UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF LOUISIANA

IN RE: VIOXX PRODUCTS LIABILITY LITIGATION	:	MDL NO. 1657
	:	SECTION: L (3)
	:	JUDGE FALLON
	:	MAG. JUDGE KNOWLES

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

ORDER & REASONS

Before the Court is Defendant Merck and Co, Inc.'s Motion for Summary Judgment (Rec. Doc. No. 35872). The Court heard oral argument regarding this motion on Tuesday March 23, 2010. For the following reasons, Merck's motion is GRANTED IN PART and DENIED IN PART.

I. GENERAL BACKGROUND

Vioxx (known generically as rofecoxib) 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.

Traditional NSAIDs 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. This relief, however, comes with significant adverse side effects. Specifically, traditional NSAIDs greatly increase the risk of gastrointestinal perforations, ulcers, and bleeds ("PUBs"). This risk is increased when high doses are ingested, which is often necessary to remedy chronic or acute inflammation and pain. Scientists estimated that traditional NSAID-induced PUBs caused a significant number of deaths and hospitalizations each year.

In the early 1990s, scientists discovered that the COX enzyme had 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.

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." Vioxx is a COX-2 inhibitor.

On May 20, 1999, the Food and Drug Administration ("FDA") approved Vioxx for sale in the United States. From its initial approval, Vioxx gained widespread acceptance among physicians treating patients with arthritis and other conditions causing chronic or acute pain. Subsequently, Vioxx was introduced into markets around the world, including France in April of

2000, and Italy in the summer of 2000.

Before and after its initial approval, Vioxx was subjected to a number of studies and tests, including, but not limited to, VIGOR, APPROVe, ViP, VICTOR, ADVANTAGE, the Alzheimer's studies, Professor Kronmal's reanalysis of Merck's clinical data, the Solomon study, the Juni study, the Ray study, the Graham study, the Kimmel study, the Levesque study, the Mamdani study, the Ingenix study, the Johnsen study, the Nussmeier study, and the Fitzgerald hypothesis. In addition, a large amount of scientific literature was written on the effects of Vioxx and other COX-2 inhibitors.

On September 30, 2004, Merck withdrew Vioxx from all markets worldwide, when interim unblinded data from a long-term, blinded, randomized placebo-controlled clinical trial, known as APPROVe, seeking to assess whether Vioxx could help prevent the recurrence of precancerous colon polyps, indicated that the use of Vioxx increased the risk of cardiovascular thrombotic events such as myocardial infarctions and ischemic strokes.

Thousands of lawsuits followed in both state and federal court. 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.

One of this Court's first priorities was to assist the parties in 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] Only one of the trials resulted in a verdict for the

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[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 &*

plaintiff. Of the five remaining trials, one resulted in a hung jury and four resulted in verdicts for the defendant. 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.[2]

On November 9, 2007, Merck and the NPC 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.[3] The private Settlement Agreement establishes a pre-funded 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.* § "Recitals".[4]

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]In their efforts to develop a comprehensive, joint settlement agreement, counsel for Merck and the Negotiating Plaintiffs' Counsel ("NPC") met together more than fifty times and held several hundred telephone conferences. Although the parties met and negotiated independently, they kept this Court-as well as the coordinate state courts of Texas, New Jersey, and California-informed of their progress in settlement discussions.

[3]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.

[4]For a more detailed factual background of the various mechanics of the Settlement Agreement, including the provisions for the mandatory resolution of governmental liens, *see In re Vioxx Prods. Liab. Litig.*, 2008 WL 3285912 (E.D. La. Aug. 7, 2008) (denying motions to enjoin disbursement of interim settlement payments).

Having settled a large majority of the personal injury cases within this MDL, the Court now turns its attention to government actions suits that have been filed against Merck. Several government entities have pending litigation in this Court, 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.

II. BACKGROUND OF THIS ATTORNEY GENERAL CASE

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 No. 1657. 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 asserts 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. Plaintiff further seeks multiple forms of relief on behalf of both the State and its' citizens. Regarding its' redhibition claims, Plaintiff seeks restitution, damages, costs, penalties and fees. As for the LUTPA claims, Plaintiff seeks injunctive relief, restitution, ancillary and monetary damages, actual damages, fees and costs. Under the NJCFA, Plaintiff seeks restitution, compensatory damages, treble damages, fees and costs. Plaintiff seeks only restitution under its unjust enrichment theory.

On February 19, 2010, Merck filed a motion for summary judgment on all of the claims

asserted by the Louisiana Attorney General. On March 9, 2010, the Louisiana Attorney General responded in opposition to Merck's motion, and on March 16, 2010, Merck filed a reply.

II. SUMMARY JUDGMENT STANDARD

A district court can grant a motion for summary judgment only when the "'pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.'" *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (quoting Fed. R. Civ. P. 56 (c)). When considering a motion for summary judgment, the district court "will review the facts drawing all inferences most favorable to the party opposing the motion." *Reid v. State Farm Mut. Auto. Ins. Co.*, 784 F.2d 577, 578 (5th Cir. 1986). The court must find "[a] factual dispute . . . [to be] 'genuine' if the evidence is such that a reasonable jury could return a verdict for the nonmoving party . . . [and a] fact . . . [to be] 'material' if it might affect the outcome of the suit under the governing substantive law." *Beck v. Somerset Techs., Inc.*, 882 F.2d 993, 996 (5th Cir. 1989) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)).

"If the moving party meets the initial burden of showing that there is no genuine issue of material fact, the burden shifts to the non-moving party to produce evidence or designate specific facts showing the existence of a genuine issue for trial." *Engstrom v. First Nat'l Bank of Eagle Lake*, 47 F.3d 1459, 1462 (5th Cir. 1995) (citing *Celotex*, 477 U.S. at 322 - 24, and Fed. R. Civ. P. 56(e)). The mere argued existence of a factual dispute will not defeat an otherwise properly supported motion. *See Anderson*, 477 U.S. at 248. "If the evidence is merely colorable, or is not significantly probative," summary judgment is appropriate. *Id.* at 249 - 50 (citations omitted).

III. ARGUMENT AND ANALYSIS

In this case, Merck first asserts that *all* of the Louisiana Attorney General's claims fail because they are premised on inadequate theories of causation. Alternatively, Merck claims that Plaintiff is unable to state a claim under any of the four causes of action that have been asserted. Merck attacks each cause of action individually. The Court will first consider Merck's arguments regarding the lack of causation and will then proceed to consider each of Plaintiff's four theories of liability.

A. Causation

Plaintiff sets forth two theories of causation. Plaintiff's first theory of causation rests on the proposition that, but for Merck's conduct, the State of Louisiana, through its Medicaid program, could and would have refused to pay for all Vioxx prescriptions, or at least, would have refused to pay for Vioxx prescriptions for certain classes of individuals, such as those individuals who were also on steroids. Alternatively, Plaintiff propounds a second theory of causation that, had the full extent of the risks of Vioxx been known, fewer prescriptions would have been filled either because 1) fewer doctors would have prescribed, and fewer consumers would have taken, the drug, or 2) because Plaintiff would have removed Vioxx from the preferred drug list (PDL). According to Merck, these theories of causation are facially insufficient. First, the Court will address Plaintiff's theory that it legally could, and would, have banned Vioxx entirely as to all consumers, or a certain subgroup of consumers. Then, the Court will address Plaintiff's argument that even if it could not or would not have completely banned Vioxx, a smaller number of Vioxx prescriptions would have been prescribed but for Merck's misrepresentations.

i. Louisiana's Authority to Deny Coverage of Vioxx Prescriptions to All Consumers or a Certain Subgroup of Consumers

Merck first claims that *all* of the Plaintiff's Medicaid related claims fail because Louisiana lacked discretion under federal and state law to deny coverage for Vioxx and accordingly cannot demonstrate causation. The Attorney General responds that under federal law, LDHH has the authority to refuse to pay for any "drug that does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary." 42 U.S.C. § 1396r-8(d)(4)(C).

Louisiana has chosen to participate in the federal Medicaid program, which is intended to enable states to provide cost effective health care for poor citizens. *See* La. Rev. Stat. Ann. § 46:153.3; 42 U.S.C. §§ 1396 - 1396v. Accordingly, Louisiana must comply with federal Medicaid law and the requirement that certain services be made available to all participants in the plan. *See* 42 U.S.C. § 1396a(a)(10). Therefore, Louisiana is subject to Medicaid's regulations regarding payments for outpatient prescription drugs, such as Vioxx. Pursuant to these regulations, under most circumstances a state must "reimburse any use for a covered outpatient drug which is either (1) approved by the Federal Drug and Food administration ("FDA") or (2) supported by one or more citations in any congressionally-recognized compendia." *Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1327 (S.D. Fla. 2006).

Under four limited circumstances, a state possesses discretion to deny coverage for covered outpatient drugs. 42 U.S.C. § 1396r-8(d)(1)(B). Those circumstances include 1) if the prescribed use for the drug is not for a medically accepted indication (i.e. the FDA has not approved the drug for the use prescribed); 2) if the drug is listed in § 1396r-8(d)(2),or is

subsequently determined by the Secretary of the U.S. Department of Health and Human Services (DHH) to be subject to clinical abuse or misuse; 3) if an agreement between the state and the drug manufacturer restricts use of the drug; or 4) if the drug has been excluded by a state-established restrictive (or exclusive) formulary. *Id.*

Thus, Plaintiff must show that they had discretion to deny coverage of Vioxx under one of these circumstances. It is undisputed that Vioxx was approved by the FDA and that all prescriptions covered by the State of Louisiana were for approved uses. Further, there is no claim or allegation that any agreement was struck between Louisiana and Merck to restrict the use of Vioxx in the State. Thus, the first and third circumstances are not applicable.

Plaintiff argues that it could have restricted Vioxx both under Louisiana's Drug Utilization Review ("DUR") program and also by means of a restrictive formulary. A state's DUR program exists to make recommendations to the Secretary of DHH regarding drugs which are subject to "gross overuse or inappropriate or medically unnecessary care. Until the Secretary amends the list of excluded drugs to include a particular drug, however, the state may not exclude that drug from coverage except through its formulary committee based solely on clinical factors." *Edmonds*, 417 F.Supp.2d at 1330. Plaintiff alleges that but for Merck's misrepresentations, it would have "significantly restricted its reimbursements for Vioxx through implementation of Drug Utilization review prospective deny edits." Rec. Doc. No. 36598, 24. However, Vioxx was never placed on the Secretary's list of excluded drugs, nor is there a single piece of evidence in the record indicating that the Secretary would have placed Vioxx on the excluded drugs list had Plaintiff made such a recommendation. Thus, Louisiana never had a legal right, via their DUR program, to deny Vioxx coverage.

Thus, the only remaining circumstance which would have allowed Plaintiff to deny

Vioxx coverage is through a restrictive formulary. A formulary is "a list of Medicaid-eligible drugs for which the state will provide reimbursement when prescribed for medically accepted indications." *Edmonds*, 417 F. Supp. 2d at 1328. In establishing a formulary, states must comply with certain guidelines and must utilize a committee comprised of doctors, pharmacists and other individuals appointed by the Governor. 42 U.S.C. § 1396r-8(d)(4). The formulary must include "the covered outpatient drugs of any manufacturer which has entered into and complies with" a rebate agreement. *Id.* In this case, Merck and Louisiana had entered into a rebate agreement. However, even when a rebate agreement exists:

> A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling ... the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

Id. § 1396r-8(d)(4)(C). If a state chooses to utilize this provision, and exclude certain drugs from its formulary, it must establish a prior authorization program which will provide an opportunity for physicians to obtain coverage for excluded drugs at the discretion of the state. *Id.* § 1396r-8(d)(4)(D); *see also Edmonds*, 417 F. Supp. 2d at 1328.

States, without creating a formulary, may also choose to set up a prior authorization program. 42 U.S.C. § 1396r-8(d)(5). Under this type of program, physicians must obtain the approval of the drug before dispensing it to a patient. *Id.* However, if no formulary exists, the state does not have discretion to deny this authorization. *Edmonds*, 417 F. Supp. 2d at 1330.

Instead, the doctor retains the power to make the ultimate decision after providing the state an opportunity to convince him that the use of a different drug would be appropriate. *Id.*

Thus, the question of whether Louisiana has discretion to deny coverage for Vioxx as lacking "a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment" hinges upon the choices that the Louisiana legislators made when opting to participate in the federal Medicaid program. Prior to 2001, there is little doubt that Louisiana was prohibited from adopting a formulary by its own statutory scheme. *See* LA. REV. STAT. ANN. §§ 46:153.3(B)(2)-(3); *In re Rezulin Prods. Liab. Litig.*, 524 F. Supp. 2d 436, 440 (S.D.N.Y 2007) ("Rezulin II"). However, in 2001, Louisiana amended its statutory scheme by deleting the prohibition on adopting a formulary and providing instead that "[t]he department may establish a drug list that utilizes a prior approval process or any other process or combination of processes that prove to be cost-effective in the medical assistance program." LA. REV. STAT. ANN. § 46:153.3(B)(2)(a). Under the new law, an entity known as the Medicaid Pharmaceutical & Therapeutics Committee ("P&T Committee") was established to recommend to LDHH which drugs should be placed on a preferred drug list. *See* LA. REV. STAT. ANN. § 46:153.3(D). Medicaid-eligible drugs on the preferred drug list are covered automatically, while physicians seeking to prescribe drugs that are not on the list must seek prior approval under Louisiana's prior authorization program.

Merck contends that Louisiana's post 2001 statutory scheme still does not create a restrictive formulary and simply maintains the pre 2001 prior authorization program.[5] However,

[5]The primary authority cited by Merck for its argument is *Rezulin II*, in which the court held that "Louisiana allegedly was injured only because it was obligated by law to pay for the drugs prescribed for Medicaid recipients and not because Louisiana itself was deceived." 524 F. Supp. 2d. at 442. However, the drug at issue in that case had been removed from the market

read in the light most favorable to the Plaintiff, the new statutory provision gives the LDHH discretion to establish a restrictive formulary. Although Merck argues that LDHH never actually excluded any drugs from its formulary but instead continued to use a prior authorization program, LDHH was at liberty to exclude Vioxx from the formulary had Merck not allegedly engaged in "fraudulent marketing practices."[6] Plaintiff does not allege that Louisiana ever actually adopted a restrictive formulary, nor do they need to. Instead, Plaintiff asserts only that the statutory ban on adopting a restrictive formula had been removed and that LDHH had discretion to adopt one if it felt it was appropriate. Evidence in the record, specifically the affidavit of Mr. Hood, supports that Attorney General's argument that LDHH would have established a restrictive formulary had it known the true risks of Vioxx. See Rec. Doc. No 36598-86, ex. 77, ¶ 17-18. These allegations are sufficient to defeat summary judgment.

ii. LDHH Would Have Reimbursed Fewer Vioxx Prescriptions but for Merck's Alleged Conduct

Next, Merck attacks the Plaintiff's theory of causation that fewer Vioxx prescriptions would have been covered by LDHH but for Merck's conduct. Plaintiff raises this theory in two forms - first, that fewer doctors would have prescribed, and fewer patients would have filled, Vioxx prescriptions had Merck not concealed information regarding the drug; secondly, that LDHH would have removed Vioxx from its preferred drug list, reducing the number of Vioxx

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prior to the statutory amendment that lifted the ban on establishing a formulary. Accordingly, it is inapposite in this case.

[6]Merck argues that claims for losses allegedly sustained as a result of Vioxx sales prior to June 10, 2002, should be dismissed because it was on that date that the prior authorization program went into effect. However, the statutory amendment lifting the ban on the formulary went into effect on June 13, 2001. Once the ban was lifted, LDHH had discretion to create a restrictive formulary that excluded Vioxx had it chosen to do so.

prescriptions written by doctors. Merck argues that both versions fail because each relies on a showing of individualized proof based on what individual doctors and patients would have done had they known the risks of Vioxx.

Courts have often rejected the argument that "generalized allegations and aggregate proof" are sufficient to adequately prove causation. *See In re Schering-Plough Intron/Temodar Consumer Class Action*, No. 06-5774, 2009 WL 2043604, at *25 (D.N.J. July 10, 2009). In the absence of a generalized approach, proving causation in this case would require thousands of individual examinations to see whether doctors and patients relied upon Merck's misrepresentations or whether their decisions were based on other factors. Courts considering similar theories of causation have concluded such a tenuous causal connection is insufficient. *See In re Zyprexa Products Liability Litigation*, 2009 WL 4260857 (E.D.N.Y. Dec. 1, 2009), *Ironworkers Local Union No. 68 v. Astrazeneca Pharmaceuticals LP*, 585 F. Supp. 2d 1339 (M.D. Fla. 2008).

In *Zyprexa*, the State of Mississippi brought suit against Eli Lilly & Co. for Lilly's alleged failure to warn of the drug Zyprexa's side effects and for off label promotion of the product. Various claims were brought including claims under Mississippi's Medicaid fraud statute and the Mississippi Product Liability Act. Similar to this case, Mississippi argued that more Zyprexa prescriptions were filled, and paid for by the state, as a result of doctors being misinformed about off label use and as a result of an inadequate warning label. In a well reasoned and lengthy opinion, the court concluded that Mississippi's aggregate basis of causation must fail as "individualized proof is needed...to overcome the possibility that a Mississippi patient was prescribed Zyprexa for some reason other than belief in the accuracy of Lilly's warnings or representations." *Zyprexa*, 2009 WL 4260853, at *56.

In *Ironworkers*, the court granted the defendant's motion to dismiss consumer fraud and RICO claims based on the alleged inflation of prescription drug prices via deceptive marketing. *Id.* at 1341-42. The court reasoned that because the drug could only be obtained by getting a prescription from a doctor, proving causation would require inquiries into the thought process of each doctor and each patient to determine whether their judgment was affected by the fraudulent marketing. *Id.* at 1344. Accordingly, the court concluded that "[p]laintiff's alleged harm is simply too remote from Defendants' alleged RICO violation to satisfy the proximate cause requirement." *Id.* at 1345.

In this case, like in *Zyprexa* and *Ironworkers*, it is not sufficient for Plaintiff to generally assert that Merck's misrepresentations led to the prescription of Vioxx. Each decision by each doctor and each patient was different. The effect that any alleged misrepresentations had on each decision is unique. Many patients may have chosen to use Vioxx even if they had been fully informed of the risks associated with it. Likewise many doctors may have weighed the risks and benefits of the drug and felt that in a specific case, prescribing Vioxx was an acceptable risk. It is simply impossible, or close to it, to determine the individual thought process of each of the thousands of doctors and patients involved. A review of the record shows that Plaintiff, understandably, has made no attempt to do so.

Plaintiff attempts to avoid an analysis of each individual doctor and patient choice by arguing that LDHH itself would have removed Vioxx from its preferred drug list but for Merck's actions. As previously discussed, while Louisiana law permitted the creation of a restrictive formulary, LDHH never implemented one. Thus, Louisiana was operating under a prior authorization system where doctors who prescribed drugs not listed on the preferred drug list had to get prior authorization. However, since there was no restrictive formulary set up to exclude

Vioxx, prior authorization for Vioxx could not be denied. Assuming *arguendo*, that LDHH would have chosen to remove Vioxx from its preferred drug list, doctors still would have been able to prescribe Vioxx. They merely would have had to make a phone call prior to doing so. While this added step may very well have discouraged some doctors, it likely would not have discouraged all. Again, under this theory, the plaintiff would have to show that each individual doctor would have chosen not to seek prior authorization, which would have been granted had it been sought. Thus, for the reasons stated previously, and for the reasons stated in *Zyprexa*, the individual proof rule bars this theory of causation.

Accordingly, Plaintiff has not adequately plead causation under the theory that fewer Vioxx prescriptions would have been covered but for Merck's actions. Nevertheless, Plaintiff may proceed under the theory that LDHH had discretion to refuse payment for all Vioxx prescriptions by placing Vioxx on a restrictive formulary, and that LDHH would have done so if the true nature of the drug had been disclosed.

B. Plaintiff's Specific Claims

Having dealt with the general issue of causation, the Court now turns to an analysis of the vitality of the Plaintiff's specific claims - each of which Merck has attacked. The Plaintiff urges the following specific claims which the Court will address in turn.

i. Redhibition

Plaintiff has asserted a claim for redhibition. Merck contends that Plaintiff's claim must fail both because Plaintiff lacks standing and also because Plaintiff has no available remedy. The Court will address each argument in turn. Then, the Court will address the issue of causation, specific to Plaintiff's redhibiton claim.

a. Standing

Merck argues that Plaintiff's redhibition claims fail because the State was not a buyer of Vioxx and also because the State lacks the statutory authority to recover on behalf of consumers under a theory of redhibition. Plaintiff responds by arguing that it does qualify as a buyer of Vioxx even though it never possessed the drug because it paid the entire purchase price of the drug. The State also argues that paying the entire purchase price of Vioxx gave them ownership of the drug upon payment, and that ownership was then passed on to the Medicaid recipient. Alternatively, Plaintiff argues that "Louisiana law broadly empowers LDHH to stand in the shoes of persons on whose behalf it paid Medicaid benefits to collect the amounts paid in benefits."

Under Louisiana law, a "seller warrants the buyer against redhibitory defects, or vices, in the thing sold." La. Civ. Code Ann, art. 2520. There are two ways that a product can have a redhibitory defect. First, if the product is rendered entirely useless so that it is safe to presume that the buyer would not have purchased the product if he had been aware of the defect, then the buyer has a right to obtain recision of the sale. *Id.* Second, if a product has a defect that diminishes its utility to a point where the buyer would still have bought the product, but at a lesser price, if he had been aware of the defect, then the buyer has a right to recover the difference between the excess price and the amount which he would have paid otherwise. *Id.* In order to prevail on a redhibition claim, a plaintiff must establish the following three 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 he purchased the thing, but was neither known or apparent to him; (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) (quoting *Dalme v. Blockers Mfd. Homes, Inc.*, 2000-00244 (La. App. 3 Cir. 1/25/01); 779 So. 2d 1014, 1028.)

The Louisiana Civil Code does not contain a definition for the term "buyer." The Civil Code defines a "sale" as "a contract whereby a person transfers ownership of a thing to another for a price in money." LA. CIV. CODE ANN. art. 2439. Merck, focusing on the "transfer of ownership," claims that the LDHH was not a buyer of Vioxx because they never took possession of Vioxx. On the other hand, the Attorney General focuses on the "for a price in money" language and claims that it was a buyer of Vioxx because it paid the entire price of the drug on behalf of the Medicaid beneficiaries. To hold otherwise, Plaintiff argues, would create a situation where pharmaceutical companies would be immune from redhibition lawsuits because the State would never have had ownership and the patient would never have paid the price in money, and accordingly there would be no buyer. Alternatively, Plaintiff argues that upon payment, LDHH did take ownership of the drug which was subsequently transferred to the patients.

The parties do not cite to any Fifth Circuit or Louisiana authority directly on point.[7] Courts considering similar claims regarding the sale of prescription drugs under the laws of other states have considered insurance companies the buyers in some circumstances. *See Desiano v. Warner-Lambert Co.*, 326 F.3d 339, 350 (2d Cir. 2003). In *Desiano*, the Court was considering

[7] Merck does cite to one decision of a district court in New York applying Louisiana law dealing with payments for prescription drugs made by health benefits providers ("HPBs"). *See In re Rezulin Prods. Liab. Litig.*, 392 F. Supp. 2d 597 (S.D.N.Y. 2005) ("*Rezulin I*"). Unlike Medicaid providers, Health Benefit Providers pay only a part of the drug price. In that case, the court held that HBPs were not buyers because they did not gain ownership of the drug within the meaning of the Louisiana Civil Code." *See id. at* 611. However, unlike Medicaid providers, HBPs pay only a part of the drug price. Accordingly, the patients, who also pay part of the drug price would be able to assert redhibition claims on their own behalf.

a motion to dismiss certain consumer fraud and other claims under New Jersey law. *Id.* at 345. The Court concluded, when considering "a motion to dismiss ... the court is obliged to accept as true Plaintiffs' assertion that they were, in fact, the purchasers of the drug." *Id.* at 350. In reaching this conclusion, the Court pointed out that "[a]lthough this court has not to date held that insurance companies are, *in all circumstances*, the 'purchasers' of the drugs for which they reimburse pharmacies, we, like several other courts, have indicated that in a variety of contexts they are the buyers." *Id*. Accordingly, the Court denied Defendant's motion to dismiss on those claims. *Id.*

In this case, Plaintiff alleges that it paid the entire cost of the drug and suffered a financial injury as a result. Furthermore, Plaintiff alleges that it was a buyer of Vioxx. Considering the *Desaino* court's recognition that insurance companies, who only pay a portion of the drug price, are buyers under certain circumstances, granting dismissal of Plaintiff's redhibition claim at this stage would be inappropriate. A contrary holding would create an untenable situation whereby drug companies would be immune from redhibition suits for Medicaid funded prescription drugs. Because the Plaintiff is a buyer of Vioxx, the Court need not address Merck's argument that LDHH is not authorized to stand in the shoes of Medicaid beneficiaries and bring claims on their behalf pursuant to Louisiana law.

b. Remedies under Redhibition

Merck argues that Plaintiffs claim for redhibition must fail because Plaintiff cannot prove entitlement to restitution or a reduction in price. Under a claim of redhibition, proof of a defect "gives a buyer the right to obtain rescission of the sale." LA. CIV. CODE ANN. art. 2520. Further, "[a] buyer who obtains rescission because of a redhibitory defect is bound to return the thing to the seller." LA. CIV. CODE ANN. art. 2532. Alternatively, "the court may limit the remedy of the

buyer to a reduction of the price." LA. CIV. CODE ANN. art. 2541. Merck contends that because Plaintiff can neither return Vioxx to Merck due to its consumption, nor prove a reduction in price for what a reasonable person would have paid had they known of the defect, Plaintiff has no remedy available to him. Plaintiff responds that he is entitled to the full value paid for Vioxx because the destruction of Vioxx was either due to its redhibitory defect or a fortuitous event. According to Plaintiff, either situation requires that the seller bear the loss.

LA. CIV. CODE ANN art. 2532 states,

> If the redhibitory defect has caused the destruction of the thing the loss is borne by the seller, and the buyer may bring his action even after the destruction has occurred.
>
> If the thing is destroyed by a fortuitous event before the buyer gives the seller notice of the existence of a redhibitory defect that would have given rise to a rescission of the sale, the loss is borne by the buyer.

Merck argues that the destruction of Vioxx pills were not due to any fortuitous event, but rather the intentional consumption of the medication for pain relief. Further, Merck states that the redhibitory defect, primarily that Vioxx increases the risk of cardiovascular problems, did not cause the destruction of Vioxx.

In *Edmundson Bros. v. F.M. Carriere & Son, Inc.*, 88-772 (La. App. 3 Cir. 11/8/89), 552 So.2d 1229, the plaintiff was the manufacturer of hot sauce. The plaintiff purchased guar gum from the defendant in order to stabilize the hot sauce for export. After using the guar gum, the plaintiff found that the gum caused the sauce to separate, making it unsalable. Plaintiff did not return the guar gum, as it had already been used, and sought full recovery for the losses Plaintiff

occasioned. In discussing whether the plaintiff had a valid redhibition claim, the court disagreed with the district court's finding that an action in redhibition required the return of the item. Instead, the appellate court noted that "[i]f plaintiff proved that it was unable to return the guar gum because of its badness of its quality, no tender or return would be necessary." *Id.* at 1232.

Both guar gum and Vioxx are single use products. That is, utilizing either product causes the product to be destroyed or "used up." In both cases, the defect in the product could not have reasonably been discovered until it was used, and one time use of either product makes that product impossible to return for the purposes of rescission. Further, the use of the product conferred zero value on the plaintiff in both *Edmundson* as well as in the instant case. Here, no value was conferred on the State for failing to return the pills. The Court recognizes that rescission is required of the buyer in a redhibition claim in order to prevent that buyer from receiving a windfall. However, in the present case, Vioxx pills are not of any value to the buyer or seller. Even if the State of Louisiana could return every Vioxx pill it purchased, these pills would have zero value to the seller. Thus, the Court finds that Plaintiff may seek damages for the full value they paid despite the fact that rescission is not feasible.

Secondly, Merck argues that Plaintiff is barred from seeking a remedy because evidence shows that LDHH was aware of Vioxx's alleged defect. Louisiana law disallows a remedy under redhibition where "defects in the thing [] were known to the buyer at the time of the sale" LA. CIV. CODE ANN art. 2521. According to Merck, LDHH knew that Vioxx caused posed some cardiovascular risks. However, it is a disputed question of fact as to whether LDHH knew the extent of the risks, and whether Merck misled LDHH regarding the risks. Thus, this issue is not appropriate for summary judgment.

c. Causation under Redhibition

Plaintiff argues that he need not prove causation to be successful on his claims of redhibition.[8] Under Louisiana law, "[a] defect is redhibitory when it renders the thing useless, or its use so inconvenient that *it must be presumed* that a buyer would not have bought the thing had he known of the defect." LA. CIV. CODE ANN art. 2520 (emphasis added). Plaintiff assumes that this language presumes causation and cites to Louisiana case law stating that the test for whether the defect is redhibitory is an objective, not a subjective one. *See Mire v. Eatel Corp., Inc.*, 2002-1705 (La.App.1st Cir.5/9/03), 849 So.2d 608, 614. However, Plaintiff is mistaken in assuming that an objective test forgoes causation.

First, the Court will address Plaintiff's second theory of causation, namely that fewer Vioxx prescriptions would have been filled but for Merck's actions because fewer doctors would have prescribed them and/or because LDHH would have removed Vioxx from the preferred drug list. This theory of causation assumes that Plaintiff did not have the legal authority to ban Vioxx coverage, so Plaintiff must show that doctors and/or patients would not have prescribed and taken Vioxx had they known of its defect. Redhibition requires only that a reasonable doctor or reasonable patient would not have prescribed or taken Vioxx. However, what a reasonable person would have done is based on the circumstances of each individual medical case. The scope of the risks inherent in Vioxx are enshrouded in facts such as age, sex and history of cardiovascular problems. Thus, what constitutes a reasonable doctor or a reasonable patient still requires an individualized analysis, albeit an objective one. For the reasons stated above,

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[8]Plaintiff also claims that causation is not required to prove restitution under LUPTA. The Court need not address causation requirements under LUPTA for the reasons set forth below in section B(ii).

Plaintiff cannot show causation under redhibition using this theory.

Thus, in order to be successful in a redhibition claim, Plaintiff must prove his first theory of causation, namely that Plaintiff could and would have created a restrictive formulary from which it excluded Vioxx. The Court agrees with Plaintiff that the language of Louisiana's redhibition statute allows for an objective, reasonable person standard to be applied. Thus, Plaintiff must show that a reasonable state department of health and hospitals would have created a restrictive formulary and would have excluded Vioxx from such a formulary but for Merck's misrepresentations. This is a question of fact whose proof is dependant on adequate and credible evidence.

Accordingly, Plaintiff has a viable claim for redhibition. Merck's motion for summary judgment regarding Plaintiff's redhibition claim is DENIED.

ii. LUPTA Claims

Merck next makes several arguments regarding the Attorney General's LUTPA claim. First, Merck asserts that the Louisiana Products Liability Act ("LPLA") precludes claims under the LUTPA.

The LUTPA provides for both a private cause of action and a cause of action brought by the Attorney General. The private cause of action, established in section 1409, provides that "[a]ny person who suffers an ascertainable loss of money or movable property, corporeal or incorporeal, as a result of the use or employment by another person of an unfair or deceptive method, act or practice declared unlawful by R.S. 51:1405, may bring an action individually ... to recover actual damages." LA. REV. STAT. ANN. § 51:1409. The conduct declared unlawful by section 1405 includes "[u]nfair methods of competition and unfair or deceptive acts or practices

in the conduct of any trade or commerce."*Id.* § 51:1405.

Although the LUTPA defines a "person" in broad terms as "a natural person, corporation, trust, partnership, incorporated or unincorporated association, and any other legal entity," the Fifth Circuit has construed the private right of action under the LUTPA narrowly. *Id.* § 51:1402; *see also Gardes Directional Drilling v. U.S. Turnkey Exploration Co.*, 98 F.3d 860, 867-68 (5th Cir. 1996) (discussing the split regarding the narrow interpretation and the broad interpretation, and adopting the narrow one); *Dale v. IDS Fin. Servs. Inc.*, No. 91-289, 1992 WL 111834, at *2-3 (M.D. La. Apr. 27, 1992) (describing the origin of the narrow interpretation adopted by the Fifth Circuit). Pursuant to this narrow reading, a plaintiff must be either a business competitor of the defendant, or a consumer of the defendant's product in order to assert a private cause of action under the LUTPA. Under the statute, a "consumer" is "any person who uses, purchases, or leases goods or services," and a "consumer transaction" is "any transaction involving trade or commerce to a natural person, the subject of which transaction is primarily intended for personal, family, or household use." LA. REV. STAT. ANN. § 51:1402.

Under the LUTPA, the Attorney General can also assert a claim for injunctive relief pursuant to section 1407, which reads:

> Whenever the director and the attorney general have reason to believe that any person is using, has used, or is about to use any method, act, or practice declared by R.S. 51:1405 to be unlawful, the director may instruct the attorney general to bring an action for injunctive relief in the name of the state against such person to restrain and enjoin the use of such method, act, or practice.

Id. § 1407. Further, the statute provides that:

> The Court may issue such additional orders or render judgments against any

> party, as may be necessary to compensate any aggrieved person for any property, movable or immovable, corporeal or incorporeal, which may have been acquired from such person by means of any method, act or practice declared unlawful by R.S. 51:1405.

Id. § 1408. Together, these provisions apparently allow "the Attorney General to recover restitution in a lawsuit for an injunction." *Morris v. Sears, Roebuck & Co.*, 99-2772, p. 4 (La. App. 4 Cir. 5/31/00); 765 So. 2d 419, 422. *See also* James E. Boren, Comment, *The Louisiana Unfair Trade Practice and Consumer Protection Act: An Analysis*, 34 La. L. Rev. 634, 643 n.61 (1974); Comment, *Louisiana's Consumer Protection Law - Three Years of Operation*, 50 Tul. L. Rev. 375, 384-87 (1976).

The availability of remedies under the LUTPA, however, was altered when the Louisiana Legislature enacted the LPLA in 1988, 16 years after the LUTPA was passed. The LPLA "establishes the exclusive theories of liability for manufacturers for damage caused by their products." LA. REV. STAT. ANN. § 9:2800.52**.** "Damage" is defined as "damage to the product itself and economic loss arising from a deficiency in or loss of use of the product only to the extent that [a redhibition cause of action] does not allow recovery for such damage or economic loss." LA. REV. STAT. ANN. § 9:2800.53(5). A "manufacturer" is defined as a "person or entity who is in the business of manufacturing a product for placement into trade or commerce." LA. REV. STAT. ANN. § 9:2800.53(1).

Under the LPLA, a manufacturer is liable for damages caused by an unreasonably dangerous product. The four kinds of unreasonably dangerous product are: (1) in construction or composition; (2) in design; (3) because an adequate warning about the product has not been provided; and (4) because it does not conform to an express warranty of the manufacturer about

the product. LA. REV. STAT. ANN. §§ 9:2800.55-58. The sole exception to the exclusivity provisions under the LPLA is redhibition, which the Act expressly preserved. Thus, the plain language of the LPLA demonstrates the legislature's intent to make the LPLA and Louisiana redhibition law the sole vehicles for a suit against a manufacturer for damages arising from a defective product.

Plaintiff argues that its' LUTPA claims are not precluded by the LPLA for two reasons. First, relying on *State ex. Rel. Guste v. General Motors*, 354 So. 2d 770, 775 (La. App. 4th Cir. 1978), they argue that the LPLA only precludes causes of action for damages and that restitution is not included in the statutory definition of damages. This argument is misplaced. The LPLA precludes other causes of action against manufactures for *damage* resulting from their product, not *damages*. As discussed above, "damage" is expressly defined by the LPLA and includes economic loss.

Second, plaintiff argue that its claims are not based on damage caused by a product, but instead are based on damage caused by Merck's deceptive trade practices, and that the LPLA is therefore not applicable. However, this argument also fails as several courts which have considered the issue have concluded that LUTPA claims are barred by the exclusivity provision. *See Bladen v. C.B. Fleet Holding Co.*, 487 F. Supp. 2d 759, 767-73 (W.D. La. 2007) ("LUTPA complaints ... are precluded by the clear statutory declaration found within the LPLA); *Cantu v. C.B. Fleet Holding Co.*, Inc., No. 06-2168, 2007 WL 689566 (W.D. La. 2007) ("[I]f this court were to permit the plaintiffs to allege a cause of action for violations of LUTPA, it would be contrary to the fundamental principals of the LPLA."); Bracey *v. C.B. Fleet Holding*, No. 063238, 2006 WL 3733808 (E.D. La. 2006) ("[T]he exclusivity of the LPLA is well-established

in both the statute and its attendant case law."). Furthermore, the Fifth Circuit had made it clear that similar common law causes of action, such as fraud by misrepresentation, are precluded by the LPLA. *Jefferson v. Lead Industries Ass'n, Inc.*, 106 F.3d 1245, 1251 (5th Cir. 1997) (affirming and adopting the district court's Order and Reasons of May 31, 1996).

In *Bladen*, the defendant manufacturer of the drug Phosphosoda moved to dismiss Plaintiff's LUTPA claim. 487 F. Supp. 2d at 762. This claim was based on allegations that the manufacturer had knowingly failed to disclose and misrepresented the risks inherent in the drug. *Id.* at 762-63. In concluding that the Plaintiff's LUTPA claim was precluded, Judge Doherty underwent a thorough and thoughtful analysis of the statutory scheme, as well as the case law pertaining to LUTPA claims, and other similar common law causes of action. Emphasizing the fact that the Legislature was aware of the LUTPA when they drafted the LPLA, Judge Doherty stated:

> [T]his Court finds plaintiffs' LUTPA allegations against Fleet are not cognizable under the facts presented, and thus must be dismissed for the following reasons in particular: (1) the LPLA language is clear and unambiguous and provides the exclusive theory of liability against manufacturers; (2) the LPLA does not authorize the recovery of punitive damages; (3) the LPLA contains no exception for LUTPA claims; (4) the state jurisprudence contains no exception for the LUTPA; and (5) the jurisprudence addressing this issue, whether directly on point or by analogy, argue for such a finding.

Id. at 770-71. Accordingly, Judge Doherty granted the defendants motion. *Id.* at 772.

The fact that the Plaintiff in this case has not specifically asserted a claim under

the LPLA does not allow them to circumvent the LPLA's exclusivity provision. There is little doubt that Merck was the manufacturer of Vioxx or that Vioxx was a product, as defined by the LPLA. Additionally, the Attorney General's LUTPA claims, based on knowing and intentional misrepresentation in the marketing of a drug, are remarkably similar to the Plaintiff's LUTPA claims in *Bladen*. Accordingly, the Plaintiffs' attempt to frame its allegations as deceptive trade practice claims in order to avoid preclusion by the LPLA is not convincing.

Because the LPLA is the exclusive vehicle of relief for damage caused by the product of a manufacturer, it is unnecessary to address Merck's other arguments at this time. Accordingly, summary judgment is granted as to Plaintiff's LUTPA claim, and the claim is DISMISSED WITH PREJUDICE**.**

iii) The Attorney General's NJCFA Claims

Although the Plaintiff has asserted various claims under Louisiana law, he has also asserted claims under the New Jersey Consumer Fraud Act (NJCFA) because Merck is headquartered in New Jersey and the alleged fraudulent conduct occurred in New Jersey. Plaintiff previously indicated at oral argument for motions to dismiss, held on Tuesday July 28, 2009, that he consented to dismissal of the NJCFA claims. Accordingly, Plaintiff's NJCFA claim fails as a matter of law, the claim is DISMISSED WITH PREJUDICE.

iv) The Attorney General's Unjust Enrichment Claims

Finally, Merck argues that Plaintiff's unjust enrichment claim fails for several reasons. First, Merck asserts that like claims under LUTPA, unjust enrichment claims are precluded by the LPLA. Next, Merck argues that express statutory authority does not exist allowing the

Attorney General to proceed as parens patriae. Finally, they argue that unjust enrichment is an equitable remedy available only when no other remedy exists. In this case, they argue, because plaintiff has asserted other causes of action, other remedies exist. Plaintiff does not appear to oppose Merck's arguments regarding the unjust enrichment claim in their opposition memorandum, nor did Plaintiff raise any opposition at oral argument.

Louisiana law provides that claims for unjust enrichment "shall not be available if the law provides another remedy for the impoverishment or declares a contrary rule." La. Civ. Code Ann. art. 2298. In this case, in addition to a claim for unjust enrichment, Plaintiff has asserted claims for redhibition, violations of the LUTPA and violations of the NJCFA. Although, as discussed above, the Court has dismissed the LUTPA claim and the NJCFA claim, the Court has denied dismissal of the Plaintiff's redhibition claim. Accordingly, there does appear to be another remedy for the impoverishment at issue.

Furthermore, even if Plaintiff's redhibition claim ultimately fails, an unjust enrichment claim would still be precluded. In *Garber v. Badon & Ranier*, a plaintiff asserted several causes of action, including unjust enrichment. No. 07-1497, p. 10; 981 So. 2d 92, 99-100 (La. App. 3 Cir. 4/2/08). After all of his other causes of action failed, Plaintiff claimed that there was no other remedy for his alleged impoverishment and that he could therefore state a valid claim for unjust enrichment. *Id.* The court rejected this argument, stating that "it is not the success or failure of other causes of action, but rather the existence of other causes of action, that determine whether unjust enrichment can be applied." *Id.* Accordingly, summary judgment on Plaintiff's unjust enrichment claim is GRANTED and the claim is DISMISSED WITH PREJUDICE.

III. CONCLUSION

For the above stated reasons, Merck's Motion for Summary Judgment (Rec. Doc. No. 35872) is GRANTED IN PART and DENIED IN PART. IT IS ORDERED that the Plaintiff's LUTPA claim, NJCFA claim, and unjust enrichment claim, are hereby DISMISSED WITH PREJUDICE. Plaintiff may proceed with his claim for redhibition.

New Orleans, Louisiana, this 31st day of March, 2010.

United States District Judge