

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

AMERICAN FEDERATION OF STATE	:	
COUNTY AND MUNICIPAL	:	
EMPLOYEES, DISTRICT COUNCIL 47	:	
HEALTH AND WELFARE FUND, <i>et al.</i>,	:	CIVIL ACTION
	:	
Plaintiffs,	:	NO. 08-5904
	:	
v.	:	
	:	
ORTHO-MCNEIL-JANSSEN	:	
PHARMACEUTICALS, INC., <i>et al.</i>,	:	
	:	
Defendants.	:	

MEMORANDUM OPINION AND ORDER

RUFE, J.

March 12, 2012

Plaintiffs American Federation of State, County and Municipal Employees (“AFSCME”) District Council 47 Health and Welfare Fund, and Philadelphia Firefighters Union (“PFU”) Local No. 22 Health and Welfare Fund bring this action against Defendants Ortho-McNeil-Janssen Pharmaceuticals, Inc. (“OMJ”), Sandoz, Inc., and ALZA Corporation. Defendants have moved for summary judgment, which Plaintiffs oppose. Because Plaintiffs have not established that they in fact suffered any injury, the motion will be granted.

I. FACTUAL AND PROCEDURAL BACKGROUND

In December 2008, Plaintiffs, the Health and Welfare Funds of AFSCME District Council 47 and PFU Local No. 22, filed this putative class action on behalf of themselves and similarly situated third-party payors. Plaintiffs provide medical coverage, including prescription

drug coverage, to their members and their members' dependents. Defendants OMJ and Sandoz market and distribute the fentanyl transdermal system patch ("fentanyl patch"), which is manufactured by Defendant ALZA, an affiliate of OMJ. The fentanyl patch is a Schedule II narcotic, available only through a doctor's prescription, designed to deliver a steady, controlled dosage (measured in micrograms per hour ("mcg/hour")) of a powerful medication that provides relief for severe and chronic pain. ALZA contracted with OMJ and Sandoz to manufacture and supply fentanyl patches throughout the United States. OMJ distributes the patches under the brand name Duragesic and Sandoz distributes the patches as a generic equivalent. The package insert for the fentanyl patches instructs prescribing physicians to advise patients that the fentanyl patch "should not be used if the seal is broken, or if the patch is cut, damaged, or changed in any way. Using a patch that is cut, damaged, or changed in any way can expose the patient or caregiver to the contents of the patch, which can result in an overdose of fentanyl that may be fatal."¹

On February 12, 2008, OMJ announced a recall of 25 mcg/hour fentanyl patches stamped with expiration dates on or before December 31, 2009. The official press release stated that the patches were "being recalled as a precaution from wholesalers and pharmacies" and that:

[The 25mcg/hr fentanyl patches] being recalled may have a cut along one side of the drug reservoir within the patch. The result is possible release of fentanyl gel from the gel reservoir into the pouch in which the patch is packaged, exposing patients or caregivers directly to fentanyl gel. Fentanyl patches that are cut or damaged in any way should not be used. Exposure to fentanyl gel may lead to serious adverse events, including respiratory depression and possible overdose, which may be fatal. . . . Anyone who has [the 25mcg/hr] patches should check the box or foil pouch

¹ Exh. 1-B to Defs.' Mot. Summ. J. (emphasis omitted).

for the expiration date to see if they have patches that are being recalled. The recalled patches all have expiration dates on or before December 2009. The cut edge in affected patches can be seen upon opening the sealed foil pouch that holds the patch. Affected patches should not be handled directly.²

The press release provided telephone numbers that “anyone with . . . patches being recalled” should call and noted that “[p]atients using fentanyl patches who have medical questions should contact their health-care providers.”³ The federal Food and Drug Administration classified this action as a Class II voluntary recall to remove a “defective product from the market” where the product “may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.”⁴

The same month it issued the press release, OMJ sent “Dear Physician” and “Dear Pharmacist” letters repeating much of the same information in the press release. The “Dear Physician” letter provided telephone numbers for patients to call “for assistance with this recall.”⁵ The “Dear Pharmacist” letter noted that “[i]t is expected that most patients and their caregivers would have learned of this recall via the media, following [the press release].”⁶ Neither of these letters stated that patients should discard undamaged patches, and the record before the Court does not reveal whether any patients called for assistance, or whether any physicians or pharmacists advised patients to discard or return the patches.

² Exh. 1-A to Defs.’ Mot. Summ. J.

³ Id.

⁴ Exh. 1-C to Defs.’ Mot. Summ. J.

⁵ Exh. 1-G to Plffs.’ Opp.

⁶ Exh. 1-H to Plffs.’ Opp.

Plaintiffs filed suit, seeking damages from Defendants for alleged violations of the Pennsylvania Unfair Trade Practices and Consumer Protection Law (“UTPCPL”),⁷ breach of express and implied warranties, and unjust enrichment because, as third-party payors, Plaintiffs “have paid or will pay expenses related to the purchase of and reimbursement for supplies of 25 mcg/hour fentanyl patches [for their members] that were unusable, worthless, and had to be discarded.”⁸ Defendants filed a motion to dismiss, and this Court dismissed the two warranty claims but allowed the UTPCPL and unjust enrichment claims to proceed to discovery.⁹ The parties thus have had the opportunity to develop the record, and Defendants now move for summary judgment on the remaining claims.

II. STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 56(c), a court may grant summary judgment only “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.”¹⁰ A fact is “material” if it could affect the outcome of the suit, given the applicable substantive law.¹¹ A dispute about a material fact is “genuine” if the evidence presented “is such that a reasonable jury could return a verdict for the nonmoving party.”¹²

⁷ 73 Pa. Stat. §§ 201-1 *et seq.*

⁸ Compl. ¶¶ 21, 23.

⁹ Mem. Opin. and Order of March 11, 2010.

¹⁰ Fed. R. Civ. P. 56(a).

¹¹ Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

¹² Id.

A party moving for summary judgment has the initial burden of supporting its motion by reference to admissible evidence¹³ showing the absence of a genuine dispute of a material fact or showing that there is insufficient admissible evidence to support the fact.¹⁴ Once this burden has been met, “the non-moving party must rebut the motion with facts in the record and cannot rest solely on assertions made in the pleadings, legal memoranda, or oral argument.”¹⁵ In considering a summary judgment motion, the Court does not weigh the evidence or make credibility determinations; “the evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in [its] favor.”¹⁶

III. DISCUSSION

Plaintiffs cannot prevail in this case unless they are able to establish that they have been injured; without a showing of injury, Plaintiffs lack standing to prosecute this action in federal court and cannot recover under the asserted UTPCPL and unjust enrichment claims.

Standing, as is relevant in this case, includes three elements: “(1) an injury in fact (i.e., a concrete and particularized invasion of a legally protected interest); (2) causation (i.e., a fairly traceable connection between the alleged injury in fact and the alleged conduct of the defendant); and (3) redressability (i.e., it is likely and not merely speculative that the plaintiff’s injury will be

¹³ See Callahan v. A.E.V., Inc., 182 F.3d 237, 252 n.11 (3d Cir. 1999).

¹⁴ See Fed. R. Civ. P. 56(c).

¹⁵ Berkeley Inv. Grp. Ltd. v. Colkitt, 455 F.3d 195, 201 (3d Cir. 2006).

¹⁶ Anderson, 477 U.S. at 255.

remedied by the relief plaintiff seeks in bringing suit).”¹⁷ “The party invoking federal jurisdiction bears the burden of establishing these elements, and, on summary judgment, the plaintiff cannot rely on mere allegations but must set forth by affidavit or other evidence specific facts demonstrating that these requirements have been met.”¹⁸

Plaintiffs also must be able to show they suffered a loss in order to proceed with UTPCPL and unjust enrichment claims. To prevail on a claim under the UTPCPL, a statute that prohibits “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce,”¹⁹ Plaintiffs must be able to establish justifiable reliance, causation, and injury.²⁰ To recover on a claim for unjust enrichment under Pennsylvania law, Plaintiffs must show that they conferred a benefit on Defendants, that Defendants knew of the benefit and accepted or retained it, and that it would be inequitable to allow Defendants to keep the benefit without paying for it.²¹ “[U]njust enrichment is not a substitute for failed tort claims in Pennsylvania but, instead, will generally be used to imply quasi-contract liability.”²²

¹⁷ Freeman v. Corzine, 629 F.3d 146, 153 (3d Cir. 2010) (quoting Common Cause of Pa. v. Pennsylvania, 558 F.3d 249, 258 (3d Cir. 2009)) (all internal quotations omitted).

¹⁸ Id. (internal quotations omitted).

¹⁹ 73 Pa. Stat. § 201-2. Although Plaintiffs’ Complaint specifically alleges a claim under the UTPCPL, Plaintiffs argue in their opposition to the motion for summary judgment that the New Jersey Consumer Fraud Act, N.J. Stat. Ann. §§ 56:8-1 *et seq.*, applies to Plaintiffs’ consumer fraud claims pursuant to choice-of-law principles. Plffs.’ Opp. at 7 n.34. Assuming without deciding that Plaintiffs could plead under one state’s statute but proceed under another’s, the New Jersey statute requires Plaintiffs to establish unlawful conduct, an ascertainable loss that is actual, not hypothetical, and that the loss was caused by the unlawful conduct. Zafarana v. Pfizer, Inc., 724 F. Supp. 2d 545, 556 (E.D. Pa. 2010) (applying New Jersey law). The Court’s analysis would not change under New Jersey law.

²⁰ Hunt v. U.S. Tobacco Co., 538 F.3d 217 (3d Cir. 2008); Toy v. Metro. Life Ins. Co., 928 A.2d 186, 202 (Pa. 2007).

²¹ Mitchell v. Moore, 729 A.2d 1200, 1203 (Pa. Super. Ct. 1999).

²² Zafarana, 724 F. Supp. 2d at 560-61 (applying Pennsylvania law) (citations omitted). If New Jersey law were to apply to unjust enrichment (although it appears Plaintiffs still rely on Pennsylvania law for this claim), then the Court notes that there is no separate tort cause of action for unjust enrichment in New Jersey; instead, unjust enrichment

Defendants argue that Plaintiffs cannot prove they suffered an injury because there is no evidence that Plaintiffs actually paid for defective fentanyl patches or for any patches that were either returned to Defendants or discarded, especially as the recall was directed to wholesalers and retailers. Although Plaintiffs are correct that there is a disputed issue of fact as to whether the recall extended beyond the patches held by wholesalers and retailers to all fentanyl patches manufactured during the covered period, including those purchased for use by Plaintiffs' members, that does not create an issue of material fact as to actual injury. At summary judgment, Plaintiffs must be able to produce some evidence from which a reasonable jury could conclude that Plaintiffs paid for patches that were not used for their intended purpose.²³ Plaintiffs have not shown that they paid for any patches that were discarded or returned; nor have Plaintiffs produced any evidence that undamaged patches were unsuitable for their intended use (because the cut-edge defect is obvious upon opening the outer foil pouch, undamaged patches can be used).²⁴ Because there is no evidence that any patches for which Plaintiffs paid were not used as

provides the underlying logic for several torts, and also provides the basis for establishing quasi-contract liability. Castro v. NYT Television, 851 A.2d 88, 98 (N.J. Super. Ct. App. Div. 2004), cited in Zafarana, 724 F. Supp. 2d at 556-57. Under New Jersey law, unjust enrichment requires that the defendant have received a benefit from the plaintiff and that allowing the defendant to keep this benefit would be unjust. VRG Corp. v. GKN Realty Corp., 641 A.2d 519, 526 (N.J. 1994). Again, the Court's analysis would not change were New Jersey law applied.

²³ In their statement of undisputed material facts, Defendants state that "Plaintiffs admitted they have no evidence that any of their plan participants ever discarded any of [the patches at issue] without using them." Defs.' Stat. Undis. Mat. Facts at ¶ 16. Plaintiffs did not counter the substance of this statement, but responded that "Plaintiffs maintain that this statement is not pertinent, let alone material, because they are not required to present evidence that their plan participants discarded recalled patches to establish their consumer fraud and unjust enrichment claims." Plffs.' Resp. Defs.' Stat. Undis. Mat. Facts at ¶ 16.

²⁴ Defendants include in their statement of undisputed material facts that "[t]he risk of serious harm was remote in part because the Cut Reservoir Defect was immediately obvious, such that individuals could avoid contact with a cut patch." Defs.' Stat. Undis. Mat. Facts at ¶ 8. Plaintiffs "dispute this statement because although Defendants' internal document refers to the obvious appearance of the defect, patches with cut reservoirs were not, in fact, immediately obvious to Defendants, whose failed quality control measures allowed patches with cut reservoirs to be introduced into the marketplace." Plffs.' Resp. Defs.' Stat. Undis. Mat. Facts at ¶ 8. Plaintiffs have not produced any evidence to counter Defendants' assertion that the defect is visible once the outer pouch is opened.

intended, Plaintiffs have not shown that they suffered a loss or injury.²⁵

Plaintiffs argue that all of the patches were “worthless and unusable to Plaintiffs due to the risk of exposure to a fatal narcotic overdose from merely opening their pouches.”²⁶ But there is no evidence that any of Plaintiffs’ participants were subjected to a risk not warned against in the package insert (the possibility that patches may be damaged), or that any of the participants even received damaged patches. The untenable nature of Plaintiffs’ argument was summarized by the Court of Appeals for the Fifth Circuit in a similar case:

The wrongs [Plaintiffs] allege – failure to warn and sale of a defective product—are products liability claims. Yet, the damages they assert – benefit of the bargain, out of pocket expenditures—are contract law damages. The plaintiffs apparently believe that if they keep oscillating between tort and contract law claims, they can obscure the fact that they have asserted no concrete injury.²⁷

Plaintiffs here contend that they need not establish a defective product because their claims are not products liability claims but are instead “based on Defendants’ uniform misrepresentations in their fentanyl patch labeling and their gross failure to assure their patches actually delivered the drug in the dose and duration claimed in the labeling.”²⁸ Plaintiffs, however, have not established either that they relied on any of the alleged misrepresentations, or

²⁵ There is a question as to how many patches were damaged. Defendants point to evidence of few complaints to argue that the problem was not wide spread. Plaintiffs contend that Defendants destroyed the recalled patches while this litigation was pending, which prevented Plaintiffs and their experts from examining the patches to determine how many were damaged, and argue that this constituted spoliation of evidence. Plffs.’ Opp. at 12-14. The Court need not resolve this dispute because the question is not whether a particular percentage of patches were damaged (as there is no evidence that all patches were damaged) but whether Plaintiffs paid for any damaged patches.

²⁶ Plffs.’ Opp. at 16.

²⁷ Rivera v. Wyeth-Ayerst Labs., 283 F.3d 315, 320-21 (5th Cir. 2002). The court in Rivera distinguished the case upon which the Plaintiffs in this case rely, Coghlan v. Wellcraft Marine Corp., 240 F.3d 449 (5th Cir. 2001), noting that the decision in Coghlan (which concerned a suit over a boat promised to be all fiberglass that was partly made of wood), “explicitly distinguishes valid, contract law suits from the ‘no-injury products liability law suit’ plaintiffs bring.” Rivera, 283 F.3d at 320.

²⁸ Plffs.’ Opp. at 7.

that the alleged misrepresentations affected them; that is, that they paid for patches that did not deliver the drug in the dose and duration claimed in the labeling. Plaintiffs cannot recover if they “paid for an effective pain killer, and [their members] received just that—the benefit of [their] bargain.”²⁹ Although Plaintiffs argue that “Defendants promised one thing but delivered another,”³⁰ there is simply no evidence that “another” was in fact delivered to any of Plaintiffs’ members. Without evidence that Plaintiffs paid for discarded or returned patches, “[i]t is not enough to allege that a product line contains a defect or that a product is at risk for manifesting this defect; rather, the plaintiffs must [demonstrate] that their product actually exhibited the alleged defect.”³¹ The only evidence—as opposed to argument—cited by Plaintiffs for the proposition that all of the patches were worthless is the fact that all of the recalled patches returned to Defendants were destroyed without regard to whether they were damaged.³² Because Plaintiffs have no evidence that any patches for which they paid were part of the returned and destroyed lots, Defendants’ handling of the returned patches is legally irrelevant.³³

IV. CONCLUSION

Plaintiffs have proved unable to support the allegations in their Complaint with evidence of actual injury. Defendants’ motion for summary judgment therefore will be granted.

²⁹ Rivera, 283 F.3d at 320.

³⁰ Plffs.’ Opp. at 9.

³¹ O’Neil v. Simplicity, Inc., 574 F.3d 501, 503 (8th Cir. 2009).

³² Plffs.’ Opp. at 10.

³³ There are presumably logistical and business reasons why Defendants would not attempt to sort the usable patches from the unusable, and the destruction of the patches cannot serve as a substitute for evidence of harm to Plaintiffs.

