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United States District Court,
W.D. Wisconsin.

Carl THULIN, Relator for the United States of America, State of California, State of Illinois, State of Indiana, State of Michigan, State of Minnesota, State of Montana, State of Tennessee, and State of Wisconsin, Plaintiffs,
v.
SHOPKO STORES OPERATING CO., LCC, Defendant.

No. 10–CV–196–WMC. | Nov. 5, 2013.

Attorneys and Law Firms

Aaron N. Halstead, Hawks Quindel Ehlke & Perry, S.C., Madison, WI, Brian Wojtalewicz, Wojtalewicz Law Firm, Ltd., Appleton, MN, Ross Begelman, Begelman Orlow & Mellentz, Cherry Hill, NJ, James G. Vander Linden, Levander & Vander Linden, P.A., St. Louis Park, MN, Marc M. Orlow, Begelman, Orlow & Melletz, Cherry Hill, NJ, Robert P. Christensen, Robert P. Christensen, P.A., St. Louis Park, MN, Leslie K. Herje, U.S. Attorney's Office, Madison, WI, Allie Pang, United States Department Of Justice, Civil Fraud Section, Washington, DC, Erika Hiramatsu, Doj/Bureau Of Medi–Cal Fraud And Elder Abuse, San Diego, CA, Robert A. Barba, Office Of The Attorney General Of Illinois, Chicago, IL, Don Banta, Office Of The Attorney General, Indianapolis, IN, Elizabeth Louise Valentine, Michigan Department Of Attorney General, Lansing, MI, Lori Swanson, Attorney General, St. Paul, MN, Steve Bullock, Attorney General, Helena, MT, Robert E. Cooper, Jr., Office Of The Attorney General, Nashville, TN, Thomas L. Storm, Wisconsin Department Of Justice, Madison, WI, for Plaintiffs.

Breton T. Leone–Quick, Ellen L. Janos, Thomas S. Crane, Mintz Levin Cohn Ferris Glovsky & Popeo, Boston, MA, Matthew J. Duchemin, Quarles & Brady, Matthew J. Splitek, Madison, WI, for Defendant.

Opinion

OPINION AND ORDER

WILLIAM M. CONLEY, District Judge.

***1** As relator for the United States of America, State of California, State of Illinois, State of Indiana, State of Michigan, State of Minnesota, State of Montana, State of Tennessee and State of Wisconsin, plaintiff Carl Thulin brings this *qui tam* action pursuant to 31 U.S.C. § 3730(b). Specifically, Thulin alleges that defendant Shopko Stores Operating Co., LLC ("Shopko") violated the False Claims Act, 31 U.S.C. § 3729, and analogous state laws in its submission of claims to state Medicaid agencies. Shopko filed a motion to dismiss Thulin's complaint, arguing that it both (1) fails to state a claim as required by Federal Rule of Civil Procedure 12(b)(6); and (2) fails to plead the alleged fraud with specificity as required by Fed.R.Civ.P. 9(b). Because the claims are premised on an untenable legal theory, the court will grant Shopko's motion to dismiss as to the FCA claim with prejudice. As for the state law claims, the court declines to exercise its supplemental jurisdiction pursuant to 28 U.S.C. § 1367 and Seventh Circuit practice, dismissing those claims without prejudice.

ALLEGATIONS OF FACT

In addition to considering the plaintiff's complaint, the court takes judicial notice and has also considered certain exhibits attached to defendant's motion to dismiss and plaintiff's opposition brief: exhibits 6–9 attached to defendant's opening brief (dkt.50–6 to 50–9); exhibits 1–2 attached to defendant's reply brief (dkt.62–1 to 62–2); and Exhibits A and B attached to plaintiff's opposition brief (dkt.61–1, 61–2). These exhibits consist of publically-available guides, payer sheets, and other materials describing the National Council for Prescription Drug Programs. Exhibits 10–14 attached to defendant's opening brief (dkt. # # 50–10 to 50–14) consist of similar materials specific to Idaho, and exhibits 15–19 (dkt.50–15 to 50–19) consist of Minnesota-specific materials.

The court may take judicial notice of undisputed matters in the public record without converting a motion to dismiss into a motion for summary judgment. *See, e.g., Pugh v. Tribune Co.*, 521 F.3d 686, 691 n. 2 (7th Cir.2008) ("We may take judicial notice of documents in the public record ... without converting a motion to dismiss into a motion for summary judgment."). These exhibits help to fill in significant gaps in the complaint and provide the court with important context

to fully understand and evaluate the nature of plaintiff's allegations. [1]

Of course, as with the well-pleaded allegations in the complaint itself, the court views these facts and reasonable inferences in a light most favorable to plaintiff as the non-moving party.

A. The Parties

Plaintiff Carl Thulin is a pharmacist and was employed by Shopko in Idaho from roughly 2006 until 2009. Shopko owns and operates a chain of retail pharmacies in the eight states listed above.

B. Overview of Medicaid and Dual–Eligible Customers

Medicaid is a state-administered program that is jointly-funded by federal and state governments. 42 U.S.C. § 1396a(a); 42 C.F.R. § 430.0. As a condition of receiving federal funding, states must operate their Medicaid program through "an approved state plan." 42 C.F.R. § 433.10. Among the obligations imposed by the federal government on participating states is the "coordination of benefits" between the Medicaid program and private insurance companies. Some Medicaid recipients also have health insurance coverage from private, third-party insurers. These individuals are sometimes referred to as "dual-eligibles." Shopko provides pharmacy prescription medication services to "dual-eligible" customers. Thulin's complaint primarily focuses on Shopko's billing of those individuals' prescriptions.

***2** Because Medicaid is the payer of last resort, states are required to determine the liability of any third-party insurers first. 42 U.S.C. § 1396a(a)(25)(A); 42 C.F.R. §§ 433.136, 433.138–39. When a Medicaid agency is billed for items or services furnished to a recipient who also has private coverage, the state must pay the claim to the provider "to the extent that payment allowed under the [state] payment schedule exceeds the amount of the third party payment." 42 C.F.R. § 433.139(b)(1).

C. Claims Transmission System

One of the provisions of the Health Insurance Portability and Accountability Act of 1996, Pub.L. No. 104–191 requires the Secretary of Health and Human Services to "adopt standards for transactions and data elements for such transactions to enable health information to be exchanged electronically." 42 U.S.C. § 1320d–2(a)(1). In implementing this provision, the Secretary adopted the so-called "Telecommunication Standard" of the National Council for Prescription Drug Programs ("NCPDP") version 5, release 1, known as NCDPD 5.1. 45 C.F.R. § 162.1102(a)(1). Under these rules, pharmacies are required to use NCPDP 5.1 for all claims submissions to all health plans, including all state Medicaid programs. 45 C.F.R. §§ 162.1101(a), 160.103. The use of NCPDP 5.1 Telecommunication Standard was mandated during the relevant period of this case. 45 C.F.R. §§ 162.1801–162.1802.

NCPDP 5.1 provides standard specifications for data inputs, known as "fields," although states are generally free to choose which fields to require pharmacies to complete in their claims transmission. States set forth these requirements using documents known as "payer sheets," which as defendant demonstrates may not include all of the NCPDP 5.1 fields. For every claim submission, there is a "submit" transaction from the pharmacy to the "payer" and a "response" transaction from the payer to the pharmacy. For dual-eligible claims, there are four transactions: one to the private insurer; one from the private insurer; one to the state Medicaid agency; and one from the state Medicaid agency. A payer or "submit" transaction could contain 168 NCPDP fields; a "response" transaction could contain 83 fields. (Def.'s Mot. to Dismiss, Ex. 6 (NCPDP Telecommunication Standard Implementation Guide 5.1) (dkt.# 50–6).)

No one data field represents an invoice or a request for a specific amount of money from a pharmacy to a Medicaid state agency. Rather, the state Medicaid agency uses the data collected in the form to determine the amount of reimbursement allowed according to the state's "payer sheets."

D. Shopko's Alleged Billing Practice

Thulin alleges that Shopko submitted false claims through a computer system which is programmed by Shopko and used for the filling and billing of prescriptions, including prescriptions for dual-eligibles. Under this system, the private insurance claim is submitted first and paid by the private insurer or a pharmacy benefit management company ("PBM") hired by the insurer to manage and administer the prescription drug benefit consistent with the insurance policy. Thulin alleges that this "first paid claim is then readjusted by the Shopko computer to a higher dollar amount and the claim is sent to Medicaid." (Compl.(dkt.# 1) ¶ 37.) The Medicaid claim is then adjudicated by Medicaid. (These two claims are both submitted electronically within seconds of each other

at the time the prescription is dispensed.)[2] Central to his claims, Thulin alleges that "[t]his internal program of the two systems bills more for dual eligible patients than was allowed under the assignment of rights and benefits provision of federal law and contract provisions of private insurance companies." (*Id.*)[3]

***3** Thulin attaches to his complaint thirty-one records from the Shopko pharmacy where he worked. Each document consists of three pages, which plaintiff purports discloses billing information for specific transactions.[4] In his complaint, Thulin describes the data using two specific examples. In both examples, Medicaid reimbursed Shopko for more than the co-pay amount. (Compl.(dkt.# 1) ¶¶ 37–38.) Thulin contends that "many thousands of these false claims have been submitted by Shopko stores for Medicaid payment from the past to the present and continuing." (*Id.* at ¶ 40.)

Plaintiff further alleges that Shopko is a "large provider of prescription services and a sophisticated national company with vast resources to research and understand the law as it pertains to pharmacy and the reimbursement of prescription medications" and that it "knows the prices and reimbursement rates that [it] receives from these private insurance companies and PBMs." (Compl. (dkt.# 1) ¶¶ 32–33.) As such, Shopko, has "the knowledge and ability to comply with the lower assigned-right price." (*Id.* at ¶ 31.) Thulin further alleges that state Medicaid agencies lack this knowledge because they are not a party to the contracts between Shopko and the private insurance companies or PBMs and, therefore, "do not know the price benefit that the dual eligible patient assigns to the government." (*Id.* at ¶ 35.) As a result, Thulin alleges: "The state Medicaid agency is at the mercy of the provider, Shopko, to accurately calculate the assigned benefit of the drug pricing." (*Id.*) Similarly, Thulin explains, the dual-eligible customer does not know the prices he has legally assigned to the state Medicaid agency, relying on Shopko "to accurately calculate and assign the benefit to the government." (*Id.*)

E. Thulin's Discovery of the Fraud

Thulin was a pharmacist at Shopko from September 2006 until October 2009 in Idaho. In this position, he observed that Shopko's computer system did not present the billing and payment amount information on the patients' receipts or otherwise make it available to the pharmacist or technician processing prescriptions. Still, Thulin somehow gained access to documents showing billing transactions, like those attached as Exhibit A to his complaint. Thulin alleges that hard copy and electronic documents of this alleged fraud are in the exclusive possession and control of Shopko. Thulin further alleges that the state Medicaid agencies were unaware of this fraud.

F. Causes of Action

Thulin alleges causes of action under the federal False Claims Act, 31 U.S.C. § 3729 *et seq.*, and similar laws of the eight defendant states, Count II (Cal. Gov't Code § 12650 *et seq.*); Count III (740 Ill. Comp. Stats. 175/4, 175/3, 175/1); Count IV (Ind.Code § 5–11–5.5); Count V (Mich. Comp. Laws §§ 400.601, 752.1001); Count VI (Minn.Stat.15C.01); Count VII (Mont.Code Ann. Ch. 465, § 17–8–401); Count VIII (Tenn.Code Ann. §§ 75–1–181, 4–18,101); and Count IX (Wis.Stat. § 20.931).

***4** Thulin filed this complaint on April 9, 2010, as a *qui tam* plaintiff on behalf of the United States government and the states of California, Illinois, Indiana, Michigan, Minnesota, Montana, Tennessee and Wisconsin. The complaint was originally filed *in camera* and remained under seal until February 18, 2011, to provide an opportunity for the government to investigate the complaint. Neither the federal government nor any of the named states opted to intervene.

OPINION[5]

Shopko moves for dismissal of Thulin's complaint with prejudice pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b). To survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' " *Ashcroft v. Iqbal,* 556 U.S. 662, 129 S.Ct. 1937, 1949 (2009) (*quoting Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 570 (2007)). When reviewing a Rule 12(b)(6) motion to dismiss, the court "accept[s] as true all well-pled facts alleged, taking judicial notice of matters within the public record, and drawing all reasonable inferences in the plaintiff's favor." *Adkins v. VIM Recycling, Inc.,* 644 F.3d 483, 493 (7th Cir.2011).

"The FCA is an anti-fraud statute and claims under it are subject to the heightened pleading requirements of Rule 9(b)." *United States ex rel. Gross v. AIDS Research Alliance–Chicago,* 415 F.3d 601, 604 (7th Cir.2005). Federal Rule of Civil Procedure 9(b) requires that "[i]n all averments of

fraud ..., the circumstances constituting fraud ... shall be stated with particularity." In the FCA context, the Seventh Circuit requires that a complaint allege a false claim "at an individualized transaction level." *United States ex rel. Fowler v. Caremark RX, LLC,* 496 F.3d 730, 740–41 (7th Cir.2007), *overruled on other grounds by, Glaser v. Wound Care Consultants, Inc.,* 477 F.3d 502, 507 (7th Cir.2007) (internal citation omitted).

I. FCA Claim

Shopko is liable under the FCA if it "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A); *see also United States ex rel. Durcholz v. FKW, Inc.,* 189 F.3d 542, 544 (7th Cir.1999) (explaining that a violation of the FCA requires "knowing presentation of a claim that is either fraudulent or simply false") .[6] To state a cause of action, Thulin must adequately allege three elements: "(1) a false or fraudulent claim; (2) which was presented, or caused to be presented, by the defendant to the United States for payment or approval; (3) with the knowledge that the claim was false." *Fowler,* 496 F.3d at 740–41 (internal citation omitted). The FCA "is not an appropriate vehicle for policing technical compliance with administrative regulations." *Durcholz,* 189 F.3d at 545 n. 2.

Plaintiff has properly pled, and there is no dispute, that Shopko submitted claims to state Medicaid agencies for payment. The dispute is over whether the allegations of Thulin's complaint supports a finding as a matter of law that (1) the claims were false; and (2) Shopko had knowledge that the claims were false. As the Seventh Circuit has observed, these elements are closely related since "it is impossible to meaningfully discuss falsity without implicating the knowledge requirement." *United States ex rel. Lamers v. City of Green Bay,* 168 F.3d 1012, 1018 (7th Cir.1999). Consistent with the Seventh Circuit's treatment of similar FCA claims, this court will also analyze Thulin's allegations with regard to these two requirements together. *Id.*

***5** In order for a claim to be false or fraudulent, it must be prohibited by a federal regulation or statute. *See United States ex rel. Crews v. NCS Healthcare of Ill., Inc.,* 460 F.3d 853, 858 (7th Cir.2006) ("[I]f there is no requirement to adjust the claim, there is no liability for a failure to do so.") (internal citation omitted). Thulin alleges that Shopko failed to disclose the actual amount of the co-pays, as opposed to falsely stated the amount. Absent an obligation to disclose this information, however, the omission of this information cannot be false or fraudulent. *See United States ex rel. Berge v. Bd. of Trustees of the Univ. of Al.,* 104 F.3d 1453, 1461 (4th Cir.1997) ("There can only be liability under the False Claims Act where the defendant has an obligation to disclose omitted information."); *United States ex rel. Haight v. Catholic Healthcare West,* No. CV–01–2253–PHX–FJM, 2007 WL 2330790, at *5 (D.Ariz. Aug. 14, 2007) ("The False Claims Act does not impose liability for omissions unless the defendant has an obligation to disclose the omitted information."); *United States ex rel. Milam v. Regents of Univ. of Cal.,* 912 F.Supp. 868, 883 (D.Md.1995) (same).

Thulin must also allege with specificity that Shopko had knowledge that the claims were false as submitted. 31 U.S.C. § 3729(a)(1). "The *mens rea* element, 'knowingly,' requires that the defendant have actual knowledge of (or deliberately ignore or act in reckless disregard of) the truth or falsity of the information.... Thus, 'innocent' mistakes or negligence are not actionable." *Fowler,* 496 F.3d at 742 (quoting *Durcholz,* 189 F.3d at 544).

Thulin's claims rest on his contention that Shopko may only seek reimbursement for the amount of the co-pay allowed under the contracts between private health insurers and Shopko. As far as this court can discern, Thulin has two bases for this assertion. First, Thulin alleges that Shopko violates the federal assignment requirement by seeking reimbursement for more than the co-pay. Second, Thulin argues that certain federal and state regulations limit reimbursement of dual-eligible prescriptions to the co-pay amount. The court addresses each in turn.

A. Federal Assignment Requirement

When dual-eligibles apply for benefits to the state agency that administers Medicaid, they are required to assign to the State any rights they have under their private insurance plan. Title 42 U.S.C. § 1396k(a)(1)(A) provides:

> (a) For the purpose of assisting in the collection of medical support payments and other payments for medical care owed to recipients of medical assistance under the State plan approved under this subchapter, a State plan for medical assistance shall—
>
> (1) provide that, as a condition of eligibility for medical assistance under the State plan to an individual who has the legal capacity to execute an assignment for himself, the individual is required—

> (A) to assign the State any rights, of the individual or of any other person who is eligible for medical assistance under this subchapter and on whose behalf the individual has the legal authority to execute an assignment of such rights, to support (specified as support for the purpose of medical care by a court or administrative order) and to payment for medical care from any third party[.]

***6** Moreover, states are required to condition eligibility for Medicaid on this assignment:

> (a) A State plan must provide that, as a condition of eligibility, each legally able applicant or recipient is required to:
>
> (1) Assign to the Medicaid agency his or her rights, or the rights of any other individual eligible under the plan for whom he or she can legally make an assignment, to medical support and to payment for medical care from any third party[.]

42 C.F.R. § 433.145.

A private insurance company generally negotiates for prescription medications at a discounted, lower price than otherwise available to the general public. Thulin alleges that "[i]n most cases, those medications are paid for by the private insurance company less a small co-pay or deductible amount per prescription that is paid by [the] patient." (Compl.(dkt.# 1) ¶ 25.) Thulin further alleges that "[i]n all provider contracts Shopko enters into with private insurance companies and pharmacy benefit management companies ('PBMs'), Shopko agrees to accept as payment in full these lesser amounts agreed upon with the private insurance company." (*Id.*) Therefore, Thulin contends that since "the government obtains the rights and benefits of the private health insurance for these dual-eligible patients," ShopKo's "[b]illing for more than [the co-pay] is contrary to the private insurance contract and the assignment of that contracted rate to Medicaid." (Compl.(dkt.# 1) ¶¶ 25, 28.)[7]

1. Falsity

Thulin's argument that ShopKo acted fraudulently requires at least two inferences that appear without support in the plain language of the assignment requirement, corresponding regulations, case law, or logic. *First,* the plain language of 42 U.S.C. § 1396k(a)(1)(A) requires Medicaid recipients who also have access to private health care insurance to assign any rights "to payment for medical care from any third party" to the State. On its face, at least, this provision does not apply to medical care providers. Plaintiff offers no basis for reading this provision to require medical providers to assign their right to medical reimbursement payments from private health care insurers to the State.

Second, as defendant explains, there are two contracts at play here. The first is the contract between the dual eligible customer and his or her private health insurer; the second is the contract between Shopko and the private health insurer. Any limits on what Shopko may charge its dual eligible customers are covered by the contract between Shopko and the private health insurer. Accordingly, under plaintiff's theory, the assignment regulation which applies to Medicaid recipients requires Shopko to assign its rights under a contract to which the Medicaid recipient is not even a party. Once again, plaintiff fails to provide any basis for reading this obligation into the language of 42 U.S.C. § 1396k(a)(1)(A), corresponding regulations, or case law interpreting this law. While the court is to accept as true all well-pled facts and draw all reasonable inferences in plaintiff's favor, the court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Iqbal,* 129 S.Ct. at 1949.

***7** Tellingly, when faced with this challenge from defendant, plaintiff's response falls short. Instead of providing any support for his position that the assignment regulation applies to providers like Shopko, plaintiff attempts to muddle defendant's actual argument, claiming that defendant is really arguing that state regulations take supremacy over federal assignment law or that the NCPDP somehow insulates Shopko from the assignment law. (Pl's Opp'n (dkt.# 61) 10–13.) Thulin, however, fails to explain how the assignment law applies to Shopko in the first instance or provide any support for his legal claim.

2. Knowledge

Even assuming plaintiff's complaint adequately pleads a false or fraudulent claim, the complaint fails to adequately plead the knowledge requirement. At the very least, the above discussion demonstrates that Thulin's theory of liability is premised on an interpretation of the assignment requirement which is open to debate. "[I]mprecise statements or differences in interpretation growing out of a disputed legal question are ... not false under the FCA ." *Lamers,* 168 F.3d at 1018 (citing *Hagood v. Sonoma Cnty. Water Agency,* 81 F.3d 1465, 1477 (9th Cir.1996)); *see also United States v. Medica Rents Co. Ltd.,* Nos. 03–11297, 06–10393, 07–10414, 2008 WL 3876307, at *3 (5th Cir. Aug. 19, 2008) (holding that the

"substantial confusion created by contradictory instructions and guidance ... does not support a reasonable inference that [the defendant] knowingly submitted false or fraudulent claims").

Indeed, numerous district courts have dismissed similar FCA claims at least in part because a debate surrounding the plaintiff's theory of falsity precludes any finding of knowledge. *See, e.g., United States ex rel. Colucci v. Beth Israel Med. Ctr.,* 785 F.Supp.2d 303, 316 (S.D.N.Y.2011) ("Even assuming the claims submitted by [defendants] were 'false,' given the lack of clarity in the law, it cannot be said that defendants 'knew' the claims were false."); *United States ex rel. Raynor v. Nat'l Rural Utils. Co-op Fin. Corp.,* No. 8:08CV48, 2011 WL 976482, at *9 (D.Neb. Mar. 15, 2011) ("[N]othing indicates that [plaintiff's] allegations of GAAP violations are anything more than imprecise statements or differences in interpretation of a disputed or unclear legal question, neither of which are false claims under the FCA."); *United States v. Sodexho, Inc.,* No. 03–6003, 2009 WL 579380, at *17 (E.D.Pa. Mar. 6, 2009) ("The lack of clarity regarding the proper interpretation of the regulations indicates that no basis exists for imposing FCA liability on Defendants, who merely adopted a reasonable interpretation of regulatory requirements which favored their interests."); *United States ex rel. Englund v. Los Angeles Cnty.,* No. CIV. S–04–282 LKK/JFM, 2006 WL 3097941, at *7 (E.D.Cal. Oct. 31, 2006) ("Claims are not 'false' under the FCA when reasonable persons can disagree regarding whether the service was properly billed to the Government.").

***8** Moreover, except for pleading Shopko's knowledge of co-pay amounts (Compl.(dkt.# 1) ¶¶ 33–34), plaintiff's allegations of knowledge fail to meet the pleading requirements under Rule 8, not to mention the heightened requirement under Rule 9(b). (*See* Compl. (dkt.# 1) ¶¶ 46–47 (alleging that Shopko "knowingly presented" and "knowingly made" false claims).) Plaintiff states in his opposition brief that "Shopko knows, via the law and the contracts they sign, the prices that the dual eligible parties they serve are assigned to the States." (Pl's Opp'n (dkt.# 61) 28.) To the extent plaintiff is alleging that Shopko knows that the assignment law applies to it as a provider (rather than pleading that it knows the prices it negotiates with private health insurers), the pleading is not at all clear. Neither does plaintiff allege facts to support *how* Shopko knows of such an obligation, nor *who* in the organization has actual knowledge. *See Fowler,* 396 F.3d at 743 ("This allegation also fails because the Relators do not provide any information to satisfy the knowledge requirement of the False Claims Act. There is no evidence in the proposed third amended complaint that Caremark had actual knowledge of this issue or otherwise ignored or disregard it. At best, the 'scheme' as currently alleged by the Relators merely rises to a breach of contract dispute between the health plans, the government and Caremark.").

B. Regulatory Reimbursement Limits

As described in exhaustive detail in defendant's opening brief in support of its motion for summary judgment, the NCPDP allows for state Medicaid agencies to collect co-pay data but does not require it. (Def.'s Opening Br. (dkt.# 50) 21–25.) The NCPDP Guide labels various fields related to co-pay amounts as " "O" for optional, while other fields are labeled as "M" for mandatory or "RW" for required when other information is available or in certain specified situations. (*Id.* at 22 (citing Def.'s Mot. to Dismiss, Ex. 6 (NCPDP Telecommunication Standard Implementation Guide 5.1 (dkt.# 50–6).) Based on this, defendant persuasively argues that there is no federal obligation for providers such as Shopko to disclose co-pay data and, therefore, plaintiff's contention that Shopko is limited to seeking a dual-eligible's co-pay amount from Medicaid is fundamentally flawed.

In response, plaintiff cites to a Q & A section in the NCPDP Guide, wherein a Medicaid provider describes his or her understanding that entering the "co-pay" amount is an "industry standard." (Pl.'s Opp'n (dkt.# 61) 12.)[8] This passage provides insufficient support—at least standing alone—to permit a finding as a matter of law that federal regulations limit a provider's Medicaid claims for dual eligibles to the co-pay owed under the provider's contract with the private health insurer. Indeed, plaintiff's citation to a Q & A section neither delineates any clear limit of claims to co-pay amounts, nor identifies any source for such an obligation. If anything, the question posed as "looking for clarification on how new fields" are used (Def.'s Reply (dkt.# 62) 20), provides further support that no clear federal regulation exists requiring claims to be limited to co-pay amounts under a customer's private insurance policy.

***9** Plaintiff also cites to a 1990 CMS (which stands for Centers for Medicare & Medicaid Services) Manual. (Pl.'s Opp'n (dkt.# 61) 22–23.) In relevant part, the Manuel provides:

> 3904.7 Medicaid Payment to Providers Who Offer Discounts to Third Party Payers.—Some providers enter

> into agreements with third party payers to accept payment for less than the amount of charges. These arrangements are often referred to as "preferred provider agreements" or "preferred patient care agreements."
>
> Whenever you are billed for the difference between the payment received from the third party based on such an agreement and the charges, do not make Medicaid payment. The provider's agreement to accept payment of less than its charges constitutes receipt of a full payment for its services, and the insured has no further responsibility. Medicaid is intended to make payment only where there is a recipient legal obligation to pay.

(*Id.*) Even this passage, however, fails to provide the support for plaintiff's position for at least two reasons. First, the provision is directed at state Medicaid agencies, not providers. Assuming the provision governs the alleged claims submitted by Shopko, state Medicaid agencies would be on the hook to implement a regulation limiting providers' claims to co-pay amounts. Second, as defendant explains, the regulation providing the underlying authority for this manual instruction states that when the amount of third-party liability is determined, the state Medicaid agency "must then pay the claim to the extent that payment allowed under the agency's payment schedule exceeds the amount of the third party's payment." 42 C.F.R. § 433.139(b)(1). Accordingly, the actual regulation does *not* limit a provider's reimbursement to the co-pay amount contracted with a private health insurance company.

Thulin also points to state law regulations for support,[9] contending that Shopko as a provider is limited to collecting the co-pay or deductible as "required by the pertinent Medicaid rule or regulation for certain of the named plaintiff states." (Compl.(dkt .# 1) ¶ 29.) Specifically, Thulin points to a Minnesota provision. (*Id.* (citing Minnesota Health Care Programs Provider Manual, Ch. 2, p. 15 (Feb.2005 ed.))

Plaintiff has not, however, alleged any individual transactions in Minnesota as required to meet the pleading requirements of Rule 9(b). *Fowler,* 496 F.3d at 742 (affirming the dismissal of an FCA claim on Rule 9(b) grounds where the relator failed to "present any evidence *at an individualized transaction level* to demonstrate" that the defendant in that action committed fraud). The complaint only alleges individual transactions in Idaho. While plaintiff pleads generally that "certain of the named plaintiff states" have a provision limiting claims to the co-pay amount, he neither points to such an Idaho regulation in his complaint, nor does he identify one in his opposition brief. Indeed, the 2004 Idaho Medicaid Provider Handbook that would appear to govern the relevant period, does *not* require or request information on the amount of the co-pay. (Def.'s Opening Br. (dkt.# 5) 44 (citing Def.'s Mot. to Dismiss, Ex. 11 (Idaho Medicaid Provider Handbook, General Billing Information, 2–25 to 2–26 (June 2004) (dkt.# 50–11).)[10] Absent a false statement or an obligation to disclose information, there can be no liability under the False Claims Act. *See Berge,* 104 F .3d at 1461.

***10** All of this is not intended to discount the serious, underlying policy problem the Relator and many others have pointed out: state and federal governments have been reimbursing private parties for the costs of pharmaceuticals over and above the amount paid under more favorable formularies negotiated by private insurers and PBMs. Hopefully, changes in state and federal formularies have corrected much of this problem. But the fact that providers at times were able to obtain a higher reimbursement for dual-eligibles because of their Medicaid coverage than they would if those same individuals only had private insurance does not by itself constitute fraud.

Accordingly, plaintiff's allegations cannot support a finding of falsity or knowledge required to support a FCA claim. Moreover, because plaintiff's theory of liability fails as a matter of law under the facts affirmatively alleged, the court will dismiss his FCA claim with prejudice. *See Garcia v. City of Chi., Ill.,* 24 F .3d 966, 970 (7th Cir.1994) ("A district court does not abuse its discretion in denying leave to amend if the proposed repleading would be futile[.]").

II. State Law Claims

Thulin asks the court to exercise its supplemental jurisdiction pursuant to 28 U.S.C. § 1367 over the state law claims in the complaint. (Compl.(dkt. # 1) ¶ 7.) Having dismissed Thulin's only federal claim, the court will decline to exercise its supplemental jurisdiction and will dismiss the remaining state law claims without prejudice. *See Al's Serv. Ctr. v. BP Prods. N. Am., Inc.,* 599 F.3d 720, 727 (7th Cir.2010) (explaining that when a district court dismisses a plaintiffs' federal law claims, "the presumption is that the court will relinquish federal jurisdiction over any state law claims").

ORDER

IT IS ORDERED that:

1) Defendant Shopko Stores Operating Company, LLC's motion for a hearing on its motion to dismiss (dkt.# 51) is DENIED AS MOOT;

2) Defendant's motion to dismiss (dkt.# 49) is GRANTED;

3) Plaintiff's FCA claim is dismissed with prejudice, and plaintiff's state law claims are dismissed without prejudice; and

4) The clerk of the court is directed to enter judgment in favor of defendant and close this case.

Footnotes

1 The same cannot be said of other exhibits Shopko chose to attach to its motion, particularly exhibits concerning the status of plaintiff's pharmacist license. (Dkt.50–1 to 50–5.) The issue of Thulin's status as a licensed pharmacist is in no way relevant to the present motion. Defendant's submission of these documents was an unsubtle, backhanded and disappointing attempt to color the court's impression of plaintiff. Not only are these documents not material to plaintiff's complaint or the present motion, it was entirely inappropriate for defendant to raise Thulin's status as a licensed pharmacist at this stage in the case. Accordingly, the court has disregarded these materials.

2 In his opposition brief, Thulin argues, inconsistent with his allegations in his complaint, that "Shopko prevents the State Agency from performing this function [of ensuring that Medicaid is the payer of last resort] because they submit the beneficiary's private insurance claim simultaneously." (Pl.'s Opp'n (dkt.# 61) 21.) The court relies on the pleadings in the complaint in reviewing a motion to dismiss. *See Car Carriers, Inc. v. Ford Motor Co.*, 745 F.2d 1101, 1107 (7th Cir.1984) ("[I]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss.").

3 The specifics of this alleged theory of liability are discussed below in the opinion.

4 In his brief in opposition to defendant's motion to dismiss, plaintiff provides additional detail about the records. "The first page of each Exhibit contains information with respect to the beneficiary, the drug in question, prescribing physician and other related information. Page two details information regarding the amount billed to the private medical insurer. Page three shows the billing transactions with Medicaid including the amount submitted and the amount paid." (Pl.'s Opp'n (dkt.# 61) 19 n. 6 (citing Compl. (dkt.# 1) ¶¶ 37–39).)

5 This court has subject matter jurisdiction over plaintiff's FCA claim pursuant to 28 U.S.C. § 1331. Plaintiff requests that the court exercise its supplemental jurisdiction pursuant to 28 U.S.C. § 1367 over the state law claims.

6 In his complaint, plaintiff cites to 31 U.S.C. § 3729, without any citation to specific subsections. In his brief in opposition to defendant's motion to dismiss, plaintiff cites to both subsections (a)(1) and to (a)(2). (Pl's Opp'n Br. (dkt.# 61) 15.) Subsection (a)(1), which has been recodified (a)(1)(A), is described above. Subsection (a)(2), which has been recodified (a)(1)(B), imposes liability on any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B). Plaintiff does not explain, and the court cannot discern, any meaningful distinction between the presentment of a false claims and use of a false record in support of that claim set forth in these two subsections, at least as they relate to plaintiff's allegations and so they are treated as one.

7 Thulin further alleges that private insurance companies, through the aid of PBMs, "usually purchase prescriptions at lower prices than state Medicaid agencies." (Compl.(dkt.# 1) ¶ 27.) Shopko disputes this directing the court to a *New York Times* article, which states that Medicaid rates are "typically lower than what Medicare and commercial insurance pay." Robert Pear, *Rule Would Discourage States' Cutting Medicaid Payments to Providers,* N .Y. Times, May 3, 2011, *available at* http:// www.nytimes.com/2011/05/03/us/politics/03medicaid.html?scp=1 & sq=r#ule% 20would% 20discourage #& cst=cse. For purposes of deciding ShopKo's motion to dismiss, the court need not (and should not) resolve this factual dispute, and will instead assume as plead that a state Medicaid agency usually is unable to negotiate lower prices than a private insurer, a fact also supported for at least some prescriptions by Exhibit A to plaintiff's complaint, showing private health insurers have negotiated lower prices than state Medicaid agencies.

8 While plaintiff's complaint does not identify any federal regulation requiring providers to limit reimbursement sought from the state Medicaid agency to any co-pay owed by dual-eligible customers, Thulin asserts in his opposition brief that a provision of the NCPDP and a provision in a 1990 manual issued by the Centers for Medicare & Medicaid Services, support his theory that federal law requires such a limitation. Normally, the court would not consider allegations outside of the complaint in deciding a motion to dismiss, but given the court's decision to dismiss Thulin's claims with prejudice, the court will consider the additional allegations raised in his opposition brief.

9 Neither party discusses whether submitting a claim prohibited by a *state* law regulation could form the basis for a *federal* FCA claim. For the purpose of deciding the present motion, the court will nevertheless assume that as long as the claim submitted seeks federal money, the submission of the claim need only be prohibited law, whether federal or state.

10 Idaho did not require co-pay data until 2010, which postdates the period for which plaintiff has plead any individualized transactions. (Def.'s Opening Br. (dkt.# 50) 44.)

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United States District Court,
E.D. Louisiana.

In re VIOXX PRODUCTS LIABILITY LITIGATION.

MDL No. 1657. | June 29, 2010.

Attorneys and Law Firms

Orran L. Brown, Browngreer PLC, Richmond, VA, for Plaintiff.

Eric Michael Liddick, Harry Simms Hardin, III, Madeleine Fischer, Jones Walker, New Orleans, LA, for Defendant.

Opinion

FINDINGS OF FACT & CONCLUSIONS OF LAW

ELDON E. FALLON, District Judge.

***1 THIS DOCUMENT RELATES TO:** *STATE OF LOUISIANA, ex rel. JAMES D. CALDWELL, ATTORNEY GENERAL v. MERCK AND CO., INC.*, Case No. 05–3700.

TABLE OF CONTENTS

I. BACKGROUND AND PROCEDURAL HISTORY

Vioxx, known generically as rofecoxib, is a prescription drug used to treat chronic pain. It was designed and manufactured by Defendant, Merck. On September 30, 2004, Defendant Merck, removed Vioxx from the market after determining that the use of Vioxx increased the risk of cardiovascular thrombotic events. Thousands of lawsuits followed in both state and federal courts. On February 16, 2005, as a result of the sheer mass of these lawsuits and the potential for many more, the Judicial Panel on Multidistrict Litigation ("JPML") ordered that the Vioxx litigation be centralized, designated as an MDL, and assigned to this Court.

***2** One of this Court's first priorities was to assist the parties in conducting effective and efficient discovery and selecting and preparing certain test cases to proceed as bellwether trials in the personal injury cases. In total, the Court conducted six Vioxx bellwether trials.[1] One of the trials resulted in a verdict for the Plaintiff, four resulted in verdicts for the Defendant and one resulted in a hung jury. During the same period that this Court conducted six bellwether trials, approximately thirteen additional Vioxx-related cases were tried before juries in the state courts of Texas, New Jersey, California, Alabama, Illinois, and Florida. With the benefit of experience from these bellwether trials, as well as the encouragement of the several coordinated courts, the parties soon began settlement discussions in earnest.

On November 9, 2007, Merck and the Plaintiff's Negotiating Committee ("PNC") formally announced that they had reached a Settlement Agreement. *See* Settlement Agreement, *In re Vioxx Prods. Liab. Litig.*, MDL 1657 (E.D.La. Nov. 9, 2007) ("Settlement Agreement"), *available at* http:// www.browngreer.com/vioxxsettlement.[2] The private Settlement Agreement establishes a pre-funded voluntary opt-in program for resolving pending or tolled state and federal Vioxx claims against Merck as of the date of the settlement, involving claims of heart attack ("MI"), ischemic stroke ("IS"), and sudden cardiac death ("SCD"), for an overall amount of $4.85 billion. *Id.*

Having settled a large majority of the personal injury cases within this MDL, the Court turned its attention to government actions suits filed against Merck. Several government entities have pending litigation in this MDL, including suits brought on behalf of various states, including but not limited to Alaska, Colorado, Florida, Louisiana, Mississippi, Montana,

Pennsylvania, Utah, Oklahoma, and South Carolina. These suits seek damages for monies paid by the state for Vioxx, through the state's Medicaid program. These suits are based around similar claims-that each respective state would not have approved payment for Vioxx, through their Medicaid programs, had they known of its cardiovascular risks.

On July 6, 2005, the Louisiana Attorney General filed suit against Merck in state court seeking injunctive relief and damages. On August 5, 2005, Merck removed the case, after which it was transferred into the Vioxx MDL proceeding before this Court. On May 11, 2009, James D. Caldwell, the Attorney General for the State of Louisiana filed Plaintiff's Second Supplemental and Amending Complaint for Injunctive Relief and Damages ("Second Amended Complaint"). In the Second Amended Complaint, as *parens patriae* on behalf of the State of Louisiana, its citizens, and the Louisiana Department of Health and Hospitals ("LDHH"), the Plaintiff asserted claims for: 1) redhibition; 2) violations of the Louisiana Unfair Trade Practices Act ("LUTPA"); 3) violations of the New Jersey Consumer Fraud Act ("NJCFA"); and 4) unjust enrichment.

***3** On February 19, 2010, Merck filed a motion for summary judgment seeking dismissal of all claims asserted by the Louisiana Attorney General. On March 31, 2010, the Court granted in part and denied in part Merck's motion for summary judgment against Plaintiff's claims (See Rec. Doc. No. 38797). The Court dismissed Plaintiff's claims under LUTPA, NJCFA, and for unjust enrichment and preserved Plaintiff's redhibition claim.

A bench trial was held in this matter from April 12, 2010, to April 21, 2010. The Court has carefully considered the testimony of all witnesses, including those witnesses who testified by deposition, the exhibits entered into evidence, and the record as a whole and pursuant to Rule 52(a) of the Federal Rules of Civil Procedure issues the following Findings of Fact and Conclusions of Law. To the extent that any finding of fact may be construed as a conclusion of law, the Court hereby adopts it as such and to the extent that any conclusion of law constitutes a finding of fact, the Court adopts it as such.

II. FINDINGS OF FACT

A. MEDICAL/SCIENTIFIC HISTORY AND BACKGROUND OF VIOXX

Vioxx belongs to a general class of pain relievers known as non-steroidal anti-inflammatory drugs ("NSAIDs"). This class of drugs contains well-known medications sold either over the counter—such as Advil (ibuprofen) and Aleve (naproxen)—or by prescription—such as Daypro (oxaprozin) and Voltaren (diclofenac). NSAIDs work by inhibiting cyclooxygenase ("COX"), an enzyme that stimulates synthesis of prostaglandins, which are chemicals produced in the body that promote certain effects. (Nies Dep. 384:17–385:16, Apr. 1, 2005.)

Traditional NSAIDs work by inhibiting cyclooxygenase (COX), an enzyme that promotes pain and inflammation, and have been a longstanding treatment option for patients needing relief from chronic or acute inflammation and pain associated with osteoarthritis, rheumatoid arthritis, and other musculoskeletal conditions. However, it is well recognized that chronic use of traditional NSAIDs significantly increases the risk of gastrointestinal problems, including perforations, ulcers and bleeds ("PUBs"), causing thousands of deaths and many thousands of hospitalizations every year. (*See, e.g.,* Trial Tr. 1114:2–9, Apr. 20, 2010; Nies Dep. 386:7–18, Apr. 1, 2005.)

In the early 1990s, scientists discovered that the COX enzyme contained two forms—COX–1 and COX–2—each of which appeared to have several distinct functions. Scientists believed that COX–1 affected the synthesis or production of prostaglandins responsible for protection of the stomach lining, whereas COX–2 mediated the synthesis or production of prostaglandins responsible for pain and inflammation. This belief led scientists to hypothesize that "selective" NSAIDs designed to inhibit COX–2, but not COX–1, could offer the same pain relief as traditional NSAIDs with the reduced risk of fatal or debilitating PUBs. In addition, scientists believed that such drugs might be able to prove beneficial for the prevention or treatment of other conditions, such as Alzheimer's disease and certain cancers, where evidence suggested that inflammation may play a causative role. (Nies Dep. 384:17–385:16, Apr. 1, 2005.)

***4** In light of these scientific developments, Merck & Co., Inc. ("Merck") and several other pharmaceutical companies began the development of such drugs, which became known as "COX–2 inhibitors" or "coxibs." Merck developed a COX–2 inhibitor and named it Vioxx.

On November 23, 1998, Merck submitted a new drug application for Vioxx to the Food and Drug Administrations ("FDA") and requested an expedited review of its application. Six months later, on May 20, 1999, the FDA approved

Vioxx for sale in the United States. (DX 73.) From its initial approval, Vioxx gained widespread acceptance among physicians treating patients with arthritis and other conditions causing chronic or acute pain.

B. VIOXX'S GASTROINTESTINAL SAFETY IS SUPERIOR TO OTHER NSAIDS

1. CLINICAL DATA INDICATES VIOXX'S GASTROINTESTINAL SAFETY RELATIVE TO OTHER NSAIDS

The totality of the data, including clinical trials of Vioxx and meta-analyses of trials of Vioxx and other COX–2 inhibitors, shows that COX–2 inhibitors, including Vioxx, pose a lower risk of gastrointestinal complications than do traditional NSAIDs. (Trial Tr. 1136:3–25, Apr. 20, 2010.)

Endoscopy studies have been a standard and well-established means of evaluating the gastrointestinal toxicity and safety of drugs in clinical trials. (Trial Tr. 313:3–14, Apr. 13, 2010.) Two endoscopy studies with a total of 1516 patients compared Vioxx to placebo and ibuprofen and found treatment with Vioxx was associated with a significantly lower percentage of patients with endoscopic gastroduodenal ulcers than treatment with ibuprofen. (DX 73, MRK–99420021418:207–209.)

Merck's pre-marketing investigation of Vioxx's gastrointestinal safety also included an analysis of pooled osteoarthritis efficacy studies. Using a predefined set of diagnostic criteria, these studies found a significantly lower incidence of perforations, ulcers and bleeds in patients taking Vioxx, as compared to patients taking a traditional NSAID. In the pooled studies, the comparator NSAIDs were ibuprofen 2400 mg daily, diclofenac 150 mg daily, and nabumetone 1500 mg daily. (Trial Tr. 1143:1–7, April 20, 2010.) Each of these dosages was listed in the product label as an appropriate and approved dose for chronic use in the treatment of osteoarthritis. (Trial Tr. 1246:17–1247:6, 1254:4–10, Apr. 20, 2010 .) The study protocols, including the dosages of comparator drugs, were approved by the FDA, which gave no indication it believed the dosing of comparator drugs was in any way improper. (*Id.* at 1247:7–13, 1250:15–1251:6; *see also id.* at 1251:11–1254:3.)

Merck continued to study Vioxx's gastrointestinal safety after FDA approval. The VIGOR trial compared gastrointestinal outcomes in approximately 8,000 rheumatoid arthritis patients taking either 500 mg of naproxen twice daily (totaling 1000 mg of naproxen per day) or 50 mg of Vioxx daily. (Trial Tr. 1115:5–14, Apr. 20, 2010; Reicin Test. 2195:25–2196:19, Sept. 20, 2006.) Designed to perform a "rigorous testing of the GI safety of rofecoxib," VIGOR's objective was "to demonstrate that rofecoxib at twice the maximum chronic dosage would be associated with a significant reduction in confirmed clinical upper GI events." (DX 187 32:15–18, 30:1–4; Reicin Test. 2196:20–2197:2, Sept. 20, 2006.) Its primary endpoint was all clinical gastrointestinal events: perforations, ulcers, bleeding and obstruction. (Trial Tr. 1116:2–5, Apr. 20, 2010; *see also* Morrison Dep. 62:18–63:5, Dec. 18, 2003.) The comparator dose of naproxen 1000 mg daily is within the range of commonly used doses of naproxen. (*See* Trial Tr. 327:10–328:25, Apr. 13, 2010.)

***5** Data from the VIGOR study confirmed that patients taking Vioxx 50 mg daily—double the recommended dose for chronic use—had approximately half the number of clinically serious perforations, ulcers and bleeds as did patients taking naproxen 500 mg twice daily—a recommended dose for chronic use. (Trial Tr. 1118:11–1119:10, Apr. 20, 2010.) A statistically significant reduction in confirmed gastrointestinal events was also seen in predefined subgroups of patients over 65 years old, under 65 years old, with a history of previous gastrointestinal events, without a history of gastrointestinal events, positive for the bacteria *H. pylori,* negative for *H. pylori,* and with concomitant steroid use. (*Id.* at 1124:4–1125:11.) Although there was a risk reduction in the VIGOR subgroup of patients without concomitant steroid use, the reduction was not statistically significant. (*Id.* at 1121:15–1122:7.) However, the rate of adverse gastrointestinal events in the Vioxx arm of the study was similar in both the steroid users and steroid non-users subgroups. (*Id.* at 1125:12–1126:2.)

The fact that there was not a statistically significant risk reduction for all PUBs in the steroid non-users group did not mean that Vioxx's gastrointestinal benefits relative to naproxen extended only to steroid users. (Trial Tr. 1123:12–16, Apr. 20, 2010.) There was a reduction of gastrointestinal complications in the steroid non-users group, although it did not reach statistical significance, and the most important endpoint was the entire study population, which included steroid non-users. (*Id.* at 1123:17–1124:3.) Vioxx demonstrated superior gastrointestinal safety on the basis of that endpoint. (*Id.*) As a general matter, the fact that some subgroups do not reach statistical significance does not alter the validity of a study or its outcomes. (*Id.*)

The VIGOR gastrointestinal results have been confirmed by more recent studies. A meta-analysis of Vioxx clinical studies involving approximately 17,000 patients showed that, relative to traditional NSAIDs, Vioxx use resulted in better gastrointestinal outcomes and that this benefit extended to steroid non-users. (Trial Tr. 1126:3–15, 1129:4–14, Apr. 20, 2010.)

A second meta-analysis by Rostom examined 69 clinical studies of COX–2 inhibitors and traditional NSAIDs. (Trial Tr. 1131:18–1132:20, Apr. 20, 2010.) The studies consistently showed that COX–2 inhibitors are safer than other NSAIDs in terms of gastrointestinal side effects. (Trial Tr. 1132:21–1134:17, Apr. 20, 2010.) The authors specifically found that Vioxx reduced the risk of perforations, ulcers, obstructions and bleeds ("POBs") by 58% and PUBs by 56%. (*Id.* at 1134:18–24.)

Plaintiff contends that Vioxx is toxic to the gastrointestinal system, and that Vioxx does not differ substantially from other NSAIDs in terms of its gastric toxicity. Plaintiff argued at trial that Merck exaggerated GI benefits by using comparator NSAID dosages in their clinical trials that did not reflect real world conditions, and that Merck GI studies used clinically insignificant endpoints of endoscopic ulcers in its studies comparing GI toxicity of Vioxx to placebo and other NSAIDs. However, the weight of the evidence indicates that Vioxx has gastrointestinal benefits as compared to traditional NSAIDS and Merck's marketing of this aspect of the drug was consistent with the conclusions of their clinical trials.

2. THE VIOXX LABEL REPORTED ON THE DRUG'S GASTROINTESTINAL BENEFITS

i. THE 1999 LABEL

***6** The Vioxx label approved by the FDA in 1999 stated: "Serious gastrointestinal toxicity such as bleeding, ulceration, and perforation of the stomach, small intestine or large intestine, can occur at any time, with or without warning symptoms, in patients treated with nonsteroidal anti-inflammatory drugs (NSAIDs)." (DX 73, MRK–99420021422:280–82.) The label additionally cautioned that "NSAIDs should be prescribed with extreme caution in patients with a prior history of ulcer disease or gastrointestinal bleeding.... For high risk patients, alternate therapies that do not involve NSAIDs should be considered." (*Id.*)

Vioxx's 1999 gastrointestinal warning did not make claims about Vioxx's gastrointestinal safety relative to other NSAIDs. (DX 73.) Rather, the label included a paragraph noting that it was "unclear" how the rates of gastrointestinal complications found with traditional NSAID usage applied to Vioxx. (*Id.* at MRK–99420021422:296–97.) The paragraph provided data about the number of "serious upper GI event[s]" in 3,357 patients who had received Vioxx in clinical trials of six weeks to one year at daily doses ranging from 12.5 mg to 50 mg and noted that "[a]pproximately 23% of these 3357 patients were in studies that required them to be free of ulcers at study entry. It is unclear if this study population is representative of the general population." (*Id.* at MRK–99420021422:304–06.) The paragraph concluded: "Prospective, long-term studies required to compare the incidence of serious, clinically significant upper GI adverse events in patients taking *VIOXX v. comparator NSAID* products have not been performed." (*Id.*)

A separate section of the 1999 Vioxx label ("Special Studies") reported data from two endoscopy studies in a total of 1516 patients that compared the percentage of patients who developed endoscopically detectable gastroduodenal ulcers with Vioxx 25 mg daily, Vioxx 50 mg daily, ibuprofen 2400 mg daily, or placebo. (*Id.* at MRK–99420021418–21.) The label noted that patients receiving aspirin were not enrolled in the studies. (*Id.* at MRK–99420021418:201–02.) In addition to providing detailed tables of the study results, the label reported: "Treatment with VIOXX 25 mg daily or 50 mg daily was associated with a significantly lower percentage of patients with endoscopic gastroduodenal ulcers than treatment with ibuprofen 2400 mg daily. However, the studies cannot rule out at least some increase in the rate of endoscopic gastroduodenal ulcers when comparing VIOXX to placebo." (*Id.* at MRK–99420021418:207–10.) The evidence in the record does not support a finding that the summary of the endoscopy studies in the 2001 Vioxx label was inaccurate with regard to the drug's gastrointestinal benefits or that the state of the ongoing research about Vioxx's gastrointestinal safety relative to traditional NSAIDs was misrepresented in the labeling.

ii. THE 2002 LABEL

***7** The 2002 Vioxx label included a NSAID class gastrointestinal warning. (DX 273, MRK–LBL0000064.) The label stated: "Although the risk of GI toxicity is not completely eliminated with VIOXX, the results of the VIOXX GI outcomes research (VIGOR) study demonstrate that in patients treated with VIOXX, the risk of GI toxicity with VIOXX 50 mg once daily is significantly less than with naproxen 500 mg twice daily." (*Id.*) The label provided

information about the VIGOR protocol and the scope of the study, including that the study had been conducted with rheumatoid arthritis patients and that patients were not allowed to use concomitant aspirin. (DX 273, MRK–LBL0000064.)

The 2002 label also stated that VIGOR demonstrated a statistically significant risk reduction for all PUBs ("PUBs and complicated PUBs") in subgroups of patients under 65 years of age, over 65 years of age, with a history adverse gastrointestinal events, without a history of adverse gastrointestinal events, positive for *H. pylori* infection, negative for *H. pylori* infection, and with concomitant steroid use. (DX 273, MRK–LBL0000063.) The label did not specify the findings for a subgroup comprised of steroid non-users. Nor did the label specify findings for any subgroup regarding the secondary endpoint of confirmed complicated PUBs. The label reported the relative risk reduction only for the subgroups in which the reduction was statistically significant. (*See* DX 2549–A; DX 273, MRK–LBL0000063; Trial Tr. 1271:25–1272:19, Apr. 20, 2010.) The evidence in the record in this case does not support a finding that results of the ongoing research about Vioxx's gastrointestinal safety relative to traditional NSAIDs was misrepresented in the 2002 label.

C. THERE ARE CARDIOVASCULAR RISKS ASSOCIATED WITH VIOXX

1. COX–2 INHIBITORS SUCH AS VIOXX DO NOT HAVE THE CARDIOPROTECTIVE PROPERTIES OF ASPRIN

COX–2 inhibitors do not share the cardioprotective properties of aspirin. Scientists have long known that aspirin, by irreversibly inhibiting COX–1 activity in blood platelets, inhibits synthesis of thromboxane, a prostaglandin that facilitates platelet aggregation (clotting) and constriction of blood vessels. (*See, e.g.,* Nies Dep. 140:18–20, Mar. 2, 2005; Nies Dep. 391:13–22, 392:13–16, Apr. 1, 2005; Trial Tr. 965:11–966:10, Apr. 19, 2010.) By suppressing synthesis of thromboxane, aspirin effectively "thins" the blood, reducing the risk of a heart attack. Studies during Vioxx development confirmed that Vioxx, designed to inhibit COX–2 but not COX–1, does not inhibit clotting or affect bleeding time relative to placebo. (DX 73, MRK–99420021414:26–31, MRK–99420021421:249–54.)

2. CLINICAL RESULTS INDICATE THAT VIOXX IS CARDIOTOXIC

In March 2000, Merck learned the preliminary results of the VIGOR trial. (Scolnick Dep. 885:25–886:4, June 1, 2005.) VIGOR was an approximately 8,000 patient trial designed to assess the incidence of serious gastrointestinal adverse events in rheumatoid arthritis patients treated with Vioxx as compared to the incidence of such events in patients treated with naproxen, a traditional NSAID. (Trial Tr. 1115:5–14, Apr. 20, 2010; Reicin Test. 2196:5–19, Sept.20, 2006.) Over treatment periods averaging nine months, half of the patients in the study took daily doses of Vioxx 50 mg (double the highest recommended dose for continuous use), while the other half took twice-daily doses of naproxen 500 mg (a common, submaximal therapeutic dose). (Reicin Test. 2195:25–2196:19, 2198:3–7, Sept. 20, 2006.) The results of VIGOR indicated that those taking Vioxx had a greater risk of heart attack and the overall category thromboembolic events. These results were statistically significant for the subgroups of aspirin indicated (higher risk) and non-aspirin indicated (lower risk) subjects of the study. (Trial Tr. 476:24–479:23, Apr. 12, 2010; LAAG 59, MRK–NJ0071324–25.)

***8** There is dispute over whether the higher rates of heart attacks and thromboembolic events in the Vioxx population were due to a cardiotoxic effect of Vioxx or a cardioprotective effect of naproxen .[3] (*Compare* Trial Tr. 479:24–480:4, 489:5–13, Apr. 14, 2010 *with* Nies. Dep. 455:25–456:18, Apr. 1, 2005.) But the weight of the credible evidence supports the conclusion that the increase was due to the cardiotoxic effect of Vioxx.

In April 2002, after considering additional incoming clinical trial data and analysis, the FDA approved a new label for Vioxx, which detailed the cardiovascular findings in VIGOR. (DX 273; Reicin Test. 2261:15–20, Sept. 20, 2006.) Specifically, the label stated that "[t]he VIGOR study showed a higher incidence of adjudicated serious cardiovascular thrombotic events in patients treated with Vioxx 50 mg once daily as compared to patients treated with naproxen 500 mg twice daily.... This finding was largely due to a difference in the incidence of myocardial infarction between the groups." (DX 273, MRK–LBL0000063.) This information was placed in the precautions section of the label rather than in the warnings section. Further, the "[p]recautions" section of the label stated "[t]he significance of the cardiovascular findings from these 3 studies (VIGOR and 2 placebo-controlled studies) is unknown. Prospective

studies specifically designed to compare the incidence of serious CV events in patients taking VIOXX versus NSAID comparators or placebo have not been performed." (*Id.* at MRK–LBL0000065.)

In consultation with the FDA, Merck designed a study protocol (known as "Protocol 203") for systematic analysis of adjudicated cardiovascular safety data from three large scale, long-term, placebo-controlled trials designed to assess the utility of Vioxx in the prevention and treatment of colon or prostate cancer. (Reicin Test. 2297:2–8, 2298:5–2300:25, 2301:12–2303:2, Sept. 20, 2006.)

One of these trials was known as APPROVe. APPROVe was a blinded, randomized, placebo-controlled clinical trial designed to assess whether Vioxx could help prevent the recurrence of precancerous colon polyps. An external committee adjudicated the study, and found adverse events that represented potential thrombotic cardiovascular events (Reicin Test. 2309:15–2310:20, Sept. 21, 2006; Morrison Test. 1817:15–23, Nov. 8, 2006.)

On September 24, 2004, Merck learned that APPROVe's external safety monitoring board recommended that the study be terminated early in light of interim data the board had received the preceding week. (Morrison Test. 1817:24–1818:3, Nov. 8, 2006.) The monitoring board concluded that, after 18 months of continuous daily use, study participants on Vioxx 25 mg began to experience a gradually increasing rate of confirmed adverse cardiovascular events as compared to study participants on placebo. (Morrison Test. 1819:7–1821:18, Nov. 8, 2006; Reicin Test. 2309–15–2310:20, Sept. 21, 2006.) The interim results from the APPROVe study prompted Merck to withdraw Vioxx from the market on September 30, 2004. (Reicin Test. 2313:12–16, Sept. 21, 2006.)

3. THE FDA DETERMINED THAT VIOXX IS CARDIOTOXIC, AND WOULD REQUIRE PROPER WARNINGS IF MERCK DECIDED TO PLACE IT BACK ON THE MARKET

***9** On February 16–18, 2005, the FDA convened Special Advisory Committee hearings to obtain recommendations on future regulatory treatment for the entire class of selective COX–2 inhibitors. (LAAG 287; Trial Tr. 979:11–24, Apr. 19, 2010; Trial Tr. 1222:23–1223:5, Apr. 20, 2010.) The Special Advisory Committee consisted of 32 leading scientists and clinicians in the relevant fields from throughout the country. (Trial Tr. 979:11–980:1, Apr. 19, 2010; Trial Tr. 1223:15–23, Apr. 20, 2010; LAAG 287.) During its hearings, the Committee scrutinized the entire existing body of scientific research on coxibs, including the final APPROVe data and more recently unblinded data from long-term, placebo-controlled trials involving Celebrex and other coxibs. (Reicin Test. 2314:2–10, Sept. 21, 2006.) The Committee also examined available data on traditional NSAIDs and heard presentations from scientists, physicians, pharmaceutical companies, government regulators, and members of the public. (LAAG 287.) These experts voted 32 to 0 that "the available data support a conclusion that rofecoxib significantly increases the risk of cardiovascular events." (LAAG 287; Trial Tr. 979:11–980:8, Apr. 19, 2010). With Vioxx having already been removed from the market, the Committee members voted 17 to 15 that Vioxx's benefits outweighed its risks and the drug could be once again made available for prescription provided that a black box warning was displayed on its label. (LAAG 287; Trial Tr. 1224:12–20, Apr. 20, 2010.) To date, Merck has not sought to reintroduce Vioxx to the market. (Trial Tr. 1338:21–23, Apr. 20, 2010.)

On April 6, 2005, FDA's Center for Drug Evaluation and Research issued a memorandum setting forth a comprehensive analysis of the available data on coxibs and traditional NSAIDs in support of the regulatory actions the agency had decided to take. (DX 338.) This memorandum was based on an analysis of all of the data provided to the February 2005 Special Advisory Committee, as well as additional data available only to the FDA, including the entire regulatory histories and data contained in the NDA files and post-marketing databases for all NSAIDs. (DX 338, 3–4; *see also* Trial Tr. at 1227:7–18, Apr. 20, 2010.)

The FDA concluded that any increased cardiothrombotic risk appeared to be a class effect common to both coxibs and traditional NSAIDs (other than aspirin and possibly naproxen), the agency required all NSAIDs on the market (other than aspirin) to include a "black box" warning about a potential increased risk of adverse cardiovascular thrombotic events. (DX 338, 13–14.) Although Merck never brought Vioxx back on the market, other coxibs such as celobrex remain available in the United States with black box warnings.

With this background in mind, the Court now turns to an analysis of the State of Louisiana's claims.

D. THE STATE OF LOUISIANA COULD NOT HAVE DENIED REIMBURSEMENT FOR VIOXX

PRESCRIPTIONS UNDER THE MEDICAID PHARMACY PROGRAM

***10** The State in essence claims that had it known that Vioxx presented cardiovascular risks it would not have approved reimbursement under the State's Medicaid program. This claim is not supported by the weight of the evidence.

1. Federal Medicaid Requirements

Medicaid, an entitlement program created in 1965 by Title IX of the Social Security Act, is jointly funded by state and federal governments to provide health care coverage to low-income families with dependent children and to elderly, blind, and disabled individuals. 42 U.S.C.A. § 1396–1; 42 U.S.C.A. § 1396a(a)(10)(A)-(C) (West 2003 & Supp.2009). The state and federal shares of a Medicaid program's costs depend on the state's per capita income. (Trial Tr. 663:18–664:1, Apr. 15, 2010; Trial Tr. 861:16–862:8, Apr. 16, 2010.) In Louisiana, the federal government bears approximately 70% of the Medicaid costs. (Trial Tr. 861:12–14, Apr. 16, 2010.) States create and administer their own programs, but in exchange for this federal funding, they must accept significant federal regulation of the nature, scope, and attributes of their Medicaid programs. *See* 42 U.S.C.A. § 1396 *et seq.*

Under federal law, state Medicaid programs are permitted, but not required, to offer prescription drug benefits to Medicaid-eligible individuals. 42 U.S.C.A. § 1396a(a)(10); *see also* 42 U.S.C.A. § 1396d(a)(12) (West 2003 & Supp.2009). Louisiana elected to offer prescription drug benefits in its Medicaid program. (Trial Tr. 864:19–865:2, Apr. 16, 2010.)

States that decide to provide a pharmacy benefit receive both federal funding and rebates from pharmaceutical companies under the Medicaid Drug Rebate Program. 42 U.S.C.A. §§ 1396r–8(a), (b)(West 2003 & Supp.2009). This rebate program—created by the Omnibus Budget Reconciliation Act of 1990 ("OBRA 90")—requires a drug manufacturer to enter into a national rebate agreement with the Secretary of the Department of Health and Human Services ("HHS") in order for states to receive federal funding for coverage of its drug products for Medicaid patients. *Id.* (*See also* Trial Tr. 663:3–17, 665:16–666:1, Apr. 15, 2010.) These rebates are shared between the states and the federal government according to their respective shares of the program's cost. (Trial. Tr. at 665:16:16–661:1, Apr. 15, 2010.) In exchange for these rebates, which reduce the cost of the Medicaid programs, manufacturers are guaranteed coverage of their drugs under Medicaid, unless a particular drug is specifically exempted from coverage by the Medicaid statute. (*Id.* at 665:16:16–661:6.) *See also* 42 U.S. § 1396r–8(d)(2) (specifying categories of drugs excluded from Medicaid coverage). States may negotiate with pharmaceutical companies for supplemental rebates in addition to those provided under the federal rebate program. (Trial Tr. 817:24–818:8, 871:13–872:10, Apr. 16, 2010.)

States that elect to provide a prescription drug benefit must reimburse for all "covered outpatient drugs" that are subject to a national rebate agreement. "Covered outpatient drugs" are prescription drugs approved as safe and effective for their intended uses under the Federal Food, Drug, and Cosmetic Act. 42 U.S.C.A. §§ 1396r–8(a)(1), (d)(1)(B), (k)(2)(A) & (k)(6).

***11** There are only four exceptions to the Medicaid mandatory reimbursement requirement. Coverage may be denied where: (1) a prescription is not made for a "medically accepted indication"; (2) a prescription is made for a category of drugs (such as barbiturates) or for an indication (such as smoking cessation) specified in 42 U.S.C.A. § 1396r–8(d)(2) or a drug has been determined by the Secretary of HHS to be subject to clinical abuse or misuse; (3) a state has executed a special rebate agreement with the manufacturer, approved by the Secretary of HHS, specifically restricting coverage of the prescription; or (4) a state has established a formulary meeting statutory requirements and exclusion of the drug from the formulary is based on the drug's label and is for a specified population and/or condition for reasons of safety or efficacy, and the exclusion conforms with procedures set forth in the federal Medicaid statute (including making specified findings in writing and securing approval from the Secretary of HHS). 42 U.S.C.A. §§ 1396r–8(d)(1), (2), (4).

The federal Medicaid statute defines "medically accepted indications" as all uses approved by the FDA, as well as any non-approved uses supported by the compendia listed in the statute: the American Hospital Formulary Service Drug Information, the United States Pharmacopeia–Drug Information, or the DRUGDEX Information System. 42 U.S.C.A. §§ 1396r–8(k)(6), (g)(1)(B)(i).

Although reimbursement for covered outpatient drugs is mandatory, save for the exceptions set forth above, states are permitted to subject any covered outpatient drug to a prior authorization requirement, as long as the prior authorization program meets certain standards. 42 U.S.C.A. § 1396r–8(d)(1)(A). First, to establish a prior authorization program, a

state must obtain approval of the plan from the Center for Medicare and Medicaid Services and enact enabling legislation. 42 C.F.R. § 430.12(c). Second, to comply with federal law, the state's approval system must: (a) provide a response by telephone or other telecommunication device within 24 hours of the request for authorization; and (b) permit a 72–hour supply of a covered outpatient drug to be dispensed in an emergency situation (as defined by the Secretary of HHS). 42 U.S.C.A. §§ 1396r–8(d)(1)(A), (d)(5). The establishment of a prior authorization requirement for a given drug involves setting criteria for permissible use of the product. (*See* Trial Tr. 681:11–23, Apr. 15, 2010.) Prior authorization requirements are not intended to interpose the state between a doctor and patient or to deny access to a drug altogether. (*Id.*)

2. HISTORY OF LOUISIANA'S MEDICAID PHARMACY PROGRAM

Louisiana's Medicaid Program is administered by the Louisiana Department of Health and Hospitals ("LDHH"). *See* La.Rev.Stat. Ann. § 46:153.3 (2009). Prior to June 13, 2001, Louisiana law mandated that LDHH "provide reimbursement for any drug prescribed by a physician that, in his professional judgment and within the lawful scope of his practice, he considers appropriate for the ... patient." La.Rev.Stat. Ann. § 46:153.3(B)(2) (1999). Specifically, it required Medicaid reimbursement of all FDA-approved drugs, except for certain specified categories of drugs (such as infertility drugs). La.Rev.Stat. Ann. § 46:153.3(B) (1999). (*See also* Trial Tr. 717:3–12, Apr. 15, 2010; Trial Tr. 820:16–23, 865:20–866:1, 866:19–23, Apr. 16, 2010.) Therefore, prior to June 13, 2001, Louisiana law precluded the establishment of a Medicaid restrictive formulary[4] pursuant to 42 U.S.C.A. § 1396r–8(d)(4). La.Rev.Stat. Ann. § 46:153.3(B) (1999). During this time, Louisiana law also did not permit the establishment of a preferred drug list ("PDL") or prior authorization requirements in the Medicaid pharmacy program. La.Rev.Stat. Ann. § 46:153.3(B)(3) (1999).

***12** On June 13, 2001, the Louisiana State Legislature modified the State's Medicaid pharmacy program. 2001 La. Acts 395, *amending* La.Rev.Stat. Ann. § 46:153.3. Pursuant to the authority conferred by Act 395, LDHH instituted a preferred drug list and a prior authorization program, which became effective on June 10, 2002 following legislative approval of the preferred drug list. *See* 2001 La. Acts 395, *amending* La.Rev.Stat. Ann. § 46:153.3; 28 La. Reg. 979–80 (May 2002) (implementing an Emergency Rule to create a prior authorization program for drugs prescribed to Medicaid recipients); *see also* 28 La. Reg. 1639, 1640 (July 2002) (Notice of Intent to promulgate final rule establishing prior authorization program for Medicaid prescription drug program). (*See also* Trial Tr. 820:24–821:3, 848:23–25, Apr. 16, 2010.) Under this program, prescription drugs placed on the preferred drug list are covered automatically, while reimbursement for drugs not on the preferred drug list is conditioned on a prior authorization. (*See* Trial Tr. 867:3–22, Apr. 16, 2010; Trial Tr. 378:21–379:10, Apr. 13, 2010.)

Act 395 also authorized the creation of the Medicaid Pharmaceutical & Therapeutics ("P & T") Committee, which is responsible for recommending to the Secretary of LDHH which drugs to include on the preferred drug list and which drugs should require prior authorization. 2001 La. Acts 395, *amending* La.Rev.Stat. Ann. § 46:153.3(C). (*See also* Trial Tr. 822:12–16, 867:23–868:4, Apr. 16, 2010.) The Act not only specified that the Committee must have twenty-one members, but established criteria for the members. For example, Act 395 mandated that one member be a physician from Tulane with an expertise in pharmacology, while another be a practicing physician who participates in the Title XIX program as a surgeon recommended from a list of three names provided by the Louisiana Medical Society. 2001 La. Acts 395, *amending* La.Rev.Stat. Ann. § 46:153.3(C). Act 395 required that all members be appointed by the Governor and confirmed by the Senate. *Id.*

Under Act 395, the P & T Committee is "responsible for developing and maintaining a pharmacopoeia established in conjunction with a prior approval process as provided in Subparagraph (B)(2)(a) of this Section." 2001 La. Acts 395, *adding* La.Rev.Stat. Ann. § 46:153.3(C)(5)(a). Mirroring the prior authorization requirements under federal law, Act 395 required that the prior authorization program "[p]rovide for the dispensing of a minimum of a seventy-two hour supply of a covered outpatient prescription drug in an emergency situation as provided by federal rule or regulation." *See* La.Rev.Stat. Ann. § 46:153.3(B)(2)(a)(ii). Act 395 also made clear that "[t]he department shall not implement the pharmacopoeia authorized by this Subsection until the initial pharmacopoeia is submitted to and approved by the House and Senate Committees on Health and Welfare." 2001 La. Acts 395, *adding* La.Rev.Stat. Ann. § 46:153.3(C)(5)(c).

3. AT NO TIME WHILE VIOXX WAS ON THE MARKET WAS THERE A SYSTEM IN PLACE IN LOUISIANA THAT ALLOWED FOR DENIAL

OF REIMBURSEMENT OF MEDICAID VIOXX PRESCRIPTIONS

***13** Because Vioxx was a "covered outpatient drug" subject to a rebate agreement between the Secretary of HHS and Merck, LDHH was required under federal and Louisiana law to provide reimbursements for Vioxx prescriptions the entire time the drug was on the market. In 1999, when Vioxx was approved by the FDA, LDHH had an open formulary system, as discussed above, and therefore was required to cover Vioxx prescriptions automatically. (*See* Trial Tr. at 868:5–8, 896:4–6, Apr. 16, 2010.)

Following Louisiana's enactment of Act 395 and LDHH's establishment of the prior authorization program in 2002, all covered drugs were included on the preferred drug list until the P & T Committee determined whether they should be retained on the list or subjected to a prior authorization requirement. (Trial Tr. at 727:10–728:23, Apr. 15, 2010; Trial Tr. at 831:9–20, 874:7–875:18, Apr. 16, 2010.) Vioxx prescriptions thus remained automatically reimbursable until June 10, 2002, when the Secretary of LDHH adopted the P & T Committee's May 8, 2002 recommendation that Vioxx not be included on the preferred drug list, but instead require prior authorization to be prescribed. (Trial Tr. 738:9–17, Apr. 15, 2010 (COX–2 inhibitors were first considered for inclusion on the preferred drug list on May 8, 2002); Trial Tr. at 838:13–840:11, Apr. 16, 2010 (Vioxx was not recommended for the preferred drug list by the P & T Committee and required a prior authorization when the list was implemented on June 10, 2002).) As explained below this change was made for purely cost containment purposes and had nothing to do with safety concerns.

Nevertheless, LDHH's obligation to pay for Vioxx prescriptions continued even after the implementation of the preferred drug list. When it established the prior authorization program, LDHH prohibited for six months any restriction on prescriptions written prior to June 10, 2002, the date the prior authorization program became effective. (DX 3639, 5; *see also* Trial Tr. at 418:17–420:13, Apr. 13, 2010.) After that six-month period, reimbursement of Vioxx prescriptions was conditioned on prior authorization. But while physicians were required to seek prior authorization, such authorization could not be withheld. (Biglane Dep. 93:18–94:7, Oct. 28, 2009; Trial Tr. 873:5–16, Apr. 16, 2010.) *See* also 28 La. Reg. 1639, 1640 (July 2002). The Louisiana prior authorization program has a policy of deferring to prescribing physicians and has never rejected a request for prior authorization. (Trial Tr. 823:18–824:1, Apr. 16, 2010.) No denial process has ever been created. (Trial Tr. 824:2–9, Apr. 16, 2010.)

On July 14, 2003, LDHH Secretary David Hood accepted the recommendation of the P & T Committee to place Vioxx on the preferred drug list, making it once again automatically reimbursable. (*See* Trial Tr. 749:23–750:16, Apr. 15, 2010.) In summary prior authorization was only required for Vioxx prescriptions written and filled between June 10, 2002 and July 14, 2003, and even during that time, prior authorization could not be withheld and was always granted.

E. THE STATE OF LOUISIANA DID NOT MEET THEIR BURDEN OF SHOWING THAT THEY COULD AND WOULD HAVE ESTABLISHED AN EXCLUSIVE FORMULARY AND EXCLUDED VIOXX FROM IT HAD THE STATE KNOWN DIFFERENT INFORMATION ABOUT THE DRUG

***14** Plaintiff argues that it would have taken steps to modify its pharmacy program in order to deny reimbursement for Vioxx entirely if it had had different information about Vioxx. As previously noted, there are only four circumstances under which a state Medicaid program is entitled to deny coverage for a covered outpatient drug. The only avenue of the four potentially applicable to the State of Louisiana was to establish an exclusive formulary. Plaintiff claimed that, had it known of different information about Vioxx, LDHH would have established an exclusive formulary pursuant to 42 U.S.C.A. § 1396r–8(d)(4) for the purpose of excluding Vioxx from the formulary, and thereby denied coverage for the drug. The credible evidence shows, however, that LDHH could not, and would not, have established such a formulary.

1. THE LOUISIANA LEGISLATURE WOULD NOT HAVE APPROVED AN EXCLUSIVE FORMULARY

As discussed above, until the Louisiana Legislature passed Act 395 on June 13, 2001, LDHH was legally prohibited from establishing an exclusive formulary. La.Rev.Stat. Ann. § 46:153.3(B) (1999). Act 395 was not self-executing. It required LDHH to get approval by the House and Senate Committees on Health and Welfare before implementing a "pharmacopoeia" or formulary. 2001 La. Acts 395, *adding* La.Rev.Stat. Ann. § 46:153.3(C)(5)(c). LDHH did not promulgate regulations to implement a prior authorization system until a year later. *See* 28 La. Reg. 979–80 (May 2002); 28 La. Reg. 1639 (July 2002). (*See also* Trial Tr. 406:18–21, 413:24–414:14, 416:24–417:2, Apr. 13, 2010.) In the interim, LDHH was required to identify P & T Committee members to

be appointed by the Governor, form the Committee, establish Committee by-laws, contract with Provider Synergies to perform drug assessments, review drugs to construct the initial preferred drug list, and gain approval of the list from the legislature. (*Id.* at 417:12–418:5; Trial Tr. 728:24–730:14, Apr. 15, 2010.)

These legalities would have had to be completed for an exclusive formulary as well. *See* 42 U.S.C.A. § 1396r–8(d)(4)(A) (an exclusive formulary must be "developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State"); La.Rev.Stat. Ann. § 46:153.3(D)(5)(d) (pharmacopoeia authorized by Act 395 cannot be implemented until initial pharmacopoeia is submitted to and approved by the Louisiana House and Senate committees on health and welfare). Federal Medicaid law does permit a state's Drug Use Review ("DUR") Board to create an exclusive formulary if so authorized by the state (42 U.S.C.A. § 1396r–8(d)(4)(A)). Act 395 created the P & T Committee and authorized it to "develop [ ] and maintain[ ] a pharmacopoeia established in conjunction with a prior approval process." 2001 La. Acts 395, *adding* La.Rev.Stat. Ann. § 46:153.3(C)(5)(a). However, development of an exclusive formulary by the DUR Board was not authorized by Act 395 and would have conflicted with the establishment and duties of the P & T Committee.

***15** To establish an exclusive formulary, the State of Louisiana would also have been required to file an amended state plan and seek approval from the federal Center for Medicare and Medicaid Services ("CMS"). *See* 42 C.F.R. § 430.12(c). (*See also* Trial Tr. 444:3–8, Apr. 13, 2010.)

Additionally, the evidence shows that LDHH would not have been able to gain the necessary legislative approval if it had attempted to institute an exclusive formulary. Louisiana had experimented with a closed formulary in the 1980s, and it had met with considerable opposition from physicians, pharmacists and patient advocates. (Trial Tr. 402:18–403:15, 451:19–24, Apr. 13, 2010.) Consequently the State moved to an open formulary which required the Medicaid program to reimburse for all covered prescription drugs. *See* La.Rev.Stat. Ann. § 46:153.3(B)(2) (1999).

When LDHH began to work toward passage of Act 395, the State wanted a system that would ensure that when a doctor made an individual prescribing decision, there was a mechanism in place to get the prescribed drug to the patient. (Trial Tr. 431:16–23, Apr. 13, 2010.) As Secretary Hood testified, an exclusive formulary would not have been politically "palatable." (*Id.* at 409:15–19 .) Further, the fact that Act 395 provided for a prior authorization process, but no actual denial of prescriptions, was a selling point that helped to get buy in from other actors in the political process. (Trial Tr. 824:10–17, Apr. 16, 2010.)

Legislative opposition to an exclusive formulary was evident even after Act 395 was passed. LDHH was required to return to the Louisiana House and Senate Joint Committee on Health and Welfare to gain approval of the prior authorization process and the initial formulary it had designed pursuant to the powers granted by Act 395. *See* 2001 La. Acts 395, *adding* La.Rev.Stat. Ann. § 46:153.3(C)(5)(c). (*See also* Trial Tr. 404:1–13, 406:2–25, Apr. 13, 2010.) Mr. Hood admitted that, in the course of this process, legislators expressed their opposition to any system akin to the closed formulary of the 1980s. (*Id.* at 407:3–7, 407:23–408:4.) The Chairman of the Committee declared that the legislative intent was never to institute a formulary where LDHH "could say automatically these drugs are excluded." (Rec. Doc. No. 40187–1, Testimony Before the Louisiana Health and Welfare Committee, May 9, 2002 (Ex. A to Merck's Notice of Filing of Transcript of Certain Testimony Before Legislative Committee Hearings Played During the Testimony of David W. Hood).) Rather, he insisted, the legislature "didn't do anything different other than say it's a preferred provider list." As LDHH Secretary, Mr. Hood assured the Committee that the prior authorization program would not restrict access to drugs. (Trial Tr. 407:22–408:24, 409:15–19, Apr. 13, 2010.) Specifically, he stated:

> There was brought up the concern about would this be a replay of the 1989 formulary that was put into effect. The answer is no. There was no prior authorization in 1989. That meant that it was either you use the drug on the list or you don't get the drug, period. But that's not the case now. We do have prior authorization.

***16** (Rec.Doc. No. 40187–1.)

Given the political opposition to restricting Medicaid recipients' access to FDA-approved drugs, it is not plausible to conclude by a preponderance of the evidence that, had LDHH received different or additional information about Vioxx, it could have garnered the necessary legislative

approval to institute an exclusive formulary, radically transforming the Louisiana Medicaid pharmacy program, for the narrow purpose of trying to deny reimbursement for a single drug.

2. HAD LDHH KNOWN DIFFERENT INFORMATION ABOUT VIOXX THEY WOULD NOT HAVE SOUGHT APPROVAL BY THE LEGISLATURE FOR AN EXCLUSIVE FORMULARY

Apart from the question of whether LDHH *could* have instituted an exclusive formulary while Vioxx was on the market, Plaintiff did not carry its burden that, had the State possessed different clinical information about Vioxx, it *would* have sought to restrict Vioxx Medicaid reimbursements entirely. The record shows, in fact, that neither LDHH nor any reasonable department of health and hospitals would have attempted to establish an exclusive Medicaid formulary for the sole purpose of cutting off reimbursements for Vioxx.

David Hood was Secretary of LDHH from 1998 to February of 2004, nearly the entire time that Vioxx was on the market. (Trial Tr. 368:18–22, Apr. 13, 2010). As Secretary, David Hood had exclusive authority within LDHH to implement changes to the State's prior authorization program and preferred drug list. (*Id.* at 369:17–370:8; *see also* Trial Tr. 882:8–20, Apr. 16, 2010; Trial Tr. 741:12–19, Apr. 15, 2010). Mr. Hood admitted that, as Secretary of LDHH, he never made any decisions about a prescription drug, including Vioxx, based on his independent assessment or understanding of the drug's risks and benefits. (Trial Tr. 423:8–14, 426:21–427:5, Apr. 13, 2010.) Mr. Hood is not a medical doctor and he readily acknowledged that he was not qualified to make independent assessments of the clinical risks and benefits of prescription drugs. (*Id.* at 400:16–17, 426:7–17.) For such assessments, he relied upon the judgment of the LDHH staff and the doctors, pharmacists and pharmacologists on the P & T Committee. (*See id.* at 423:8–14, 426:18–20, 372:10–15, 372:21–373:1, 373:12–374:2, 375:15–25; *see also* Trial Tr. at 830:24–831:2, Apr. 16, 2010.) The P & T Committee, in turn, contracted with Provider Synergies to complete clinical evaluations of drugs and make recommendations to the Committee about which products to place on the preferred drug list. (Trial Tr. 380:7–15, 432:9–20, Apr. 13, 2010; *see also id.* at 434:13–20.) Mr. Hood testified that he was aware that Vioxx carried cardiovascular and gastrointestinal risks, but he relied upon the judgment of the P & T Committee and Provider Synergies. (*Id.* at 421:17–423:14, 426:18–427:5.)

Mr. Hood testified that he was unaware of any instance in which the Louisiana P & T Committee came to a decision about the safety and/or efficacy of an FDA-approved drug that was at odds with the FDA's determination. (Trial Tr. 430:5–22, 431:8–15, Apr. 13, 2010; *see also* Trial Tr. 722:7–11, Apr. 15, 2010 (Mr. Castille testifying that the State of Louisiana does not make determinations independent of the FDA about a drug's safety and efficacy).) Mr. Hood acknowledged that FDA approval of a medicine is important to DHH and the P & T Committee as "an indication" that a product is "a safe drug." (Trial Tr. 429:20–23, Apr. 13, 2010.)

***17** LDHH's motive in establishing a preferred drug list and prior authorization process was to save money. Toward this end, Provider Synergies is charged with providing the P & T Committee with an analysis of the comparative costs of drugs. (Trial Tr. 826:17–22, 877:23–878:10, Apr. 16, 2010.) Provider Synergies plays a critical role in reducing prescription drug costs to LDHH by securing supplemental rebate agreements from drug manufacturers. (Trial Tr. 767:9–12, Apr. 15, 2010; Trial Tr. 825:15–25, 877:10–22, 890:14–16, Apr. 16, 2010.) A pharmaceutical company's unwillingness to provide a supplemental rebate for its drugs would adversely affect the company's chances that its products would be placed on the preferred drug list. (*See* Trial Tr. 734:5–9, Apr. 15, 2010.)

Charles Castille, the Undersecretary of DHH, testified that Merck's initial refusal to provide supplemental rebates to Louisiana was "generally the reason" that Merck's products, including Vioxx, were not included on the preferred drug list in 2002. (Trial Tr. 734:10–17, Apr. 15, 2010.) By the time the P & T Committee considered Vioxx for inclusion on the preferred drug list in 2003, Merck had offered Louisiana a supplemental rebate on its drugs. (Trial Tr. 746:5–8, Apr. 15, 2010.) The Committee decided to include Vioxx on the preferred drug list because Merck's supplemental rebate offer made Vioxx more cost-effective to the State than Celebrex. (Trial Tr. 889:10–890:13, Apr. 16, 2010.)

The P & T Committee's prioritization of cost continued throughout the time Vioxx was on the market and beyond. At the May 5, 2004 P & T Committee meeting, Provider Synergies reported that the manufacturer of Celebrex had offered an additional rebate, but that it was not sufficient to warrant putting the drug back on the preferred drug list. (DX 2119, 4; DX 2120, 25–31; Trial Tr. 754:7–755:11, 790:14–791:10, Apr. 15, 2010.)

By the August 11, 2004 meeting of the P & T Committee, however, Provider Synergies and Pfizer had negotiated an acceptable price. (*See* Trial Tr. 794:1–11, Apr. 15, 2010.) The Committee voted to follow Provider Synergies' recommendation that all three COX–2 drugs be placed on the preferred drug list. (Trial Tr. 757:7–758:7, Apr. 15, 2010.)

Because Mr. Hood made decisions about drugs in reliance on the recommendations of LDHH staff, P & T Committee members and Provider Synergies and there is no evidence in the record of what recommendations these entities would have made had they possessed different data, it is not legally sustainable to conclude that Mr. Hood would have acted to deny reimbursements for Vioxx had the State received different information about the drug.

Mr. Hood also conceded that as LDHH Secretary he never even considered restricting the State's reimbursement of an FDA-approved drug. (Trial Tr. 428:2–5, Apr. 13, 2010.) He acknowledged that, while Secretary, he did not know of any authority under which he could have instituted an exclusive formulary had he decided one was necessary on account of Vioxx. (*Id.* at 438:20–439:14, 439:24–440:7.)

***18** Mr. Hood stated that in order to deny reimbursement for Vioxx prescriptions, he would have consulted with LDHH attorneys. (*Id.* at 381:13–382:5; *see also id.* at 440:8–21.) This is not sufficient to establish that the State would have pursued the option of an exclusive formulary. There is no factual record from which it could be inferred that Mr. Hood would have been advised that an exclusive formulary was an option. This is particularly so given the political opposition to such a formulary. Further, Charles Castille, an attorney and LDHH Undersecretary, testified that "the State could not have, for example, have done what, let's say, the FDA could do, and take a drug off the market. We obviously did not have that authority." (Trial Tr. 742:11–743:4, Apr. 15, 2010.) Taking a drug off the preferred drug list was "the most restrictive thing" LDHH could do, Mr. Castille testified. (*Id.* at 743:3–4.)

The evidence shows that the P & T Committee's decisions about which drugs to include on the preferred drug list were driven by cost, not safety concerns, such that additional information about Vioxx's potential cardiovascular risks would not have prompted the Committee to seek to deny reimbursements for Vioxx prescriptions. For safety, the P & T Committee relied on the FDA. The credible evidence supports the conclusion that the P & T Committee, and LDHH simply did not have the institutional structure, expertise, or resources to scrutinize the safety of every FDA approved drug.

3. TO DATE, LDHH HAS NOT INSTITUTED AN EXCLUSIVE FORMULARY AND CONTINUES TO REIMBURSE MEDICAID PRESCRIPTIONS FOR COMPARATOR DRUGS SUCH AS CELOBREX

One can determine what a reasonable department of health and hospitals would have done had it received different information about Vioxx by examining what LDHH actually did in a closely analogous situation. On April 6, 2005, FDA's Center for Drug Evaluation and Research issued a memorandum setting forth a comprehensive analysis of the available data on traditional NSAIDs, such as ibuprofen and diclofenac, as well as COX–2 inhibitors such as Vioxx and Celebrex. (*See* DX 338.) The memorandum concluded that there is a "class effect" for increased cardiovascular risks with all NSAIDs (except aspirin and possibly naproxen) and that it was not possible, based on available clinical trial data, to create a "rank ordering" of these drugs. (*Id.* at 10–11.) In other words, in 2005 the FDA concluded that Celebrex, Vioxx and other traditional NSAIDs (except aspirin and naproxen) carried significant cardiovascular risks. Consequently, the FDA required manufacturers of all NSAIDs—including COX–2 inhibitors—to place a "black box" warning on the drugs' labeling about such potential cardiovascular risks. (DX 338, 14; *see also* Trial Tr. 795:10–22, Apr. 15, 2010 .)

LDHH did not institute an exclusive formulary in response to this development. Instead, it continued to keep these drugs on its preferred drug list. (*See* DX 2165.) In 2004, Celebrex, another COX–2 inhibitor, was found to carry an increased risk of cardiovascular thrombotic events and it possessed no statistically significant gastrointestinal benefit. (Trial Tr. 641:6–15, Apr. 15, 2010.) But despite these facts, and despite the addition of a black box cardiovascular warning to the Celebrex label in 2005, LDHH continued to include Celebrex on its preferred drug list as recently as 2008. (*Id.* at 642:2–10; DX 2165.) Similarly, the NSAID diclofenac has been shown to carry a statistically significant increased cardiovascular risk, yet even after that risk was established, diclofenac remained on the Louisiana preferred drug list. (Trial Tr. at 1047:20–1050:3, Apr. 19, 2010; DX 2165.) In fact, the Louisiana preferred drug list contains a large number of drugs that carry black box warnings. (Trial Tr. 686:6–11, Apr. 15, 2010.)

F. PLAINTIFF HAD ACCESS TO LITERATURE AND CLINICAL STUDIES THAT INDICATED CARDIOVASCULAR CONCERNS OVER VIOXX

***19** Plaintiff asserts that had it known of the cardiovascular risks of Vioxx it would have taken action. The evidence however, reveals that Plaintiff had sufficient information about these risks and did not take any action.

Following Louisiana's enactment of Act 395 and LDHH's establishment of the prior authorization program in 2002, all covered drugs were included on the preferred drug list until the P & T Committee determined whether they should remain on the list or be subject to a prior authorization requirement. (Trial Tr. 727:10–728:23, Apr. 15, 2010; Trial Tr. at 831:9–20, 874:7–875:18, Apr. 16, 2010.) Since March 19, 2002, LDHH has contracted with Provider Synergies LLC to perform clinical and economic analyses of prescription drug data for the P & T Committee, which uses that information to make recommendations about which drugs to include on the preferred drug list. (Trial Tr. 732:11–22, 766:3–10, 768:9–19, Apr. 15, 2010; Trial Tr. 878:11–879:4, 879:17–21, 880:11–19, 881:21–25, 896:15–19, Apr. 16, 2010.) Thus, the Court looks to the information that Plaintiff, specifically the P & T Committee, had available to it from 2002 on and what actions they took in response to that information.

1. THE P & T COMMITTEE RECEIVES THEIR INFORMATION ABOUT DRUGS FROM PROVIDER SYNERGIES AND BASES THEIR DECISIONS ON THAT INFORMATION

The P & T Committee relies heavily on both the FDA's and Provider Synergies' independent assessments of the clinical evidence regarding the risks and benefits of prescription drugs. (*See* Trial Tr. 429:20–23, Apr. 13, 2010; Trial Tr. at 722:7–11, 766:11–17, Apr. 15, 2010; Trial Tr. 830:9–12, Apr. 16, 2010.) Provider Synergies relies "on independent, peer-reviewed, published clinical data and FDA labeling and findings as [the] primary source of information for [its] reviews." (Trial Tr. 767:16–21, Apr. 15, 2010.) This included clinical data sponsored by Merck. Provider Synergies does not rely on marketing materials, internal emails, or formulary dossiers from pharmaceutical companies, although it does request clinical study information from manufacturers from time to time. (Trial Tr. 775:20–776:4, Apr. 15, 2010.)

Provider Synergies briefs the P & T Committee on the clinical strengths and weaknesses of the drugs the Committee considers for placement on or exclusion from the preferred drug list. (*See* Trial Tr. at 739:14–20, Apr. 15, 2010; Trial Tr. 880:11–19, Apr. 16, 2010.)

2. LDHH AND THE P & T COMMITTEE WERE PROVIDED WITH DATA AND INFORMATION THAT INDICATED CARDIOVASCULAR CONCERNS ABOUT VIOXX

In 2002, 2003, & 2004 monographs on "Selective Cyclooxygenase (COX)–2 Inhibitors" were prepared by Provider Synergies and distributed to P & T Committee members. These monographs reported the results of controlled clinical trials, including VIGOR, that tested Vioxx's safety and efficacy, as well as studies that compared the safety and efficacy of Vioxx and Celebrex. (LAAG 439; LAAG 426; DX 2118). These monographs were used by the P & T Committee at meetings to determine whether Vioxx should be placed on or taken off of the preferred drug list. (DX2071 (Tr. of May 8, 2002 P & T Meeting); DX2095 (Tr. of May 21, 2003 P & T Committee Meeting); DX2120 (Tr. of May 5, 2004 P & T Committee Meeting).)

***20** The 2002 monograph included a section entitled "Cardiovascular Concerns." This section summarized the findings of a meta-analysis of COX–2 inhibitors published by Dr. Steven Nissen and Dr. Eric Topol in *JAMA* in August 2001 and noted that the authors of the analysis "concluded that a prospective trial may be necessary to evaluate the potential risk of cardiovascular events with these agents." (*See* LAAG 439, 6 & 6, n. 33; *see also* Trial Tr. 884:18–885:10, Apr. 16, 2010.) Reference to the *JAMA* article in the monographs indicated that the reviewers who prepared the monograph were familiar with the ongoing scientific discussion about the possible reasons for the VIGOR cardiovascular outcomes, including the possibility that Vioxx had a prothrombotic, cardiotoxic effect. (*See* Trial Tr. 942:13–944:3, Apr. 19, 2010.)

Additionally, in July of 2003, the LDHH Pharmacy Director, M.J. Terrebonne, and then-Secretary of LDHH, David Hood, received a letter from Pfizer, the manufacturer of Celebrex, requesting a review of Celebrex's exclusion from Louisiana's preferred drug list. (Trial Tr. 843:20–844:13, Apr. 16, 2010.) The Pfizer letter went to lengths to emphasize that Vioxx (unlike Celebrex) had a cardiovascular warning on its label, including a statement that Vioxx should be used with caution in patients with a history of ischemic heart disease. (*Id.* at 844:14–846:6.) Ms. Terrebonne testified that, having attended the P & T Committee meetings at which Vioxx was discussed, she already knew of the cardiovascular concerns

with Vioxx raised in the July 2003 Pfizer letter. (*Id.* at 846:7–11.)

3. MERCK ATTEMPTED TO NEUTRALIZE CONCERNS THAT VIOXX WAS CARDIOTOXIC

The 2002, 2003 and 2004 monographs provided by Provider Synergies to the P & T Committee all cited to the *Journal of the American Medical Association (JAMA)* article by Mukherjee which reported on the VIGOR results and concluded, according to Provider Synergies, "that a prospective trial may be necessary to evaluate the potential risk of cardiovascular events" with COX–2 inhibitors. (LAAG 439, 6, n. 33; LAAG 426, 10, n. 58; DX 2118, 13, n. 62.) The monographs cautioned against the method of meta-analysis used in *JAMA* to establish cardiovascular risks (LAAG 439, 6; LAAG 426, 10; DX 2118, 13), and the 2003 and 2004 monographs included citations to the Merck sponsored Reicin and Konstam articles which further undercut the findings of the VIGOR study. (LAAG 426, 10, nn .60–61; DX 2118, 13, nn. 65–66). These Merck sponsored articles were provided to Provider Synergies on April 19, 2002, in response to Provider Synergies' Valerie Taylor's request for cardiovascular information regarding Vioxx. Merck cited the Reicin and Konstam studies in response to the *JAMA* article and claimed that the Reicin article demonstrated that "no difference exists between [Vioxx], comparator non-selective NSAIDs, and placebo in the risks of cardiovascular thrombotic events." (LAAG 573.)[5] Merck stated that the Konstam article concluded, "[Vioxx] was not associated with excess CV thrombotic events compared with either placebo or non-naproxen NSAIDs." (*Id.*) They went on to re-urge the "naproxen theory" stating, "The data suggest, but are insufficient to ascertain, the cardioprotective effects of naproxen." (*Id.*)

***21** However, despite these two articles which may have counterbalanced the VIGOR data, the 2003 and 2004 monographs provided to the P & T Committee concluded that

> The VIGOR study raised some questions regarding the cardiovascular safety of rofecoxib (Vioxx). Patients receiving rofecoxib (Vioxx) had a significantly higher risk of developing a cardiovascular thrombotic event compared to patients receiving naproxen. Aspirin for cardiovascular prophylaxis was not permitted in the study, which does not reflect "real world" use of the NSAIDS. Although the significance of this potential cardiovascular risk is unknown, it does raise questions.
>
> (LAAG 426, 12; DX 2118, 15.)

The point is that since February of 2002 the P & T Committee was aware of the potential cardiovascular risks of Vioxx that were indicated in VIGOR. Further, the 2003 and 2004 monographs provided further, more extensive information to the P & T Committee regarding the controversy surrounding Cox–2 inhibitors including Vioxx and yet at no time did the P & T Committee make any recommendations to try to restrict its use. Plaintiff's protestations now ring hollow.

III. CONCLUSIONS OF LAW

To establish a claim in redhibition, the plaintiff must satisfy the following elements:

> (1) the thing sold is absolutely useless for its intended purposes, or that he would not have bought it had he known of the defect; (2) that the defect existed at the time that he purchased the thing, but was neither known nor apparent to him; and (3) that the seller was given the opportunity to repair the defect.

Alston v. Fleetwood Motor Homes of Indiana, 480 F.3d 695, 699 (5th Cir.2007).

This Court concludes that Plaintiff's redhibition claim fails because Plaintiff did not prove causation. As such, the Court need not reach a conclusion as to whether Vioxx suffered from a redhibitory defect, whether the Plaintiff was on notice of the defect at the time of purchase, or what remedy Plaintiff may have been entitled to.

Plaintiff failed to satisfy its burden of proving causation because it did not establish at trial that: had it known different facts about Vioxx (a) the State could have established an exclusive formulary; (b) and the State would have established such a formulary and excluded Vioxx from it.

Louisiana could not have adopted an exclusive formulary before June 13, 2001. Prior to that time, Louisiana law required that LDHH "provide reimbursement for any drug prescribed by a physician that, in his professional judgment and within the lawful scope of his practice, he considers appropriate for the diagnosis and treatment of the patient." La.Rev.Stat. Ann. § 46:153.3(B)(2) (1999).

Upon the enactment of Act 395 on June 13, 2001, LDHH instituted a Medicaid pharmacy program utilizing a preferred drug list and prior authorization system—not an exclusive formulary. *See* 2001 La. Acts 395, *amending* La.Rev.Stat. Ann. § 46:153.3; 28 La. Reg. 979–80 (May 2002) (implementing an Emergency Rule to create a prior authorization program for drugs prescribed to Medicaid recipients); *see also* 28 La. Reg. 1639, 1639–41 (July 2002) (Notice of Intent to promulgate final rule establishing prior authorization program for Medicaid prescription drug program). Under this program, prescription drugs placed on the preferred drug list are covered automatically, while reimbursement for drugs not on the preferred drug list is conditioned on prior authorization. (*See* Trial Tr. 378:21–379:10, Apr. 13, 2010.) While the prior approval procedure creates an incentive for physicians to prescribe drugs on the preferred drug list, authorization for a drug not on the list cannot be withheld. *See Edmonds v. Levine,* 417 F.Supp.2d 1323, 1329 (S.D.Fla.2006) ("The Medicaid Act does not authorize a state to use [this type] of prior authorization program to deny coverage for a covered drug; it can only condition reimbursement upon a prescribing doctor first calling a state pharmacist to obtain approval for the drug."); *see also Pharm. Research & Mfrs. v. Meadows,* 304 F.3d 1197, 1201, 1207 (11th Cir.2002). Plaintiff does not dispute that under the Medicaid drug program LDHH actually adopted in 2002, reimbursements for Vioxx could not be denied.

***22** Plaintiff has not presented any evidence that LDHH ever prepared a proposed plan amendment for submission to the Center for Medicare and Medicaid Services, whose authorization would be required before LDHH could adopt an exclusive formulary. 42 C.F.R. § 430.12. Mr. Hood admitted that neither the P & T Committee nor the State ever considered a proposal to adopt an exclusive formulary to restrict reimbursement coverage of an FDA-approved drug during the time he was Secretary. (Trial Tr. 430:5–22, Apr. 13, 2010.)

An exclusive formulary would have significantly limited the State's power to consider and negotiate drug costs, and would have frustrated the intent of the Act. No witness affiliated with LDHH testified that the State would have created an exclusive formulary which would have conflicted with the entire purpose of Act 395. This Court therefore concludes that LDHH would not have attempted to institute an exclusive formulary in June 2001 or at any other point.

IV. CONCLUSION

Based on the above findings of fact and conclusions of law, the Court rules in favor of the Defendant, Merck. Plaintiff's redhibition claim is hereby dismissed with prejudice and costs.

Footnotes

1 *See Plunkett v. Merck & Co.,* No. 05–4046 (E.D. La. Filed Aug. 23, 2005) (comprising both the first and second bellwether trials, as the first trial resulted in a hung jury); *Barnett v. Merck & Co.,* No. 06–485 (E.D. La. Filed Jan. 31, 2006) (third bellwether trial); *Smith v. Merck & Co.,* No. 05–4379 (E.D. La. Filed Sept. 29, 2005) (fourth bellwether trial); *Mason v. Merck & Co.,* No. 06–0810 (E.D. La. Filed Feb. 16, 2006 (fifth bellwether trial); *Dedrick v. Merck & Co.,* No. 05–2524 (E.D. La. Filed June 21, 2005) (sixth bellwether trial).

2 When the parties formally announced the Settlement Agreement, Vioxx-related discovery had been moving forward in the coordinate jurisdictions for more than six years. Over 50 million pages of documents had been produced and reviewed, more than 2,000 depositions had been taken, and counsel for both sides had filed thousands of motions and consulted with hundreds of experts in the fields of cardiology, pharmacology, and neurology.

3 The VIGOR data was published in the New England Journal of Medicine. *See* Claire Bombardier, et al., *Comparison of Upper Gastrointestinal Toxicity of Rofexcoxib and Naproxen in Patients with Rheumatoid Arthritis,* 343 New Eng. J. Med. 1520 (Nov. 23, 2000). Approximately five years later, the Journal published an "Expression of Concern" detailing certain inaccuracies in the underlying data and raising concerns about the conclusions of the original paper. *See* Gregory D. Curfman, et al., *Expression of Concern,* 353 New Eng. J. Med. 2813 (Dec. 29, 2005). The Journal subsequently published several responses from the original authors. *See* Correspondence, *Response to Expression of Concern Regarding VIGOR Study,* 354 New Eng. J. Med. 1196 (Mar. 16, 2006).

4 42 U.S.C.A. § 1396r–8(d) refers simply to a "formulary." In practice and in the relevant case law, a formulary established pursuant to 42 U.S.C.A. § 1396r–8(d)(4) is referred to as a "restrictive" or "exclusive" formulary.

5 The Court reserved ruling on several trial and deposition exhibits. Upon further consideration, the Court now admits LAAG 573 into the record. Further, the remaining exhibits are not admitted.

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2003 WL 22048255
Only the Westlaw citation is currently available.
United States District Court,
D. Massachusetts.

UNITED STATES OF AMERICA
ex rel. David Franklin, Plaintiff,
v.
PARKE–DAVIS, DIVISION OF WARNER–LAMBERT COMPANY and Pfizer, Inc., Defendant.

No. Civ.A. 96–11651PBS. | Aug. 22, 2003.

Attorneys and Law Firms

Robert A. Bertsche, Prince, Lobel Glovsky & Tye LLP, Boston, MA, Stuart G. Svonkin, Torys LLP, Toronto, ON, for Movant.

David B. Chaffin, Hare & Chaffin, Boston, MA, Barbara D. Diggs, Robert B. Fiske, Jr., James E. Murray, James P. Rouhandeh, Davis Polk & Wardwell, New York, NY, for Defendant.

Thomas M. Greene, Thomas G. Hoffman, Greene & Hoffman, P.C., Boston, MA, for Plaintiff.

Thomas E. Kanwit, United States Attorney's Office, Boston, MA, for Interested Party.

Opinion

MEMORANDUM AND ORDER

SARIS, J.

I. INTRODUCTION

***1** In this *qui tam* action, Relator Dr. David Franklin brings a claim under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, alleging that Defendant Parke–Davis (Franklin's former employer) promoted the drug Neurontin for uses not approved by the Food and Drug Administration, resulting in federal reimbursement payments for Neurontin prescriptions that were ineligible under Medicaid. Parke–Davis moves for summary judgment. The government, which has not intervened, has filed a Statement of Interest. After hearing, Parke–Davis's motion is *DENIED.*

II. DISCUSSION

In its earlier opinion on Parke–Davis's motion to dismiss, the Court canvassed the history of this suit, the complaint's factual allegations, and the relevant law. *United States v. Parke–Davis,* 147 F.Supp.2d 39 (D.Mass.2001). Presuming familiarity with that opinion, the Court here will limit the discussion to the select legal and factual issues upon which summary judgment turns.

1. Double–Falsehood Requirement under the FCA?

The False Claims Act ("FCA") imposes liability on any person who, *inter alia:*

> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; [or]
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government

31 U.S.C. § 3729(a).

Parke–Davis argues that it can only be held liable under the FCA if Relator proves that Parke–Davis intentionally made a material false statement that led to the filing of a false claim. Under Parke–Davis's interpretation, the FCA contains a double falsehood requirement: An FCA plaintiff must prove a false statement that led to a false claim. Parke–Davis contends that Relator has failed to show that Parke–Davis made any material false statements.

Parke–Davis's legal argument is inconsistent with the text of the FCA. While § 3729(a)(2) contains a double-falsehood requirement ("knowingly makes, uses, or causes to be made or used, *a false record or statement* to get *a false or fraudulent claim* paid or approved by the Government") (emphasis added), FCA liability under § 3729(a)(1) arises when a defendant "knowingly presents, or causes to be presented ... *a false or fraudulent claim"* (emphasis added). Thus, there is no double falsehood requirement under § 3729(a)(1): One will suffice. *See Shaw v. AAA Eng'g & Drafting, Inc.,* 213 F.3d 519, 531 (10th Cir.2000) ("Section 3729(a)(1) ... requires only the presentation of a 'false or fraudulent claim for payment or approval' without the additional element of a 'false record or statement." '); *United States ex rel. Fallon*

v. Accudyne Corp., 921 F.Supp. 611, 627 (W.D.Wis.1995) ("The primary distinction between a claim under section 2 and a claim under section 1 is that section 2 requires an affirmative false statement. To provide any distinct meaning to section 1 it is clear that no such express false statement is required.").

***2** Because Relator has not limited his FCA claim to § 3729(a)(2), he need not show two falsehoods to prevail. Under § 3729(a)(1), Relator is not required to present evidence that Parke–Davis lied to physicians about Neurontin's off-label efficacy or safety to induce them to prescribe Neurontin for uses ineligible under Medicaid. Though such evidence would be probative as to whether Parke–Davis caused to be presented false Medicaid claims, truthful off-label marketing (ineligible for federal safe harbors) and financial incentives like kickbacks would suffice.

To be sure, the Court's earlier opinion on Parke–Davis's motion to dismiss focused on allegations of false statements under § 3729(a)(2):

> Defendant argues that an impermissible off-label promotion [*i.e.*, a promotion that violates the Food and Drug Administration's ("FDA's") strictures on off-label marketing] does not necessarily include a false statement or fraudulent conduct. For example, it points out, off-label promotion of a drug might simply consist of a representative of a pharmaceutical company distributing the finding of one doctor's experience with an off-label use of a particular drug to other physicians. However, Relator alleges more than a mere technical violation of the FDA's prohibition on off-label marketing. The gravamen of Relator's claim is that Parke–Davis engaged in an unlawful course of fraudulent conduct including knowingly making false statements to doctors that caused them to submit claims that were not eligible for payment by the government under Medicaid. Thus, the alleged FCA violation arises—not from unlawful off-label marketing activity itself—but from the submission of Medicaid claims for uncovered off-label uses induced by Defendant's fraudulent conduct. *Cf. United States ex rel. Marcus v. Hess,* 317 U.S. 537, 543–44, 63 S.Ct. 379, 87 L.Ed. 443 (1943) (payments under government contract that was executed as a result of collusive bid constituted actionable false claims). *A much closer question would be presented if the allegations involved only the unlawful—yet truthful—promotion of off-label uses to physicians who provide services to patients who are covered by Medicaid, as well patients who are not, without any fraudulent representations by the manufacturer.*

Parke–Davis, 147 F.Supp.2d at 52 (emphasis added). With the benefit of a more fulsome factual record, it is now apparent that the "much closer question" can no longer be ducked. Under § 3729(a)(1), the only issue is whether Parke–Davis "caused to be presented" a false claim, and § 3729 does not require that the "cause" be fraudulent or otherwise independently unlawful.

2. Existence of a False Claim

Parke–Davis contends that Relator cannot prove the *sine qua non* of a False Claims Act violation: the existence of a false claim. In the early phases of this litigation, "Defendant d[id] not dispute that an off-label prescription submitted for reimbursement by Medicaid is a false claim within the meaning of the FCA." *Parke–Davis,* 147 F.Supp.2d at 51. Now Parke–Davis argues that forty-two state Medicaid programs permit reimbursement for off-label, non-compendium drug prescriptions, and that therefore claims for Medicaid reimbursement for off-label Neurontin prescriptions in those states were not false claims. Parke–Davis contends that the Medicaid statute gives states the discretion to provide reimbursement for such prescriptions; in particular, Parke–Davis points to 42 U.S.C. § 1396r–8(d)(1)(B): "A state may exclude or otherwise restrict coverage of a covered outpatient drug if—(i) the prescribed use is not for a medically accepted indication...." Parke–Davis argues that the language "may exclude or otherwise restrict" indicates that states have the option not to exclude (*i.e.*, may provide) coverage for drugs for which the prescribed use is not for a medically accepted indication.

*3 Relator contends that Parke–Davis is wrong as to the scope of Medicaid coverage in the forty-two states. Indeed, Relator argues that the Medicaid statute does not authorize states to provide such broad coverage. Relator emphasizes that the Medicaid statute allows states to "exclude or otherwise restrict coverage *of a covered outpatient drug,*" 42 U.S.C. § 1396r–8(d)(1)(B) (emphasis added), implying that states are given discretion only within the category of "covered outpatient drugs." The Medicaid statute defines this category to exclude drugs for which the prescribed use is not a medically accepted indication. *Parke–Davis,* 147 F.Supp.2d at 45 ("Covered outpatient drugs do not include drugs that are 'used for a medical indication which is not a medically accepted indication." ') (quoting 42 U.S.C. § 1396r–8(k)(3)). Thus, in Relator's view, § 1396r–8(d)(1)(B)(i) is simply superfluous, giving states the discretion to exclude drugs that are not covered by Medicaid to begin with. Basic rules of statutory construction, however, disfavor this interpretation. *See, e.g., United States v. Flores,* 968 F.2d 1366, 1371 (1st Cir.1992) ("Courts should not lightly read entire clauses out of statutes, but should, to the exact contrary, attempt to give meaning to each word and phrase.").

It is not clear which side gets the better of the statutory-tail-chases-cat debate. The Court would appreciate an amicus brief from federal officials, providing the federal government's understanding of the extent to which the Medicaid statute empowers states to provide coverage of off-label, non-compendium prescriptions. *Cf. Meyer v. Holley,* 537 U.S. 280, 123 S.Ct. 824, 830, 154 L.Ed.2d 753 (2003) ("[W]e ordinarily defer to an administering agency's reasonable interpretation of a statute.") (citing *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.,* 467 U.S. 837, 842–45, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984)).

The debate may be immaterial. If the Medicaid statute gives states the discretion to cover off-label, non-compendium prescriptions, and a state exercised its discretion to cover such prescriptions, then an off-label Neurontin prescription in that state would not be a false claim. On the other hand, if the Medicaid statute does *not* give states the discretion to cover off-label, non-compendium prescriptions, but a state misconstrued the statute and authorized coverage of such prescriptions, an FCA action against Parke–Davis in that state would likely fail, as it would be difficult to establish Parke–Davis's scienter.

In any event, even Parke–Davis concedes that eight states do not provide reimbursement for off-label drug prescriptions not included in a medical compendium, and in those states, a Medicaid-reimbursement request for an off-label, non-compendium prescription constitutes a false claim. Thus, at best Parke–Davis's argument goes to the amount of damages, and does not provide a basis for summary judgment of no liability under the FCA. At this juncture, the Court declines to do a state-by-state analysis of Medicaid coverage.

*4 Parke–Davis also raises a factual argument about why Relator cannot show a false claim: Parke–Davis points out that the Medicaid reimbursement claim forms for prescription drugs do not require the claimant to list the indication for which the drug is being prescribed. Thus, Parke–Davis argues, Relator cannot show that any Medicaid claim sought reimbursement for an off-label, non-compendium use. But the Relator has provided analysis linking patients' treatment histories to Neurontin prescriptions that generated reimbursement claims; Relator contends this analysis demonstrates that many reimbursement claims must have been for off-label, non-compendium indications, given the patients' treatment histories. Parke–Davis has submitted expert testimony contesting the reliability of comparing data from pharmacy claim forms with diagnosis data from patient medical-services claim forms. Relator's expert evidence suffices to survive summary judgment.

3. Causation

The text of § 3729(a)(1) requires a causal connection between Parke–Davis's actions and the false claims at issue. Parke–Davis contends that the Relator must show that Parke–Davis "either exerted 'control over' or otherwise directly influenced, the submission of a false claim." (Mem. of Law in Supp. of Defs.' Mot. for Summ. J., Docket No. 297, at 18.) Parke–Davis argues that Relator cannot meet this standard, as the causal chain includes several links: Parke–Davis markets Neurontin to doctors, who prescribe it for their patients, who take the prescriptions to their pharmacists, who file claims for Medicaid reimbursement.

But Parke–Davis misstates the legal standard for causation. The FCA does not provide a special definition for causation, and neither the Supreme Court nor any Circuit Court of Appeals has grafted such a special definition on the FCA. Absent an FCA-specific definition of causation, the Court will apply common-law tort causation concepts, which Judge Campbell of the First Circuit has summarized:

> Causation in tort law is generally divided into two concepts: causation

> in fact, or actual causation, and proximate or legal causation. *See* W. Page Keeton et al., *Prosser & Keeton on Torts* §§ 41–42 (5th ed.1984). The terms for these two concepts are sometimes confused, as are the concepts themselves. Regardless of the terminology, however, there are two questions that must be answered to determine if a defendant's conduct "caused" a plaintiff's injury. The first question is whether there was in fact some causal relationship between the conduct and the outcome. The *Restatement* expresses this test as whether the defendant's conduct was a "substantial factor" in producing the harm. *Id.* The second question is whether the circumstances and causal relationship are such that the law will impose liability on the defendant. Sometimes this is expressed as a foreseeability test, *see* Keeton, *supra,* § 42, at 273. *Cf. Restatement (Second) of Torts,* § 431(b)(1965) (different terminology).

***5** *Rodriguez–Cirilo v. Garcia,* 115 F.3d 50, 54 (1st Cir.1997) (Campbell, J., concurring).

Whether Parke–Davis's conduct was a substantial factor in causing the presentation of false Medicaid claims is a question of fact. Relator has produced enough evidence on this score to create at least a genuine issue of material fact. In particular, Relator has produced circumstantial evidence (*e.g.,* the rates of off-label prescriptions before and after physician conferences hosted by Parke–Davis) and direct evidence (the "Verbatim" market-research reports recording doctors' state of mind after marketing meetings).

Parke–Davis also disputes that Relator can reliably extrapolate the prescription activities of a small sample of ten doctors to the off-label prescription rates of over 3000 physicians in fifty states, and, as discussed above, Parke–Davis challenges the reliability of the underlying data used to determine whether a prescription is for off-label uses. But the Court will defer the daunting task of determining whether a reliable statistical method exists for measuring nation-wide damages.

As for proximate or legal causation, the Court has already held that Parke–Davis could have foreseen false Medicaid claims being filed, even with the intervening links in the causal chain:

> Defendant argues that Relator has not stated a claim because he has not accounted for the independent actions of the physicians who wrote the off-label prescriptions and the pharmacists who accepted and filled the off-label prescriptions. In other words, Defendant argues that—as a matter of law—Relator's allegations cannot establish the causation requirement of the FCA because the actions of these professionals were an intervening force that breaks the chain of legal causation. *See* [*United States ex rel.] Cantekin [v. Univ. of Pittsburgh*], 192 F.3d [402], 416 [(3rd Cir.1999)] (applying intervening cause analysis to claim under the FCA). Under black letter law, however, such an intervening force only breaks the causal connection when it is unforeseeable. *See id. Accord* D. Dobbs, et al., *Prosser and Keeton on Torts* § 44, at 303–04 (5th ed. 1984) ("The courts are quite generally agreed that [foreseeable intervening forces] will not supercede the defendant's responsibility."); Restatement (Second) of Torts § 443 (1965) ("The intervention of a force which is a normal consequence of a situation created by the actor's ... conduct is not a superseding cause of harm which such conduct has been a substantial factor in bringing about."). In this case, when all reasonable inferences are drawn in favor of the Relator, the participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud.

Parke–Davis, 147 F.Supp.2d at 52–53.

While it is now clear that Relator's theory of the case is not limited to a "scheme of fraud," the Court holds that Relator has presented evidence showing that it was foreseeable that Parke–Davis's conduct (including non-fraudulent promotion of off-label Neurontin uses) would ineluctably result in false Medicaid claims. *Cf. United States ex rel. Cantekin v. Univ. of Pittsburgh,* 192 F.3d 402, 416 (3rd Cir.1999) ("It is a basic principle of tort law that once a defendant sets in motion a tort, the defendant is generally liable for the damages ultimately caused, unless there are intervening causes.").

***6** Parke–Davis places heavy reliance on *United States ex rel. Kinney v. Hennepin County Medical Center,* Civ. Action. No. 971680 (RHK/JMM), 2001 WL 964011 (D. Minn. Aug 22, 2001). *Kinney* dealt with "claims to Medicare

and Medicaid for the payment of ambulance services that [the realtor] allege[d] were false because the ambulance transports were not 'medically necessary." '*Id.*.. at *1. One of the defendants, a group of doctors that provided services to the defendant ambulance service, was alleged to have caused the false claims by "having its physicians falsely certify [the] ambulance runs as 'medically necessary' when they did not meet the either the Medicare or Medicaid criteria for medically necessary." *Id.* at *8. The court rejected this causation argument. *See id.* at *10. A critical factor was that the ambulance service's computerized accounting system *automatically* coded ambulance runs as "medically necessary," and that the physicians' determinations were irrelevant. *See id.* Here, in contrast, Relator has provided evidence that Parke–Davis's actions were not irrelevant, but rather played a key role in setting in motion a chain of events that led to false claims.

The instant case is closer to *United States ex rel. Pogue v. Diabetes Treatment Centers of America,* 238 F.Supp.2d 258 (D.D.C.2002). In that case,

> The Fourth Amended complaint describe[d] a twelve year fraudulent scheme in which [defendant] DTCA ran diabetes centers in various hospitals, and appointed doctors to serve as medical directors. Relator alleges the doctors were paid not for their nominal services as medical directors, but on a per-patient basis for referring their patients to the DTCA centers, in violation of the Stark laws' prohibition of self-referral. *See* 42 U.S.C. § 1395nn. The hospitals in which the centers were housed paid DTCA a per-patient fee, which Relator alleges was a kickback of the type prohibited by the Anti–Kickback laws. *See* 42 U.S.C. § 1320a–7b(b). Then the hospitals submitted reimbursement claims to Medicare for the care provided to the patients.

Pogue, 238 F.Supp.2d at 267. According to the relator, the reimbursement claims were false because they impliedly certified compliance with the Anti–Kickback and Stark laws. *Id.* at 261. Defendant DTCA "argue[d] that even if implied certification is a legitimate basis for Relator's claims, it cannot be held liable because it did not submit claims for Medicare reimbursement and did not certify compliance with healthcare statutes and regulations." *Id.* at 266. The court rejected this argument, stating, "An argument that the presentation of the claims was the work of another is unavailing as a means to avoid liability under the False Claims Act." *Id. Cf. United States v. Mackby,* 261 F.3d 821, 824–26, 828 (9th Cir.2001) (affirming FCA liability of owner/managing director of physical-therapy clinic who instructed the clinic's billing company to use an improper code on Medicare reimbursement claim forms; stating, "[A] person need not be the one who actually submitted the claim forms in order to be liable"); *United v. Krizek,* 111 F.3d 934, 935–37, 942 (D.C.Cir.1997) (where psychiatrist's wife submitted invalid Medicare and Medicaid reimbursement claims, stating, "[W]e note that [the psychiatrist] is no less liable than his wife for these false submissions.... Dr. Krizek delegated to his wife authority to submit claims on his behalf. In failing 'utterly' to review the false submissions, he acted with reckless disregard."); *see generally United States v. Neifert–White Co.,* 390 U.S. 228, 233, 88 S.Ct. 959, 19 L.Ed.2d 1061 (1968) (holding that because the FCA is a remedial statute, it should not be given a cramped reading).

4. FCA Claim Based on Anti–Kickback Violations

***7** The government attempts to resuscitate a claim the Court dismissed, namely, that Parke–Davis's alleged violation of the Medicaid Anti–Kickback provision, 42 U.S.C. § 1320a–7b(b), caused false claims, because Medicaid claimants impliedly certify that their claims have not been tainted by kickbacks.

The Court agrees with the government that recent caselaw supports implied-certification FCA claims in the healthcare context, including kickback-based claims. *See, e.g., United States ex rel. Augustine v. Century Health Servs., Inc.,* 289 F.3d 409, 415 (6th Cir.2002) (in Medicare-reimbursement context, stating, "[A] number of courts have held that a false implied certification may constitute a false or fraudulent claim even if the claim was not expressly false when it was filed. Instead, liability can attach if the claimant violates its continuing duty to comply with the regulations on which payment is conditioned. We adopt this theory of liability...."); *Mikes v. Straus,* 274 F.3d 687, 700 (2nd Cir.2001) (holding that claimants of Medicare reimbursement implicitly certify that they have complied with statutes or regulations that expressly require compliance as a prerequisite to Medicare payments); *Pogue,* 238 F.Supp.2d at 266 (affirming earlier holding that Medicare claimants impliedly certify compliance with Anti–Kickback laws, stating that "the developing law

has supported [the court's] finding that violations of the Anti–Kickback and Stark laws can support a claim under the False Claims Act").

But while the Government's brief was persuasive on several points, the Government is (still) not a party to this suit, and the Court declines to use the Government's brief to revive Relator's claim. Evidence of kickbacks is relevant, however, to Relator's more clear-cut claim under § 3729(a)(1): Parke–Davis "caused to be presented" claims for reimbursement for off-label prescriptions that were ineligible for coverage under Medicaid.

ORDER

Defendant Parke–Davis's Motion for Summary Judgment (Docket No. 292) is *DENIED*.

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United States District Court,
N.D. Illinois,
Eastern Division.

UNITED STATES of America; State of California; State of Delaware; State of Florida; State of Hawaii; State of Illinois; State of Massachusetts; State of Nevada; State of Tennessee; State of Texas; State of Virginia; and District of Columbia; ex rel. Edward West, Plaintiffs,
v.
ORTHO-McNEIL PHARMACEUTICAL, INC. and Johnson and Johnson, Defendants.

No. 03 C 8239. | July 20, 2007.

Attorneys and Law Firms

George A. Zelcs, Korein Tillery, Chicago, IL, Jill Irene Rogers-Manning, Simmons Cooper, Alton, IL, John Anthony Bruegger, Kenneth J. Brennan, Randy Scott Cohn, Rosalind M. Robertson, Stephen C. Jones, Simmonscooper LLC, East Alton, IL, for Plaintiffs.

State of California, pro se.

State of Delaware, pro se.

State of Florida, pro se.

State of Hawaii, pro se.

State of Illinois, pro se.

State of Massachusettes, pro se.

State of Nevada, pro se.

State of Tennessee, pro se.

State of Texas, pro se.

State of Virginia, pro se.

United States, pro se.

Scott R. Lassar, Charles John Biro, Jordan Samuel Ginsberg, Scott David Stein, Sidley Austin LLP, Chicago, IL, for Defendants.

Opinion

MEMORANDUM OPINION AND ORDER

VIRGINIA M. KENDALL, United States District Judge.

*1 Plaintiff-Relator Edward West ("Relator" or "West") brings this qui tam action on behalf of the United States under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3732, and on behalf of California, Delaware, Florida, Hawaii, Massachusetts, Nevada, Tennessee, Texas, Virginia and the District of Columbia, under each state's respective laws modeled after the FCA.[1] West alleges that Defendant Ortho-McNeil Pharmaceutical, Inc. ("Ortho-McNeil") and its corporate parent, Defendant Johnson & Johnson knowingly caused to be presented false or fraudulent claims for payment and knowingly made false statements to get said governments to pay false or fraudulent claims. Defendants have moved to dismiss West's First Amended Complaint for failure to plead with particularity, pursuant to Rule 9(b), and for failure to state a claim, pursuant to Rule 12(b)(6). Because West's claims against Ortho-McNeil do not adequately set forth the "who, what, when, where and how" of the alleged fraud, they do not meet the pleading standard set forth in Rule 9(b). Additionally, West does not allege facts that plausibly suggest a claim against Johnson & Johnson either for its own conduct or the conduct of its subsidiary, Ortho-McNeil.

BACKGROUND

Ortho-McNeil is a pharmaceutical company and a wholly-owned subsidiary of Johnson & Johnson. (1st Am.Compl.¶ 11.) West is a resident of Illinois and a former sales representative of Ortho-McNeil. (*Id.* ¶ 10.) West filed this qui tam action on behalf of the United States, California, Delaware, Florida, Hawaii, Massachusetts, Nevada, Tennessee, Texas, Virginia and the District of Columbia, who are the real parties in this action. (*Id.* ¶¶ 1, 8-9.)

I. Procedural History

West brought this qui tam action under the FCA and the similar laws of several states and the District of Columbia. (*Id.* ¶¶ 1, 8-9.) The FCA allows a private person, the relator, to bring a civil action on behalf of the United States Government when a false claim has been submitted to the Government.

37 U.S.C. §§ 3729, 3730(b). In a private action, the FCA first requires the relator to serve on the Government "[a] copy of the complaint and written disclosure of substantially all material evidence and information the person possesses." 37 U.S.C. § 3730(b)(2). The complaint then remains under seal for 60 days during which time the government may elect to intervene and proceed with the action. *Id* . The United States, the states involved and the District of Columbia all have declined to intervene. The United States has submitted a Statement of Interest in which it advocates several points of law, but the United States does not take a position on whether West has pleaded his claim adequately under Rule 9(b).

In his First Amended Complaint, West claims that Defendants: (1) knowingly caused to be presented to the United States Government, and the governments of several states and the District of Columbia, false or fraudulent claims for payment; (2) knowingly made false statements to get false or fraudulent claims paid for by said governments; and (3) knowingly made false records or statements to conceal, avoid, or decrease obligations to pay money to said governments. (1st Am.Compl.¶¶ 104-06, 113, 119-21, 127-29, 135-37, 142-44, 158-60, 166-68, 174-76, 182-84, 190-92, 198-200.) As factual support for these claims, West first alleges that Defendants utilized a wide array of kickbacks and unlawful remuneration to increase sales of its pharmaceutical drugs Levaquin and Ultram. (*Id.* ¶¶ 62-99.) Second, West alleges that Defendants marketed Levaquin and Ultram for non-FDA approved-"off-label"-uses. (*Id.* ¶¶ 100-01.)

***2** The U.S. Judicial Panel on Multidistrict Litigation transferred West's action to the District of Massachusetts, but separated and remanded to this Court the claims relating to off-label marketing. As such, remaining before this Court are the claims that Defendants: (1) knowingly caused to be presented to the United States Government and the governments of several states and the District of Columbia, via their off-label marketing practices, false or fraudulent claims for payment; and (2) knowingly made false statements, as part of their off-label marketing practices, to get false or fraudulent claims paid for by said governments.

II. Medicaid

The Medicaid program provides "medical assistance to individuals and families whose resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396. In order for a drug to be eligible for reimbursement through Medicaid, the drug's manufacturer must enter into a rebate agreement with Medicaid that ensures that the price Medicaid pays is a competitive one. 42 U.S.C. § 1396r-8(a)(1). Medicaid providers, such as pharmacies, pay drug manufacturers for prescription drugs and, in turn, submit claims to state Medicaid agencies for reimbursement. 42 U.S.C. § 1396a(a) (23), (a)(32). While claims are submitted to state Medicaid agencies, the federal government reimburses states for a substantial portion of the funds allotted. 42 U.S.C. § 1396. For this reason, claims submitted to state Medicaid agencies are considered claims presented to the federal government and may give rise to liability under the FCA. *U.S. ex rel. Tyson v. Amerigroup Illinois, Inc.*, 2005 WL 2667207 at *3 (N.D.Ill.2005).

III. Off-Label Marketing and Medicaid

Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be introduced into interstate commerce unless the Food and Drug Administration ("FDA") finds that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Although doctors are allowed to prescribe a drug for off-label uses, drug manufacturers are prohibited from marketing or promoting a drug for a use that the FDA has not approved. 21 U.S.C. §§ 331(d), 355(a). Moreover, Medicaid generally reimburses providers only for "covered outpatient drugs." 42 U.S.C. §§ 1396b(i)(10), 1396r-8(a)(3). "Covered drugs" do not include drugs "used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(3). A medically accepted indication is one "approved under the Federal Food, Drug, and Cosmetic Act" or one included in certain, specified drug compendia. 42 U.S.C. § 1396r-8(k)(6); *see U.S. ex rel. Franklin v. Parke-Davis,* 147 F.Supp.2d 39, 45 (D.Mass.2001).

IV. West's Allegations of Off-Label Marketing

West alleges that, with the knowledge and consent of marketing executives at Ortho-McNeil, sales representatives marketed two of Ortho-McNeil's drugs, Levaquin and Ultram, for uses not yet approved by the FDA. (1st Am.Compl. ¶ 100.) More specifically, Ortho-McNeil sales representatives: (1) instructed doctors that Levaquin should be used to treat prostatitis, a non-FDA approved use; (2) disseminated articles to doctors that promoted the use of Ultram for non-FDA approved conditions, including osteoarthritis and diabetic neuropathy; and (3) disseminated articles to doctors that recommended that Ultram be given at dosage levels not approved by the FDA. (*Id.* ¶ 101.) Placing these acts in terms of the FCA, West alleges that "each prescription that was written as a result of defendants' illegal marketing practices ...

represents a false or fraudulent record or statement," and claims for reimbursement for such prescriptions represent false or fraudulent claims for payment. (*Id.* ¶ 106.)

DISCUSSION

***3** West's action currently includes 12 counts: Count I, based on 31 U.S.C. § 3729(a)(1) and (a)(2) of the FCA, and Counts III through XIII, excluding VII, based on the similar laws of California, Delaware, Florida, Hawaii, Massachusetts, Nevada, Tennessee, Texas, Virginia, and the District of Columbia, respectively. Count II, brought under 31 U.S.C. § 3729(a)(7), did not involve alleged off-label marketing practices and thus was transferred to the District of Massachusetts. West voluntarily dismissed Count VII, his claim brought under the Illinois Whistleblower Reward and Protection Act.

The heightened pleading standard set forth in Rule 9(b) applies to actions brought under the FCA. *See U.S. ex rel. Garst v. Lockheed-Martin Corp.,* 328 F.3d 374, 376 (7th Cir.2003) ("False Claims Act condemns fraud but not negligent errors or omissions"). Rule 9(b) requires that "in all averments of fraud ... the circumstances constituting fraud ... shall be stated with particularity." These circumstances must include the "who, what, when, where, and how: the first paragraph of any newspaper story." *DiLeo v. Ernst & Young,* 901 F.2d 624, 627 (7th Cir.1990). When a fraud scheme involves numerous transactions over time, a plaintiff need not plead specifics with respect to every instance of the fraud, but must plead at least representative examples of the fraud. *Bantsolas ex rel. U.S. v. Superior Air and Ground Ambulance Transport, Inc.,* 2004 WL 609793 at *4 (N.D.Ill.2004); *Garst,* 328 F.3d at 376, 379.

I. West's claims against Ortho-McNeil under 31 U.S.C. § 3729(a)(1), § 3729(a)(2) and similar laws of several states and the District of Columbia

A person violates the FCA when he "(1) knowingly presents, or *causes* to be presented, to an officer or employee of the United States Government ... a false or fraudulent claim for payment or approval" or "(2) knowingly makes, uses, or *causes* to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." 31 U.S.C. § 3729(a) (1), (a)(2) (emphasis added). A person acts knowingly when he or she: "(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof or specific intent to defraud is required." 37 U.S.C. § 3729(b). West does not contend that Defendants submitted false claims; instead, he alleges that Defendants knowingly *caused* such claims to be submitted. To meet Rule 9(b)'s heightened pleading for a claim under § 3729(a) (1), West must identify specific false claims for payment as well as (1) who submitted the false claim, (2) what the person submitted, (3) when he submitted the claim, (4) where he did so and (5) how he did so. *Garst,* 328 F.3d at 376. He also must plead how Defendants caused the claim to be submitted. *Id.* West's § 3729(a)(2) claim requires him to identify particular false records or false statements that Defendants made in order to get the government to pay money. *U.S. ex rel. Lamers v. City of Green Bay,* 168 F.3d 1013, 1018 (7th Cir.1999).

***4** West alleges that Defendants caused false claims to be submitted by having Ortho-McNeil sales representatives instruct physicians that Levaquin should be used to treat prostatitis, a non-FDA approved use, and by having sales representatives disseminate articles to physicians promoting the use of Ultram for non-FDA approved conditions and at non-FDA approved dosage levels. West's allegations do not meet the heightened pleading standard set forth in Rule 9(b). *See, e.g., U.S. ex rel. Fowler v. Caremark RX, Inc.,* 2006 WL 2425331 at *7 (N.D.Ill.2006). With respect to the sales representatives' allegedly false statements to doctors, West does not identify which sales representatives made the statements, when they made them, to which doctors they made them or how they communicated them. Nor does West identify which executives at Ortho-McNeil told sales representatives to make these false statements. At best, West describes the general subject of the alleged misrepresentations (Levaquin and Ultram should be used for non-FDA approved uses) and the general category of individuals (sales representatives) who made them. Such generalized allegations are insufficient where "they do not even hint at the identity of those who made the misrepresentations, the time misrepresentations were made, or the places at which the misrepresentations were made." *Uni*Quality, Inc. v. Infotronx, Inc.,* 974 F.2d 918, 923 (7th Cir.1992).

Likewise, with respect to the sales representatives' alleged distribution of articles to doctors, West does not identify which sales representatives distributed the articles, what the articles or representatives stated that was false, when the sales representatives distributed them, to which doctors they

distributed them or how they distributed them. While West need not plead every false statement made by Defendants or every false claim made, he does not set forth the circumstances of any particular false statement or cite a single example of a false claim or a provider that made a false claim.

West tacitly concedes these deficiencies in his Complaint, but argues that the Rule 9(b) standard should be relaxed when the plaintiff does not have access to all the facts necessary to detail his claim. Absent rare circumstances, however, relaxing the Rule 9(b) pleading standard would undermine the purposes of fraud pleading generally and the FCA specifically. *See Karvelas v. Melrose-Wakefield Hospital,* 360 F.3d 220, 230-231 (1st Cir.2004) (refusing to relax Rule 9(b) pleading standard where evidence of FCA claim was allegedly unavailable to plaintiff). The FCA, for instance, prohibits qui tam actions based upon publicly disclosed information unless the relator is the "original source" of that information. 31 U.S.C. § 3730(e)(4)(B). An "original source" is a person "who has direct and independent knowledge of the information on which the allegations are based." *Id.* The private enforcement provisions of the FCA allow for whistleblower-type actions that enhance the Government's enforcement of the statute.[2] *See Fanslow v. Chicago Mfg. Center, Inc.,* 384 F.3d 469, 478-79 (7th Cir.2004). If a relator cannot plead with particularity alleged violations of the FCA, he stands in no better position to assist the Government than any other citizen.

***5** Requiring a relator to plead with particularity also comports with the FCA's requirement that the complaint be filed under seal for 60 days while the Government decides whether to intervene. Unless a relator makes particular allegations prior to discovery, the Government would be forced to decide "whether or not to intervene absent complete information about the relator's cause of action." *Karvelas,* 360 F.3d at 230-231 (quoting Boese, *Civil False Claims and Qui Tam Actions* § 4.04[C]).

If West has direct knowledge that sales representatives caused physicians to submit claims based on prescriptions of Levaquin and Ultram for non-FDA approved uses, he must allege specifically the "who, what, when, where, and how" of the false statements and the false claims. Without concrete examples of false statements and false claims, it seems as if West has filed suit based upon his suspicion that Defendants engaged in unlawful conduct with the hope that discovery will unearth some specific FCA violation. *See U.S. ex rel. Robinson v. Northrop Corp.,* 149 F.R.D. 142, 144 (N.D.Ill.1993) (FCA Complaint may not be "filed as a pretext to uncover unknown wrongs"). Rule 9(b) does not tolerate such suits. *See Vicom, Inc. v. Harbridge Merchant Services, Inc.,* 20 F.3d 771, 777 (7th Cir.1994) (Rule 9(b) "serve[s] three main purposes: (1) protecting a defendant's reputation from harm; (2) minimizing "strike suits" and "fishing expeditions"; and (3) providing notice of the claim to the adverse party"). Accordingly, West has not pleaded with the required particularity the circumstances of his § 3729(a)(1) and (a)(2) claims. For this reason, the Court will not address whether any additional facts that West may allege would state a claim under Rule 12(b)(6).

II. West's claims against Johnson & Johnson

When considering a motion under Rule 12(b)(6), a court must take as true all facts alleged in the complaint and construe all reasonable inferences in favor of the plaintiff. *See Murphy v. Walker,* 51 F.3d 714, 717 (7th Cir.1995). The plaintiff need not allege all of the facts involved in the claim. *See Sanjuan v. American Bd. of Psychiatry and Neurology, Inc.,* 40 F.3d 247, 251 (7th Cir.1994). The claim though must be supported with enough facts, taken as true, that plausibly suggest that the plaintiff is entitled to relief. *See Bell Atlantic Corp. v. Twombly,* --- U.S. ----, ----, 127 S.Ct. 1955, 1965, --- L.Ed.2d ----, ---- (2007).

Johnson and Johnson is Ortho-McNeil's corporate parent. West has not set forth facts that plausibly suggest a cause of action against Johnson & Johnson. A corporate parent is not automatically liable for torts committed by its subsidiary. *See IDS Life Ins. Co. v. SunAmerica Life Ins. Co.,* 136 F.3d 537, 540 (7th Cir.1998). West implies that Johnson & Johnson might be liable under a "piercing the corporate veil" theory; however, he has pleaded no facts to support such a theory. *See Int'l. Financial Services Corp. v. Chromas Technologies Canada, Inc.,* 356 F.3d 731, 736-37 (7th Cir.2004). Therefore, the claims against Johnson & Johnson are dismissed.

CONCLUSION AND ORDER

***6** West's claims against Ortho-McNeil are dismissed pursuant to Rule 9(b) because he has failed to plead fraud with particularity. West's claims against Johnson & Johnson are dismissed because he has not pleaded facts that plausibly suggest a cause of action against Johnson & Johnson. Dismissal of the claims based upon West's allegations

is without prejudice to the United States. Wherefore, Defendants' Motion to Dismiss is granted. West is granted 30 days from the date of this order to file an amended complaint consistent with this opinion.

So ordered.

Footnotes

1 A qui tam action is one that is brought by a private party (the "relator") to assist the executive branch in its enforcement of the law; the Government remains the real party in interest. *See U.S. ex rel. Hall v. Tribal Development Corp.*, 49 F.3d 1208, 1212 (7th Cir.1995).

2 Consistent with this design, the FCA provides specific protections against retaliatory acts by an employer. *See* 31 U.S .C. § 3730(h); *U.S. ex rel. Tyson v. Amerigroup Illinois, Inc.*, 2006 WL 4586279 at *4 (N.D.Ill.2006) ("The Illinois Whistleblower Act is virtually identical to the FCA").

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