[DO NOT PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 10-13196

FILED
U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
OCTOBER 24, 2011
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D.C. Docket No. 1:08-md-01928-DMM

SOUTHEAST LABORERS HEALTH AND WELFARE FUND, on behalf of itself and all others similarly situated,

Plaintiffs-Appellant,

versus

BAYER CORPORATION, BAYER HEALTHCARE PHARMACEUTICAL, INC., BAYER HEALTHCARE, LLC, BAYER HEALTHCARE, A.G.,

Defendants-Appellees.

Appeal from the United States District Court
for the Southern District of Florida

(October 24, 2011)

Before EDMONDSON and MARCUS, Circuit Judges, and FAWSETT,[*] District Judge.

FAWSETT, District Judge:

Southeast Laborers Health and Welfare Fund ("Southeast") is an employee welfare benefit plan that reimburses plan members for covered medical expenses. Southeast filed this purported class action on behalf of itself and all private, non-governmental entities in the United States and its territories that purchased, reimbursed, or paid all or part of the cost of the medication Trasylol for purposes other than resale from January 1, 1999 to November 2007. Southeast alleges that Appellees Bayer Corporation, Bayer Healthcare Pharmaceutical, Inc., Bayer Healthcare, LLC, and Bayer Healthcare, A.G., ("Bayer"), the manufacturers of Trasylol, either misrepresented or suppressed emerging information revealing serious risks associated with the use of Trasylol. Southeast contends that Bayer's conduct violated, among other things, the civil RICO statute, 18 U.S.C. §§ 1962(c)(2), 1964(c); the New Jersey Consumer Fraud Act, N.J. Stat. Ann. § 56:8-1 *et seq.* ("NJCFA"); and (3) the implied warranty of merchantability under New Jersey law, N.J. Stat. Ann. § 12A:2-314. On appeal, Southeast contests the district court's dismissal of its third amended complaint with prejudice.

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[*] Honorable Patricia C. Fawsett, United States District Judge for the Middle District of Florida, sitting by designation.

I.

The allegations of the complaint reflect that aprotinin -- the chemical name for Trasylol -- was originally developed in the 1950's to treat pancreatitis. Scientists later discovered that the drug assists the body in preventing excessive bleeding during surgery. In the early 1980's, Bayer began researching aprotinin. By the late-1990's, Bayer had received various Food and Drug Administration (FDA) approvals for the use of aprotinin under the trade name Trasylol to reduce perioperative blood loss and the need for blood transfusions in patients undergoing Coronary Artery Bypass Graft ("CABG") surgeries. From 1993 through 2007, Trasylol was routinely administered to patients undergoing CABG surgery. Trasylol costs in excess of $1,000.00 per dose, and multiple doses are often required during the course of one CABG surgery. Other medications used to manage blood loss during surgery, including Amicar (aminocaproic acid) and Cyklokapron or TA (tranexamic acid), cost less than $50.00 per dose.

In February of 2006 the FDA released a public health advisory relating to Trasylol and set an advisory committee meeting for September of 2006. The advisory committee concluded in September 2006 that there was not enough evidence to recommend any change to the safety labeling of Trasylol. The FDA did release a second public health advisory about Trasylol that month, however.

In September of 2007 an expert advisory panel for the FDA recommended that Bayer be allowed to continue selling Trasylol but cautioned that Trasylol should only be used in patients at high risk of excessive bleeding during surgery. However, soon afterward, in November of 2007, the FDA concluded that it could not identify a specific patient population for whom the benefits of using Trasylol outweighed the health risks associated with its use. At the same time, Bayer voluntarily suspended its Trasylol marketing campaign. In May of 2008 Bayer notified the FDA of its intent to remove all remaining supplies of Trasylol from hospital pharmacies and warehouses.

Southeast alleges that throughout the Trasylol marketing campaign, Bayer engaged numerous doctors, referred to as "Key Opinion Leaders," to aggressively market Trasylol to the medical community and employed a fraudulent marketing scheme to mislead decision makers into believing that Trasylol's safety and efficacy profile justified its price of over $1,000.00 per dose. For example, between 1998 and 2007, the Trasylol label stated, "Data pooled from all patients undergoing CABG surgery in U.S. placebo-controlled trials showed no significantly or clinically significant increase in the incidence of postoperative renal dysfunction in patients treated with Trasylol." From 2002 to 2007, a physician's brochure from Bayer stated, "Trasyslol is generally well tolerated;

graft potency, MI, renal or hepatic dysfunction, and mortality similar to placebo." And a "key message" in Bayer's sell-sheet distributed to hospitals and doctors as recently as 2004 stated in bold letters that in CABG surgery, "Trasylol had no adverse effect on renal function."

The complaint alleges that Bayer knew these statements were false or misleading. The allegations relating to Bayer's knowledge include, among other things: (1) animal studies demonstrating severe kidney damage associated with the use of aprotinin prior to Trasylol's approval; (2) a 1992 study revealing renal dysfunction in 13 out of 20 patients treated with aprotinin; (3) evidence indicating that Bayer routinely received reports of adverse incidents associated with the use of Trasylol; (4) Bayer's refusal to sponsor or support studies seeking to identify the cause and frequency of renal problems associated with Trasylol; and (5) two independent studies completed in 2006 revealing a relationship between the use of Trasylol and increased risks of renal damage and other serious adverse reactions.

Southeast filed its original complaint in the United States District Court for the Middle District of Tennessee. The action was later transferred to the United States District Court for the Southern District of Florida as part of multi-district litigation proceedings involving Trasylol. There, Bayer filed a motion to dismiss Southeast's first amended complaint, which the district court granted without

prejudice after determining that the complaint failed to allege the requisite proximate causation for both the civil RICO and NJCFA claims. In response, Southeast filed a second amended complaint adding the breach of implied warranty claim. Upon motion from Bayer, the district court dismissed Southeast's second amended complaint, finding that Southeast failed to allege proximate causation under the relevant standards for the civil RICO, NJCFA, and implied warranty claims. A third amended complaint was then filed and was dismissed with prejudice by the court on Bayer's third motion to dismiss. Judgment was entered for Bayer on June 10, 2010. On appeal, Southeast challenges the dismissal of its civil RICO, NJCFA, and implied warranty claims. For the reasons set forth below, we affirm.

II.

"'We review *de novo* the district court's grant of a motion to dismiss under Rule 12(b)(6) for failure to state a claim, accepting the allegations in the complaint as true and construing them in the light most favorable to the plaintiff.'" Am. Dental Ass'n v. Cigna Corp., 605 F.3d 1283, 1288 (11th Cir. 2010) (quoting Mills v. Foremost Ins. Co., 511 F.3d 1300, 1303 (11th Cir. 2008)). "In assessing the sufficiency of the complaint's allegations, we are bound to apply the pleading standard articulated in Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007), and

Ashcroft v. Iqbal, 129 S. Ct. 1937 (2009)." Ironworkers Local Union 68 v. AstraZeneca Pharm. LP, 634 F.3d 1352, 1359 (11th Cir. 2011). Accordingly, "a complaint must now contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Am. Dental, 605 F.3d at 1289 (quoting Twombly, 550 U.S. at 570).

III.
A. Dismissal of the NJCFA Claim

The district court dismissed Southeast's NJCFA claim, finding that Southeast had not adequately pled a causal connection between Bayer's alleged fraudulent conduct and Southeast's ascertainable loss. On appeal, Southeast contends that the complaint alleges a clear causal link between its loss and Bayer's deceptive conduct -- that Southeast would not have paid for Trasylol at all, regardless of price, if Bayer had not suppressed the truth about this medication. Southeast additionally argues that the district court improperly characterized this allegation of a direct causal link as a fraud on the market theory. In response, Bayer maintains that Southeast failed to adequately plead a causal nexus because the complaint is devoid of allegations relating to how or why Southeast made the decision to pay for Trasylol and because Southeast's alternative theories of causation amount to nothing more than a fraud on the market theory.

The NJCFA prohibits "[t]he act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise." N.J. Stat. Ann. § 56:8-2. To state a claim under the NJCFA, "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." N.J. Citizen Action v. Schering-Plough Corp., 842 A.2d 174, 176 (N.J. Super. Ct. App. Div. 2003) (citing Cox v. Sears Roebuck & Co., 647 A.2d 454 (N.J. 1994)). Unlike claims for common law fraud, the NJCFA "does not require proof that a consumer has actually relied on a prohibited act in order to recover." Int'l Union of Operating Eng'rs Local No. 68 Welfare Fund v. Merck & Co., Inc. (Merck II), 929 A.2d 1076, 1087 (N.J. 2007). In lieu of this traditional reliance element, a NJCFA plaintiff must demonstrate that its ascertainable loss is "attributable to conduct made unlawful by the [NJCFA]." Thiedemann v. Mercedes-Benz USA, LLC, 872 A.2d 783, 791 (N.J. 2005) (citation omitted).

In general, the causal nexus between a plaintiff's ascertainable loss and the

unlawful conduct of a defendant may not be presumed in NJCFA claims. Weinberg v. Sprint Corp., 801 A.2d 281, 291 (N.J. 2002). Instead, "a private plaintiff must show that he or she suffered an 'ascertainable loss . . . as a result' of the unlawful conduct." Meshinsky v. Nichols Yacht Sales, Inc., 541 A.2d 1063, 1067 (N.J. 1988) (citations omitted). In other fraud actions, however, elements similar to ascertainable loss and causal nexus may be presumed in certain circumstances. For example, the Supreme Court has adopted a presumption of reliance in the securities fraud context where the defendant disseminates a fraud to an efficient capital market. See Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, 552 U.S. 148, 159 (2008) (citing Basic Inc. v. Levinson, 485 U.S. 224, 247 (1988)). This presumption of reliance, referred to as the "fraud on the market theory," has been described as follows:

> The fraud on the market theory is based on the hypothesis that, in an open and developed securities market, the price of a company's stock is determined by the available material information regarding the company and its business. . . . Misleading statements will therefore defraud purchasers of stock even if the purchasers do not directly rely on the misstatements. . . . The causal connection between the defendants' fraud and the plaintiffs' purchase of stock in such a case is no less significant than in a case of direct reliance on misrepresentations.

Basic, 485 U.S. at 241-42 (quotation omitted). In this manner, evidence of a fraud disseminated to an open market creates a rebuttable presumption of reliance in the securities fraud context. Id. at 247.

In Merck II, the New Jersey Supreme Court addressed the propriety in NJCFA claims of using a fraud on the market theory to demonstrate ascertainable loss and proof of a causal nexus between the defendant's acts and the claimed damages, stating:

> Fraud on the market is essentially a creature of federal securities litigation. In that context, plaintiffs who purchased securities are permitted to demonstrate that they were damaged simply because defendant engaged in behavior otherwise prohibited and there was a change in price. The theory therefore presumes reliance.
>
> We have rejected the fraud on the market theory as being inappropriate in any context other than federal securities fraud litigation. Therefore, to the extent that plaintiff seeks to prove only that the price charged for Vioxx was higher than it should have been as a result of defendant's fraudulent marketing campaign, and seeks thereby to be relieved of the usual requirements that plaintiff prove an ascertainable loss, the theory must fail.

Merck II, 929 A.2d at 1088 (internal citations omitted). The N.J. Citizen Action court also rejected a fraud on the market theory advanced by the plaintiffs in that case -- that the defendants' misleading advertising inflated the price the plaintiffs paid for their products. 842 A.2d at 178. The court expressed similar concern that allowing a fraud on the market theory to satisfy the mandatory elements of ascertainable loss and causal nexus "would virtually eliminate the requirement that there be a connection between the misdeed complained of and the loss suffered. Adopting [a fraud on the market] theory would therefore fundamentally alter the concept of

causation in the [NJCFA] context." 842 A.2d at 178. Thus, a fraud on the market theory is insufficient to establish either ascertainable loss or proximate causation in NJCFA claims.

In the present case, the district court dismissed Southeast's NJCFA claim, finding that Southeast failed to allege "a premise of proximate causation that is distinguishable from one that relies on a fraud-on-the-market analysis." Specifically, the district court determined that "[t]here is no substantive difference between the question of whether [Southeast] would have paid for Trasylol at all instead of a lower-priced alternative versus whether Plaintiff paid too much for Trasylol because of the actual value of the drug."

Southeast, conceding that a fraud on the market theory may not be used to establish ascertainable loss or causation, argues that the district court mischaracterized its allegations by failing to recognize the distinction between paying too much for a drug and not paying for a drug at all.[1] Southeast argues that in Merck

[1] The Supreme Court has foreclosed Southeast from asserting a "fraud-on-the-FDA" theory of causation -- that is, that Southeast relied on FDA's approval of Trasylol, which itself was the product of fraud. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348 (2001) (finding state law "fraud on the FDA" claims to be preempted by federal law). Southeast has also disclaimed a chain of causation that runs through the decisions of individual doctors, alleging in its second and third amended complaints that "physicians' decisions to prescribe Trasylol were completely separate and distinct from the decision of [Southeast] and Class Members to pay for Trasylol. . . . Irrespective of the physician's decision to prescribe Trasylol, an alternative drug or no drug at all, [Southeast] and Class Members had an independent choice whether or not to pay for Trasylol."

II, the New Jersey Supreme Court tacitly endorsed a theory of causation for NJCFA claims whereby a third-party payor is permitted to state a causal nexus between the alleged fraudulent conduct and the payor's ascertainable loss that is distinct from a fraud on the market theory, by simply asserting that absent the allegedly fraudulent conduct, a medication would not have been on the market.

In International Union of Operating Engineers Local No. 68 Welfare Fund v. Merck & Co., Inc. (Merck I), 894 A.2d 1136 (N.J. Super. Ct. App. Div. 2006), rev'd, 929 A.2d 1076 (N.J. 2007), the New Jersey appellate court certified a class of third-party payors who had paid for the drug Vioxx. 894 A.2d at 1153. The Merck I court found that the payors could establish a sufficient nexus between the alleged fraud and the ascertainable loss for purposes of a NJCFA claim by demonstrating, via expert proof, either that Merck's scheme "allowed the company to achieve more favorable placement on the formularies than it otherwise might have," or "that absent Merck's misconduct, Vioxx would not have been on the market at all." Id. at 1145.

In Merck II, the New Jersey Supreme Court reversed the appellate court's class certification, finding that the fraud on the market theory is "inappropriate in any context other than federal securities fraud litigation," and "[t]herefore, to the extent that plaintiff seeks to prove only that the price charged for Vioxx was higher than it should have been as a result of defendant's fraudulent marketing campaign, and seeks

thereby to be relieved of the usual requirements that plaintiff prove an ascertainable loss, the theory must fail." Merck II, 929 A.2d at 1088 (citations omitted).

However, the Merck II court did not specifically address the appellate court's statement that a causal nexus between the alleged fraud and the ascertainable loss could be established by demonstrating "that absent Merck's misconduct, Vioxx would not have been on the market at all." Merck I, 894 A.2d at 1145. In the instant appeal, Southeast argues that by failing to address the lower court's statement, the Merck II court tacitly endorsed this theory of causation. We disagree.

A theory of causation relying solely on an allegation that the medication in question would not have been on the market absent the alleged fraudulent conduct is no more than a state law "fraud on the FDA" theory, a theory that has been specifically rejected by the Supreme Court. Buckman, 531 U.S. at 348. In Buckman, plaintiffs sought damages under state tort law, arguing that absent defendant's fraudulent representations, the FDA would not have approved the orthopedic bone screws and the plaintiffs would not have been injured by these devices. Id. at 343-44. The Court dismissed plaintiffs' state law "fraud on the FDA" claims, concluding that such claims are in "conflict with, and . . . therefore impliedly pre-empted by, federal law." Id. at 348 (footnote omitted). The conflict was found to arise "from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud

against the [FDA], and that this authority is used by the [FDA] to achieve a somewhat delicate balance of statutory objectives. The balance sought by the [FDA] can be skewed by allowing fraud-on-the-FDA claims under state tort law." Id. Accordingly, the Merck II court could not have implicitly approved of a state law "fraud on the FDA" theory of causation for NJCFA claims whereby a third-party payor is permitted to state a causal nexus between the alleged fraudulent conduct and the payor's ascertainable loss by simply asserting that absent the allegedly fraudulent conduct, the FDA would not have approved the medication to be on the market.

Southeast additionally argues that the complaint sets forth a second, direct chain of causation that is also distinct from a fraud on the market theory, contending that (1) the plan documentation stating that Southeast would only pay for "medically necessary" expenses and (2) the FDA's pronouncement that it could not identify any specific patient population for whom the benefits of using Trasylol outweigh the safety risks, establish a causal nexus between Bayer's alleged fraudulent conduct and Southeast's decision to pay for Trasylol. Such a theory of causation, supported by factual allegations connecting the alleged fraud to the implementation of the plan documentation, may be sufficient to allege a causal nexus in a hypothetical NJCFA claim. In the present case, however, the complaint fails to provide any factual allegations connecting the FDA's pronouncement to Southeast's determination of

medical necessity as a precondition to its payment. Even if Trasylol was in fact medically unnecessary and contraindicated for all uses, Southeast alleges no facts indicating how it would have independently evaluated Trasylol's medical appropriateness, aside from relying on the intermediaries of prescribing physicians, the FDA, or the market. Reliance on the first of these intermediaries Southeast itself has disclaimed, while reliance on the second and third of these intermediaries is precluded by Buckman and Merck II, respectively. Thus, Southeast's supposedly "direct chain of causation" is unsupported by factual allegations. On the facts alleged, the only causal nexus between the revelation of Trasylol's true risk profile and Southest's determination not to pay for Trasylol is merely a repackaged form of indirect causation -- relying either on the FDA's approval decisions for Trasylol or a market capable of efficiently digesting the truth and relaying it to Southeast in the form of a market price. Contrary to Southeast's suggestion, either theory of causation is far from direct, and foreclosed by the relevant case law.

Finally, Southeast raises a novel theory of causation, arguing that Bayer's alleged material omissions give rise to a presumption of causation. This argument was not raised below, and on that ground we may decline to address its merits on appeal. See Formby v. Farmers and Merchs. Bank, 904 F.2d 627, 634 (11th Cir. 1990) ("As a general rule, an appellate court will not consider a legal issue or theory

raised for the first time on appeal." (quotation omitted)). Southeast contends that it raised this argument in a reply to Bayer's motion to dismiss by stating that "payment for a product by someone exposed to misleading materials 'would be sufficient to establish *prima facie* proof of causation,'" quoting Varacallo v. Mass. Mut. Life Ins. Co. (Varacallo), 752 A.2d 807, 817 (N.J. Super. Ct. App. Div. 2000). However, this argument was made in the context of explaining that a NJCFA claim requires proof of a causal nexus, not actual reliance. At no point did Southeast reference a presumption of causation arising from an allegation of an omission or otherwise acknowledge the discussion of this presumption in Varacallo.[2] Accordingly, the argument is waived. See Four Seasons Hotels & Resorts, B.V. v. Consorcio Barr S.A., 377 F.3d 1164, 1169 (11th Cir. 2004) (finding an argument waived where nothing in the party's brief to the district court "could have possibly alerted the district judge to the argument [made on appeal]").

Moreover, even if this argument had been raised below, it would have been to no avail. Southeast primarily depends on Varacallo to support its argument that Bayer's alleged material omissions give rise to a presumption of causation. Such

[2] Furthermore, pages 813 and 814 of the Varacallo opinion, cited in Southeast's response to the motion to dismiss, discuss the proposition that common law fraud requires proof of reliance while NJCFA claims only require proof of a causal nexus between the concealment of the material fact and the loss. Varacallo, 752 A.2d at 813-14. In contrast, pages 817 and 818 of the Varacallo opinion, cited in Southeast's reply brief, specifically discuss the presumption of causation arising from an allegation of an omission. Id. at 817-18.

dependence is ill-founded. The Varacallo court confronted a situation unlike the circumstances of the present case. There, the court addressed the following narrow question: "For purposes of certifying a class, must the plaintiffs offer direct proof that the entire class relied on defendant's representation that omitted material facts, where the plaintiffs have established that the defendant withheld these material facts for the purpose of inducing the very action the plaintiffs pursued?" Varacallo, 752 A.2d at 817. In addition, Varacallo testified that he had read the alleged misstatements and relied upon them in deciding to purchase the policies at issue. Id. at 811.

In contrast in the present case, the question is not whether Southeast must offer direct proof that the entire proposed class relied upon Bayer's representations. Instead, the question is whether Southeast itself can establish a causal nexus between the alleged omission and its ascertainable loss. However, unlike the facts in Varacallo, the third amended complaint in the instant case is devoid of allegations that Southeast, or any other proposed class member, actually relied on Bayer's representations. The allegations of Southeast's complaint are therefore distinguishable from Varacallo and do not raise a presumption of causation. Accordingly, we affirm the district court's dismissal of Southeast's NJCFA claim.

B. Dismissal of the Civil RICO Claim

The district court dismissed Southeast's civil RICO claim after finding that

Southeast failed to sufficiently allege a direct relationship between its payment for Trasylol and Bayer's alleged fraudulent concealment. On appeal, Southeast argues that the causal chain is "simple, direct and uninterrupted."

The federal RICO laws provide civil and criminal liability for persons engaged in a pattern of racketeering activity. See 18 U.S.C. §§ 1962-1964. To state a claim for a RICO violation, a plaintiff must allege: "(1) a violation of section 1962; (2) injury to business or property; and (3) that the violation caused the injury." Avirgan v. Hull, 932 F.2d 1572, 1577 (11th Cir. 1991) (citing O'Malley v. O'Neill, 887 F.2d 1557, 1561 (11th Cir. 1989)). In order to adequately plead the first element, a violation of § 1962, a plaintiff must allege: "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity."[3] Williams v. Mohawk Indus., Inc., 465 F.3d 1277, 1282 (11th Cir. 2006) (quotation omitted).

Civil RICO plaintiffs "must also satisfy the requirements of 18 U.S.C. § 1964(c)." Williams, 465 F.3d at 1282. Section 1964(c) 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." 18 U.S.C. § 1964(c) (emphasis added). To establish the "by reason of" element of § 1964(c), a plaintiff must demonstrate that the defendant's

[3] The alleged racketeering activity here was mail and wire fraud. See 18 U.S.C. § 1961(1)(B).

violation was not only the "but for" cause of the plaintiff's injury but also its proximate cause. Holmes v. Sec. Investor Protection Corp., 503 U.S. 258, 268 (1992); Williams, 465 F.3d at 1287.

"When a court evaluates a RICO claim for proximate causation, the central question it 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 Holmes, the Supreme Court discussed three specific factors for courts to consider in evaluating the directness between an alleged injury and the injurious conduct as follows:

> 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.

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

In the present case, the district court conducted a thorough analysis of Southeast's civil RICO allegations and found that the factors described in Holmes weighed heavily against a finding of proximate causation. The first Holmes factor

was found to be the most problematic to Southeast's claims because, although Southeast alleged that it had an independent choice of whether or not to pay for Trasylol, Southeast failed to explain how or why it made the choice to pay for Trasylol and how or why Bayer's alleged concealment of the dangers of Trasylol led Southeast to pay for Trasylol.

On appeal, Southeast continues to assert that it would never have incurred the expense of Trasylol if Bayer had been honest about Trasylol's safety and efficacy, arguing that, taken together, (1) the plan documentation stating that Southeast would only pay for "medically necessary" expenses and (2) the FDA's pronouncement that it could not identify any specific patient population for whom the benefits of using Trasylol outweighed the safety risks, establish a direct injury to Southeast. Yet, despite being provided with several opportunities, Southeast failed to allege facts plausibly demonstrating that Southeast would have independently determined[4] that Trasylol was not "medically necessary" if Bayer had disclosed the allegedly suppressed material information. In the absence of such factual allegations, it cannot reasonably be inferred that Bayer's allegedly fraudulent conduct led directly to Southeast's decision to pay for Trasylol. Consequently, the complaint fails to meet

[4] As with its NJCFA claim, Southeast may not rely on a fraud-on-the-market or fraud-on-the-FDA theory of causation for its RICO claim.

the direct relation requirement, and the district court properly dismissed Southeast's civil RICO claim.[5]

C. Dismissal of the Implied Warranty Claim

Finally, Southeast challenges the district court's dismissal of its implied warranty claim under New Jersey law, disputing the district court's conclusion that Southeast had "not adequately pled that Trasylol's defect proximately caused its economic damages," and had "not alleged that Trasylol was not fit for its intended use in preventing perioperative bleeding."

Under New Jersey law, "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." N.J. Stat. Ann. § 12A:2-314(1). In order for "[g]oods to be merchantable," they must be "fit for the ordinary purposes for which such goods are used." Id. § 12A:2-314(2). This "implied warranty of merchantability means that the product is reasonably fit for the purpose intended; it does not imply absolute perfection." Jakubowski v. Minn. Mining & Mfg., 199 A.2d 826, 831 (N.J. 1964). In order to establish an implied warranty claim, a plaintiff must prove "that the product was not reasonably fit for the ordinary purposes for which it was sold and

[5] The parties submitted supplemental briefs addressing this court's recent decision in Ironworkers Local Union 68 v. AstraZeneca Pharmaceuticals, LP, 634 F.3d 1352 (11th Cir. 2011). The holding in the present case is not inconsistent with the Ironworkers decision.

such defect proximately caused injury to the ultimate consumer." Hollinger v. Shoppers Paradise of N.J., Inc., 340 A.2d 687, 692 (N.J. Super. Ct. Law Div. 1975) (citations omitted).

Southeast does not assert that Trasylol's alleged defect physically harmed any of its plan members. Instead, Southeast contends that the complaint states a claim for breach of implied warranty under New Jersey law because a harmful medication is per se unmerchantable. In support of this theory, Southeast relies primarily on Mones v. Imperial Bottling Works, Inc., 185 A. 483 (N.J. 1936).

In Mones, the court held that a magnesia solution that failed to comply with the United States Pharmacopoeia requirements was unmerchantable because it was sold to a business for purposes of resale and the business could not legally resell it. 185 A. at 483. On these facts, the New Jersey Supreme Court concluded that "[c]ertainly a dealer who purchases for resale cannot be said to be without warranty if the goods which he purchases cannot be resold without violating the law of this state." Id. Thus, Mones does not stand for the proposition that a drug is per se unmerchantable because it is harmful, even where it does not cause harm to the plaintiff. Instead, Mones stands for the familiar proposition that a breach of implied warranty claim is properly asserted where a good is not reasonably fit for the ordinary purposes for which it was sold. The remaining cases cited by Southeast similarly fail to support

Southeast's theory that a harmful medication is per se unmerchantable.

In the present case, the complaint alleges that Trasylol was "not fit for the ordinary purpose for which anti-fibrinolytic drugs are used." Nonetheless, Southeast does not allege that Trasylol failed to act as an anti-fibrinolytic or that it or any of its members were physically harmed by Trasylol. Moreover, Southeast has failed to identify any case law to support its theory that the potential of a drug to cause harmful side effects, in the abstract, renders a drug per se unmerchantable, even as to plaintiffs that did not suffer the side effects. Thus, the complaint does not allege that Trasylol is unfit for the ordinary purpose for which it was sold, a requirement to state a claim for breach of implied warranty under New Jersey law.

In addition, Southeast has not alleged that Trasylol's defect proximately caused Southeast's economic damages. To succeed on a breach of warranty claim, the plaintiff's injury must arise as a proximate result of the alleged defect of the product. See Santor v. A & M Karagheusian, Inc., 207 A.2d 305, 313 (N.J. 1965) (requiring product defect to "cause[] injury or damage" to support a breach of implied warranty claim); Hollinger, 340 A.2d at 692 (to be liable for breach of warranty, the "defect [must] proximately cause[] injury to the ultimate consumer"). Here, the alleged product defect is that Trasylol created an undue risk of kidney failure and other bodily harms. However, Southeast does not assert that Trasylol's alleged defect physically

harmed Southeast, nor does Southeast assert a derivative claim on behalf of any its members that might have suffered physical injuries from ingesting Trasylol. Instead, the economic harm for which Southeast seeks recovery is the excess money that it paid for the high-priced Trasylol instead of the cheaper generic alternative drugs. But this harm was not caused by the condition which rendered Trasylol unmerchantable, namely, its unsafe condition. Instead, it was allegedly caused by Bayer's misrepresentations and fraud. However, fraud is not relevant misconduct for purposes of a breach of warranty claim. See Santor, 207 A.2d at 313 ("The liability [for a product defect under tort or contract law] does not depend on . . . proof of legal or equitable fraud."). Thus, the alleged product defect underlying Southeast's breach of warranty claim did not cause Southeast's asserted injury. Accordingly, Southeast's implied warranty claim was properly dismissed.

IV.

For the foregoing reasons, the district court's judgment dismissing Southeast's third amended complaint is **AFFIRMED**.