IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

In re: AVANDIA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	:	**AVANDIA MDL 1871** **2007-MD-1871**
THIS DOCUMENT RELATES TO	:	
Allied Services Division Welfare Fund v. GSK	:	**09-CV-730**
UFCW Local 1776 and Participating Employers Health and Welfare Fund v. GSK	:	**10-CV-2475**
United Benefit Fund v. GSK	:	**10-CV-5419**

MEMORANDUM OPINION AND ORDER

RUFE, J. **October 22, 2013**

Plaintiffs bring these actions against Defendant GlaxoSmithKline LLC ("GSK") alleging RICO violations, violations of state consumer protection laws, and unjust enrichment in GSK's marketing and sales of Avandia.[1] These actions have been filed in the Avandia Marketing, Sales Practices and Products Liability MDL. GSK has moved to dismiss the complaints for failure to state a claim. As similar factual and legal claims are raised in the three complaints, GSK has filed a single motion to dismiss the claims raised in the three cases. The Court, therefore, addresses the adequacy of the pleadings in each of the three complaints herein.

[1] In Civ. A. No. 10-5419, only one complaint was filed [Doc. No. 1]. In Civ. A. No. 10-2475, the operative complaint is the First Amended Complaint [Doc. No. 7]. In Civ. A. No. 09-730, the operative complaint is the Second Amended Complaint [Doc. No. 17]. On September 24, 2013, Plaintiff Allied Services Division Welfare Fund filed a Motion for Leave to File a Third Amended Complaint, which GSK has opposed. As the Court has not yet ruled on that Motion, the Court considers only the viability of the allegations set forth in the Second Amended Complaint filed in Civ. A. No. 09-730 herein.

I. FACTUAL BACKGROUND[2]

GSK, either directly or through related companies, produces, markets and distributes oral medications to treat Type II diabetes mellitus. These medications are sold under the brand names Avandia, Avandamet and Avandaryl (collectively "Avandia"). Plaintiffs are employee welfare benefit plans and employee benefit plans as defined by the Employee Retirement Income Security Act ("ERISA").[3] Plaintiffs provide medical coverage, including prescription drug coverage, to their members and their members' dependents and, along with other similarly-situated third-party payors ("TPPs"), have paid for Avandia since the Food and Drug Administration ("FDA") approved it for sale in the United States on May 25, 1999.[4]

The FDA approves drugs for sale when the manufacturer can establish, through well-designed, placebo-controlled clinical trials, that a drug is safe to use and effective (compared to a placebo) as a treatment for all conditions listed or suggested on the drug's proposed label. The FDA also can direct additional research or conduct limited independent research on drug quality, safety, and effectiveness. Once the FDA approves a drug, its manufacturer or distributor can market the drug to doctors, pharmacy benefit managers, health insurance companies and plans, and state and federal agencies, but the information provided cannot be false or misleading.

TPPs generally have Pharmacy Benefit Managers ("PBMs") prepare a formulary, a list of drugs which are approved for coverage when prescribed to the TPP's beneficiaries. In preparing the formulary, the PBM examines research regarding a drug's safety and efficacy, and also assesses cost-effectiveness, for the TPP. If one drug has some advantage over other competing drugs, that drug can be given a priority status on the formulary, which means that a patient will

[2] The facts set forth herein are taken from the operative complaints, and the allegations will be accepted as true for the purpose of resolving these motions to dismiss. Although the operative complaints are not identical, the alleged facts set forth in this Memorandum Opinion appear in each unless otherwise noted.
[3] 29 U.S.C. §§ 1002(1), 1003(a).
[4] Avandamet, which combines Avandia and metformin in one pill, was approved by the FDA on October 10, 2002. Avandaryl, which combines Avandia and glimepiride in one pill, was approved by the FDA on November 23, 2005.

pay a lower co-payment when his or her doctor prescribes that drug. Because PBMs rely on existing research on safety and efficacy, when a company acts, as Plaintiffs allege GSK did, to conceal material information about a drug's safety, the PBM will not have the information it needs to make an informed decision. Here, the TPPs opted to include Avandia on their formularies, sometimes at a higher preference level than competing drugs, and covered Avandia prescriptions at the favorable, formulary rate.

GSK marketed and promoted Avandia as a safe and effective treatment for Type II diabetes that would control blood sugar levels in individuals better than other established medications and thus would lower a user's cardiovascular risk and improve overall health. Cardiovascular disease is the leading cause of death for individuals with Type II diabetes (more than 65% of diabetics will die of heart attack or stroke), so reduction of cardiovascular risk is a primary goal of any diabetes treatment.

Among other marketing tactics, many of which were directed at physicians or PBMs for TPPs, Plaintiffs allege that GSK employed "ghostwriters" to lend the appearance of independence and objectivity to scientific papers actually authored by GSK, focused on short-term studies so that significant side effects were unlikely to be revealed, and pressured a scientist into retracting statements recommending that clinical trials should be conducted to test the hypothesis that Avandia use was associated with increased heart attacks and heart-related diseases. Plaintiffs also allege that GSK knowingly made false statements to consumers, TPPs, doctors, and pharmacies, and concealed negative information regarding Avandia's cardiovascular risks.

TPPs and PBMs relied, in part, on GSK's representations about the safety and efficacy of Avandia, including promises of better cardiovascular outcomes compared with other diabetes

drugs, when deciding whether and how to include Avandia on their formularies. Plaintiffs further allege that GSK knew or should have known that its misrepresentations would harm TPPs, as the TPPs paid a significant premium for a drug which they later learned was associated with serious health risks.

Since at least 1999, GSK has been aware of, and the FDA has been monitoring, clinical trials and reports of heart-related adverse events associated with Avandia use. Early on, Plaintiffs allege, it was clear that certain adverse events, such as fluid retention, edema, and congestive heart failure, were associated with Avandia use. In 2001, the FDA asked GSK to add a warning to the prescription label, cautioning doctors that use of Avandia could cause fluid retention.[5] The FDA also issued a warning letter to GSK, instructing the company to stop denying or downplaying the risk of heart attacks and heart diseases in its marketing. In April 2006, the FDA required GSK to add a warning based upon data suggesting a potential increased incidence of heart attack and heart-related chest pain in some patients taking Avandia.

On May 21, 2007, Steven E. Nissen, M.D. and Kathy Wolski, M.P.H. published a paper in *The New England Journal of Medicine* documenting their meta-analysis of 42 clinical trials and other relevant published and unpublished studies of Avandia, all of which were trials or studies looking at the long-term effects of Avandia use (more than 24 weeks). The Nissen study reported that, although Avandia does lower blood sugar levels, Avandia is also associated with a statistically significant increase in the risk of myocardial infarction (specifically, a 43% increased risk) and a borderline-significant increase in the risk of death from heart-related diseases compared to competing diabetes medications. Other studies reached similar conclusions. Scientists have suggested possible mechanisms or contributing factors for this

[5] Congestive heart failure is characterized by, *inter alia*, abnormal fluid retention, often resulting in edema in the legs and feet.

increased cardiac risk, noting in particular the elevated LDL cholesterol levels and apoB protein levels found in Avandia users, compared with those taking placebos.[6]

According to a 2007 Senate Report, GSK received a leaked draft of the Nissen study before it was published,[7] the results of which were shared with at least 40 GSK executives, including the CEO, the head of research, and the Vice President of Corporate Media Relations. Immediately after the Nissen study was published, GSK responded with a marketing campaign to increase consumer confidence in Avandia, including the publishing of full-page advertisements in more than a dozen United States newspapers on June 5, 2007, as well as the release of promotional materials directed at physician prescribers. The campaign focused on certain key messages. Despite acknowledging, in internal documents, that the results of the Nissen study were similar to the results of GSK's own findings, GSK publically challenged the methodology of and the conclusions reached by the Nissen study. GSK pointed to the company's own RECORD study,[8] characterizing it as having employed a "scientifically rigorous way to examine the safety and benefits" of Avandia and as being reassuring with regard to heart-related risks. However, GSK knew that the RECORD study's results were completely compatible with the Nissen study's findings, that the RECORD study did not take into account mitigating factors such as the use of cholesterol-lowering medications with Avandia, and that the study was not designed with sufficient power to answer questions regarding cardiovascular risks.[9] In short, all

[6] Avandia's product labeling disclosed the association between Avandia use and higher LDL levels.
[7] *The New England Journal of Medicine* sent Dr. Nissen's paper out to independent experts in the field for peer review prior to accepting the paper for publication. One of those experts violated the journal's policies by sharing that confidential pre-publication draft with GSK.
[8] When Dr. Nissen's study was published, the RECORD study was incomplete and unpublished. GSK approached *The New England Journal of Medicine* about publishing an interim analysis of the RECORD data. The Journal sent the interim analysis to eight experts for peer review, and many of the reviewers were critical of the study's methods and conclusions. Nevertheless, *The New England Journal of Medicine* published the RECORD study on June 5, 2007, accompanied by an editorial criticizing the study's design, methods, and conclusions.
[9] GSK also pointed to the DREAM and ADOPT studies, which had previously been conducted by GSK, to support their position that Avandia was safe. However, neither of these studies was designed to assess whether the use of Avandia by diabetics was associated with cardiovascular risks.

three complaints allege that through its public statements and marketing efforts, GSK engaged in deceptive behavior with regard to the safety of Avandia, even after the Nissen study was published, and it took steps to avoid detection of their deceptive behavior.

On May 23, 2007, the FDA recommended that GSK add a "black box" warning to its product label to more prominently address the risk of congestive heart failure (not heart attack—which was the risk at issue in the Nissen study) associated with the use of Avandia. In June 2007, the United States House of Representatives held a hearing to examine how the FDA had assessed the safety of Avandia. In response, two FDA advisory panels met to evaluate Avandia in July 2007. In November 2007, the FDA required GSK to add a black box warning regarding the possible increased risk of heart attacks and other ischemic events.

The complaint in Civil Action No. 10-5419 alleges that in the fall of 2007, the United States Department of Veteran's Affairs, followed by PBMs Prime Therapeutics and HealthTrans, and health insurers such as Kaiser Permanente and government providers, dropped Avandia from their formularies.

In February 2010, senior members of the United States Senate published a Senate Report that summarized a Senate investigation and concluded that GSK was aware of the possibility that Avandia use was correlated with increased cardiac risks years before the risks became publicly known, and had failed to timely notify the FDA and the public of the risk despite an arguable duty to do so. That report also noted that in order to contradict the findings of Dr. Nissen's study, GSK executives had engaged in certain practices designed to minimize or misrepresent findings that Avandia use was associated with greater cardiovascular risk. For example, GSK issued assurances that RECORD study's results contradicted the Nissen study, although GSK knew the RECORD study was not designed to answer questions about cardiovascular safety, and

intimidated certain independent researchers in an attempt to prevent them from voicing concerns about Avandia's risks.

In July 2010, an FDA advisory panel met to review scientific data on Avandia. Of the thirty-three panel members, eighteen felt there were significant safety concerns, twelve recommended that it be taken off the market, ten recommended that the black box warning should be enhanced and additional restrictions on use should be implemented, and seven members voted for enhanced warnings without restriction on prescriptions. Only three members voted for Avandia to continue to be sold with the existing warnings, and one member abstained. Around that time, the FDA placed on hold an ongoing study comparing Avandia and a competing drug, Actos (the TIDE study). Ultimately, in September 2010, the FDA announced significant restrictions on access to Avandia, allowing its continued use by patients already taking the drug only after their doctors reviewed with them statements describing the cardiovascular risks associated with Avandia,[10] and limiting new prescriptions to patients whose blood sugar was inadequately controlled with other medications and who decided, in consultation with their physician, not to take Actos. Around the same time, the European Medicines Agency suspended marketing authorization for Avandia in Europe, and advised physicians to transition patients to other treatment options.

Since its introduction in 1999, more than one million individuals in the United States have used Avandia on a regular basis. A monthly supply sold for between $90 and $220, with the TPPs typically paying between $135 and $140 per month per prescription, and patient co-pays covering the balance. In contrast, the typical cost for metformin, another medication used to treat Type II diabetes, was $45-55 for a monthly supply, with TPPs typically paying $40-50

[10] GSK is required to provide comprehensive risk information for dissemination to patients, and each patient's receipt and understanding of the materials must be documented in the patient's medical records.

per month per prescription. Although Plaintiffs also propose Actos as a safer alternative to Avandia, the complaints do not indicate the amount the TPPs typically pay for Actos prescriptions.

Plaintiffs seek to litigate their claims as class actions, filing on behalf of themselves and other health insurance companies, TPPs, health maintenance organizations (HMOs), health and welfare benefit plans, and other health benefit providers which paid for Avandia after May 25, 1999. Plaintiffs assert violations of RICO,[11] based on acts of mail fraud, wire fraud, tampering with witnesses, and use of interstate facilities to conduct unlawful activity. Plaintiffs also assert that GSK violated the Pennsylvania Unfair Trade Practices and Consumer Protection Law (UTPCPL),[12] and other state consumer protection and unfair and deceptive practices laws.[13] Finally, Plaintiffs assert claims for unjust enrichment. They seek both monetary damages and equitable relief.

II. STANDARD OF REVIEW

Pursuant to Federal Rule of Civil Procedure 12(b)(6), dismissal of a complaint for failure to state a claim upon which relief can be granted is appropriate where a plaintiff's "plain statement" lacks enough substance to show that he is entitled to relief.[14] In determining whether a motion to dismiss should be granted, the court must consider only those facts alleged in the complaint, accepting the allegations as true and drawing all logical inferences in favor of the non-moving party.[15] Courts are not, however, bound to accept as true legal conclusions couched as factual allegations.[16] Something more than a mere *possibility* of a claim must be alleged;

[11] 18 U.S.C. § 1962(c)-(d).
[12] 73 Pa. C.S.A. § 201-1 - 201-9.3.
[13] The Complaint cites the applicable statute from each of the fifty states.
[14] *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007).
[15] *ALA, Inc. v. CCAIR, Inc.*, 29 F.3d 855, 859 (3d Cir. 1994); *Fay v. Muhlenberg Coll.*, No. 07-4516, 2008 WL 205227, at *2 (E.D. Pa. Jan. 24, 2008).
[16] *Twombly*, 550 U.S. at 555, 564.

rather plaintiff must allege "enough facts to state a claim to relief that is plausible on its face."[17] The complaint must set forth "direct or inferential allegations respecting all the material elements necessary to sustain recovery under *some* viable legal theory."[18] The court has no duty to "conjure up unpleaded facts that might turn a frivolous . . . action into a substantial one."[19] Legal questions that depend upon a developed factual record are not properly the subject of a motion to dismiss.[20]

III. DISCUSSION

GSK has filed a motion to dismiss each case, arguing generally that Plaintiffs have failed to establish causation, because they have failed to adequately allege a cognizable injury and proximate causation—a necessary element of each of Plaintiffs' claims. They further argue that Plaintiffs' RICO claims fail because Plaintiffs fail to allege a predicate act; that the Pennsylvania UTPCPL claim fails because the act does not allow consumer fraud claims based on the sale of a prescription drug; and that the unjust enrichment claims fail because they are predicated on invalid tort claims. Finally, GSK seeks dismissal of Plaintiffs' nationwide class allegations to the extent that they rely upon varying state consumer protection laws.

A. **RICO**

Plaintiffs allege two RICO violations: (1) the existence of a marketing enterprise which engaged in a pattern of racketeering activity;[21] and (2) a conspiracy related to that marketing and promotion enterprise.[22] To state a RICO claim, Plaintiffs must first establish statutory standing, by alleging: (1) that the Plaintiff suffered an injury to business or property; and (2) that the injury

[17] *Id.* at 570.
[18] *Id.* at 562 (quoting *Car Carriers, Inc. v. Ford Motor Co.*, 745 F.2d 1101, 1106 (7th Cir. 1984)) (internal quotation marks omitted).
[19] *Id.* (quoting *McGregor v. Indus. Excess Landfill, Inc.*, 856 F.2d 39, 42-43 (6th Cir. 1988)).
[20] *See, e.g., TriState HVAC Equip., LLP v. Big Belly Solar, Inc.*, 836 F. Supp. 2d 274 (E.D. Pa. 2011).
[21] The 18 U.S.C. § 1962(c) claim.
[22] The 18 U.S.C. § 1962(d) claim.

was caused by GSK's violations of 18 U.S.C. § 1962.[23] GSK argues that Plaintiffs' RICO claims must be dismissed for failure to allege facts demonstrating statutory standing, including injury and causation, as well as for failure to allege that GSK committed a predicate act (i.e. racketeering activities).

Statutory Standing

Injury: As noted in the factual summary above, the complaints include factual allegations supporting Plaintiffs' claim that GSK was misleading the public, as well as PBMs and TPPs, with regard to Avandia's safety. The complaints allege that GSK intended to mislead PBMs and TPPs, so that they would include and prioritize Avandia on their formularies and cover prescriptions for Avandia without restrictions. Moreover, it is alleged that the intervening acts of physician prescribers were not independent and unforeseeable to GSK; in fact, it is alleged, the marketing campaign was *designed* to mislead physicians, so as to increase the number of Avandia prescriptions written and covered by TPPs.[24] Plaintiffs also allege that doctors are more likely to prescribe drugs which are included on a patient's insurer's formulary. Absent GSK's conduct, Plaintiffs allege, many patients would have been prescribed Metformin, another effective medication for diabetes treatment, which Plaintiffs claim is significantly cheaper and carries less risk than Avandia. The TPPs would then have covered the cost of prescriptions for a less expensive drug, at substantial savings to them.[25] Accordingly, Plaintiffs argue that they suffered a concrete economic injury, which is unaffected by whether any given

[23] *Maio v. Aetna, Inc.*, 221 F.3d 472, 483 (3d Cir. 2000).
[24] The Court will discuss whether misrepresentations by GSK *caused* the TPPs to include Avandia on their formularies in the next section. In this section, it confines itself to an analysis of injury.
[25] GSK argues that Plaintiffs have not alleged that they would have saved money had doctors prescribed alternative medications, pointing out that while some diabetes medications cost less than Avandia, others are priced similarly to Avandia, and moreover, doctors could prescribe two or more less expensive medications in combination, resulting in a monthly cost equivalent to or even greater than the cost of Avandia. While the Court recognizes that this may be true, that argument is more relevant to summary judgment or the calculation of damages; here, at the pleading stage, Plaintiffs' claims of injury are sufficient.

patient who ingested Avandia became ill, and which may be redressed by economic damages.[26] The Court finds that Plaintiffs' claims sufficiently allege an economic injury at this pleading stage of the litigation.

Causation: To state a claim under RICO, Plaintiffs must plead not only "but-for" causation (factual cause), but proximate causation, which demands some direct relation between the injury asserted and the injurious conduct alleged.[27]

Plaintiffs allege that GSK's misrepresentations concerning Avandia's safety increased the number of prescriptions for Avandia written by doctors and filled by patients, as doctors would have prescribed other, safer medications to patients absent the alleged misconduct. As noted above, some of these safer medications, such as Metformin, are significantly less expensive than Avandia. Plaintiffs also argue that GSK's misrepresentations led TPPs to include and prioritize Avandia on their drug formularies without restrictions. Plaintiffs therefore paid for Avandia, which was not as safe as marketing materials suggested, rather than covering the cost of less risky and less costly alternatives which physicians would have otherwise prescribed, and that their injuries were foreseeable and natural consequences of GSK's scheme to mislead the public, including physicians and insurers, with regard to Avandia's safety.

GSK argues that Plaintiffs have failed to allege a "specific representation by GSK that caused it to pay for a prescription of Avandia."[28] Plaintiffs have put forth factual allegations which, if proved, would support a finding that GSK deliberately *concealed* Avandia's cardiovascular risk, as well as issuing affirmatively misleading statements. For example,

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[26] *In re Warfarin Sodium Antitrust Litig*., 391 F3d 516, 531 (3d Cir. 2004); *Desiano v. Warner-Lambert Co.,* 326 F.3d 339 (2d Cir. 2003); *Am.. Fed'n of State County and Mun. Employees, District Council 47 Health and Welfare Fund v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, No. 08-5904, 2010 WL 891150, at *3 (E.D. Pa., March 11, 2010); *In re Neurontin Mktg. and Sales Practices Litig.*, 2011 WL 3852254, at *54-57 (D. Mass. Aug. 31, 2011); *In re Neurontin Mktg. and Sales Practices Litig.*, 433 F. Supp. 2 172, 185-86 (D. Mass. 2006).
[27] *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 265-68 (1992).
[28] Mem. of Law in Supp. of Def.'s Mot. to Dismiss at 9.

Plaintiffs allege facts suggesting that GSK manipulated scientific literature and available data, citing the United State Senate's finding that GSK had executed "an orchestrated plan to stifle opinion" by intimidation and that GSK's executives "focused on strategies to minimize findings that Avandia may increase cardiovascular risk." Although it is not clear from the Complaints the extent to which the alleged misrepresentations and concealments were directed at the TPPs or their PBMs, the Complaints allege that PBMs routinely rely upon existing scientific literature when making formulary decisions, and that they did rely upon such literature when making formulary decisions about Avandia. Therefore, Plaintiffs have adequately alleged that GSK misrepresented the safety of Avandia, and that these misrepresentations influenced the inclusion of Avandia on the formularies.

Defendant next argues that Plaintiffs cannot establish proximate cause because the company's research and marketing materials regarding the safety and efficacy of Avandia were directed at prescribing physicians, and not the insurers. However, the Court finds guidance in the First Circuit's decision in the Neurontin litigation, in which the court affirmed a jury verdict of liability against an insurance company and held that first-party reliance is not a necessary element of proximate cause in every private RICO claim.[29] Where misrepresentations are directed at prescribing doctors, rather than TPPs, but a TPP, as payor, is a "primary and intended victim" and the injury to the insurer is foreseeable,[30] the doctor's independent actions do not break the causal chain.[31] Moreover, the First Circuit reasoned, the physicians to whom the pharmaceutical company made its misrepresentations never "paid anything toward a Neurontin prescription, so there is no risk of multiple recoveries due to a suit by another of those actors.

[29] *In re Neurontin Mktg. and Sales Practices Litig.* 712 F.3d 21, 36-37 (1st Cir. 2013) (*citing Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 640 (2008).
[30] *Id.* at 37-39. The First Circuit wrote: "Pfizer has always known that, because of the structure of the American health care system, physicians would not be the ones paying for the drugs they prescribed. . . . Those payments came from Kaiser and other TPPs." *Id.* at 38-39.
[31] *Id.*

[The TPP] is also in the best position to enforce the law because [the TPP] is the party that directly suffered economic injury from [defendant's] scheme."[32] Finally, the First Circuit noted that a finding of liability would have a deterrent effect on similar, wrongful conduct.[33]

The First Circuit also noted that some of the misrepresentations had been directed at the TPP's Drug Information Service ("DIS"), which functions similarly to the PBMs in this case, reviewing research and summarizing available evidence regarding safety and efficacy of medications to guide formulary decisions for TPPs. Because of the manufacturer's strategy, the court found that important negative study results were not publically available, and therefore the "[a] reasonable factfinder could readily conclude that misinformation received by the DIS would be widely disseminated, utilized, and relied upon throughout [plaintiff's] organization to cause but-for injury."[34] The appellate court found that the district court and the jury had correctly concluded that the manufacturer's publication strategies and other communications directly affected TPPs' decisions about the drug's placement on the formulary without restrictions, and the TPP's reliance on the drug manufacturer's intentional misrepresentations and omissions caused the TPP injury, because it reimbursed for Neurotin prescriptions rather than less costly alternatives.[35] The First Circuit concluded that the TPP had met both the direct relationship and functional tests for proximate causation which had been articulated in *Holmes* and its progeny.[36]

Similarly, in other TPP litigation, the Second Circuit found that the TPP's "quantity effect theory," which is the theory of injury Plaintiffs rely upon here, was potentially viable, although other theories of liability were not.[37] The Second Circuit described the chain of causation as follows: 1) TPPs place a drug on their formularies; 2) the manufacturer distributes

[32] *Id.*, at 37-38.
[33] *Id.*, at 39-40.
[34] *Id*. at 40.
[35] *Id.*, at 41..
[36] *Id.*, at 38.
[37] *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F. 3d 121, 136 (2nd Cir. 2010).

misinformation about the drug; 3) physicians rely on that misinformation; and 4) TPPs pay for an excess number of prescriptions for that drug. Although the court noted that "even now, TPPs pay for Zyprexa and for the most part have not implemented close control or review of Zyprexa prescriptions"[38] the court found that the TPPs might be able to establish causation and therefore held that the theory was potentially viable. The Second Circuit remanded the case to the District Court for further consideration of whether the claims could survive a motion for summary judgment.

Turning to the facts before this Court, the Court must determine whether Plaintiffs have adequately pled that GSK's misrepresentations were the but-for and proximate cause of the alleged injury to Plaintiffs. Here, the TPPs have alleged that doctors relied upon GSK's misrepresentations, and also alleged that the TPPs themselves relied upon GSK's misrepresentations when making formulary decisions. "Defendant controlled all knowledge of the tests upon which the claims of Avandia's efficacy and safety were based, [so] all Class members . . . were obligated to rely on Defendant's representations about Avandia. Further, Defendant perpetuated this reliance by . . . suppress[ing] the dissemination of any critical information about Avandia."[39] Although Plaintiffs argue that "had the truth about the significant, life-threatening health risks associated with Avandia been known, Plaintiffs would not have paid for this dangerous drug,"[40] GSK argues that Plaintiffs have pled no facts from which the Court can infer that Plaintiffs would have made different coverage decisions regarding Avandia if GSK had provided more or different information about the risks. In support of this argument, GSK points out that Plaintiffs have not alleged that they removed Avandia from their formularies or limited coverage for Avandia after the Nissen study was published in 2007.

[38] *Id.*
[39] Civ. A. No. 09-730, Compl. ¶191.
[40] Resp. to Def.'s Mot. to Dismiss, filed by Allied Services and UFCW, at 19.

Although alternative diabetes drugs were available, including those which Plaintiffs indicate could have been covered at lower cost—Metformin and the sulfonylureas—Plaintiffs continued to cover Avandia as a formulary drug. [41] Therefore, GSK argues, Plaintiffs' allegations that they would not have included Avandia on their formularies if GSK had not concealed the risks are not plausible.

The Court recognizes the logic of this argument, but finds that Plaintiffs may be able to prove that GSK's earlier misrepresentations regarding Avandia's risks were a proximate cause of formulary and coverage decisions made prior to 2007, as well as prescribing physicians' decisions prior to 2007, notwithstanding their failure to remove Avandia from their formularies after Dr. Nissen's study was published. At this stage in the litigation, the Court finds that Plaintiffs have alleged sufficient facts to survive a motion to dismiss. However, because the named TPPs did not act to remove Avandia from their formularies or even restrict their coverage of Avandia in light of research published and widely publicized in 2007, whereas other TPPs did take such actions, the Court notes the potential difficulty in proving causation in the next stage of the litigation.[42]

The Court thus finds that Plaintiffs have alleged sufficient facts regarding the causal relationship between GSK's concealment of the drug's true safety profile and Plaintiffs' injuries to satisfy the causation requirements of RICO at this stage in the litigation. The Court sees the alleged chain of causation as follows: 1) the manufacturer distributes misinformation about the drug; 2) TPPs rely upon that misinformation and place Avandia on their formularies;

[41] In its complaint, United Benefit Fund alleges that other TPPs, including the United States Department of Veteran's Affairs, Kaiser Permanente, and the County of Santa Clara, as well as two PBMs, Prime Therapeutic and HealthTrans, dropped Avandia from their formularies in 2007, following the publication of Dr. Nissen's study.
[42] *UFCW*, 620 F.3d at 134.

3) physicians rely upon that misinformation (and possibly formulary status) and prescribe the drug; and 4) TPPs pay for an excess number of prescriptions for that drug. As the Complaints sufficiently plead causation and injury, the Court finds that the TPPs have statutory standing to assert RICO claims against GSK.

Elements of a RICO Claim

In addition to establishing statutory standing, to state a RICO claim under § 1962(c), Plaintiffs must allege that: (1) an enterprise that engaged in interstate commerce existed; (2) GSK was associated with that enterprise; (3) GSK participated in the affairs of the enterprise; and (4) GSK participated in a pattern of racketeering activity (i.e. at least two racketeering acts).[43] GSK argues that Plaintiffs have failed to adequately allege two or more predicate acts of racketeering, as defined by § 1961. Plaintiffs allege that GSK both acted on its own and with non-employees, including scientists who agreed to be ghost-writers for GSK-conducted research, in its efforts to mislead the public with regard to the safety of Avandia.[44] They further argue that they have adequately alleged that GSK engaged in the following predicate "racketeering activities": mail fraud, wire fraud, use of interstate facilities to conduct unlawful conduct, and witness tampering.

When fraud is the predicate act, a plaintiff must satisfy the heightened pleading standard of Federal Rule of Civil Procedure 9(b).[45] "To satisfy this standard, the plaintiff must plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation."[46] To state a claim for mail fraud, Plaintiff must plead, with specificity, the use of a mailing through the United States Postal Service or interstate use of

[43] *Sedima S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 496 (1985).
[44] Defendant does not contest Plaintiffs' allegations regarding the existence of an enterprise.
[45] *Warden v. McLelland*, 288 F.3d 105, 114 (3d Cir. 2002).
[46] *District 1199P Health and Welfare Plan v. Janssen, L.P.*, No. 06-3044, 2008 WL 5413105, at *10. (D.N.J. Dec. 23, 2008) (citing *Lum v. Bank of America*, 361 F.3d 217, 223-24 (3d Cir. 2004)).

a wire in furtherance of a scheme to defraud.[47] Here, among other allegations, Plaintiffs allege that GSK orchestrated a plan to stifle the opinion of Dr. Buse, who, in 1999, wrote to Defendant regarding his research indicating that Avandia had the potential to increase heart-attacks and heart-related diseases, and received several telephone calls and a letter in response which threatened legal action against him if he publicized such findings. Under pressure from GSK, Dr. Buse signed a retraction letter prepared by GSK. Similarly, in February 2010, Defendant allegedly sent a letter to the editor of *European Heart Journal*, urging him not to publish Dr. Nissen's editorial on the cardiovascular risks of Avandia. Plaintiffs note that these attempts to suppress the voices of scientists were just one part of GSK's elaborate scheme to conceal the true risks of Avandia use. That scheme also included the issuance of press releases, televised advertisements, and the nationwide distribution of marketing materials to prescribing doctors and TPPs, all involving the use of the mail and interstate wires. Plaintiff pleads all of these actions in sufficient detail to survive a motion to dismiss.

Plaintiffs also argue that GSK violated the witness tampering act, 18 U.S.C. § 1512. As noted above, Plaintiffs allege that Defendant intimidated certain scientists, including Dr. Buse, to prevent them from publishing research which might reveal the true risks of Avandia use. Defendant argues that Plaintiffs have not alleged that such tampering had any impact on an official federal proceeding or investigation, as required under the statute.[48] However, as Plaintiffs allege in their complaint, the FDA, a government agency, was engaged in continuing oversight of Avandia, which included periodic reviews and proceedings regarding the safety and efficacy of Avandia. Therefore, if Defendant intimidated Dr. Buse to suppress his research on

[47] *Id.*, at *11.
[48] 18 U.S.C. §§ 1512, 1515.

the risks of Avandia, Plaintiffs may be able to establish that the intimidation did interfere with FDA proceedings. The allegations are sufficient at this point in the proceedings.

Plaintiffs argue that GSK also used interstate facilities to engage in unlawful conduct, in violation of 18 U.S.C. § 1952, but fail to allege any unlawful conduct as defined by that statute.[49] Therefore, Plaintiffs have failed to state a claim under 18 U.S.C. § 1952.

B. **State Consumer Protection Act Claims**

Standing to Assert Claims Under the Laws of Other States

The parties agree that each Plaintiff has standing to assert claims under the consumer protection laws of the state in which it is located. Allied Services may raise claims under the law of Illinois, UFCW may bring claims under the laws of Pennsylvania, and United Benefit Funds may assert claims under the laws of New York.

However, the complaints assert claims under the consumer protection laws of every state. GSK argues that a TPP lacks standing to assert claims under the laws of states other than the state in which it is located, and therefore those claims should be dismissed. Allied Services and UFCW agree that a TPP has standing to proceed *only* under the consumer protection law of the state in which that TPP is based, and indicate that the complaints merely include claims under the laws of the other states in the event that the Court certifies a nationwide class of TPPs.[50] Because other members of the proposed class may have viable claims under the laws of other states, the Court will not dismiss those claims at this time.

United Benefit Fund, in contrast, argues that a TPP can also assert claims under the law of the states where their members resided and made reimbursed drug purchases. However,

[49] See 18 U.S.C. §1952(b), defining unlawful conduct to include illegal gambling, sale of liquor, prostitution, narcotics sales, use of extortion, bribes, or arson, or any indictable act. This section does not apply to civil RICO claims.
[50] Doc. No. 23 at 25.

although United Benefit Fund's complaint alleges that it represents approximately 2,500 members, and no discovery from GSK is needed to learn where those members purchased Avandia, United Benefit Fund's complaint does not allege that a single member filled a prescription for Avandia outside of New York. Accordingly, United Benefit Fund may only assert a claim under New York law.

United Benefit Fund also argues that it has standing to sue GSK under Pennsylvania's UTPCPL, despite being a citizen of New York, on the grounds that GSK is a "Pennsylvania merchant" [51] whose wrongful actions were orchestrated in and emanated from Pennsylvania. However, the UTPCLP was enacted to protect Pennsylvania consumers, and United Benefit Fund cites to no authority for the proposition that Pennsylvania law should apply when wrongdoing emanating from Pennsylvania affects non-residents.[52] Accordingly, the Court finds United Benefit Fund, a New York-based company, lacks standing to assert claims on its own behalf except under the consumer protection laws of New York State.[53]

For the reasons above, the Court finds that each TPP has standing to sue only under the consumer protection act of the state in which the TPP is located.

Elements of Consumer Protection Act Claims

1. UFCW

Plaintiff UFCW is located in Pennsylvania, and asserts claims under Pennsylvania's UTPCPL on behalf of UFCW and other Pennsylvania-based TPPs. GSK argues that UFCW has not adequately alleged that GSK committed unfair or deceptive acts or practices under

[51] In *Johnson v. SmithKline Beecham Corp*, 724 F.3d 337, 349 (3d Cir. 2013), the Third Circuit held that GSK is a citizen of Delaware for purposes of diversity jurisdiction. However, it is undisputed that GSK's headquarters is in Pennsylvania. For the purpose of this motion, the Court will accept as true the allegation that GSK's wrongful actions emanated from Pennsylvania.

[52] *See Baker v. Family Credit Counseling Corp.*, 440 F.Supp.2d 392, 414 (E.D. Pa. 2006) (noting that states have a strong interest in applying their own consumer protection laws to their own citizens, and refusing to apply the UTPCPL to non-residents of Pennsylvania).

[53] *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 156-57 (E.D. Pa. 2009).

Pennsylvania's UTPCPL, as it has not adequately alleged exposure to a misrepresentation, injury, justifiable reliance, or causation.[54]

UFCW has alleged that GSK deliberately concealed information about the increased cardiovascular risks associated with Avandia use, and provided misinformation about its safety, knowing that the information it provided would be considered by the TPPs and the PBMs they work with as they determined whether they would cover the costs of Avandia for their members. It is further alleged that GSK did so in order to increase sales and profits. The factual allegations include details about the people involved and the methods used to deceive the public, as well as facts from which the Court can infer that Plaintiffs were intentionally exposed to the misrepresentations; for example, it was alleged that GSK marketed Avandia directly to the PBMs, and that GSK knew that the PBMs would rely upon the reported results of GSK's own research when making formulary decisions. UFCW also alleges financial consequences: Once it decided to include Avandia on its formulary, it was required to pay for members' prescriptions for Avandia despite the availability of cheaper and safer alternatives. Plaintiffs adequately allege that they relied upon GSK's misrepresentations about Avandia's safety in deciding to place Avandia on their formularies, as they allege that they were reliant upon studies and marketing materials which had been impacted by GSK's alleged scheme to suppress publication of information about risks associated with Avandia use. They also allege that the decision to put

[54] GSK also argues that the UTPCPL does not apply to the sale of prescription drugs, because of the learned intermediary doctrine, relying on cases in which the plaintiffs were patients who used prescription drugs, and those drugs had been prescribed by physicians who had been adequately warned about the risks. However, here, Plaintiffs are TPPs who allege that they themselves relied on misinformation GSK provided. Unlike patients, whose doctors would weigh many factors before prescribing a medication for them, including factors unique to each patient as wells as disclosed risks, PBMs would not weigh patient-specific information, but rather would focus only on general factors, such as the available safety and efficacy information, in deciding whether to include a drug on a TPP's formulary. Plaintiffs allege that GSK intended the TPPs to be misled by the research and marketing materials and to rely on those misrepresentations when making formulary decisions. That is, providing misinformation to induce the TPPs to include Avandia on their formularies was part of GSK's scheme. Based upon these allegations, the Court does not find that UTPCPL claims are *necessarily* barred by the learned intermediary doctrine. However, upon a proper motion, this challenge can be asserted again once the parties have developed a complete factual record.

Avandia on their formulary, based on this alleged misinformation, caused financial losses. Therefore, the Court finds that UCFW has adequately stated a claim under Pennsylvania law.

2. Allied Services

Allied Services is based in Illinois, and asserts a claim on its own behalf and on behalf of other Illinois-based TPPs under the Illinois Consumer Fraud Act.[55] To state a under this Act, Allied Services must allege that (1) GSK engaged in an unfair and/or deceptive act or practice; (2) GSK intended TPPs to rely on that act or practice;[56] (3) the act or practice impacted on trade or commerce; and (4) the act or practice was the proximate cause of an actual injury to Plaintiff.[57] For the reasons set forth above, the Court finds that Allied Services has alleged that GSK engaged in deceptive practices, that GSK intended the TPPs to rely on those practices. For the reasons set forth in its discussion of RICO claims, the Court also finds that the allegations of proximate causation are adequate as to the Illinois Consumer Fraud Act.

3. United Benefit Fund

United Benefit Fund is based in New York. To state a claim under New York's Consumer Protection Act[58] a plaintiff must allege "that the defendant engaged in a material deceptive act or practice that caused actual . . . harm."[59] While the plaintiff need not allege justifiable reliance, it must plead that the deceptive act or practice was the cause of the alleged harm.[60] Again, for the reasons set forth above, the Court finds that the allegations of proximate causation are adequate under New York law, and the claims brought under the New York Consumer Protection Act will not be dismissed.

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[55] 815 ILL. COMP. STAT. §§ 505/1 – 505/12.
[56] Actual reliance is not an element of the claim. *Connick v. Suzuki Motor Co., Ltd.*, 675 N.E.2d 584 (Ill. 1996).
[57] *Zekman v. Direct Am. Marketers, Inc.*, 695 N.E.2d 853, 860-61 (Ill. 1998).
[58] N.Y. Gen. Bus. Law § 349, et seq.
[59] *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, N.A.*, 85 N.Y. 2d 20, 26 (N.Y. 1995).
[60] *Id*.

C. **Unjust Enrichment**[61]

Finally, GSK argues that Plaintiffs' unjust enrichment claims must be dismissed. Unjust enrichment is an equitable concept most commonly invoked in the context of quasi-contractual relationships in which one party is enriched, the enriched party knew about and accepted the benefit, and the conferral of that benefit without recovery or compensation would be unjust.[62] GSK argues that Plaintiffs have not adequately alleged that they received anything less than what they paid for (i.e. a drug which treated diabetes by effectively controlling blood sugar).

To state an unjust enrichment claim under Pennsylvania law, Plaintiffs must allege: 1) a benefit conferred on one party by another; 2) appreciation of the benefit by the recipient; 3) acceptance and retention of the benefit under circumstances that would make it inequitable for the recipient to retain the benefit without providing compensation.[63] Plaintiffs allege that it conferred a benefit on GSK by paying for or reimbursing the cost of Avandia prescriptions for its members, which payment was appreciated, accepted, and retained by GSK. Plaintiff further argues that because GSK hid the dangers of Avandia, GSK's retention of those payments is unjust. However, Plaintiffs have failed to allege: 1) that Avandia injured a single one of its beneficiaries; 2) that Avandia failed to perform as advertised for its members;[64] or 3) that their beneficiaries were advised to or did discard purchased Avandia medication when they learned of

[61] The briefs filed by United Benefit Fund ask the Court to apply Pennsylvania law, the law of the forum, with regard to its unjust enrichment claims. Allied Services Division Welfare Fund's briefs include both the Pennsylvania and Illinois standards for pleading unjust enrichment. The two standards are substantially similar, and therefore the Court need not engage in a choice of law analysis. *See HPI Health Care Services, Inc. v. Mt. Vernon Hosp., Inc.*, 545 N.E. 2d 672, 679 (Ill. 1989) ("To state a cause of action based on a theory of unjust enrichment, a plaintiff must allege that the defendant has unjustly retained a benefit to the plaintiff's detriment, and that defendant's retention of the benefit violates the fundamental principles of justice, equity, and good conscience.")

[62] *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 936 (3d Cir. 1999); *In re Actiq Sales and Mktg. Practices Litig.*, 790 F. Supp. 2d 313, 329 (E.D. Pa. 2011)

[63] *Allegheny Gen. Hosp. v. Phillip Morris, Inc.*, 228 F.3d 429, 447 (3d Cir. 2000); *Am. Fed'n. of State County and Mun. Employees, Inc.*, 2010 WL 891150, at *7.

[64] Plaintiffs do not dispute GSK's claim that Avandia effectively lowers blood sugar in Type 2 diabetes.

the risks.[65] Therefore, based on the allegations before the Court, it appears that Plaintiffs have received the benefit of their bargains. Accordingly, the Court finds that they have failed to state a claim for unjust enrichment under Pennsylvania law.[66]

IV. CONCLUSION

For the foregoing reasons, the Court will dismiss Plaintiffs' unjust enrichment claims, but Plaintiffs will be allowed to proceed on their RICO claims and on claims asserted under the state consumer protection laws of the state in which the TPP operates. An appropriate Order follows.

[65] *Cf Am. Fed'n. of State County and Mun. Employees*, 2010 WL 891150.
[66] *District 1199P*, 2008 WL 5413105 (addressing the issue of injury in the RICO context).