

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION**

**IRONWORKERS LOCAL UNION NO. 68 &
PARTICIPATING EMPLOYERS HEALTH &
WELFARE FUNDS, ET AL.,**

Plaintiffs,

-vs-

Case No. 6:07-cv-5000-Orl-22DAB

**ASTRAZENECA PHARMACEUTICALS
LP, ET AL.,**

Defendants.

ORDER

This cause comes before the Court for consideration of Defendant AstraZeneca's Motion to Dismiss (Doc. 19) and Defendant Parexel's Motion to Dismiss (Doc. 18). Plaintiffs filed a consolidated response to both motions (Doc. 28),¹ and Defendant AstraZeneca subsequently filed a reply (Doc. 33). Upon careful consideration of the motions and memoranda, the Court determines that both motions are due to be **GRANTED**.

I. BACKGROUND

In this putative class action, various union health and welfare benefit funds² and an individual consumer seek redress for economic injuries they say they sustained as a result of a "nationwide,

¹ Plaintiffs simultaneously filed a RICO Case Statement under seal. Magistrate Judge Baker denied the motion to file under seal, finding that the Case Statement was not necessary to the determination of the Motions to Dismiss. *See* Doc. 41.

² These funds provide health and medical benefits to union members. In relation to prescription drugs, the funds cover all or a portion of their members' prescription drug costs either through direct payment or subsequent reimbursement.

uniform marketing campaign involving fraudulent misstatements and deceptive conduct in the promotion of Seroquel,” an atypical antipsychotic drug manufactured by Defendant AstraZeneca. Doc. 17 at 4. According to Plaintiffs, this alleged scheme was devised and carried out by Defendant AstraZeneca in alliance with Defendant Parexel, a medical marketing firm employed by AstraZeneca in 2001 to provide “publications planning, meetings support, branding strategy, marketing solutions and advocacy programs relating to Seroquel.” *Id.* at 46.

Plaintiffs allege that the AstraZeneca/Parexel alliance both “misrepresented the comparative safety, efficacy and superiority of Seroquel over other traditional/typical or atypical antipsychotics,” *Id.* at 4, and “illegally marketed and promoted Seroquel for unapproved or ‘off-label’ uses,” *Id.* at 3. This scheme was allegedly accomplished through the following mechanisms: concealment of unfavorable results of clinical trials; aggressive promotion of the drug as safe and effective for uses not approved by the FDA; substantial contributions to non-profit mental health organizations; sponsorship of peer-selling events at which physicians were given financial incentives both to attend the event and to speak favorably about Seroquel to their peers; employment of “ghost-writers” to author seemingly-independent medical publications touting the superior safety and effectiveness of Seroquel; and distribution of marketing and promotional materials directly to physicians which concealed or misrepresented facts about the drug’s safety and effectiveness.

As a result of Defendants’ conduct, Plaintiffs claim that they were duped into paying hundreds of millions of dollars for Seroquel both to treat conditions for which the drug was not approved and where less expensive, and equally safe and effective, alternative treatments existed. Meanwhile, according to Plaintiffs, Defendant AstraZeneca saw a marked increase in demand for Seroquel; the company raked in over \$4.6 billion in sales of the drug in 2007 alone. *Id.* at 57. Plaintiffs maintain

that had they known of Defendants' fraudulent scheme, they would have taken steps to minimize the number of doses of Seroquel they purchased by, among other things, excluding Seroquel from approved schedules or actively dissuading doctors from prescribing Seroquel to their patients. *Id.* at 59.

Plaintiffs have filed a consolidated complaint (Doc. 17) asserting claims under the federal Racketeer Influenced and Corrupt Organizations ("RICO") statute and state consumer protection laws as well as common law claims for fraud, misrepresentation, civil conspiracy and unjust enrichment. Defendants now seek to dismiss the complaint in its entirety for failure to state a claim.

II. LEGAL STANDARD

In deciding a motion to dismiss, the court must accept as true all the factual allegations in the complaint, drawing all inferences derived from those facts in the light most favorable to the plaintiff. *Brown v. Crawford County*, 960 F. 2d 1002, 1010 (11th Cir. 1992). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974) *overruled on other grounds by Davis v. Sherer*, 468 U.S. 183 (1984); *Little v. N. Miami*, 805 F. 2d 962, 965 (11th Cir. 1986). However, a plaintiff must supply more than just any conceivable set of facts tending to support a claim, but "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1974 (2007).

III. DISCUSSION

A. Counts I and II: Civil RICO Claims

In Counts I and II of the consolidated complaint, Plaintiffs seek to recover damages by way of the civil remedies provision of the federal RICO statute.³ In general, the federal RICO statute prohibits any person from participating in a pattern of racketeering activity or from collecting an unlawful debt. *See generally* 18 U.S.C. § 1962. A pattern of racketeering activity is defined to encompass a wide range of acts which are indictable as crimes involving fraud, bribery, theft, embezzlement or extortion. *See* 18 U.S.C. § 1961(1). In this case, Plaintiffs allege that Defendants' pattern of racketeering activity involved acts that are indictable under 18 U.S.C. §§ 1341 and 1343, relating to mail and wire fraud.

The civil remedies provision of the federal RICO statute provides that "[a]ny person injured in his business or property by reason of a violation of section 1962 of this chapter may sue therefor in any appropriate United States district court and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney's fee." 18 U.S.C. § 1964(c). Thus, the essential elements of a civil RICO claim are: (1) a violation of section 1962; (2) injury to business or property; and (3) a causal connection between the violation and the injury. *Avirgan v. Hull*, 932 F.2d 1572, 1577 (11th Cir. 1991). It is the third element on which Defendants primarily focus their motions to dismiss.

Defendants present two main arguments with regard to causation. First, Defendants maintain that Plaintiffs have failed to demonstrate any detrimental reliance on the alleged misstatements made

³ Plaintiffs allege in Count I that Defendants violated 18 U.S.C. § 1962(c), which prohibits any person "employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce" from participating in the conduct of the enterprise's affairs "through a pattern of racketeering activity or collection of unlawful debt." Plaintiffs allege in Count II that Defendants violated 18 U.S.C. § 1962(d), which prohibits any person from conspiring to violate any of the other § 1962 provisions.

by Defendants in furtherance of their scheme to defraud. Second, Defendants assert that even if Plaintiffs have shown detrimental reliance, they still cannot establish the requisite causal connection between Defendants' RICO violation and Plaintiffs' injuries.

The most recent United States Supreme Court authority on pleading and proving detrimental reliance in relation to a civil RICO claim is *Bridge v. Phoenix Bond & Indem. Co.*, 128 S. Ct. 2131 (2008), where the Court confronted the issue of whether first-party reliance was required to sustain a RICO claim predicated on mail fraud. In holding that it was not, the Court opined that first-party reliance was neither a required element of a civil RICO claim nor a prerequisite to establishing proximate cause. *Id.* at 2143-44. Even so, Defendants argue that *Bridge* did not entirely do away with RICO's reliance requirement and urge that Plaintiffs must at least allege that *someone* relied on Defendants' alleged misrepresentations. While, the Court does not read *Bridge* to absolutely require proof or allegation of detrimental reliance in order to sustain a RICO claim predicated on mail or wire fraud, the Court recognizes, as the *Bridge* Court did, that "the complete absence of reliance may prevent the plaintiff from establishing proximate cause." *Id.* at 2144. Nonetheless, it is clear from the complaint that Plaintiffs in this case have alleged third-party reliance by prescribing physicians.⁴ *See, e.g.,* Doc. 17 at 21 ("[P]hysicians, relying upon and influenced by the misleading and incorrect information provided by AstraZeneca about Seroquel, wrote off-label prescriptions for Seroquel for use by their patients."). Whether this alleged third-party reliance is sufficient to establish proximate cause is another issue, one to which the Court now turns.

⁴ In light of the Court's other rulings herein, the Court need not reach the issue of whether these allegations are sufficiently pled under Fed. R. Civ. P. 9(b).

As was established by the United States Supreme Court in *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258 (1992), civil RICO claims must be supported by a showing that the alleged injury was proximately caused by the alleged unlawful act. *Id.* at 269. The Supreme Court used the term proximate cause “to label generically the judicial tools used to limit a person’s responsibility for the consequences of that person’s own acts.” *Id.* at 268. In this regard, the Court intimated that the term demanded “some direct relation between the injury asserted and the injurious conduct alleged.” *Id.* That is, “the central question [a court] must ask is whether the alleged violation led directly to the plaintiff’s injuries.” *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 461 (2006). In addition, the *Holmes* Court provided the following three policy reasons for imposing the proximate cause requirement:

First, the less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff’s damages attributable to the violation, as distinct from other, independent, factors. Second, quite apart from problems of proving factual causation, recognizing claims of the indirectly injured would force courts to adopt complicated rules apportioning damages among plaintiffs removed at different levels of injury from the violative acts, to obviate the risk of multiple recoveries. And, finally, the need to grapple with these problems is simply unjustified by the general interest in deterring injurious conduct, since directly injured victims can generally be counted on to vindicate the law as private attorneys general, without any of the problems attendant upon suits by plaintiffs injured more remotely.

Holmes, 503 U.S. at 269-70 (internal citations omitted).

In view of the “direct relation” standard enunciated by the *Holmes* Court and the various policies supporting that standard, the Court concludes that Plaintiffs have not established that their injuries were proximately caused by Defendants’ alleged scheme to defraud. Indeed, allowing Plaintiffs to move forward on their civil RICO claims would present precisely the types of problems the *Holmes* Court sought to avoid.

In relation to the first *Holmes* factor, this case raises serious concerns regarding the ascertainment of damages caused by Defendants' alleged fraudulent conduct, as opposed to damages caused by other, independent, factors. The key independent factor in this case stems from the fact that consumers may only obtain Seroquel through a prescription from a physician. Presumably, these physicians use their independent medical judgment to decide whether Seroquel is the best treatment for a given patient. This independent judgment can be influenced by a number of things, only one of which may be representations by a manufacturer as to a particular drug's relative safety and efficacy. Thus, in the context of this case, establishing that Plaintiffs' injuries were caused by Defendants' misconduct would require an inquiry into the specifics of each doctor-patient relationship implicated by the lawsuit. In other words, each physician who prescribed Seroquel to an individual consumer or health and welfare fund member would have to be questioned as to whether his or her independent medical judgment was influenced by Defendants' misrepresentations, and to what extent. Furthermore, as Defendant AstraZeneca points out in its motion, this individualized inquiry would likely have to be conducted with regard to each consumer purchase transaction or third-party reimbursement payment made over the last approximately ten years. This is precisely the type of "intricate, uncertain inquir[y]" the *Holmes* Court sought to prevent. *Anza*, 547 U.S. at 460.

In relation to the second and third *Holmes* factors, Defendants have not plausibly identified any victims of Defendants' alleged fraudulent marketing scheme other than Plaintiffs. Thus, admittedly, this case likely would not require the adoption of complicated apportionment rules in order to fairly compensate victims at various levels of injury, nor does it implicate concerns about whether more direct victims can be relied upon to "vindicate the law as private attorneys' general." *Holmes*, 503 U.S. at 269-70. Nonetheless, as one district court put it, the proximate cause inquiry is

not “a quest for the best (or, realistically, least bad) plaintiff”; rather, “[b]y its very nature, the common law proximate cause requirement adopted by the Supreme Court in *Holmes* . . . leaves open the possibility that some injuries caused by [a] . . . RICO violation may thus be left unremedied for lack of a proper plaintiff.” *Serv. Employees Intern. Union Health and Welfare Fund v. Philip Morris, Inc.*, 249 F.3d 1068, 1072, 1075-76 (D.C. Cir. 2001) (internal quotations omitted). Such is the case here. The highly complex damages assessment presented by this case strongly weighs against a finding that Plaintiffs were directly injured by Defendants’ alleged fraudulent conduct. Moreover, as Defendants suggest, the causal nexus between Plaintiffs’ alleged harm and Defendants’ alleged scheme to defraud is even further attenuated by Plaintiffs’ affirmations that they continued to pay for Seroquel even after Defendants’ alleged misconduct was uncovered. *See, e.g.*, Doc. 17 at 69 (“Plaintiffs and members of the Class have *and continue to* make payments for Seroquel that they would not make had Defendants not engaged in their pattern of racketeering activity.” (emphasis added)). In sum, Plaintiffs’ alleged harm is simply too remote from Defendants’ alleged RICO violation to satisfy the proximate cause requirement. Accordingly, Plaintiffs’ civil RICO claims must be dismissed.⁵

B. Counts III-VII: State and Common Law Claims

As the class certification issue has not yet been reached in this case, the Court has considered the state and common law claims asserted by Plaintiffs in the context of only the three states in which the representative plaintiffs claim to reside, i.e., New Jersey, Pennsylvania, and Tennessee.

⁵ The Court recognizes that Parexel and AstraZeneca stand on unequal footing with respect to the extent of their participation in the alleged RICO conspiracy, as well as the degree of accountability for Plaintiffs’ alleged harm; however, the Court’s ruling on causation renders this distinction inconsequential.

1. Counts III, VI and VII: State Consumer Protection Statutes; Common Law Fraud and Negligent Misrepresentation

In Count III, Plaintiffs allege that Defendants' alleged scheme to defraud violates the consumer protection statutes of all but four states. In order to prevail on a consumer protection claim in New Jersey, Pennsylvania, and Tennessee, a causal nexus between the actionable conduct and the injury sustained must be shown. *Weinberg v. Sun Co., Inc.*, 777 A.2d 442, 446 (Pa. 2001) ("Nothing in the legislative history [of the UTCPL] suggests that the legislature ever intended statutory language directed against consumer fraud to do away with the traditional common law elements of reliance and causation."); *Hunt v. U.S. Tobacco Co.*, 538 F.3d 217, 224 (3d Cir. 2008) (citing *Weinberg*); *N.J. Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174, 178 (N.J. Super. Ct. App. Div. 2003) (stating that in order to maintain a claim under the New Jersey Consumer Fraud Act, "a plaintiff must allege each of three elements: (1) unlawful conduct by the defendants; (2) an ascertainable loss on the part of the plaintiff; and (3) a causal relationship between the defendants' unlawful conduct and the plaintiff's ascertainable loss."); *White v. Early*, 211 S.W.3d 723, 741 (Tenn. Ct. App. 2006) (noting that to recover damages under the Tennessee Consumer Protection Act, a plaintiff must show that the defendant's wrongful conduct proximately caused her injury).⁶ As the Court earlier concluded with respect to the civil RICO claims, Plaintiffs have not established that their injuries were proximately caused by Defendants' alleged scheme to defraud. Therefore, their state consumer protection claims must also fail.

⁶ The Court additionally notes, and the parties do not dispute, that class actions are prohibited under the Tennessee Consumer Protection Act. *Walker v. Sunrise Pontiac-GMC Truck, Inc.*, 249 S.W.3d 301, 310 (Tenn. 2008).

The common law fraud and negligent misrepresentation claims alleged by Plaintiffs in Counts VI and VII likewise fail for lack of causation. *See McCabe v. Ernst & Young, LLP*, 494 F.3d 418, 438 (3d Cir. 2007) (noting that “proximate causation is a required element of both common law fraud and misrepresentation under New Jersey law.”); *Konover Const. Corp. v. East Coast Const. Servs. Corp.*, 420 F. Supp. 2d 366, 370 (D.N.J. 2006) (“Both negligent and fraudulent misrepresentation require a plaintiff to demonstrate that it sustained an injury that was caused by the defendant’s misrepresentation as an element of the claims.”); *French v. First Union Sec., Inc.*, 209 F. Supp. 2d 818, 825 (M.D. Tenn. 2002) (“In order to recover for damages, a party must not only prove they have sustained damages, but also that those damages were proximately caused by the acts or omissions of the Defendants. This is true regardless of the nature of the action.”); *Gunsalus v. Celotex Corp.*, 674 F. Supp. 1149, 1159 (E.D. Pa. 1987) (“[I]n order to prevail on [intentional or negligent misrepresentation] claims, plaintiff must also prove justifiable or reasonable reliance and a causal connection between the representations and the alleged harm.”). Therefore, Counts III, VI and VII of the consolidated complaint must be dismissed.

2. Count V: Civil Conspiracy

Under Pennsylvania, New Jersey and Tennessee common law, a civil conspiracy claim must be supported by an actionable underlying tort. *Levy v. Franks*, 159 S.W.3d 66, 82 (Tenn. Ct. App. 2004) (“[T]here is no liability under a theory of civil conspiracy unless there is underlying wrongful conduct.” (citing *Tenn. Pub. Co. v. Fitzhugh*, 52 S.W.2d 157, 158 (Tenn. 1932))); *Pelagatti v. Cohen*, 536 A.2d 1337, 1342 (Pa. Super. Ct. 1987) (“[A]bsent a civil cause of action for a particular act, there can be no cause of action for civil conspiracy to commit that act.”); *Farris v. County of Camden*, 61 F. Supp. 2d 307, 326 (D.N.J. 1999) (noting that under New Jersey law, a civil conspiracy “is not an

independent cause of action, but rather a liability expanding mechanism which exists only if [the plaintiff] can prove the underlying independent wrong.”(internal quotations omitted)). Because all tort claims asserted by Plaintiffs have been dismissed, there is no actionable underlying tort left to support their civil conspiracy claim. Count V must, accordingly, be dismissed.

3. Count IV: Unjust Enrichment

Finally, the Court finds the Third Circuit Court of Appeals’ decision in *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912 (3d Cir. 1999),⁷ persuasive on the issue of whether Plaintiffs’ unjust enrichment claim should be allowed to proceed where all other tort claims have failed. In *Steamfitters*, the court observed that “[i]n the tort setting, an unjust enrichment claim is essentially another way of stating a traditional tort claim.” *Id.* at 936. As such, the court could “find no justification for permitting plaintiffs to proceed on their unjust enrichment claim once we have determined that the District Court properly dismissed the traditional tort claims because of the remoteness of plaintiffs’ injuries from defendants’ wrongdoing.” *Id.* at 937. Other federal courts have found wisdom in this reasoning. *See Perry v. Am. Tobacco Co., Inc.*, 324 F.3d 845, 851 (6th Cir. 2003) (dismissing group health insurance subscribers’ unjust enrichment claim against tobacco manufacturers on remoteness grounds); *Blystra v. Fiber Tech Group, Inc.*, 407 F. Supp. 2d 636, 644 n.11 (D.N.J. 2005) (treating plaintiffs’ unjust enrichment claims as “subsumed by their other tort claims, and not as an independent cause of action.”); *In re Guidant Corp. Implantable Defibrillators*

⁷ *Steamfitters* was one of several cases filed in various state and federal courts by union health and welfare funds seeking to hold tobacco companies responsible for the additional health care costs incurred by smokers. The union funds asserted claims similar to those asserted by Plaintiffs in this case, e.g., federal RICO claims and state law claims for misrepresentation, negligence and unjust enrichment. The Third Circuit ultimately affirmed the district court’s dismissal of the claims for failure to establish proximate cause.

