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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

STATE OF NEVADA,)	3:05-cv-00322-HDM-RAM
EX REL. H. DEAN STEINKE)	
Relator)	
)	ORDER
Plaintiffs,)	
)	
v.)	
)	
MERCK & CO., INC.,)	
)	
Defendant.)	
)	

Before the court is defendant's Motion to Dismiss Plaintiffs' Amended Complaint (#34). Plaintiffs filed an opposition (#38). The states of California, Delaware, Illinois, Texas, and the District of Columbia have filed an amici curiae brief in opposition to the motion (#41). Defendants replied (#49). Defendants filed a response to the amicus curiae brief (#54).

I. BACKGROUND

This is a *qui tam* action brought under the Nevada False Claims Act, N.R.S. § 357.010 et seq., for Merck's alleged failure to include certain discounted and free Zocor and Vioxx products in the "Best Price" reports Merck submitted to the federal government

1 pursuant to the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8.

2 The complaint alleges that Merck failed to include discounts
3 under the Simvastatin Acute Care Value Enhancement ("SAVE") program
4 for Zocor. The program provided discounts of up to 92% from the
5 catalog price for Zocor if a hospital maintained a 70% market share
6 or established Zocor as the exclusive statin drug on its formulary.

7 The complaint also alleges that Merck failed to include a 92%
8 discount for Vioxx under the Vioxx Incentive Program ("VIP") if a
9 hospital committed to maintain an 80% market share.

10 Lastly the complaint alleges that Merck gave away free goods
11 to "effectively lower" the price that Merck charged providers for
12 these pharmaceuticals.

13 **II. MOTION TO DISMISS**

14 **A. FAILURE TO STATE A CLAIM - 12(b) (6)**

15 In considering a motion to dismiss for failure to state a
16 claim under Fed.R.Civ.P. 12(b) (6), the court must accept as true
17 all material allegations in the complaint as well as all reasonable
18 inferences that may be drawn from such allegations. *LSO, Ltd. v.*
19 *Stroh*, 205 F.3d 1146, 1150 (9th Cir. 2000). The allegations of the
20 complaint also must be construed in the light most favorable to the
21 nonmoving party. *Shwarz v. United States*, 234 F.3d 428, 435 (9th
22 Cir. 2000). The purpose of a motion to dismiss under Rule 12(b) (6)
23 is to test the legal sufficiency of the complaint. *Navarro v.*
24 *Block*, 250 F.3d 729, 732 (9th Cir. 2001). The court can grant the
25 motion only if it is certain that the plaintiff will not be
26 entitled to relief under any set of facts that could be proven
27 under the allegations of the complaint. *Cahill v. Liberty Mut.*
28 *Ins. Co.*, 80 F.3d 336, 338 (9th Cir. 1996).

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2 **B. ANALYSIS**

3 Merck makes four arguments for dismissal under Rule 12(b)(6):
4 (1) Plaintiffs have misread the relevant portion of the Rebate
5 Statute and Rebate Agreement, (2) Merck's Best Price reports are not
6 "knowingly" false as a matter of law, (3) the claims are barred
7 under the doctrine of conflict preemption, and (4) Plaintiffs have
8 not satisfied the heightened pleading requirements under Rule 9(b).
9 The court will address each contention in turn.

10 **C. MISREADING THE REBATE STATUTE AND AGREEMENT**

11 Merck contends that under a proper reading of the Rebate
12 Statute, Nevada has not pled facts that would create a cause of
13 action under the Nevada False Claims Act.

14 "In construing a statute, we first consider its text. When the
15 statute's language is plain, the sole function of the courts -- at
16 least where the disposition required by the text is not absurd --
17 is to enforce it according to its terms." *In re County of Orange*,
18 262 F.3d 1014, 1018 (9th Cir. 2001). A "cardinal principle of
19 statutory construction [is] that we must give effect, if possible,
20 to every clause and word of a statute." *Williams v. Taylor*, 529
21 U.S. 362, 404 (2000) (internal quotations omitted). The court is
22 thus "reluctant to treat statutory terms as surplusage in any
23 setting." *Duncan v. Walker*, 533 U.S. 167, 174 (2001).

24 However, if an agency is responsible for administering a
25 statute, the court confronts two questions when reviewing the
26 agency's interpretation. First, the court must determine if
27 "Congress has directly spoken to the precise question at issue. If
28 the intent of Congress is clear, that is the end of the matter; for

1 the court, as well as the agency, must give effect to the
2 unambiguously expressed intent of Congress." *Chevron, U.S.A., Inc.*
3 *v. NRDC, Inc.*, 467 U.S. 837, 842 (1984). If Congress has not
4 directly addressed the question and the agency has made an
5 administrative determination, the court must determine if "the
6 agency's answer is based on a permissible construction of the
7 statute." *Id.*

8 Congress defined "best price" as:

9 [T]he lowest price available from the manufacturer
10 during the rebate period to any wholesaler, retailer,
11 provider, health maintenance organization, nonprofit
12 entity, or governmental entity within the United States,
13 excluding [certain governmental entities not applicable
14 to this case.]

15 42 U.S.C. § 1396r-8(c)(1)(C)(i).

16 Congress expressly provided some "special rules" to be used in
17 the calculation of "best price."

18 The term best price --

19 (I) shall be inclusive of cash discounts,
20 free goods that are contingent on any purchase
21 requirement, volume discounts, and rebates (other than
22 rebates under this section);

23 ... and

24 (III) shall not take into account prices
25 that are merely nominal in amount.

26 42 USCS § 1396r-8(c)(1)(C)(ii).

27 Under the statute, the Secretary of Health and Human Services
28 is given broad enforcement powers. See e.g. § 1396-r8(b)(3)(B),

1 §1396-r3(b)(3)(C). In addition, the Secretary promulgates
2 regulations and interpretations for the program through the Centers
3 for Medicare and Medicaid Services ("CMS").

4 Merck urges the court to adopt a reading of the best price
5 statute as to exclude any prices less than 10% of the Average
6 Manufacturer's Price ("AMP"). In support of this interpretation,
7 Merck cites to the Rebate Agreement which defined "nominal price"
8 as "any price less than 10% of the AMP in the same quarter for
9 which the AMP is computed." Rebate Agreement, § I(s). Merck
10 claims this is consistent with the CMS release of December 14, 1994
11 which states in part, "any prices that are nominal in amount, that
12 is, less than 10% of the AMP ... are excluded from the best price
13 calculation." CMS release No. 14 (1994).

14 Nevada maintains that such a reading would render part (I) of
15 the special exceptions section superfluous as any free good would
16 be, by definition, less than 10% of the AMP. Nevada contends the
17 proper interpretation of "best price" is to include cash discounts,
18 free goods that are contingent on any purchase requirement, volume
19 discounts, and rebates if the price of those goods is less than 10%
20 of the AMP and those prices are tied to a purchase agreement.

21 The congressional record addresses what prices should be
22 excluded under the "best price" statute. The exclusion of "prices
23 that are merely nominal" was intended to exclude those prices that
24 "manufacturers offer to special purchasers, such as the sale of
25 birth control pills for a penny a pack to Planned Parenthood." 136
26 Cong. Rec. S 12954, *S12962 (1990). Likewise the legislative
27 history shows that the Rebate Statute was intended to ensure that

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1 Medicaid was "to receive the best discounts in the market...." *Id.*
2 at *S12954.

3 The legislative history shows no material change between the
4 bill as enacted and the bill as introduced for the computation of
5 "best price."¹

6 Nevada also urges the court to give meaning to the word
7 "merely" as used in subsection III of the "special rules" section
8 of the Rebate Statute. The Oxford English Dictionary defines
9 "merely" as

- 10 1. a. Without admixture or qualification; purely;
11 exclusively.
- 12 b. Without the help of others; solely.
- 13 2. a. Absolutely, entirely; quite, altogether.
14 b. As a matter of fact, actually.
- 15 3. Without any other quality, reason, purpose,
16 view, etc.; only (what is referred to) and nothing
17 more.

18 Oxford English Dictionary Online at <http://dictionary.oed.com>
19 (2006). Thus, Nevada contends that the phrase "prices that are
20 merely nominal in amount" relate to prices that are without
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23 The change from "lowest price" to "best price" is a change in
24 nomenclature that does not affect the analysis of how the "best price"
25 is defined under the statute. The addition of the parenthetical
26 phrase "other than rebates under this section" indicates the intent
27 to exclude from the calculation of "best price" rebates paid under §
28 1396r-8, which is not at issue in this case.

1 qualifications; to do otherwise would render the qualifier "merely"
2 as surplusage.

3 Nevada's interpretation is consistent with a letter from CMS
4 Administrator, Mark McClellan, to W.J. "Billy" Tauzin, President
5 and CEO of the Pharmaceutical Research and Manufacturers of
6 America, regarding the giveaway of free drugs to help those
7 affected by the Hurricane Katrina disaster. Mr. McClellan states
8 in his letter, "[u]nder the plain terms of the Medicaid statute,
9 free goods 'that are contingent on any purchase requirement' must
10 be included in the calculation of the best price." Ex. E to
11 Defendant's Motion.

12 This interpretation is also consistent with CMS release No. 14
13 which stated:

14 "best price data '... must be adjusted by the
15 Manufacturer if ... other arrangements subsequently
16 adjust the prices actually realized.' Thus, we consider
17 any price adjustment which ultimately affects the price
18 actually realized by the manufacturer as 'other
19 arrangements' and, as required by the rebate agreement,
20 included in the calculations of AMP and best price."

21 CMS Release No. 14 at 1 (1994).

22 This court concludes that the phrase "prices that are merely
23 nominal in amount" is "all prices that are less than 10% of the
24 AMP, but without other qualifications." This interpretation gives
25 deference to the Secretary's interpretation of "nominal price" and
26 also gives meaning to the word "merely" contained in the statute.
27 A "merely nominal price" is a price that is less than 10% of the

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1 AMP and is not tied to other conditions of performance or
2 consideration in addition to the "nominal prices."

3 It is undisputed that Merck did not include prices tied to its
4 SAVE and VIP incentive programs in its calculation of best price.
5 The SAVE and VIP discount and marketing plans described in the
6 complaint required additional valuable consideration and conditions
7 precedent that were more than a "merely nominal price." Therefore,
8 these prices are not without qualification.²

9 **D. MERCK'S REPORTS**

10 Merck next urges that it cannot be found to have acted
11 knowingly for purposes of the False Claims Act ("FCA") as a matter
12 of law because Merck complied with the express terms of the Rebate
13 Agreement. Further, Merck contends that even if the reports were
14 false, it is based on both an honest mistake and a reasonable
15 interpretation and cannot be "knowingly false" as required by the
16 FCA.

17 Nevada responds by contending that Merck failed to comply with
18 the express terms of Rebate Agreement by omitting the prices for
19 free and discounted goods under the VIP and SAVE incentive plans.
20 Nevada argues that whether Merck acted reasonably is a factual
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22 ²Merck concedes that the definition of "merely" means "nothing
23 else or more; only." Thus, Merck proposes the definition of "merely
24 nominal" to be "only nominal in amount" or "nothing more than nominal
25 in amount." See # 49 at fn 5. Even if the court were to accept
26 Merck's definition, the prices are tied to incentive programs and are
27 not "only nominal in amount" nor "nothing more than nominal in
28 amount."

1 question that must be resolved at trial and not on a motion to
2 dismiss.

3 For purposes of the Nevada FCA, a person acts knowingly if the
4 person "(a) has knowledge of the information; (b) acts in deliberate
5 ignorance of whether the information is true or false; or (c) Acts
6 in reckless disregard of the truth or falsity of the information."
7 N.R.S. § 357.040(2).

8 The Nevada Supreme Court has held that the scienter
9 requirement in the FCA requires the "knowing presentation of what
10 is known to be false." *Int'l Game Tech. v. Second Judicial Dist.*
11 *Court*, 127 P.3d 1088, 1105 (Nev. 2006). It does not mean "to take
12 advantage of a disputed legal question." *Id.* This is to avoid
13 punishing "honest mistakes or incorrect claims submitted through
14 mere negligence." *Id.*

15 As the court explains later in the opinion, the "FCA is meant
16 to encourage private persons to reveal instances when a person has
17 cheated or attempts to cheat the government by submitting documents
18 containing manufactured or omitted facts or data." *Id.* at 1106

19 A reasonable interpretation does not render a statement "not
20 false," but rather the good faith nature of the action "forecloses
21 the possibility that the scienter requirement is met." *United*
22 *States ex rel. Oliver v. Parsons Co.*, 195 F.3d 457, 464 (9th Cir.
23 1999).

24 Nevada has alleged that by omitting the prices of free and
25 discounted drugs given to hospitals as part of Merck's incentive
26 plans in the best price reports Merck did not act reasonably in
27 failing to comply with the terms of the Rebate Agreement. On the
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1 basis of the pleadings the court cannot conclude as a matter of law
2 that Nevada has failed to allege a claim under the FCA.

3 **E. CONFLICT PREEMPTION**

4 Merck also argues that the doctrine of conflict preemption
5 precludes this lawsuit. Merck contends that Nevada is seeking to
6 have its definition of "nominal price" be enforced by the court.
7 This, Merck says, would create conflicting obligations between the
8 state and federal requirements. Merck also contends that the fraud
9 claim is precluded under *Buckman Co. V. Plaintiffs' Legal Comm.*,
10 531 U.S. 341 (2001).

11 Nevada responds by contending the state is not seeking to have
12 its definition of "nominal price" enforced, rather Nevada is
13 seeking to enforce the Rebate Statute. In addition, Nevada
14 responds, the Rebate Statute provides statutory remedies that are
15 "in addition to other penalties as may be prescribed by law." 42
16 U.S.C. § 1396r-8(b)(3)(C)(ii).

17 A state law claim is invalidated if "compliance with both
18 federal and state regulations is a physical impossibility" or when
19 "state law stands as an obstacle to the accomplishment and
20 execution of the full purposes and objectives of Congress."
21 *Siuslaw Concrete Constr. Co. v. Washington, Dep't of Transp.*, 734
22 F.2d 952, 955 (9th Cir. 1986).

23 Instructive on the preemption analysis is the decision in re
24 *Pharm. Indus. Average Wholesale Price Litig.*, 321 F.Supp.2d 187 (D.
25 Mass. 2004) ("PhARM IV"). In that case, the court found that
26 Congress did not have a clear and manifest purpose to preempt state
27 law when it passed the Rebate Statute. *PhARM IV* at 198. Rather,
28 the court found that Medicaid is an example of cooperative

1 federalism and "that matters of public health and medical fee
2 regulation have been a field traditionally occupied by the states,
3 and states have historically played a significant role in
4 investigating and prosecuting Medicaid fraud." *Id.*

5 In distinguishing *Buckman* the court found that because
6 *Buckman* claimed fraud on an agency of the United States and because
7 United States agencies are "uniquely federal" there is no state
8 interest in such circumstances. *Pharm IV at 198.*

9 *Buckman* involved state-law causes of actions based on claims
10 that the defendant made fraudulent representations to the FDA as to
11 the intended use of the bone screws and that, as a result, the
12 devices were improperly given market clearance and were
13 subsequently used to the plaintiffs' detriment. The Supreme Court
14 held that the claims were preempted because the "federal statutory
15 scheme amply empowers the FDA to punish and deter fraud against the
16 Agency, and that this authority is used by the Agency to achieve a
17 somewhat delicate balance of statutory objectives." *Buckman at*
18 *347.* Unlike *Buckman*, the "Secretary does not make an independent
19 determination with respect to Best Price, but merely acts as a
20 go-between." *PhARM at 199.*

21 Second, the court found the statute at issue in *Buckman*
22 expressly gave the federal government, not private litigants, the
23 power to file suit for non-compliance, "whereas here the [Rebate]
24 statute provides that the federal remedies are 'in addition to
25 other penalties as may be prescribed by law.'" *Id.*

26 The court also found that the "United States considers the
27 Best Prices statute to be one of cooperative federalism and does
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1 not seek the right to exclusive rebate enforcement power."³ *Id.*
2 Therefore, the court concluded that there is no "unique federal
3 interest" to be upset by allowing states to pursue claims under the
4 Best Price statute. *Id.* at 200.

5 Merck has failed to show that the Nevada state law requiring
6 compliance with the Rebate Statute causes conflicting requirements
7 between state law and federal law. Merck has also failed to show
8 that the FCA stands as an obstacle to the accomplishment and
9 execution of the full purposes and objectives of Congress when the
10 United States has expressly disclaimed the necessity for exclusive
11 enforcement powers under the Rebate Statute. Accordingly, the
12 court concludes that the doctrine of conflict preemption does not
13 bar this lawsuit.

14 **F. FAILURE TO PLEAD WITH PARTICULARITY 9(b)**

15 Merck lastly contends that Nevada has failed to plead fraud
16 with particularity as required by Fed. R. Civ. P. 9(b). If a
17 plaintiff makes an allegation of fraud or mistake, "the
18 circumstances constituting fraud or mistake shall be stated with
19 particularity." However, "[m]alice, intent, knowledge, and other
20 condition of mind ... may be averred generally." Fed.R.Civ.P.
21 9(b). This requirement is satisfied in the plaintiff pleads "(i)
22 some of the specific customers defrauded, (ii) the type of conduct
23 at issue, (iii) the general time frame in which the conduct
24 occurred, and (iv) why the conduct was fraudulent." *United States*

26 ³The United States, in a letter addressed to this court, has
27 stated it agrees with the reasoning in *PhARM IV* on the issue of
28 conflict preemption. See # 27.

1 *v. Smithkline Beecham Clinical Labs.*, 245 F.3d 1048, 1051 (9th Cir.
2 2001). The pleading requirement is also relaxed "with respect to
3 matters within the opposing party's knowledge. In such situations,
4 plaintiffs can not be expected to have personal knowledge of the
5 relevant facts." *Neubronner v. Milken*, 6 F.3d 666, 672 (9th Cir.
6 1993). Rule 9(b) is therefore satisfied if the complaint provides
7 notice of the alleged misrepresentations.

8 Here Nevada has pled that it has been defrauded by Merck's
9 best price reports that failed to take into account free or
10 discounted pharmaceuticals given to hospitals as part of an
11 incentive program between 1999 and the present in
12 violation of the Nevada False Claims Act. The court finds that
13 this satisfies the requirements of Rule 9(b).

14 **III. CONCLUSION**

15 Accordingly, **IT IS ORDERED** that defendant's Motion to Dismiss
16 Plaintiffs' Amended Complaint (#34) be **DENIED**.

17 DATED: This 31st day of May, 2006.

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19 
20 UNITED STATES DISTRICT JUDGE