). Moreover, "the Ninth Circuit has relaxed the pleading rule 'with respect to matters within the opposing party's knowledge,' since 'plaintiffs can not be expected to have personal knowledge of the relevant facts.'" *Neubronner v. Milken*, 6 F.3d 666, 672 (9th Cir. 1993) (citations omitted). This is particularly true with regard to Medicaid fraud involving violations of the Rebate Act. As *Pharm IV* found, "[a]s a practical matter, the confidentiality of the pricing information and the lack of audit powers inhibits the ability of the states to monitor drug fraud… ." 321 F.Supp.2d at 187. As this Court has held, so long as the complaint "provides notice of the alleged misrepresentations," Rule 9(b) is met. *Furman*, 1993 WL 331014 at *1. Nevada's First Amended Complaint more than meets this standard.

**A. Nevada Has Stated the Claim that Merck Fraudulently Concealed Its Free Drug Give-Aways in Reporting Best Price.**

Another discount that must be included in reporting Best Price, as noted above, occurs from the giving away of "free goods contingent upon any purchase requirement." 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(I). Merck gave away significant amounts of free drugs via stock bottles and did not include the resulting discount in its Best Price reports. FAC at ¶52, 53, 56, 54.

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Stock bottles are not small blister packs of patient samples. Rather, they are the same size pill bottles distributed to pharmacies. Since, as above, Merck did not include the free drugs' discount in calculating Best Price, Merck violated the Medicaid Rebate Act and its Best Price reports were false. *Id.* at ¶¶70, 114.

Merck contends that Nevada has not pled the evidence that its give-aways were contingent on purchase requirements. Merck's Memo at 25. Even though Nevada is not required to plead evidence, *Arroyo*, 591 F.Supp. at 138-39, Nevada has alleged that Merck has a policy and practice of giving away free drugs, the essential component of which was a purchase—be it in the future, the past, or at the same time as the give-away, and that this policy was evident in emails between sales representatives and managers. FAC at ¶57. The give-aways were part and parcel of Merck's marketing plan to capture the retail spill-over market by inducing hospitals to purchase and prescribe Zocor and Vioxx. *Id.* at ¶52. The free drugs reduced the cost of the drugs the hospital purchased, providing the incentive to make an initial purchase, or to keep purchasing. *Id.* at ¶¶52, 57, 64.

Merck's give-aways were not donations to a relief program, or for evaluation of a drug's therapeutic properties. *See* Merck's Memo at 26 n.12, 27 n.13. Merck only gave free drugs to hospitals or HMOs that purchased enough Merck drugs to justify the give-aways according to Merck's return-on-investment expectations. *Id.* at ¶57. While still at Merck, the Relator also learned "that such drug give-aways were one of Merck's ways of facilitating a switch from a competitor's product to a Merck product, or obtaining price parity between a competitor's drug and a Merck drug." *Id.* at ¶66. The free drugs were inextricably tied to a purchase requirement, and this fact applies to all give-aways detailed in the FAC.

Merck also argues that Nevada cannot sufficiently allege scienter because Merck was acting under a good faith interpretation of the Rebate Act. Merck's Memo at 28 and n.14. Any "reasonable interpretation" defense cannot be decided as a matter of law on a motion to

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dismiss, as illustrated by the authority Merck relies upon. *See Oliver*, 195 F.3d at 465 (the question of whether defendants' interpretation of a regulation was in fact in good faith was a genuine issue of material fact for trial); *see also Furman*, 1993 WL 331014 at *1 ("scienter is normally a question of fact").[16]

As for pleading scienter, Nevada has alleged that Merck knew it had to take into account the free drugs it gave to hospitals and HMOs in calculating and reporting Best Price, and Merck deliberately and knowingly submitted false records and/or statements of quarterly Best Price reports which did not take into account the net reduction in the prices paid by the hospitals and HMOs. FAC at ¶64, 70; *see also* ¶¶ 113-117. More than this is not needed. Scienter "need not be plead with great specificity." *Furman*, 1993 WL 331014 at *1.

**B. Nevada Has Alleged that Merck Fraudulently Concealed Free Goods From Its Best Price Reporting With Sufficient Specificity.**

According to the authority Merck relies upon:

> Rule [9(b)] does not require the pleading of detailed evidentiary matter. Rule 9(b) only requires the identification of the circumstances constituting fraud so that the defendant can prepare an adequate answer from the allegations. ... Statements of the time, place and nature of the alleged fraudulent activities must be included in the complaint. The nature of the individual case, in the end analysis, determines how much additional specificity is appropriate. *A nit-picking approach is frowned on* in making such determination. *Arroyo*, 591 F.Supp. at 138-39 (internal quotations and citations omitted) (emphasis added).

Nevada's allegations specify the time, place and nature of the fraud: The time frame of the fraud is from 1998 to the present (FAC at ¶54), and Nevada has identified as well particular incidents where the free drugs were not included in Best Price reports, e.g., the first quarter of 2001 (*id.* at ¶¶60, 61) and the second quarter 2001 (*id.* at ¶¶58, 59). The place of

[16] *United States ex rel. Butler v. Hughes Helicopter*, 71 F.3d 321 (9th Cir. 1995), is equally unhelpful to Merck. There, the question of whether the defendant "knowingly" submitted false claims turned on whether, according to the *evidence at trial*, the government was aware of the information that was the basis of the alleged false claims so that the defendant could not have "knowingly" submitted false claims. *Id.* at 327. The defendant's good faith or reasonable interpretation of a contract or statute was not at issue.

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the fraudulent conduct is where Best Price is reported—to the Secretary. FAC at ¶¶26, 57. The nature of the fraud involves Merck's Best Price reports which falsely concealed Merck's practice and policy of giving away free drugs that were inextricably linked with purchase requirements as to avoid paying the full amount of rebate owed to the States, including Nevada. *Id.* at ¶¶ 52, 57, 64, 70, 71, 113-117.

Nevada also illustrates Merck's fraud with specific give-aways. FAC at ¶¶ 58-61, 65-69. In each of these illustrations, Merck deliberately and knowingly submitted Best Price reports that did not include the free drugs. *Id.* at ¶70.

Yet again, Merck nit-picks at the specific transactions, claiming it needs more detailed evidence. First, Merck complains that Nevada does not allege with each give-away that the give-away was contingent to a purchase requirement. Merck's Memo at 29-30. Nevada makes clear that all of Merck's 41 substantial stock bottle give-aways identified in the First Amended Complaint were part and parcel of Merck's practice and policy to not give-away stock bottles *unless* the hospital or HMO made a purchase, in the past, in the future, or at the same time—as evident in email correspondence between sales representatives and managers. FAC at ¶57.

Second, Merck complains that Nevada does not allege how the give-aways affected Best Price. In order to precisely calculate this, Nevada needs Merck's confidential pricing and sales information to value the give-away against the purchases. *Id.* at ¶46. "As a practical matter, the confidentiality of the pricing information and the lack of audit powers inhibits the ability of the states to monitor drug fraud... ." *Pharm IV,* 321 F.Supp.2d at 187. Nonetheless, with the limited information available, Nevada provided illustrative examples. Merck gave Vioxx to South Nassau Community Hospital, in Oceanside during the second quarter of 2001, which reduced the cost of the Vioxx the hospital purchased to about $1.65 per tablet, or $0.13 below Merck's reported Best Price, based on the most common dosage of Vioxx. FAC at

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¶¶58-59. During the first quarter of 2001, Merck gave Zocor to Christ Hospital and Medical Center in Oak Lawn, Illinois, which reduced the cost of the Zocor the hospital purchased to about $1.54 per tablet, or $0.45 below Merck's reported Best Price, based on the most common dosage of Zocor. FAC at ¶¶60-61.

The documentation of the sales to these hospitals that Nevada has obtained to date do not detail the dosages of the drugs purchased, thus preventing the "apples-to-apples" comparison of drugs given away and drugs purchased, based on dosages, that Merck demands. *See* Merck's Memo at 31. However, since Nevada used the price of the most popular dosage to compare the value of the give-away to the value of the drug sold, the same basis was used, comparing apples-to-apples.

Where Nevada has specific sales information from the Relator, there is a precise apples-to-apples comparison of Merck's planned free drug give-away of Zocor 20 mg to Blue Care Network (BCN) in Michigan, which reduced the amount purchased from about $3.18 per tablet to $1.59 per tablet. *Id.* at ¶68. Merck's Best Price report for Zocor 20 mg at this time was about $1.79. *Id.* at ¶69.[17]

As *Pharm IV* recognized, Nevada's ability to pursue Medicaid fraud should not be hamstrung by Merck, hiding behind Rule 9(b) and demanding greater specificity when it has complete and exclusive control of the sales information that shows how its give-aways impacted Best Price. FAC at ¶55. According to Merck's authority, "Rule 9(b)'s particularity

[17] According to Merck's authority, Nevada can allege that it is informed and believes that there were several other such incidents even though the BCN give-away was "only" planned—the Relator objected to the give-away and was kept out of the loop as to whether it actually occurred. *See* Merck's Memo at 31-32. Nevada has provided the facts as well as the source of its information and belief, the Relator and the documentation from Nevada's continuing investigation. FAC at ¶¶ 54, 58-62, 66-69. "'Where allegations of fraud are based only on information and belief, the complaint must set forth the source of the information and the reasons for the belief.' *United States ex rel. Karvelas v. Melrose-Wakefield-Hospital*, 360 F.3d 220, 226 (1st Cir. 2004) (internal citations and quotations omitted)"; *see* Merck's Initial Brief at 27; *see also California ex rel. Mueller v. Walgreen Corp.*, 175 F.R.D. 631, 635 (N.D. Cal. 1997) and Merck's Memo at 32.

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requirement is relaxed in instances of corporate fraud where the facts supporting the allegation of fraud are *exclusively* within the defendant's possession." *Mueller*, 175 F.R.D. at 635 (emphasis in original); *see* Merck's Memo at 32. Put another way, "when the facts relating to the alleged fraud are peculiarly within the perpetrator's knowledge, the Rule 9(b) standard is relaxed...." *United States ex rel. Russell v. Epic Healthcare Mgmt. Group*, 193 F.3d 304, 308 (5th Cir. 1999); *see* Merck's Memo at 35.

However, even without using a relaxed standard, Nevada sufficiently details Merck's fraud pursuant to Fed. Rule Civ. Proc. 9(b). Nevada was denied the rebate Merck should have paid to it had Merck included the free drugs in calculating Best Price.

**C. Nevada Has Stated A Claim that Merck Fraudulently Concealed SAVE's Non-Nominal Price Discount from Merck's Best Price Reporting.**

Under SAVE, Merck offers hospitals a non-nominal, 30% discount off the catalog price of Zocor; in exchange, Merck requires hospitals to purchase enough Zocor to comprise 55% of the hospitals' cholesterol-lowering drug (HMG) purchases. FAC at ¶ 34. In 1999, Merck distributed an internal memorandum to its sales force informing them that this discount, on average over the dosages, amounted to a cost to qualifying hospitals of about $1.80 per tablet. FAC at ¶45. During 1999, Merck's Best Price for the most popular dosage of Zocor (20 mg pill) ranged from $1.80 to $1.83 per pill. *Id.*

Merck again complains that Nevada should have the specific information per dosage. Merck's Memo at 34. But Merck's own sales bulletin did not break down the cost across dosages. Merck's catalog pricing, upon which the SAVE non-nominal discount is based, is confidential. As such, Nevada cannot determine the discount's impact on Best Price reports. *See Pharm IV*, 321 F.Supp.2d at 187 ("The confidentiality of the pricing information ... inhibits the ability of the states to monitor drug fraud"). Notwithstanding these obstacles, Nevada's information and belief that Merck periodically concealed the 30% non-nominal discount from

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its Best Price reports is bolstered by the evidence in Merck's internal sales bulletin that admits to a lower price than reported for Merck's most popular dosage. FAC at ¶¶ 45-46. This is not a fishing expedition. Merck's Memo at 34. Both Nevada and Merck are likely to rely on the same evidence in this regard, namely, the list of Merck's Zocor sales at its 30% discount.

**D. Nevada Has Alleged With Sufficient Specificity that Merck Fraudulently Concealed SAVE's Non-Nominal Discount From Its Best Price Reporting.**

Merck makes "general," "vague and nondescript" complaints that Nevada's allegations regarding Merck's non-nominal discount do not meet muster under Fed. Rule Civ. Proc. 9(b). Merck's Memo at 34-35. The FAC more than sufficiently puts Merck on notice of its fraud, i.e., time, place and nature. The time is the duration of SAVE, from 1998 through the present. FAC at ¶32. The place is where Best Price is reported—to the Secretary. FAC at ¶26. And, the nature of the fraud: Merck's 30% discount on Zocor under SAVE was not reported as Merck's Best Price, so that Merck avoided paying the full amount of rebate owed to Nevada and other states. FAC at ¶¶ 45-47, 111-121.

Additional detail, the comparison between 30% off of catalog price and Merck's reported Best Price, is exclusively within Merck's control because only Merck knows its catalog prices. Merck disingenuously exploits this fact to argue for preemption since the Secretary can "audit" such information and "impose substantial penalties for any fraud," citing 42 U.S.C. § 1396r-8(b)(3)(B). Merck Memo at 34-35. According to § 1396r-8(b)(3)(B) the Secretary can only "survey," not audit, manufacturers' prices. Significantly, that survey is limited only to those manufacturers that "directly distribute" their drugs. Merck does not, and few other manufacturers do either. Consequently, even the Secretary could not obtain Merck's catalog prices. And the penalties, which are "not to exceed $100,000," are hardly substantial. No wonder Merck wants to seek refuge with the Secretary. The worst that could happen would not even make a dent in Merck's ill-gained profits at the expense of millions of

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dollars in rebates that should have been paid. More importantly, contrary to Merck's contention, the Secretary's limited remedies are not exclusive. "Such civil money penalties are in addition to other penalties as may be prescribed by law." 42 U.S.C. § 1396r-8(b)(3)(C)(ii). This provision, *inter alia,* prompted the court to reject preemption in *Pharm IV*, 321 F.Supp.2d at 199.

Since the Rebate Act does not enable either the Secretary or Nevada to obtain Merck's catalog prices, the Rule 9(b) pleading requirements must be relaxed, again according to authority Merck cites to: where facts "are peculiarly within the perpetrator's knowledge, the Rule 9(b) standard is relaxed, and fraud may be pled on information and belief, provided the plaintiff sets forth the factual basis for his belief." *Russell*, 193 F.3d at 308. Nevada has done this. FAC at ¶¶ 34, 39, 44-47, 111-121.

Merck also complains that Nevada fails to identify a specific sale that Merck should have included in its Best Price reporting. Merck's Memo at 4. Nevada need not "describe in detail a single specific transaction," given that the allegations sufficiently put Merck on notice of its fraud. *United States ex rel. Lee*, 245 F.3d at 1052. Moreover, Nevada has identified that all sales at the 30% discount were the Best Price that should have been reported instead of what was reported. FAC at ¶¶45-46. The specific sales are all within Merck's peculiar knowledge. Merck is fully aware of these sales as part of its SAVE promotion and it is disingenuous, at best, for Merck to effectively deny that the sales occurred. *See* Merck's Initial Brief at 12, where Merck admitted to the so-called nominal priced aspect of SAVE.

## V. THE STATUTE OF LIMITATIONS DOES NOT LIMIT NEVADA'S EVIDENCE.

Merck contends that any allegations regarding fraud that occurred before April 19, 2000, five years prior to the date of the filing of the complaint, are time-barred and must be dismissed. Merck's Memo at 5, 35-36. However, as the cases Merck relies upon demonstrate, the statute of limitations only limits recovery, not the admissibility of allegations

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or evidence.[18] Merck's Memo at 36. In the Ninth Circuit, "we have the general rule that '[a] plaintiff's right to damages is limited to those suffered during the statutory period for bringing claims....'" *Polar Bear Productions, Inc. v. Timex Corp.*, 384 F.3d 700, 706 (9th Cir. 2004), *quoting Los Angeles News Serv. v. Reuters Television Int'l, Ltd.*, 149 F.3d 987, 992 (9th Cir. 1998).

By seeking to dismiss *allegations* of fraudulent activity prior to April 19, 2000, Merck is seeking to exclude evidence even before there has been any discovery. If the statute of limitations had such an affect on an action, then Merck itself could not produce the memoranda explaining the genesis of the SAVE program, since it started in 1998, and Nevada could not show how these same memoranda prove Merck's scienter. This is neither the time nor place to decide what evidence is admissible.

[18] One of these cases, *United States ex rel. Fisher v. Network Software Assoc., Inc.*, 180 F.Supp.2d 192 (D.C. Cir. 2002), holds that, to prove a conspiracy, the overt act must occur within the limitation period. *Id.* at 195. Although the evidence to establish Merck's liability—the knowing submission of false statements—must occur within the limitations period, this does not mean that the statute of limitations precludes *all* evidence prior to the start of the limitations period.

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## CONCLUSION

For the reasons set forth above, the Court should deny Merck's Motion to Dismiss. Merck's so-called Best Price reports which excluded the so-called "nominal price *discounts*" were false. There is no preemption. Nevada has sufficiently pled scienter and the details of the free drug give-away and non-nominal price discount fraud. And, there is no statute of limitation on Nevada's evidence.

DATED this 24th day of February, 2006.

GEORGE J. CHANOS
Nevada Attorney General

by: L. Timothy Terry

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STATE OF NEVADA

**CERTIFICATE OF SERVICE**

I, Nancy Key, hereby certify that a true and correct copy of STATE OF NEVADA'S OPPOSITION TO MERCK'S MOTION TO DISMISS was served on February 24, 2006, upon the following by using the ECF system and that the following is an ECF user:

**WILLIAM E. PETERSON**
MORRIS PICKERING & PETERSON
6100 Neil Road, Suite 555
Reno, NV 899511
Attorneys for Defendant
Merck & Co., Inc.

In addition, I certify that a true and correct copy of the STATE OF NEVADA'S OPPOSITION TO MERCK'S MOTION TO DISMISS was hand delivered via Reno-Carson Messenger Service to:

**MARK A. WINTER**
801 N. Division Street
Carson City, NV 89703
ATTORNEY FOR RELATOR

DATED this 24th day of February, 2006.

Nancy Key
An employee of the Office of the Attorney General

Office of the Attorney General
100 N. Carson St.
Carson City, NV
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# EXHIBIT A

REBATE AGREEMENT
Between
The Secretary of Health and Human Services
(hereinafter referred to as "the Secretary")
and
The Manufacturer Identified in Section XI of this Agreement
(hereinafter referred to as "the Labeler")

The Secretary, on behalf of the Department of Health and Human Services and all States and the District of Columbia (except to the extent that they have in force an Individual State Agreement) which have a Medicaid State Plan approved under 42 U.S.C. section 1396a, and the Labeler, on its own behalf, for purposes of section 4401 of the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, and section 1927 of the Social Security Act (hereinafter referred to as "the Act"), 42 U.S.C. 1396s, hereby agree to the following:

## I DEFINITIONS

The terms defined in this section will, for the purposes of this agreement, have the meanings specified in section 1927 of the Act as interpreted and applied herein:

(a) "Average Manufacturer Price (AMP)" means, with respect to a Covered Outpatient Drug of the Manufacturer for a calendar quarter, the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid. It is calculated as a weighted average of prices for all the Manufacturer's package sizes for each Covered Outpatient Drug sold by the Manufacturer during that quarter. Specifically, it is calculated as Net Sales divided by numbers of units sold, excluding free goods (i.e. drugs or any other items given away, but not contingent on any purchase requirements). For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The Average Manufacturer Price for a quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(b) "Base Consumer Price Index-Urban (CPI-U)" is the CPI-U for September, 1990. For drugs approved by FDA after October 1, 1990, "Base CPI-U" means the CPI-U for the month before the month in which the drug was first marketed.

(c) "Base Date AMP" means the AMP for the 7/1/90-9/30/90 quarter for purposes of computing the AMP as of 10/1/90. For drugs approved by FDA after October 1, 1990, "Base Date AMP" means the AMP for the first day of the first month in which the drug was marketed. In order to meet this definition, the drug must have been marketed on that first day. If the drug was not marketed on that first day, "Base Date" means the AMP for the first day of the month in which the product was marketed for a full month.

(d) "Best Price" means, with respect to Single Source and Innovator Multiple Source Drugs, the lowest price at which the manufacturer sells the Covered Outpatient Drug to any purchaser in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best price includes prices to wholesalers, retailers, nonprofit entities, or governmental entities within the States (excluding Depot Prices and Single Award Contract Prices of any agency of the Federal Government). Federal Supply Schedule prices are included in the calculation of the best price.

The best prices shall be inclusive of cash discounts, free goods, volume discounts, and rebates, (other than rebates under Section 1927 of the Act).

It shall be determined on a unit basis without regard to special packaging, labeling or identifiers on the dosage form or product or package, and shall not take into account prices that are Nominal in amount. For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The best price for a quarter shall be adjusted by the manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized.

(e)"Bundled Sale" refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.

(f)"Centers for Medicare & Medicaid Services (CMS)" (formerly HCFA) means the agency of the Department of Health and Human Services having the delegated authority to operate the Medicaid Program.

(g)"Consumer Price Index-Urban (CPI-U)" means the index of consumer prices developed and updated by the U.S. Department of Commerce. As referenced in section 1927(c) of the Act, it is the CPI for all urban consumers (U.S. Average) and, except for the base CPI-U, it shall be the index for the month before the beginning of the calendar quarter for which the rebate is made.

(h) "Covered Outpatient Drug" will have the meaning as set forth in Section 1927(k)(2),(k)(3) and (k)(4) of the Act, and with respect to the Manufacturer includes all such drug products meeting this definition. For purposes of coverage under this agreement, all of those Covered Outpatient Drugs are identified by the Manufacturer's labeler code segment of the NDC number. Certain Covered Outpatient Drugs, such as specified by Section 1927(d)(1)(3) of the Act, may be restricted or excluded from Medicaid payment at State option but shall be included by the Manufacturer for purposes of this agreement.

(i) "Depot Price" means the price(s) available to any depot of the federal government, for purchase of drugs from the Manufacturer through the depot system of procurement.

(j) "Individual State Agreement" means an agreement between a State and a Manufacturer authorized or approved by CMS as meeting the requirements specified in Section 1927(a)(1) or (a)(4) of the Act. Amendments or other changes to agreements under 1927(a)(4) shall not be included in this definition unless specifically accepted by CMS.

An existing agreement that met these requirements as of the date of enactment of P.L. No. 101-508 (November 5, 1990), can be modified to give a greater rebate percentage.

(k) "Innovator Multiple Source Drug" will have the meaning set forth in Section 1927(k)(7)(A)(ii) of the Act and shall include all Covered Outpatient Drugs approved under a New Drug Application (NDA), Product License Approval (PLA), Establishment License Approval (ELA) or Antibiotic Drug Approval (ADA). A Covered Outpatient Drug marketed by a cross-licensed producer or distributor under the approved NDA shall be included as an innovator multiple source drug when the drug product meets this definition.

(l) "Manufacturer" will have the meaning set forth in Section 1927(k)(5) of the Act except, for purposes of this agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the Covered Outpatient Drug.

(m) "Marketed" means that a drug was first sold by a manufacturer in the States after FDA approval.

(n) "Medicaid Utilization Information" means the information on the total number of units of each dosage form and strength of the Manufacturer's Covered Outpatient Drugs reimbursed during a quarter under a Medicaid State Plan. This information is based on claims paid by the State Medicaid Agency during a calendar quarter and not drugs that were dispensed during a calendar quarter (except it shall not include drugs dispensed prior to January 1, 1991). The Medicaid Utilization Information to be supplied includes: 1) NDC number; 2) Product name; 3) Units paid for during the quarter by NDC number; 4) Total number of prescriptions paid for during the quarter by NDC

number; and 5) Total amount paid during the quarter by NDC number. A State may, at its option, compute the total rebate anticipated, based on its own records, but it shall remain the responsibility of the labeler to correctly calculate the rebate amount based on its correct determination of AMP and, where applicable, Best Price.

(o) "National Drug Code (NDC)" is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of this agreement the complete 11 digit NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or formulation), and package size code. For the purposes of making Rebate Payments, Manufacturers must accept the NDC number without package size code from States that do not maintain their records by complete NDC number.

(p) "Net Sales" means quarterly gross sales revenue less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act) which reduce the actual price paid; and as further defined under the definition of AMP.

(q) "New Drug" means a Covered Outpatient Drug approved as a new drug under section 201(p) of the Federal Food, Drug, and Cosmetic Act.

(r) "New Drug Coverage" begins with the date of FDA approval of the NDA, PLA, ELA or ADA, for a period of six months from that date, with the exception of drugs not under the rebate agreement or classes of drugs States elect to exclude.

(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.

(t) "Noninnovator Multiple Source Drug" shall have the meaning as set forth in Section 1927(k)(7)(A)(iii) of the Act. It also includes Covered Outpatient Drugs approved under an ANDA or AADA.

(u) "Quarter" means calendar quarter unless otherwise specified.

(v) "Rebate Payment" means, with respect to the Manufacturer's Covered Outpatient Drugs, the quarterly payment by the Manufacturer to the State Medicaid Agency, calculated in accordance with section 1927 of the Act and the provisions of this agreement. The terms "Base CPI-U" and "Base Date AMP" will be applicable to the calculations under 1927(c).

(w) "Secretary" means the Secretary of the United States Department of Health and Human Services, or any successor thereto, or any officer or employee of the Department of Health and Human Services or successor agency to whom the authority to implement this agreement has been delegated.

(x) "Single-Award Contract" means a contract between the Federal Government and a Manufacturer resulting in a single supplier for a Covered Outpatient Drug within a class of drugs. The Federal Supply Schedule is not included in this definition as a single award contract.

(y) "Single-Award Contract Price" means a price established under a Single-Award Contract.

(z) "Single Source Drug" will have the meaning set forth in Section 1927 (k) (7) (A) (iv) of the Act. It also includes a Covered Outpatient Drug approved under a PLA, ELA or ABA.

(aa) "States" means the 50 states and the District of Columbia.

(bb) "State Medicaid Agency" means the agency designated by a State under Section 1902(a)(5) of the Act to administer or supervise the administration of the Medicaid program.

(cc) "Unit" means drug unit in the lowest identifiable amount (e.g. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the unit associated with each Covered Outpatient Drug, as part of the submission of data, in accordance with the Secretary's instructions provided pursuant to Appendix A.

(dd) "Unit Rebate Amount" means the unit amount computed by the Health Care Financing Administration to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due.

(ee) "Wholesaler" means any entity (including a pharmacy or chain of pharmacies) to which the labeler sells the Covered Outpatient Drug, but that does not relabel or repackage the Covered Outpatient Drug.

## II MANUFACTURER'S RESPONSIBILITIES

In order for the Secretary to authorize that a State receive payment for the Manufacturer's drugs under Title XIX of the Act, 42 U.S.C. Section 1396 et seq., the Manufacturer agrees to the following:

(a) To calculate and, except as provided under section V(b) of this agreement, to make a Rebate Payment to each State Medicaid Agency for the Manufacturer's Covered Outpatient Drugs paid for by the State Medicaid Agency during a quarter.

A separate listing of all Covered Outpatient Drugs and other information, in accordance with CMS's specifications pursuant to Appendix A, must be submitted within 30 calendar days of entering into this agreement and be updated quarterly. The Manufacturer's quarterly report is to include all new NDC numbers and continue to list those NDC numbers for drugs no longer marketed.

(b) Except as provided under V(b), to make such rebate payments for each calendar quarter within 30 days after receiving from the State the Medicaid Utilization Information defined in this agreement. Although a specific amount of information has been defined in I(n) of this agreement, the Manufacturer is responsible for timely payment of the rebate within 30 days of receiving, at a minimum, information on the number of units paid, by NDC number.

(c) To comply with the conditions of 42 U.S.C. section 1396s, changes thereto and implementing regulations as the Secretary deems necessary and specifies by actual prior notice to the manufacturer.

(d) That rebate agreements between the Secretary and the Manufacturer entered into before March 1, 1991 are retroactive to January 1, 1991. Rebate agreements entered into on or after March 1, 1991 shall be effective the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(e) To report to the Secretary, in accordance with specifications pursuant to Appendix A, that information on the Average Manufacturer Price and, in the case of Single Source and Innovator Multiple Source Drugs, the Manufacturer's Best Price for all Covered Outpatient Drugs. The Manufacturer agrees to provide such information within 30 days of the last day of each quarter beginning with (1) the January 1, 1991-March 31, 1991 quarter or (2) the quarter in which any subsequent effective date of this agreement lies. Other information in Appendix A shall also be required within 30 days of the last day of the quarter. Adjustments to AMP or Best Price for prior quarters shall also be reported on this quarterly basis.

(f) In the case of Single Source and Innovator Multiple Source drugs, to report to the Secretary, in a manner prescribed by the Secretary, the information in Appendix A on the Base Date AMP. The Manufacturer agrees to provide such information within 30 days of the date of signing this agreement.

(g) To directly notify the States of a New Drug's Coverage.

(h) To continue to make a Rebate Payment on all of its Covered Outpatient Drugs for as long as an agreement with the Secretary is in force and State Medicaid Utilization Information reports that payment was made for that drug, regardless of whether the Manufacturer continues to market that drug. If there are no sales by the Manufacturer during a quarter, the AMP and Best Price last reported continue to be used in calculating rebates.

(i) To keep records (written or electronic) of the data and any other material from which the calculations of AMP and Best Price were derived. In the absence of specific guidance in section 1927 of the Act, Federal regulations and the terms of this agreement, the 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. A record (written or electronic) outlining these assumptions must also be maintained.

III SECRETARY'S RESPONSIBILITIES

(a) The Secretary will use his best efforts to ensure that the State agency will report to the Manufacturer, within 60 days of the last day of each quarter, and in a manner prescribed by the Secretary, Medicaid Utilization Information paid for during the quarter.

(b) The Secretary may survey those Manufacturers and Wholesalers that directly distribute their covered outpatient drugs to verify manufacturer prices and may impose civil monetary penalties as provided in section 1927(b)(3)(B) of the Act and IV of this agreement.

(c) The Secretary may audit Manufacturer calculations of AMP and Best Price.

IV PENALTY PROVISIONS

(a) The Secretary may impose a civil monetary penalty under III(b), up to $100,000 for each item, on a wholesaler, manufacturer, or direct seller of a Covered Outpatient Drug, if a wholesaler, manufacturer or direct seller of a Covered Outpatient Drug refuses a request for information about charges or prices by the Secretary in connection with a survey or knowingly provides false information. The provisions of section 1128A of the Act (other than subsection (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply as set forth in section 1927(b)(3)(B).

(b) The Secretary may impose a civil monetary penalty, in an amount not to exceed $100,000, for each item of false information as set forth in 1927(b)(3)(C)(ii).

(c) The Secretary may impose a civil monetary penalty for failure to provide timely information on AMP, Best Price or Base Date AMP. The amount of the penalty shall be increased by $10,000 for each day in which such information has not been provided, as set forth in 1927(b)(3)(C)(i).

V DISPUTE RESOLUTION -- MEDICAID UTILIZATION INFORMATION

(a) In the event that in any quarter a discrepancy in Medicaid Utilization Information is discovered by the Manufacturer, which the Manufacturer and the State in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy, by NDC number, to the State Medicaid Agency prior to the due date in II(b).

(b) If the Manufacturer in good faith believes the State Medicaid Agency's Medicaid Utilization Information is erroneous, the Manufacturer shall pay the State Medicaid Agency that portion of the rebate amount claimed which is not disputed within the required due date in II (b). The balance due, if any, plus a reasonable rate of interest as set forth in section 1903(d)(5) of the Act, will be paid or credited by the Manufacturer or the State by the due date of the next quarterly payment in II(b) after resolution of the dispute.

(c) The State and the Manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of such notification. In the event that the State and the Manufacturer are not able to resolve a discrepancy within 60 days, CMS shall require the State to make available to the Manufacturer the State hearing mechanism available under the Medicaid Program (42 Code of Federal Regulations section 447.253 (c)).

(d) Nothing in this section shall preclude the right of the Manufacturer to audit the Medicaid Utilization Information reported (or required to be reported) by the State. The Secretary shall encourage the Manufacturer and the State to develop mutually beneficial audit procedures.

(e) Adjustments to Rebate Payments shall be made if information indicates that either Medicaid Utilization Information, AMP or Best Price were greater or less than the amount previously specified.

(f) The State hearing mechanism is not binding on the Secretary for purposes of his authority to implement the civil money penalty provisions of the statute or this agreement.

## VI DISPUTE RESOLUTION -- PRESCRIPTION DRUGS ACCESS AND STATE SYSTEMS ISSUES

(a) A State's failure to comply with the drug access requirements of section 1927 of the Act shall be cause for the Manufacturer to notify CMS and for CMS to initiate compliance action against the State under section 1904 of the Act. A request for compliance action may also occur when the Manufacturer shows a pattern or history of inaccuracy in Medicaid Utilization Information.

(b) Such compliance action by CMS will not relieve the Manufacturer from its obligation of making the Rebate Payment as provided in section 1927 of the Act and this agreement.

## VII CONFIDENTIALITY PROVISIONS

(a) Pursuant to Section 1927(b)(3)(D) of the Act and this agreement, information disclosed by the Manufacturer in connection with this Agreement is confidential and, not withstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency in a form which reveals the Manufacturer, or prices charged by the Manufacturer, except as necessary by the Secretary to carry out the provisions of section 1927 of the Act, and to permit review under section 1927 of the Act by the Comptroller General.

(b) The Manufacturer will hold State Medicaid Utilization Information confidential. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. Except where otherwise specified in the Act or agreement, the Manufacturer will observe State confidentiality statutes, regulations and other properly promulgated policy.

(c) Notwithstanding the nonrenewal or termination of this Agreement for any reason, these confidentiality provisions will remain in full force and effect.

## VIII NONRENEWAL AND TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of this Agreement, the Agreement shall be effective for an initial period of one year beginning on the date specified in section II(d) of this agreement and shall be automatically renewed for additional successive terms of one year unless the Labeler gives written notice of intent not to renew the agreement at least 90 days before the end of the current period.

(b) The Manufacturer may terminate the agreement for any reason, and such termination shall become effective the later of the first day of the first calendar quarter beginning 60 days after the Manufacturer gives written notice requesting termination, or the ending date of the term of the agreement if notice has been given in accordance with VII(a).

(c) The Secretary may terminate the Agreement for violations of this agreement or other good cause upon 60 days prior written notice to the Manufacturer of the existence of such violation or other good cause. The Secretary shall provide, upon request, a Manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(d) If this rebate agreement is nonrenewed or terminated, the Manufacturer is prohibited from entering into another rebate agreement as provided in section 1927(b)(4)(C) of the Act until a period of one calendar quarter has elapsed from the effective date of the termination, unless the Secretary finds good cause for earlier reinstatement.

(e) Any nonrenewal or termination will not affect rebates due before the effective date of termination.

## IX GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of this Agreement will be sent in writing.

Notice to the Secretary will be sent to:

Center for Medicaid and State Operations
Family and Children's Health Programs Group
Division of Benefits, Coverage and Payment
Post Office Box 26686
Baltimore, MD 21207-0486

Notices to CMS concerning data transfer and information systems issues are to be sent to:

Center for Medicaid and State Operations
Finance, Systems and Quality Group
Division of State Systems
Post Office Box 26686
Baltimore, MD 21207-0486

The CMS address may be updated upon written notice to the Manufacturer.

Notice to the Manufacturer will be sent to the address as provided with this agreement and updated upon Manufacturer notification to CMS at the address in this agreement.

(b) In the event of a transfer in ownership of the Manufacturer, this agreement is automatically assigned to the new owner subject to the conditions specified in section 1927 and this agreement.

(c) Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law, this Agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, and without any effect on any other provision.

(d) Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution, the Act, other federal laws, or State laws.

(e) The rebate agreement shall be construed in accordance with Federal common law and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.

(f) The terms "State Medicaid Agency" and "Manufacturer" incorporate any contractors which fulfill responsibilities pursuant to the agreement unless specifically provided for in the rebate agreement or specifically agreed to by an appropriate CMS official.

(g) Except for the conditions specified in II(c) and IX(a), this Agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Secretary and the Manufacturer.

(h) In the event that a due date falls on a weekend or Federal holiday, the report or other item will be due on the first business day following that weekend or Federal holiday.

## X APPENDIX

Appendix A attached hereto is part of this agreement.

XI SIGNATURES

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By:_____ _____
Date

Title: Deputy Director
Finance, Systems and Quality Group
Center for Medicaid and State Operations
Centers for Medicare & Medicaid Services
Department of Health and Human Services

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations, amendments or other changes to this rebate agreement.

By: _____ _____
(signature) (please print name)

Title: _____

Name of Manufacturer: _____

Manufacturer Address _____

_____

Manufacturer Labeler Code(s): _____

Date: _____

# EXHIBIT B

U.S. SENATE COMMITTEE ON
**Finance**
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
http://finance.senate.gov

MEMORANDUM

To: Reporters and Editors
Re: False Claims Act enhancements in Deficit Reduction Act of 2005
Da: Thursday, Feb. 2, 2006

Sen. Chuck Grassley, chairman of the Committee on Finance, included two key anti-fraud provisions in the Deficit Reduction Act that received final congressional approval on Wednesday and is headed to the President for his consideration. The provisions were designed to address the fraud, waste and abuse of the Medicaid program outlined last summer during a two-day hearing before the Senate Finance Committee.

The first provision provides increased funding for states that agree to pass a State False Claims Act, modeled after the federal False Claims Act. States will be provided an increased share of Medicaid funds if they agree to pass a False Claims Act that contains the same provisions as the federal version. The second provision requires any company doing more than $5 million in business with Medicaid to provide education to employees regarding the False Claims Act. As the principal author of the □986 amendments to the federal False Claims Act, Sen. Chuck Grassley, chairman of the Finance Committee, has fought long and hard to protect whistleblowers who use the False Claims Act to help the government recover taxpayer dollars from those who defraud the government. Sen. Grassley released the following statement regarding the False Claims Act provisions included in the Deficit Reduction Act:

"The False Claims Act has been the federal government's number one tool for fighting fraud, waste and abuse for the past 20 years. The passage of the Deficit Reduction Act marks a new day for the False Claims Act. It enhances and strengthens this valuable tool for fighting fraud and waste in government programs. All too often taxpayer money is wasted or lost to fraud. This fraud threatens the sustainability of government programs. Over the past 20 years, I've seen whistleblowers use the False Claims Act to recover more than $□7 billion in tax dollars. With these new provisions, the False Claims Act is evolving to help fight fraud, waste and abuse for another 20 years and beyond."

# EXHIBIT C

SEC. 6031. ENCOURAGING THE ENACTMENT OF STATE FALSE CLAIMS ACTS.

(a) IN GENERAL- Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) is amended by inserting after section 1908A the following:
'STATE FALSE CLAIMS ACT REQUIREMENTS FOR INCREASED STATE SHARE OF RECOVERIES
'SEC. 1909. (a) IN GENERAL- Notwithstanding section 1905(b), if a State has in effect a law relating to false or fraudulent claims that meets the requirements of subsection (b), the Federal medical assistance percentage with respect to any amounts recovered under a State action brought under such law, shall be decreased by 10 percentage points.
'(b) REQUIREMENTS- For purposes of subsection (a), the requirements of this subsection are that the Inspector General of the Department of Health and Human Services, in consultation with the Attorney General, determines that the State has in effect a law that meets the following requirements:
'(1) The law establishes liability to the State for false or fraudulent claims described in section 3729 of title 31, United States Code, with respect to any expenditure described in section 1903(a).
'(2) The law contains provisions that are at least as effective in rewarding and facilitating qui tam actions for false or fraudulent claims as those described in sections 3730 through 3732 of title 31, United States Code.
'(3) The law contains a requirement for filing an action under seal for 60 days with review by the State Attorney General.
'(4) The law contains a civil penalty that is not less than the amount of the civil penalty authorized under section 3729 of title 31, United States Code.
'(c) DEEMED COMPLIANCE- A State that, as of January 1, 2007, has a law in effect that meets the requirements of subsection (b) shall be deemed to be in compliance with such requirements for so long as the law continues to meet such requirements.
'(d) NO PRECLUSION OF BROADER LAWS- Nothing in this section shall be construed as prohibiting a State that has in effect a law that establishes liability to the State for false or fraudulent claims described in section 3729 of title 31, United States Code, with respect to programs in addition to the State program under this title, or with respect to expenditures in addition to expenditures described in section 1903(a), from being considered to be in compliance with the requirements of subsection (a) so long as the law meets such requirements.'.
(b) EFFECTIVE DATE- Except as provided in section 6035(e), the amendments made by this section take effect on January 1, 2007.

# EXHIBIT D

**C**
Not Reported in F.Supp., 1993 WL 331014, Fed. Sec. L. Rep. P 97,691

United States District Court, D. Nevada.
**FURMAN**
v.
**SIERRA** PACIFIC RESOURCES, et al.
**No. CV-N-92-543-HDM.**

May 18, 1993.

OPINION

McKIBBEN, District Judge.
***1** Defendants' motion to dismiss (# 35) and motion to strike the complaint (# 34) are DENIED. In considering the motion to dismiss the court construes all allegations in the complaint as true and construes them in a light most favorable to the non-moving party. *Russell v. Landrieu,* 621 F.2d 1037 (9th Cir.1980).

Averments of fraud must be stated with sufficient particularity. Fed.R.Civ.P. 9(b). A pleading is sufficient if it identifies the circumstances constituting fraud such that defendant can prepare an adequate answer. *Wool v. Tandem Computers Inc.,* 818 F.2d 1433, 1439 (9th Cir.1987). In cases of corporate fraud that standard is relaxed because plaintiffs cannot be expected to have personal knowledge of facts constituting the wrongdoing. *Id.* The complaint provides notice of the alleged misrepresentations and thus meets this standard.

Under Rule 10b-5 securities fraud includes a misstatement or omission of material fact made with scienter where the plaintiff justifiably relies on that statement proximately causing an injury. *Basic, Inc. v. Levinson,* 485 U.S. 224, 231 (1988) ; *McGonigle v. Combs,* 968 F.2d 810, 817 (9th Cir.1992), *cert. dismissed by Casares v. Spendthrift Farm, Inc.,* 113 S.Ct. 399 (1992). Under the securities law, the accuracy of the disclosure is measured not by its literal truth, but rather by its ability to accurately inform rather than mislead prospective purchasers. *In re Convergent Technologies Sec. Litig.,* 948 F.2d 507, 512 (9th Cir.1991). The determination of scienter is normally a question of fact and it need not be plead with great specificity. *Wexner v. First Manhattan Co.,* 902 F.2d 169, 172 (2nd Cir.1990). Plaintiff's allegations of failure to disclose directors' self-dealings and the need to reduce the dividend at an earlier date sufficiently state a 10b-5 claim.

The same reasoning supports plaintiff's state law claims.

Secondary securities law violation claims such as aiding and abetting, conspiracy, and control person liability require a showing that each defendant exerted power and influence over the decision making process relating to the wrongful act. *Hollinger v. Titan Capital Corp.,* 914 F.2d 1564, 1568-69 (9th Cir.1990) (*en banc* ), *cert. denied,* 111 S.Ct. 1621 (1991). In corporate fraud cases where misleading statements are "group published" through actions of the board, it is reasonable to presume that these are the collective actions of the corporate officers. *Wool,* 818 F.2d at 1441; *In re Sunrise Technologies Sec. Litig.,* [1992 Transfer Binder] Fed.Sec.L.Rep. (CCH) ¶ 97,042, 1992 WL 359636 (N.D.Cal.1992). In the present case defendants are directors and officers of Sierra Pacific Resources who all allegedly contribute toward corporate actions. Therefore, plaintiff has adequately plead claims for secondary securities law violations.

The court may strike any material from a pleading which is redundant, immaterial, impertinent, or scandalous. Fed.R.Civ.P. 12(f). Motions to strike are not favored and should be denied unless the allegations have no possible relation to the controversy and would affect the merits. *Wilson v. Cagle,* 711 F.Supp. 1521, 1534 (N.D.Cal.1988); *aff'd* 900 F.2d 263 (9th Cir.1990) (quoting 5 Wright and Miller, *Federal Practice and Procedure* § 1382, at 809-10 (1969)); *see also, Fantasy Inc. v. Fogerty,* 984 F.2d 1524, 1527-28 (9th Cir.1924) (also citing Wright and Miller). The allegations which defendants move to strike relate to demonstrating scienter and conspiracy.

***2** Accordingly, defendants' motion to strike (# 34) and defendants' motion to dismiss (# 35) are DENIED.

It is so ORDERED.

D.Nev.,1993.
Furman v. Sierra Pacific Resources

Not Reported in F.Supp., 1993 WL 331014, Fed. Sec. L. Rep. P 97,691

END OF DOCUMENT

# EXHIBIT E

UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MASSACHUSETTS

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

**BRIEF OF THE UNITED STATES AS AMICUS CURIAE**

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## STATEMENT

The United States Department of Justice, on be half of the Secretary of Health and Human Services (Secretary), submits this *amicus curiae* brief in response to the Court's request that the Secretary address two issues arising from the above-referenced litigation: first, whether the Medicaid drug rebate statute, 42 U.S.C. § 1396 r-8, preempts state law fraud claims based on fraudulent reporting of best prices to the federal government; second, whether the federal government has the authority to bring suit to recover amounts allegedly owed to the states because of the fraudulent reporting of best prices to the federal government. See Letter from Judge Patti B. Saris to Secretary Tommy G. Thompson (Jan. 8, 2004).

On the first question, we do not believe that the Medicaid rebate statute demands the preemption of Montana or Nevada's best price claims as a matter of law. As currently pled, the states' best price claims neither frustrate the ad ministration of the rebate program nor raise the same sort of concerns at issue in Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001). Given the above, we do not believe it necessary to reach the second question. This is particularly so given the strong likelihood that the United States would invite the states to join as co-plaintiffs in any federal lawsuit alleging violations of the Medicaid rebate statute or agreement. In the event the situation did arise, however, the United States retains the authority to enforce the rebate statute and agreement and to compel a drug manufacturer to comply fully with its rebate obligations and to make any payments necessitated by such compliance.

## BACKGROUND

The Medicaid program, established by Title XIX of the Social Security Act, is a cooperative federal-state program that provides medical assistance to certain low income individuals. See 42 U.S.C. 1396 *et seq.* Under the Medicaid program, "[t]he federal government

sets certain broad standards . . . and provides funds to states that elect to participate." Montana v. Abbott Labs., 266 F.Supp.2d 250, 253 (D. Mass. 2003). "Each participating state determines, within the federal guidelines, its own rules for program eligibility and content of medical care; each state then administers its program, and complements the federal funding with state appropriations." Id. The Centers for Medicare & Medicaid Services (CMS)(formerly the Health Care Financing Administration) administers th e Medicaid program on behalf of the Secretary. 42 U.S.C. § 1396a (1994 & Supp. V 1999).

States are accorded a broad measure of flexibility in tailoring the scope and coverage of their state plans to meet the particular needs of their residents and their own budgetary and other circumstances. See Alexander v. Choate, 469 U.S. 287, 303 (1985). Although the Medicaid Act does not require states to cover prescription drugs, 42 U.S.C. § 1396d(a)(12), at least 44 states and the District of Columbia currently provide prescription drug coverage for categorically needy individuals, and 32 states and the Distri ct of Columbia provide such coverage for medically needy individuals. See R. Schwalberg, Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey a nd Selected Case Study Highlights 4 (Oct. 2001). Drugs purchased by Medicaid recipients account for roughly 10% of all prescription drugs purchased in the United States. See Staff of House Comm. on Ways & Means, 106th Cong., 2d Sess. 2000 Green Book 927 (Comm. Print 2000) (Green Book); see also id. at 924 (Table 15-21).

In 1990, Congress reviewed the prices that Medicaid was paying for prescription drugs. Congress determined that Medicaid was routinely paying more for prescription drugs than other large drug purchasers, particularly with respect to single source drugs. See H.R. Rep. No. 881, 101st Cong., 2d Sess. 96 (1990). Congress concluded that "Medicaid, the means-tested

entitlement program that purchases basic health care for the poor, should have the benefit of the same discounts on single source drugs that other large public and private purchasers enjoy." Id. Congress therefore decided to "establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser." Id.

Congress passed the Medicaid drug rebate statute as part of the Omnibus Budget Reconciliation Act of 1990. 42 U.S.C. § 1396r-8. Under that statute, a drug manufacturer must enter into a rebate agreement with the Secretary [1] in order for federal matching funds to be made available for that manufacturer's covered outpatient drugs. 42 U.S.C. § 1396r-8(a)(1); Rebate Agreement at §II(a). Upon entering a rebate agreement with the Secretary, the manufacturer must pay a quarterly rebate directly to each state based on all of the manufacturer's drugs purchased by that state pursuant to its state Medicaid plan during that quarter. [2] 42 U.S.C. § 1396r-8(b)(1)(A); Rebate Agreement at § II(a). Each state must agree to cover all the manufacturer's covered outpatient drugs unless the state complies with one of several statutory provisions allowing it to exclude or restrict coverage. 42 U.S.C. §§ 1396a(a)(54), 1396r-8(d)). The federal share of any rebate amounts received under the national rebate agreement or an

---

[1] The rebate agreement provides that the Secretary enters the agreement "on behalf of the Department of Health and Human Services and all States and the District of Columbia (except to the extent they have in force an Individual State Agreement)." See Rebate Agreement at Preamble.

[2] For single source or innovator multiple source drugs, the rebate due on each unit paid for under the state plan is the difference between the average manufacturer price (AMP) and the manufacturer's best price, defined as the lowest price available from the manufacturer to any private purchaser or governmental entity within the United States, or 15.1% of AMP, whichever is greater. 42 U.S.C. § 1396r-8(c)(1)(A), (B), and (C) and (c)(2). For multiple source non-innovator drugs, the rebate is 11% of average manufacturer price. 42 U.S.C. § 1396r-8(c)(3).

individual state rebate agreement must be offset against the state's Medicaid expenditures that quarter for purposes of calculating the federal financial participation. [3] 42 U.S.C. § 1396r-8(b)(1)(B).

States may enter directly into rebate agreements with drug manufacturers as authorized by the Secretary. 42 U.S.C. § 1396r-8(a)(1). To date, the Secretary has approved supplemental drug rebate agreements in at least twenty states. States may also control their Medicaid drug costs and coverage by establishing prior authorization programs, 42 U.S.C. § 1396r-8(d)(1)(A), or by creating drug formularies, 42 U.S.C. 1396r-8(d)(1)(B)(iv). Though not part of the rebate statute, states are also permitted to set payment rates with respect to covered drugs. See 42 U.S.C. 1396a(a)(30); 42 C.F.R. 447.331-447.333.

Drug manufacturers are required under the rebate statute and agreement to calculate and report their AMPs and best prices to the Secretary on a quarterly basis. 42 U.S.C. § 1396r-8(b)(3)(A)(i); Rebate Agreement at § II(e). Any information provided by a manufacturer or wholesaler under the rebate statute is confidential and "shall not be disclosed by the Secretary . . . or a State agency . . . except as the Secretary determines to be necessary to carry out this section." 42 U.S.C. § 1396r-8(b)(3)(D); Rebate Agreement at § VII. States are required to report their total Medicaid drug utilization to each manufacturer and the Secretary sixty days after the end of each rebate quarter. [4] 42 U.S.C. § 1396r-8(b)(2)(A). Using the manufacturer

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[3] The federal share is equal to a percentage (between 50% and 83% depending on the state) of the state's Medicaid expenditures.

[4] The rebate agreement provides a dispute resolution mechanism in the event there is a discrepancy between a state and manufacturer regarding the state's Medicaid utilization information. Rebate Agreement at § V.

pricing data, CMS computes the unit rebate amount (URA) "to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due." Rebate Agreement at § I(dd).

The Secretary may survey wholesalers and manufacturers to verify reported AMPs and best prices, 42 U.S.C. § 1396r-8(b)(3)(B), and may audit manufacturer calculations of AMP and best price. Rebate Agreement at § III(c). The Secretary may impose civil money penalties on manufacturers that either fail to timely report their pricing information or submit false information to the Secretary. 42 U.S.C. § 1396r-8(b)(3)(C); Rebate Agreement at §§ III, IV. Section 1396r-8(b)(3)(C)(ii) also provides that any civil money penalties imposed under this subsection are "in addition to other penalties as may be prescribed by law." The Secretary may terminate the rebate agreement for either violations of the rebate agreement or for other good cause shown. 42 U.S.C. § 1396r-8(b)(4)(B). The rebate agreement is construed in accordance with federal common law and any "ambiguities shall be interpreted in the manner which best effectuates the statutory scheme." Rebate Agreement at IX(e).

In addition to the rebate statute and agreement, CMS has provided manufacturers with supplemental guidance regarding their best price responsibilities. First, CMS has published, as necessary, a series of Medicaid drug rebate progr am releases. These program releases clarify program requirements and respond to questions raised by manufacturers or states. See www.cms.hhs.gov/medicaid/drugs/drughmpg.asp . Second, CMS offers a "Medicaid Drug Rebate Operational Training Guide" to all pa rticipating manufacturers. The training guide serves as a reference source on technical issues such as data formatting and calculation methodologies. Finally, the Federal Register No tice of Proposed Rulemaking contains some of

the Secretary's interpretations of manufacturer best price reporting obligations. See Medicaid Program; Payment for Covered Outpatient Drugs Under Drug Rebate Agreements with Manufacturers, 60 Fed. Reg. 48442 (Sept. 19, 1995), see also, Medicaid Program; Time Limitation on Recordkeeping Requirements Under the Drug Rebate Program, 69 Fed. Reg. 508 (Jan. 6, 2004).

DISCUSSION

I. Montana and Nevada's State Law Best Price Claims Are Not Inconsistent With The Objectives Of The Medicaid Rebate Statute

Under the Supremacy Clause, a federal law may preempt state law either expressly or impliedly. U.S. Const. art. VI, cl. 2; see Gade v. National Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992); English v. General Elec. Co., 496 U.S. 72, 78-79 (1990). In this case, the rebate statute is silent as to the availability of state law actions alleging best price violations. Therefore, the only question remaining is whether implied preemption applies. The Supreme Court has held that implied conflict preemption may arise where "compliance with both federal and state regulations is a physical impossibility," Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43 (1963), or, where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Hines v. Davidowitz, 312 U.S. 52, 67 (1941).[5]

[5] The Supreme Court has also held that state law may be impliedly preempted where the federal regulatory scheme is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." Rice v. Sante Fe Elevator Corp., 331 U.S. 218, 230 (1947). Given that Medicaid is a cooperative federal-state program, that states play a significant role in defining their own state Medicaid plans, and that Congress has not expressed a clear and manifest intent to preempt the entire field of Medicaid drug reimbursement, the doctrine of field preemption is not applicable here. See also PhRMA v. Concannon, 249 F.3d 66, 75 (1st Cir. 2001); PhRMA v. Meadows, 304 F.3d 1197, 1206 (11th Cir. 2002).

Regardless of the particular strain of preemption, congressional intent is generally the touchstone of a preemption analysis. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996); Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992). Moreover, courts that perform preemption analyses should "start with the assumption that the historic police powers of the States were not to be superceded by [a] Fede ral Act unless that was the clear and manifest purpose of Congress." Rice, 331 U.S. at 230; see Medtronic, 518 U.S. at 485 ("[B]ecause the States are independent sovereigns in our federa l system, we have long presumed that Congress does not cavalierly pre-empt state law causes of action."); Mass. Ass'n of Health Maintenance Orgs. v. Ruthardt, 194 F.3d 176, 178-179 (1st Cir. 1999) ("[A]lthough the power to preempt is absolute, its exercise is not lightly to be presumed."); Greenwood Trust Co. v. Commonwealth of Massachusetts, 971 F.2d 818, 823 (1st Cir. 1992) ("Courts must tread cautiously in this arena because the authority to displace a sovereign state's law is an extraordinary power . . . that we must assume Congress does not exercise lightl y.") (internal quotation omitted). Particularly "[w]here coordinate state and federal efforts exist within a complementary administrative framework, and in the pursuit of common purposes, the case for federal pre-emption becomes a less persuasive one." N.Y. Dep't of Soc. Servs. v. Dublino, 413 U.S. 405, 421 (1973).

As a unique "system of cooperative federalism," Harris v. McRae, 448 U.S. 297, 301 (1980), the Medicaid program falls squarely within this field where courts must tread cautiously before displacing state law. Indeed, as the Supreme Court recently noted in a case challenging a state prior authorization program under the Medicai d rebate statute, "[t]he presumption against federal pre-emption of a state statute designed to foster public health . . . has special force when it appears, and the Secretary has not decided to the contrary, that the two governments are

pursuing common purposes." PhRMA v. Walsh, 123 S.Ct. 1855, 1869 (2003).[6] See also Meadows, 304 F.3d at 1206 ("Medicaid is one of several cooperative state-federal program[s] covered by the Social Security Act, and the Supreme Court has suggested that preemption for these types of programs may be difficult to establish."), cert. denied, 123 S.Ct. 2213 (2003); Concannon, 249 F.3d at 75("We also recognize that federal preemption of state law is strong medicine, and is not casually to be dispensed . . . especially . . . when the federal statute creates a program, such as Medicaid, that utilizes cooperative federalism.") (internal quotations omitted); PhRMA v. Thompson, 259 F.Supp.2d 39, 84 (D.D.C. 2003), appeal docketed, No. 03-5117 (D.C. Cir. Dec. 12, 2003); Cf. In re. Pharmaceutical Industry Average Wholesale Price Litigation, 263 F.Supp.2d 172, 187 (D. Mass. 2003)(finding that the Medicare Act did not preempt the entire field of medical fee regulation).

Against this backdrop, there is no persuasive reason why the presumption against preempting state law in the Medicaid context should not be applied to Montana and Nevada's best price claims. States obviously have a direct and compelling interest in accurate best price reporting and the rebate program, which helps to reduce the costs the states themselves incurred for drugs purchased by Medicaid patients. Furthermore, states have long played a critical role in investigating and prosecuting Medicaid fraud. See 42 U.S.C. § 1396b(q)(3) (requiring states to maintain a Medicaid Fraud Control Unit (MFCU) to investigate fraud in connection with Medicaid State plan); 42 U.S.C. § 1396a(a)(61) (requi ring state plan to provide for operation of a Medicaid fraud and abuse control unit); 42 U.S.C. § 1396a(a)(25) (requiring states to "take all

[6] The Pharmaceutical Research and Manufacturers of A merica will be hereinafter referred to as "PhRMA."

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 congressi onal 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

[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 dir ect 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 prosecu te 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, di scounts 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

[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.

rebate statute and agreement, it is not "physically impossible" for the Defendants to comply with both federal and state law and therefore no basis for implied conflict preemption exists.

B. Nevada and Montana's State Law Best Pr ice Claims Do Not Present An Obstacle To Or Impose A Buckman-Type Burden On The Medicaid Rebate Program

In the absence of a "physical impossibility", the Defendants argue that the Medicaid rebate statute impliedly preempts the States' best price claims by frustrating the Medicaid rebate program. Relying upon Buckman, the Defendants argue that the rebate statute and program recommend exclusive federal enforcement of best price violations and that the state law best price claims would only burden the rebate program. A more in-depth factual comparison of the regulatory schemes, however, reveals significant differences that render Buckman inapplicable here.

In Buckman, the Court held that the state law "fraud on the FDA" claims alleged conflicted with, and were therefore impliedly preempted by, the Food, Drug, and Cosmetic Act (FDCA), as amended by the Medical Device Amendments (MDA) of 1976. 531 U.S. at 353. The Court based its ruling on several factors. First, the Court held that the traditional presumption against preemption of state law did not apply given that "[p]olicing fraud against federal agencies [was] hardly a field which the States have traditionally occupied," id. at 347-48 (internal quotation omitted), and that the relationship between a federal agency and the entities it regulates was "inherently federal in character." Id. at 347. Second, the Court held that the extensive federal statutory scheme amply empower ed the FDA to punish and deter fraud against the Administration. Id. at 348-49. Finally, the Court held that the state law "fraud-on-the-FDA" would inevitably disrupt the FDA's ability to achieve its statutory objectives. Id. at 348. We address each of these factors in turn.

1. The Presumption Against Preempting State Law In the Medicaid Context Applies In This Case

At the outset, the presumption against preempting state law applies in this case. As discussed above, the best price claims here arise in the Medicaid context, where state and federal governments generally work in a complementary administrative framework and pursue common purposes. See Walsh, 123 S.Ct. at 1869; Dublino, 413 U.S. at 421; Meadows, 304 F.3d at 1206; Concannon, 249 F.3d at 75. That the best price claims here are brought by states-- which have historically played a significant role in inve stigating and prosecuting Medicaid fraud--further weakens the case for preemption.

Buckman does not materially change this analysis. First, in contrast to the "inherently federal" relationship between the FDA and the entities it regulates, see Buckman, 531 U.S. at 347, the states and the federal government share a compelling interest in manufacturers accurately calculating and reporting their best prices. Indeed, given that the states suffer directly from every false or fraudulent best pri ce reported, their claims cannot be fairly characterized as merely "fraud-on-the-agency." Second, in contrast to the private plaintiffs in Buckman, states have played a historical role in the inve stigation and prosecution of Medicaid fraud, see supra at 9, and therefore the state law best price claims at issue in this case directly implicate "federalism concerns" and state responsibilities. Id. at 347-48. Moreover, the states' best price claims may help fulfill Congress's objective of reducing state Medicaid drug costs and thereby better enable states to provide health care services to their poorest citizens. Cf. Meadows, 304 F.3d at 1197 ("By stretching its Medicaid dollars, the Florida [prior authorization program] has the potential for providing more and better medical services to the target population."). Against this backdrop, the fact that the manufacturers' reporting obligations are defined by the rebate statute

and agreement does not automatically negate the states' interest in accurate best price reporting or transform the federal government's interest into a "uniquely federal" one. [9] Boyle, 487 U.S. at 504-505.

For these reasons, we find no persuasive reason to disregard the states' interest in the rebate program altogether or to isolate the states' best price claims from the presumption against preemption that otherwise prevails in the Medicaid context.

2. The Statutory Scheme Does Not Demand Exclusive Federal Enforcement Of The Medicaid Rebate Program

In Buckman, the Court found that the statutory and regulatory scheme at issue provided the FDA with a "variety of enforcement options that allow[ed] it to make a measured response to suspected fraud upon the Administration." Id. at 349. Based in part on that regulatory scheme, the Court inferred that there was no room for State action in this arena. The Medicaid drug rebate scheme does not warrant a similar inference.

First, unlike the FDCA or MDA, the rebate statute does not contain any provision akin to 21 U.S.C. § 337(a) ("[A]ll such [medical device noncompliance] proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States"), that would suggest a Congressional desire for exclusive federal enforcement. Given the historical role that states play in investiga ting and prosecuting Medicaid fraud, the direct interest

[9] In Boyle, the Court held that despite the absence of any federal legislation immunizing independent contractors, federal common law should nevertheless govern their liability given the "uniquely federal interest" that the federal government had in its procurement contracts. Id. at 504-507. In this case, there is no dispute that the rebate agreement should be construed in accordance with federal common law or that the federal government has an interest in any litigation involving the rebate program. We do not believe, however, that the federal government's interest in the Defendants' best price reporting is somehow so "uniquely" federal as to warrant preemption in this case.

that states have in the rebate program, and the flexibility that the rebate statute otherwise accords states to control their Medicaid drug costs, it is not unreasonable to expect Congress to have expressly provided for *exclusive* federal enforcement if that were indeed its intent.

Second, while the drug rebate scheme is well-suited for gathering pricing data and administering the quarterly drug rebates, it is not specifically designed for identifying fraud. Although the Secretary has the authority to survey wholesaler and manufacturer AMPs and best prices, 42 U.S.C. § 1396r-8(b)(3)(B), and to assess penalties for late or false information provided, id. at section 1396r-8(b)(3)(C), neither the rebate statute nor rebate agreement provides for the periodic or systematic review of manuf acturer best price calculations or methodologies. Therefore, unlike the FDA regulatory scheme which requires applicants to provide detailed information regarding their devices for agency review, see Buckman, 531 U.S. at 348-49, the rebate program does not require manufacturers to submit invoices to support their best price calculations or to regularly explain their me thodologies for calculating AMP or best price. Without requiring manufacturers to regularly provide the invoices, data or methodologies underlying their best prices, it is unreasonable to infer that the Secretary should bear the sole responsibility for monitoring best price fraud.

Finally, the Medicaid statute's confidentiality provision does not provide a sufficient basis to infer congressional intent to bar state enforcement actions. Section 1396r-8(b)(3)(D) provides that:

> Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph . . . is confidential and shall not be disclosed by the Secretary . . . or a State agency . . . in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except–
> (i) as the Secretary determines to be necessary to carry out [Section 1927.]

In order to preserve the confidentiality of manufacturer pricing data, while allowing states to verify the accuracy of their quarterly rebates, the Secretary provides the states with the URAs, and not the AMPs or best prices. See Medicaid Program: Payment for Covered Outpatient Drugs Under Drug Rebate Agreements With Manufacturers, 60 Fed. Reg. 48442, *48475 (Sept. 19, 1995). The Secretary struck this particular balance for purposes of the ordinary administration of the rebate program in compliance with the statute. 42 U.S.C. § 1396r-8(b)(3)(D)(i)(concerning disclosure "as the Secretary determines necessary to carry out this section."). This balance does not preclude states from obtaining such data from other sources (such as Defendants). Likewise, while the confidentiality provision should encourage states to coordinate with the CMS before filing best price claims, it does not provide an adequate basis to infer Congress's desire for *exclusive* federal rebate enforcement, especially given the historical role of state MFCUs in investigating and prosecuting Medicaid fraud.

For all the above reasons, we do not believe the structure of the rebate program supports the inference that Congress intended for only the federal government or CMS to pursue Medicaid best price fraud.

3. Nevada and Montana's State Law Claims Will Not Obstruct The Secretary's Ability To Administer The Rebate Program Or To Achieve Congressional Objectives

In Buckman, the Court was persuaded that the state law "fraud on the agency" claims would put an "extraneous pull" on the FDA statutory and regulatory scheme and distort the FDA's "delicate balance of statutory objectives." 531 U.S. at 348, 353. By having to comply with the FDA's regulatory regime and fifty state tort regimes, potential applicants could be both deterred from seeking FDA approval or encouraged to submit too much information to the FDA

to avoid potential state court liability later. Id. at 350-51. The Court believed that these and other unforeseen consequences were unintended by Congress and "inevitably conflict[ed] with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." Id. at 350. Again, the concerns at issue in Buckman are less an issue in this context.

First, unlike in Buckman, the best price allegations in this case would not necessarily conflict with or otherwise distort a federal agency determination. As discussed above, CMS computes the quarterly URAs using the manufacturer reported AMPs and best prices. Although the volume of data is massive, the calculations are performed electronically by CMS's Medicaid Drug Rebate Initiative System based on formulae primarily established by the rebate statute and Agreement. See Training Guide, at § H2-H16. If the states in this case successfully prove that the Defendants' best price calculations failed to include these discounts, CMS could request manufacturers to perform a recalculation.

Buckman would be much more germane were CMS responsible for and actively engaged in negotiating with manufacturers for the drug prices. In that situation, state law fraud claims alleging best price violations could conceivably distort a substantive decision made by the agency on the proper reimbursement rate for a particular product. Here, to the extent that a state successfully identifies and prosecutes a best price violation, such as alleged in this case by Montana and Nevada, such an action would not be second-guessing any agency determination and would instead be advancing Congress's objective of reducing Medicaid drug costs.

Second, the Defendants have failed to demonstrate how state law best price claims would affect their behavior in a manner that conflicts with or facially impacts the rebate program. In Buckman, the Court identified specific ways that the "fraud on the agency" claims would likely

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 sp ecific 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 ma nufacturers 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)

based on a type of transaction already addressed by CMS, agency guidance will naturally limit the amount of state, or federal, court variati on. Given the Secretary's significant expertise in administering the Medicaid program, see Walsh, 123 S.Ct. at 1872; Wisconsin Dep't of Health & Family Servs. v. Blumer, 534 U.S. 473, 479 (2002) (Secretary's interpretations of Medicaid statute "warrants respectful consideration"), any guidance or interpretation provided by the agency regarding the Medicaid drug rebate provisions will be entitled to deference by courts and states when bringing such actions .[10] See Thompson, 259 F.Supp.2d at 69-71. Finally, while "the need for uniformity in enforcement is an important goal which should be considered in determining preemption," Abbott, 263 F.Supp.2d at 188, it is not so heavy a concern in this case as to outweigh both the States' direct financia l interest in accurate best price reporting or Congress's objective of reducing Medicaid drug costs.

For the reasons discussed above, we do not believe that the Defendants have adequately demonstrated that the state law best price claims in this case will impose such a burden on the Medicaid drug rebate program as to warrant their wholesale preemption. While time may prove otherwise, the burdens and obstacles claimed by the Defendants are simply too speculative and remote to justify preempting all state law best price claims at this stage of the proceeding.

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[10] If, upon reviewing a particular sales transacti on or type of transaction CMS concludes that a price should be included or excluded with respect to best price calculations, then such a determination would be dispositive and preclude state court action to the contrary.

II. The Federal Government Has The Authority To Enforce the Medicaid Rebate Agreements Between Manufacturers And The Secretary

Given the discussion above, we do not believe it is critical to address whether the United States has the authority to bring suit to recover amounts allegedly owed to the states due to the fraudulent reporting of best prices. Indeed, as a practical matter, we believe this situation is unlikely to materialize because the United States would likely invite the states to join as co-plaintiffs in any federal action filed against a manufacturer for alleged violations of the Medicaid rebate statute or rebate agreement. [11]

Assuming this situation arose, however, the United States has the authority to enforce the obligations set forth in the Medicaid rebate statute, 42 U.S.C. § 1396r-8, and the rebate agreement. The Secretary is already expressly empowered to survey wholesalers and manufacturers to verify reported AMPs and best prices, 42 U.S.C. § 1396r-8(b)(3)(B), to impose civil money penalties for the false or untimely submission of best prices, 42 U.S.C. § 1396r-8(b)(3)(C); Rebate Agreement at §§ III, IV, and to terminate the rebate agreement for violations or for other good cause shown, 42 U.S.C. § 1396r-8(b)(4)(B); Rebate Agreement at § VIII(c). Moreover, the Agreement expressly provides that "[n]othing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution, the Act, other federal laws, or state laws." Rebate Agreement at § IX(d).

The United States retains the right to enforce the provisions of the Medicaid rebate statute and rebate agreement by suing a drug manufacturer for an alleged best price violation

[11] In a False Claims Act action pursuant to 31 U.S.C. § 3730, the district courts have jurisdiction over state law claims that arise from the same transaction or occurrence as the action under section 3730. 31 U.S.C. § 3732(b).

pursuant to 28 U.S.C. §§ 1331, 1345, and to compel the manufacturer to fully comply with the rebate obligations it assumed under the rebate agreement. For example, if a manufacturer failed to include a particular discount or rebate in its best price calculation, the United States could seek to force the manufacturer to recalculate its best price calculation including the relevant discount, to report the corrected best price information to the Secretary, and to make any additional payments necessitated by the recalculation. In that instance, regardless of whether the states joined the federal suit, the states would benefit as they would receive an additional rebate payment from the manufacturer if the United States prevailed at trial.

## CONCLUSION

For the foregoing reasons, Montana and Nevada's state law best price claims are not inconsistent with the Medicaid rebate statute and therefore should not be preempted.

Respectfully submitted,

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