[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

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U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
MARCH 11, 2011
JOHN LEY
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No. 08-16851

D. C. Docket No. 07-05000-CV-ORL-23DAB

IRONWORKERS LOCAL UNION 68 AND PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUNDS,
on behalf of themselves and all others
similarly situated,
IRONWORKERS LOCAL UNION NO. 399 AND PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUNDS,
on behalf of themselves and all others
similarly situated,
IRONWORKERS DISTRICT COUNCIL OF PHILADELPHIA AND VICINITY BENEFIT AND PENSION PLAN,
on behalf of themselves and all others
similarly situated,
INTERNATIONAL BROTHERHOOD OF ELECTRICAL WORKERS LOCAL 98,
TEAMSTERS JOINT COUNCIL LOCAL NO. 53 RETIREE HEALTH & WELFARE FUND,

Plaintiffs-Appellants,

versus

ASTRAZENECA PHARMACEUTICALS, LP,
ASTRAZENECA PLC,
ASTRAZENECA LP,
PAREXEL INTERNATIONAL CORP.,

Defendants-Appellees,

MDL-1796 PERSONAL INJURY PLAINTIFFS,

Interested Party.

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

(March 11, 2011)

Before TJOFLAT, PRYOR and MARTIN, Circuit Judges.

TJOFLAT, Circuit Judge:

I.

These cases involve payments made by health insurers[1] for the prescription

[1] We use the term "health insurer" or, simply, "insurer" throughout this opinion to reflect generally those entities that engage in the health insurance function—i.e., the contractual assumption of a third-party's risk of future payment for health care services. See Barry R. Furrow et al., Health Law: Cases, Materials, and Problems 643 (6th ed. 2008) [hereinafter Furrow et al.] (defining insurance).

The plaintiffs are not traditional commercial insurers. They are, instead, labor unions and the self-funded health and welfare funds ("health benefit plans") of those labor unions. In simple terms, these health benefit plans are trust funds established, and funded, by the labor unions to pay for the health care services received by their enrollees—active and retired members of the unions who enrolled in the health benefit plans—when those services are covered under the terms of the health benefit plans. Therefore, through these self-funded health benefit plans, the unions assume, and thus bear, the risk of loss from payment of enrollees' covered health care services—i.e., they function as health insurers. See generally, e.g., Int'l Bhd. Of Teamsters Local 734 Health & Welfare Trust Fund v. Phillip Morris Inc., 196 F.3d 818, 823 (7th Cir. 1999) (referring to similar labor union health and welfare funds as "insurers"). (It

drug Seroquel, an antipsychotic medication[2] manufactured and marketed in the United States by AstraZeneca Pharmaceuticals LP ("AstraZeneca"). Seroquel has received Food and Drug Administration ("FDA") approval for the treatment of schizophrenia and bipolar disorder.[3] The drug, however, has been used to treat various other diseases and disorders, even though the FDA has not approved it for such uses. The practice of prescribing a drug for a use not approved by the FDA, commonly referred to as "off-label" use, is both legal and commonplace in the

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should also be noted that the unions contract with third-party administrators ("TPAs"). TPAs simply are agents that, since the unions lack the competency of an insurance company, deal with administration of the health benefit plans—i.e., collecting contributions from the unions, maintaining records, paying claims. Nevertheless, the unions remain the risk-bearing entity.)

[2] Seroquel is the brand name for the chemical drug quetiapine fumarate. The drug is available exclusively in brand-name form; no generic version of Seroquel presently exists, as AstraZeneca's patent prohibits any generic from being manufactured until 2012, at the earliest.

Seroquel is a second-generation atypical antipsychotic ("SGA") drug. The term SGA refers to the second wave of medications commonly used in the treatment of schizophrenia. The first wave consisted of approximately ten drugs—coined first-generation, or typical, antipsychotics—first introduced in the 1950s that, until the 1990s, served as the common drug therapy for schizophrenia.

[3] The Federal Food Drug and Cosmetic Act ("FDCA"), Pub. L. No. 75-717, ch. 675, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. § 301 et seq.), is a Federal law that "'regulates the manufacture, use, or sale of drugs.'" Merck KgaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 196, 125 S. Ct. 2372, 2377, 162 L. Ed. 2d 160 (2005) (quoting Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 665–66, 674, 110 S. Ct. 2683, 2686, L. Ed. 2d 605 (1990)). The FDCA is the primary federal law regulating the actions of drug manufacturers. Under the FDCA, the FDA must approve all prescription drugs on the U.S. market as safe and effective. See 21 U.S.C. § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) [of this section] is effective with respect to such drug."). A proposed prescription drug need only be approved for one indication in order to hit the market.

medical community.[4]

The insurers claim that physicians prescribed Seroquel for many of these off-label uses because AstraZeneca fraudulently induced them to do so. Specifically, the insurers say that AstraZeneca, through an illegal off-label marketing campaign, falsely represented that Seroquel was safer and more effective in treating many off-label conditions than less expensive drugs also used to treat those conditions.[5] Physicians, in turn, relying on AstraZeneca's false

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[4] Once a drug has been approved by the FDA and placed on the market, physicians may prescribe it for any purpose. The use of a drug "off-label" is therefore common in and accepted as beneficial by the health care community. Moreover, such use has been declared fully permissible under the FDCA by the Supreme Court. According to the Court, "'off label' usage . . . is an accepted and necessary corollary of the FDA's mission to regulate [pharmaceuticals] without directly interfering with the practice of medicine." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350, 121 S. Ct. 1012, 1018, 148 L. Ed. 2d 854 (2001). Examples of "off-label" uses include prescriptions of the drug for a condition not indicated on the label, treating an indicated condition at a different dose or frequency than specified on the label, or treating a different patient population than approved by the FDA.

Common non-FDA-approved Seroquel use includes treatment of: Autistic Spectrum Disorders for adults, dementia, Obsessive-Compulsive disorder, Post-Traumatic Stress Disorder, Personality Disorders, Tourette's Syndrome, Alzheimer's Disease, anxiety, Attention Deficit Disorder, Attention Deficit Hyperactivity Disorder, sleep disorders, anger management, and mood enhancement or mood stabilization. See generally Paul Shekelle, et al., U.S. Dep't of Health & Human Res., Agency for Healthcare Research & Quality, Efficacy and Comparative Effectiveness of Off-Label Use of Atypical Antipsychotics (2007), available at http://www.effectivehealthcare.ahrq.gov/ehc/products/5/63/Atypical_Antipsychotics_Final_Report.pdf.

[5] The FDCA proscribes manufacturers from promoting or marketing their drugs for off-label uses. Thus, although the FDA permits treating physicians to prescribe drugs off-label, it generally restricts pharmaceutical manufacturers—and all those within their chain of distribution—from promoting a drug's potential off-label uses to those physicians. 21 C.F.R. § 202.1(e)(6) (2008); UFCW Local 1776 v. Eli Lilly & Co., 620 F.3d 121, 127 (2d Cir. 2010). Specifically, under the FDCA, a manufacturer may not introduce any drug into interstate commerce with the intent that the drug be used for off-label purposes, and a manufacturer is deemed to have illegally "misbranded" a drug if that drug's labeling, which under the statute

representations, prescribed Seroquel instead of the cheaper—and sometimes safer or more effective—substitutes for the insurers' insureds ("enrollees"). As a result, because the insurers' insurance policies covered payment for Seroquel—either in full or in part, depending on whether the policies obligated enrollees to pay a prescription drug copayment ("co-pay")[6]—the insurers claim that AstraZeneca's fraud caused them "to unnecessarily pay for [the more expensive] Seroquel off-label prescriptions." Absent the fraud, they say they would have paid less for their enrollees' prescription drugs. Consequently, the insurers seek to recover the difference between the amount that was paid for the off-label Seroquel prescriptions and the amount that would have been paid for the less expensive substitutes.[7]

A.

Each of the cases before us is a class action brought against AstraZeneca[8]

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includes all drug manufacturer promotional and advertising material, describes any intended uses for the drug not approved by the FDA. 21 U.S.C. §§ 331, 352. Violations of the FDCA may lead to criminal prosecution.

[6] A co-pay is "[a] fixed amount [in addition to what insurance covers] that a patient pays to a health care provider [for a health care service] according to the terms of the patient's health plan." Black's Law Dictionary 385 (9th ed. 2009).

[7] The insurers seek to recover only their portion of the payment for the off-label Seroquel prescriptions and not the portion paid, as co-pays, by their enrollees, who are not parties in these cases.

[8] AstraZeneca is a Delaware limited partnership and a subsidiary of AstraZeneca PLC, a pharmaceutical company headquartered in London, England. In addition to AstraZeneca, the

on behalf of all third-party payers for health care services.[9] One of the cases, in addition to being brought on behalf of a group of insurers, includes a claim by an individual enrollee, Cheryl Martin, a resident of Tennessee. Martin, like the insurers, paid for an off-label prescription of Seroquel instead of a less expensive substitute.[10] She seeks to represent a class of similarly situated enrollees.

The allegations of these cases have been merged within a consolidated

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plaintiffs sued AstraZeneca PLC; AstraZeneca LP, a Delaware limited partnership and an AstraZeneca PLC subsidiary; and Parexel International Corp., AstraZeneca's principal marketing agent for Seroquel. According to the allegations of the Second Amended Consolidated Complaint, these firms are interrelated and operate as one; therefore, each firm is allegedly liable for the conduct of all. In this opinion, we treat them as a whole and thus refer to them collectively as "AstraZeneca."

[9] The cases before the court are Ironworkers Local Union No. 68 & Participating Employers Health & Welfare Funds, et al. v. AstraZeneca Pharmaceuticals, LP, et al., No. 6:07-cv-5000-Orl-22DAB, and International Brotherhood of Electrical Workers Local 98 v. AstraZeneca Pharmaceuticals, LP, et al., No. 6:07-cv-5001-Orl-22DAB, which were brought in the District of New Jersey, and Teamsters Joint Council Local No. 53 Retiree Health & Welfare Fund v AstraZeneca Pharmaceuticals, LP, No. 6:07-cv-5002-Orl-22DAB, which was filed in the Eastern District of Pennsylvania. The cases were transferred to the Middle District of Florida by the Judicial Panel on Multidistrict Litigation.

As noted in the text, infra, the district court combined the cases via a Consolidated Amended Complaint. The named plaintiffs in that complaint are Ironworkers Local Union No. 68 and Participating Employers Health and Welfare Funds of Trenton, NJ; Ironworkers Local Union No. 399 & Participating Employers Health and Welfare Funds of Trenton, NJ; Ironworkers District Council of Philadelphia and Vicinity Benefits and Pension Plan of Philadelphia, PA; International Brotherhood of Electrical Workers Local 98 of Philadelphia, PA; and Teamsters Joint Council Local No. 53 Retiree Health & Welfare Fund of Pennsauken, NJ. As stated, supra note 1, the named plaintiffs are union health benefit plans that provide insurance coverage to union members who enroll in their plans. They represent a nation-wide class of third-party insurers who, like the plaintiffs, paid all or part of the purchase price of Seroquel prescribed to their insureds for non-FDA uses as part of the insurance coverage they provided.

[10] Martin, it is alleged, paid a portion of the purchase price of the Seroquel prescribed to her in the form of a co-pay under her insurance coverage.

complaint consisting of seven counts.[11] Counts I and II seek treble damages under the civil provision of the federal Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1964(c).[12] Count I is based on 18 U.S.C. § 1962(c).[13] It alleges that AstraZeneca has marketed Seroquel through an "enterprise" and that its false representations to physicians concerning Seroquel's superior safety and efficacy constitutes "a pattern of racketeering activity"—i.e., violations of the mail and wire fraud statutes.[14] Count II is based on 18 U.S.C. § 1962(d).[15] It alleges

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[11] The allegations at issue are contained in the plaintiffs' Second Amended Consolidated Complaint. We refer to it as the "complaint" except that in citing portions of the allegations, we refer to the Second Amended Consolidated Complaint.

[12] 18 U.S.C. § 1964(c) provides, in pertinent part: "Any person injured in his business or property by reason of a violation of [18 U.S.C. § 1962] 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."

[13] 18 U.S.C. § 1962(c) states, in pertinent part: "It shall be unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate . . . commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity . . . ."

An "'enterprise' includes any individual, partnership, corporation, association, or other legal entity." 18 U.S.C. § 1961(4).

"Racketeering activity" consists of the commission of any of the criminal offenses, commonly referred to as "predicate acts," identified in 18 U.S.C. § 1961(1). A "pattern" of racketeering activity consists of the commission of "at least two distinct but related predicate acts." Pelletier v. Zweifel, 921 F.2d 1465, 1496 (11th Cir. 1991) (citing Sedima, S.P.R.L. v. Imrex Co., 473 U.S. 479, 496 n.14, 105 S. Ct. 3275, 3285 n.14, 87 L. Ed. 2d 346 (1985)).

[14] Mail fraud, 18 U.S.C. § 1341, and wire fraud, 18 U.S.C. § 1343, are two of the predicate acts identified in 18 U.S.C. § 1961(1). To prevail in a civil RICO action, a plaintiff must establish three elements: (1) that the defendant committed a violation of § 1962 by engaging in a "pattern of racketeering activity"; (2) that the plaintiff suffered an injury to business or property; and (3) that the plaintiff's injury occurred "by reason of" the defendant's commission of a predicate act and a causal connection exists between the commission of the predicate act and the plaintiff's injury. See Avirgan v. Hull, 932 F.2d 1572, 1577 (11th Cir.

that AstraZeneca conspired to commit the substantive § 1962(c) offense. Finally, counts III–VII, respectively, seek damages under the consumer protection statutes and the common law of forty-six States.[16]

B.

AstraZeneca moved the district court to dismiss the plaintiffs' claims under Federal Rule of Civil Procedure 12(b)(6), and the court granted its motion. See Ironworkers Local Union No. 68 v. AstraZeneca Pharms. LP, 585 F. Supp. 2d 1339, 1342, 1347 (M.D. Fla. 2008). The court ruled that the complaint did not adequately plead that AstraZeneca's false representations proximately caused the plaintiffs' purported economic losses.[17] Id. at 1345–47.

The court first noted the proximate causation a RICO plaintiff must establish to make out a case under 1964(c): a plaintiff has to show "some direct

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1991) (presenting the elements for a civil RICO claim). Regarding the causation element, the predicate must be both the "but for" and the proximate cause of the plaintiff's injury. Anza v. Ideal Steel Supply Corp., 547 U.S. 451, 457, 126 S. Ct. 1991, 1996, 164 L. Ed. 2d 720 (2006) (citing Holmes v. Secs. Investor Prot. Corp., 503 U.S. 258, 268, 112 S. Ct. 1311, 1317, 117 L. Ed. 2d 532 (1992)).

[15] 18 U.S.C. § 1962(d) states: "It shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b), or (c) of this section."

[16] The common law claims are for unjust enrichment, common law fraud, negligent misrepresentation, and conspiracy. The conspiracy claim is not a separate common law claim; rather, it is an effort to hold the defendants legally responsible for each other's conduct.

[17] The court considered the claims of the insurers and the individual enrollee, Cheryl Martin, as indistinct and conflated all plaintiffs as "payors" for off-label Seroquel prescriptions.

relation between the injury asserted and the injurious conduct alleged." Holmes v. Sec. Investor Prot. Corp., 503 U.S. 258, 268 112 S. Ct. 1311, 1318 117 L. Ed.2d 532 (1992) (emphasis added). The court concluded that the complaint's allegations failed to establish a direct relation between AstraZeneca's false representations and the plaintiffs' losses. Instead, the allegations showed that the plaintiffs' losses could have been "caused by other, independent, factors." 585 F. Supp. 2d at 1344. Key among such factors—and a potential independent intervening cause—was that Seroquel was prescribed by physicians in the exercise of their independent professional judgment, and such judgment could be informed by sources other than AstraZeneca's "representations . . . [regarding the] drug's relative safety and efficacy." Id. Ascertaining whether and, if so, to what extent AstraZeneca's representations caused a physician to prescribe Seroquel off-label in a given situation would amount to a "highly complex damages assessment," id. at 1345, that "would require an inquiry into the specifics of [the] doctor-patient relationship," id. at 1344. This complex assessment, the district court concluded, weighed against a finding of direct injury to the plaintiffs as a result of AstraZeneca's conduct, and the court therefore dismissed the plaintiffs' RICO claims. Id. at 1345.

The district court subsequently dismissed the state law[18] consumer protection and common law claims on the same proximate causation ground that required the dismissal of the RICO claims.[19] The court then entered a final judgment for AstraZeneca in conformance with its order dismissing the plaintiffs' complaint, and the plaintiffs lodged this appeal.

II.

"We review de novo the district court's grant of a motion to dismiss under 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). 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, 127 S. Ct.

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[18] The district court limited its analysis to laws of three States: New Jersey, Pennsylvania, and Tennessee, the States where the plaintiffs claimed to have issued policies and/or paid for off-label Seroquel. Ironworkers Local Union No. 68 v. AstraZeneca Pharms. LP, 585 F. Supp. 2d 1339, 1345–46 (M.D. Fla. 2008).

[19] While we have not researched the issue of whether there is any discrepancy between the proximate cause standards under RICO and the laws of the three States at issue, we stress that proximate cause analysis can take disparate forms. For example, another common test for proximate causation, beyond RICO's "direct relationship" between the fraud and harm standard, is foreseeability—i.e., whether the harm was a foreseeable consequence of the misrepresentation. As the Supreme Court has recently stressed, these tests, are not one and the same, but rather are "two of the many shapes proximate cause took at common law." Hemi Grp., LLC v. City of New York, ___ U.S. ____, 130 S. Ct. 983, 991 (2010) (alteration omitted) (citations omitted). We stress this point because, to the extent that the state law inquiries may differ from RICO, the court should have engaged in a different analysis.

1955, 167 L. Ed. 2d 929 (2007), and Ashcroft v. Iqbal, ___ U.S. ____, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009). That is, the complaint "must . . . contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Am. Dental Ass'n, 605 F.3d at 1289 (quoting Twombly, 550 U.S. at 570, 127 S. Ct. at 1974) (emphasis added).

Applying these standards, we affirm the district court's judgment; however, we do so on grounds different from those employed by the district court. See Powers v. United States, 996 F.2d 1121, 1123–24 (11th Cir. 1993) ("We may affirm the district court's judgment on any ground that appears in the record, whether or not that ground was relied upon or even considered by the court below." (citations omitted)). As subpart A presents, economic injury is a necessary element of all of the plaintiffs' claims, and, in the context of prescription drug purchases, the fact that the payer merely paid for more expensive drugs does not suffice. Instead, the purchased drugs must have been either unsafe or ineffective for their prescribed use—i.e., the prescription needs to have been medically unnecessary or inappropriate according to sound medical practice.[20]

[20] Throughout this opinion, we use the phrases "medically unnecessary and inappropriate" and "unsafe or ineffective for its prescribed use" interchangeably depending on the context. They refer to the same concept, which defines economic injury from prescription drug purchases. See infra part II.A.2.

In subpart B, we affirm the district court's dismissal of the insurers' claims in all seven counts of the complaint. The insurers, under the terms of their insurance policies, consciously exposed themselves to pay for all prescriptions of Seroquel, including those that were medically unnecessary or inappropriate—even if such prescriptions were birthed by fraud. In light of such broad exposure, conventionally a rational insurer would have charged its enrollees higher premiums than it would have if its policies offered more limited prescription drug coverage. These higher premiums, in turn, would compensate the insurer for its increased number of prescription payments, including payments for prescriptions that were medically unnecessary or inappropriate. Moreover, to the extent the insurer's payments for medically unnecessary or inappropriate prescriptions exceeded the premiums charged, only actuarial errors would be to blame. Here, the insurers plead no facts to suggest that they somehow established premiums in a manner distinct from this conventional understanding; consequently, the district court had to dismiss their claims because they failed to allege plausibly that AstraZeneca's false representations caused them to suffer economic injury.

To be clear, a drug is medically necessary and appropriate when a physician, in practicing sound medicine, may reasonably prescribe his patient that drug to treat a condition because the drug has some positive effect on and is appropriate (i.e., safe) in treating that condition. Therefore, simply because a drug is medically necessary and appropriate for a use, it does not suggest necessarily that it is the only drug that may be prescribed. In other words, several drugs can be medically necessary and appropriate in treating a given condition.

In subpart C, we affirm the district court's dismissal of the claims brought by the individual enrollee, Cheryl Martin, because the complaint fails to allege any facts concerning her economic injury from payment for medically unnecessary or inappropriate drugs that would satisfy the Twombly and Iqbal plausibility standard.

A.

Section 1 of this subpart highlights that economic injury is an essential element that must be alleged under each of the plaintiffs' causes of action. From there, section 2 establishes that, to assert a plausible economic injury arising from the purchase of prescription drugs, the plaintiffs must have alleged that the purchased drugs either were medically unnecessary or inappropriate for their prescribed use.

1.

A plaintiff asserting a claim under § 1964(c) of RICO must allege economic injury arising from the defendant's actions. Sedima, S.P.R.L. v. Imrex Co., Inc., 473 U.S. 479, 496, 105 S. Ct. 3275, 3285, 87 L. Ed. 2d 346 (1985) (declaring that a § 1964(c) plaintiff "only has standing if, and can only recover to the extent that, he has been injured in his business or property by the conduct constituting the [RICO] violation"). A "defendant who violates section 1962 is not liable for

treble damages to everyone he might have injured by other conduct, nor is the defendant liable to those who have not been injured." Id. at 496–97, 105 S. Ct. at 3285 (emphasis added) (citations omitted). Although the Supreme Court has demanded that "RICO is to be read broadly," id. at 497, 105 S. Ct. at 3285, the injury to business or property limitation on RICO standing has a "restrictive significance," Reiter v. Sonotone Corp., 442 U.S. 330, 339, 99 S. Ct. 2326, 2331, 60 L. Ed. 2d 931 (1979). It "helps to assure that RICO is not expanded to provide a federal cause of action and treble damages to every tort plaintiff." Steele v. Hosp. Corp. of Am., 36 F.3d 69, 70 (9th Cir. 1994) (citations omitted) (internal quotation marks omitted); see also Maio v. Aetna, Inc., 221 F.3d 472, 483 (3d Cir. 2000) (quoting Steele, 36 F.3d at 70). Otherwise, "[t]o allow recovery by persons who have not been injured or to allow recovery for an injury greater than that caused by the offending conduct would run counter to the plain language of [18 U.S.C. § 1964(c)]." Sikes v. Teleline, Inc., 281 F.3d 1350, 1365 (11th Cir. 2002) (citations omitted), abrogated on other grounds by Bridge v. Phoenix Bond & Indem. Co., 553 U.S. 639, 128 S. Ct. 2131, 170 L. Ed. 2d 1012 (2008).

Injury also is a necessary element of each of the plaintiffs' claims based on state law.[21] For instance, the consumer protection laws of New Jersey,

[21] Like the district court, because the case failed to reach the class certification stage, we limit our analysis to New Jersey, Pennsylvania, and Tennessee, the three States where the

Pennsylvania and Tennessee require that a plaintiff allege an "ascertainable loss" of money as a result of the defendant's fraudulent or deceitful conduct. See N.J. Stat. Ann. § 56:8-19 (West 2010) ("Any person who suffers any ascertainable loss of moneys . . . as a result of the use or employment by another person of any method, act, or practice declared unlawful under this act . . . may bring an action or assert a counterclaim therefor in any court of competent jurisdiction." (emphasis added)); 73 Pa. Cons. Stat. Ann. § 201-9.2(a) (West 2010) (creating a similar private right of action in any consumer of goods who suffers an "ascertainable loss of money" by way of statutorily proscribed fraudulent or deceitful acts); Tenn. Code Ann. § 47-18-109(a)(1) (West 2010) ("Any person who suffers an ascertainable loss of money . . . as a result of the use or employment by another person of an unfair or deceptive act or practice declared to be unlawful by this part, may bring an action individually to recover actual damages." (emphasis added)). Moreover in New Jersey, Pennsylvania, and Tennessee, without allegations of injury, a claim is not remediable when based either on common law fraud, see, e.g., Banco Popular N. Am. v. Gandi, 876 A.2d 253, 260 (N.J. 2005) (stating that to establish common law fraud in New Jersey, a plaintiff must plead and prove "resulting damages" from the defendant's material

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plaintiffs claim to do business or reside.

misrepresentation); First Nat'l Bank v. Brooks Farms, 821 S.W.2d 925, 927 (Tenn. 1991) (declaring that injury to the plaintiff caused by reasonable reliance on an intentional misrepresentation is an element of Tennessee common law fraud); Scaife Co. v. Rockwell-Standard Corp., 285 A.2d 451, 454 (Pa. 1971) (citations omitted) (declaring that "damage to the recipient" of a fraudulent misrepresentation is a necessary element of Pennsylvania common law fraud), or negligent misrepresentation, see e.g., Bortz v. Noon, 729 A.2d 555, 561 (Pa. 1999) (stating that in Pennsylvania, "[n]egligent misrepresentation requires . . . injury to a party acting in justifiable reliance on the [negligently made] misrepresentation." (emphasis added) (citations omitted)); H. Rosenblum, Inc. v. Adler, 461 A.2d 138, 142–43 (N.J. 1983) (stating that in New Jersey, "[a]n incorrect statement, negligently made and justifiably relied upon, may be the basis for recovery of damages for economic loss or injury sustained as a consequence of that reliance"), superseded on other grounds by statute, N.J. Stat. Ann. § 2A:53A-25 (West 2010), as recognized in Finderne Mgmt. Co. v. Barrett, 809 A.2d 857, 862 (N.J. Super. 2002); Jasper Aviation, Inc. v. McCollum Aviation, Inc., 497 S.W.2d 240, 242–43 (Tenn. 1972) (stating that plaintiffs may recover for pecuniary loss caused to them by their justifiable reliance on a negligently made misrepresentation).

2.

Although there is a dearth of Eleventh Circuit precedent on the issue, for tort-based causes of action, the scope of potential economic injury arising from a patient's—or her health insurer's—purchases of prescription drugs is limited. As the district court noted, when a doctor prescribes a drug, he presumably does so only if, in the exercise of his independent medical judgment, he believes the drug will benefit his patient. See Ironworkers Local Union No. 68, 585 F. Supp. 2d at 1344 ("Presumably . . . physicians use their independent medical judgment to decide whether Seroquel is the best treatment for a given patient."). This presumption applies regardless of whether the prescription is for an FDA-approved or off-label use.

Several considerations shape the physician's medical judgment, including both individual patient concerns and drug-specific information regarding the propriety of a drug's use for treatment of a patient's given condition—that is, a drug's relevant safety and efficacy under the circumstances. See, e.g., Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir. 1974)[22] ("The [prescription] choice

[22] In Bonner v. City of Prichard, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc), this court adopted as binding precedent all decisions of the former Fifth Circuit handed down prior to October 1, 1981.

[the physician] makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative."); UFCW Local 1776 v. Eli Lilly & Co., 620 F.3d 121, 135 (2d Cir. 2010) (discussing how a patient's diagnosis, any past and current medications the patient has taken, the physician's experience with prescribing the drug, and the physician's knowledge regarding the drug's side effects all function as considerations taken into account in addition to the alleged misrepresentations distributed by a drug manufacturer); see also McCombs v. Synthes, 587 S.E.2d 594, 595 (Ga. 2003) ("[T]he decision to employ prescription medication . . . involves professional assessment of medical risks in light of the physician's knowledge of a patient's particular need and susceptibilities." (citations omitted) (internal quotation marks omitted)). The physician learns about a drug through multiple sources, only one of which might be the drug manufacturer's promotions and literature. For instance, physicians typically obtain additional information about a drug's putative uses from journals, meetings, and conventions.

In light of physicians' exercise of professional judgment, a patient suffers no economic injury merely by being prescribed and paying for a more expensive drug; instead, the prescription additionally must have been unnecessary or inappropriate according to sound medical practice—i.e., the drug was either

ineffective or unsafe for the prescribed use. This is true even when the physician's decision to prescribe the more expensive drug in lieu of a cheaper alternative is the product of fraud. See, e.g., Heindel v. Pfizer, Inc., 381 F. Supp. 2d 364, 380 (D.N.J. 2004) (concluding that there is no economic injury for the purchase of a prescription drug when the drug proves at all beneficial to the patient prescribed it (quoting In re Rezulin Prods. Liab. Litig., 212 F.R.D. 61, 68–69 (S.D.N.Y. 2002))). To allow recovery based purely on the fact that the prescription was comparatively more expensive than an alternative drug—but otherwise safe and effective—would mean that physicians owe their patients a professional duty to consider a drug's price when making a prescription decision.

No such duty exists. While it might be true, as the complaint states, that "[t]he medical community generally encourages physicians to prescribe the most effective and cost-efficient treatment for their patients," Second Am. Consol. Compl. ¶ 70, "[p]hysicians generally do not take the price of a drug into account when deciding among treatment options, and often do not even know the price of the drugs they prescribe. This is particularly true in the treatment of mental disorders, which is an extremely individualized process." UFCW Local 1776, 620 F.3d at 126–27.

Rather, to assert an economic injury, the plaintiff must allege that her

purchase payments were the product of a physician's medically unnecessary or inappropriate prescriptions. The issue of whether prescriptions are medically unnecessary or inappropriate—like most health care delivery questions—depends on the standards of practice in the medical profession. See, e.g., Barry R. Furrow et al., Health Law: Cases, Materials, and Problems 336 n.2 (6th ed. 2008) [hereinafter Furrow et al.] ("The medical profession sets standards of practice and the courts have historically enforced these standards in tort suits."). Therefore, the prescription allegedly must be one that, in the practice of profession-accepted sound medicine, the physician should not have prescribed because the drug was unsafe or ineffective for its prescribed use. See, e.g., Rivera v. Wyeth-Ayerst Labs., 283 F.3d 315, 319–21 (5th Cir. 2002) (finding that plaintiffs lacked Article III standing because they did not assert a concrete injury arising from their purchase of prescription painkillers when the drugs were not alleged to have been ineffective in treating the plaintiffs' conditions or to have caused them physical injury).

Thus, when a physician's decision to prescribe a drug for a particular use purportedly was caused by false representations concerning the drug's safety and efficacy in that use, a plaintiff must allege that she not only paid for the drug, but also that its prescription was medically unnecessary or inappropriate. To make

this showing, the payer-plaintiff must allege a counterfactual: that her physician—had he known all the true information about the medication—would not have prescribed the drug under the standards of sound medical practice because the drug actually was unsafe or ineffective in treating the plaintiff's condition. See, e.g., In re Schering-Plough Corp. Intron/Temodar Consumer Class Action, No. 2:06-cv-5774, 2009 WL 2043604, at *16–20 (D.N.J. 2009) (concluding, in a case with similar facts, that insurers failed to plead RICO injury to their business or property where they failed to allege that their enrollees "'received inadequate [or] inferior [drugs] or even worse, suffered personal injuries as a result of Defendants' alleged misrepresentations.'" (quoting Maio, 221 F.3d at 488)).

B.

In light of the principles presented in subpart A, we turn now to the insurers' allegations. In short, we find that the insurers have not alleged plausible economic injury arising from their payments for medically unnecessary or inappropriate off-label Seroquel prescriptions caused by AstraZeneca's false representations to physicians. Insurers, to sustain profitability, charge their enrollees an up-front fee, i.e., a "premium," in exchange for insurance coverage. Typically, insurers adjust premiums to compensate for known risks assumed

under that coverage. Here, the insurers assumed the risk of paying for all prescriptions of drugs covered by their policies, including medically unnecessary or inappropriate prescriptions—even those caused by fraudulent marketing. The insurers, however, have not pled any facts to suggest plausibly that they did not charge their enrollees premiums or, in turn, adjust those premiums to compensate for this known risk.[23] Furthermore, to the extent the insurers' payments for medically unnecessary or inappropriate off-label Seroquel prescriptions exceeded the premiums they collected, AstraZeneca should not be held liable for the insurers' actuarial errors.

1.

In general, health insurers enter into a contractual bargain with enrollees in which, in exchange for their service—assuming the risk of payment for enrollees'

[23] After oral argument, we requested that the parties file supplemental briefs to address specifically the issue of whether the plaintiffs have pled a plausible economic injury. The plaintiffs, in their supplemental brief, state that "no premium is ever paid by the plan enrollees" into the health benefit plans. Instead, the plaintiffs say that the health benefit plans are self-funded by the labor unions, but the plaintiffs admit that they use pharmacy benefit managers ("PBMs"), which pay "for the cost of medical care with funds provided by the employer." (emphasis in original).

At oral argument, the plaintiffs' counsel admitted that the plaintiffs do charge "a premium" in exchange for health care coverage. Counsel also agreed that the "premium is adjusted from time to time depending on the market for drugs and so forth." Furthermore, at a later point in their supplemental brief, the plaintiffs declare that the health benefit plans operate similarly to health maintenance organizations because they "assum[e] the financial risk of providing benefits promised, in exchange for an up-front fee." (emphasis added). Any disparity the plaintiffs perceive between an "up-front fee" and a premium is illusory.

future health care costs—they receive a "premium," an up-front fee that represents the price of the insurance policy.[24] See Furrow et al., supra, at 643 (defining insurance generally as the contractual transfer of risk from the insured party to a financing entity, the insurer, in consideration for premium). The premium charged enrollees is essential to insurers' goal of profitable outcomes from their insurance bargains. Insurers are making a conscious gamble with profitability: will the premiums they receive be sufficient to cover the risks they have assumed?

The premiums charged may or may not be sufficient to cover the claims the insurers pay; when the claims exceed the insurers' projections, they bear the loss. When, however, the premiums received exceed the value of the claims paid by the insurers, the enrollees bear the loss because the insurers keep the remaining premium proceeds. Thus, in sum, the insurance contract represents a conscious bargain in which both sides hope to, at least, come out even—but know they might not.

Because of how paramount premiums are to their profitability, insurers engage in a technical actuarial analysis to price them. Through this ratemaking

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[24] Risk adversity drives plan enrollees' willingness to pay the proposed premium. Simply stated, enrollees are willing to pay the up-front expense in exchange for coverage because they would rather pay a modest amount now than pay a lot later in light of rising health care costs. Where financing is provided through employment-related group insurance, part of the premium is paid by the employer and the underwriting is of the group as a whole. Barry R. Furrow et al., supra note 1, at 643–44.

process, insurers aim to "predict[] future losses and future expenses and allocat[e] those costs among the various classes of insureds."[25] Staff of H. Comm. on Educ. & Labor, 100th Cong., Insuring the Uninsured: Options and Analysis (Comm. Print 1988), as reprinted in Furrow et al., supra, at 645 (internal quotation marks omitted) (describing the ratemaking process). Insurers predict losses on the basis of predicted claims costs. This prediction involves an assessment of (1) the likely number of times a covered event—e.g., a prescription of a covered drug—will occur and (2) the average cost of each covered event. Id., as reprinted in Furrow et al., supra, at 645. If there is any uncertainty surrounding projected claims, insurers will raise the premium to reflect that uncertainty. The final premium charged consists of this adjusted estimate plus an administrative expenses projection that includes estimates for all those expenses that the insurance

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[25] Different approaches exist for determining rates, and which approach is used often is determined by state law. With regard to health insurance rates, the most frequently used approaches are "experience rating" and "community rating." See Staff of H. Comm. on Educ. & Labor, 100th Cong., Insuring the Uninsured: Options and Analysis (Comm. Print 1988), as reprinted in Furrow et al., supra note 1, at 645 (explaining the different approaches to determining premium rates and their various advantages and disadvantages).

Experience rating is the most accurate measure of an insurer's loss potential. Under this model, insurers set premiums based on past experience of the group to be insured. Id., as reprinted in Furrow et al., supra note 1, at 646.

Under the community rating scheme, which proves less accurate but administratively more simple than an experience-based model, premium rates are based on the allocation of total costs to all the individuals or groups to be insured, without regard to the past experience of any particular group. Id, as reprinted in Furrow et al., supra note 1, at 646.

company charges that are not for claims, such as overhead.[26] Id., as reprinted in Furrow et al., supra, at 645.

Because the value of estimated claims drives the premium rate, the premium charged for a policy largely depends on the scope of coverage under that policy. The broader the coverage offered—i.e., the more health care services indemnified by the insurer—the higher the premiums charged for that policy. In other words, covering more health care services creates a likelihood of more claims and, correspondingly, a greater projected claims value. The insurer will fund these higher costs through escalated premiums.

2.

In the present matter, the insurers' policies broadly covered prescriptions of Seroquel because it was listed on the insurers' drug formularies. Drug formularies, in brief, are insurers' lists of medications approved for coverage. See UFCW Local 1776, 620 F.3d at 126 (discussing generally the common use and operation of drug formularies in the prescription drug insurance industry). Formularies are managed by Pharmacy Benefit Managers ("PBMs"), which act as

[26] Premiums also take into account the insurer's projected income from investments of premiums received, tax considerations, and a profit margin.

Moreover, generally an insurer may adjust its charged premium rate when the coverage is renewed to reflect such factors as increases in health care costs, increases in the use of health care, costs borne from new technologies, changes in enrollment, changes in regulations, or to adjust actuarial assumptions based on actual experience from the past year.

agents for the insurers.[27] The PBMs list a drug on the insurers' formularies—which frequently consist of at least three tiers of approved drugs[28]—only after they have approvingly assessed the drug's clinical safety, efficacy, and cost effectiveness for its FDA-approved uses. Seroquel went through this PBM approval process and was listed on the insurers' formularies based upon its FDA-approved uses in the treatment of schizophrenia and bipolar disorder.[29]

Although placed on the formularies based only upon its FDA-approved uses, Seroquel's placement on those formularies contractually obligated the insurers to pay the drug's price anytime it was prescribed. Therefore, the insurers had to pay regardless of the facts surrounding that prescription; they had to pay if the drug was prescribed for an FDA-approved use or an off-label use—even if the

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[27] Typically, insurers "have the right to customize their formulary beyond what the PBMs advise, but in practice [insurers] rarely modify the recommendations of their PBMs. On the rare occasions when [an insurer] customizes its formulary, it generally does so in consultation with the PBM[s] . . . ." UFCW Local 1776, 620 F.3d at 126.

[28] The three most common tiers of listed drugs are: (1) Generic drugs (the lowest cost on the schedule); (2) Preferred drugs (the middle cost on the schedule); and (3) Nonpreferred or Brand Name drugs (the highest cost on the schedule). See generally Helen Osborne, M. Ed., Helping Patients Understand Health Care Costs, 24 Health Care Collector 9 (Aug. 2010).

A drug's formulary tier primarily matters when the insurer's prescription drug coverage is subject to a co-pay obligation, which often is tied to the drug's location on the insurer's formulary. As a result, a higher-tiered drug (i.e., a brand name or a preferred brand name drug) often has a higher associated co-pay obligation than a lower tiered drug (i.e., a generic drug).

[29] Seroquel was listed on the insurers' formularies as a "Preferred" drug.

prescription was medically unnecessary or inappropriate.

The insurers, however, could have excluded coverage for medically unnecessary or inappropriate prescriptions of Seroquel and other formulary-listed drugs.[30] The complaint itself suggests one technique available to them: preauthorization review. See Second Am. Consol. Compl. ¶ 276 (declaring that, had the insurers known of AstraZeneca's scheme, they "could have . . . required pre-authorization" prior to their paying for off-label Seroquel prescriptions). In brief, preauthorization review entails "case-by-case evaluations conducted by insurers . . . to determine the necessity and appropriateness . . . of medical care" prior to delivery of that care to an enrollee. See, e.g., Furrow et al., supra, at 673 (discussing the operation of these costs controls generally). Therefore, preauthorization review of drug prescriptions provides insurers with a process to monitor the prescription, dispensing, and use patterns of medications to promote appropriate uses of covered drugs.[31] See Kevin J. Dunne & Ciara R. Ryan, How

[30] The decision to cover certain services is not unfettered. State laws and regulations often impose certain coverage "mandates" that require insurers to provide payment for certain services such as mammography or substance abuse treatment. See Furrow et al., supra note 1, at 675 (discussing generally how state statutes often mandate particular benefits and thus limit the reach of utilization controls).

[31] Drug utilization review ("DUR"), of which prescription drug preauthorization review systems are a subset, typically involves

> the insurer's electronic review of prescription records to (1) determine the propriety or "medical necessity" of particular prescriptions, (2) evaluate patient compliance with prescription drug protocols and (3) detect existing or potential

Management of Medical Costs is Revolutionizing the Drug Industry, 62 Def. Couns. J. 177, 178–79 (1995) (explaining the operation of insurers' drug utilization review systems, including preauthorization review). When a preauthorization review of a proposed prescription finds that prescription to be medically inappropriate or unnecessary, the insurer will deny payment for the drug before the enrollee ever receives it.[32] See Furrow et al., supra, at 673, 674 (stating that preauthorization review "denies payment for experimental and medically unnecessary [prescriptions] because such [prescriptions are] not covered under the plan contract."). In turn, because preauthorization review avoids insurers' payment for medically unnecessary or inappropriate drugs, insurers that utilize it decrease the value of their projected claims and, correspondingly, may reduce the premiums they charge enrollees.

Here, however, the insurers made the conscious business decision not to

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> prescription problems—for examples [sic], inappropriate doses, over/under utilization, adverse reactions and interactions, and duplicate drug therapy. DUR also may entail review of patient medical records.

See Kevin J. Dunne & Ciara R. Ryan, How Management of Medical Costs is Revolutionizing the Drug Industry, 62 Def. Couns. J. 177, 178–79 (1995).

[32] If the company denies coverage as a result of preauthorization review, the patient may forego the drug's use, pay for it out of her own pocket, Paula Tironi, Pharmaceutical Pricing: A Review of Proposals to Improve Access and Affordability of Prescription Drugs, 19 Annals Health L. 311, 318 (2010), or appeal the insurer's decision through the administrative review process presented in her policy, see Furrow et al., supra note 1, at 674 (discussing grievance and appeals procedures, which are required by all states and, for employee health benefit plans, by the federal Employee Retirement Income Security Act of 1974).

require preauthorization review in their policies. The complaint, by suggesting that the insurers could have required preauthorization review for off-label Seroquel, see Second Am. Consol. Compl. ¶ 276, avows that the insurers have the capacity to utilize the procedure.[33] Yet, they chose not to. Instead, they

[33] This confession is important because if an insurer exclusively provides pay-for-service insurance coverage, the adoption of a preauthorization review process will require either new personnel or the hiring of an agent as well as other new administrative costs. In this matter, however, the insurers admit they already had the competency and capacity to engage in preauthorization review of off-label drug prescriptions, but opted, instead, not to do so.

Paragraph 276 of the complaint carries further importance here because it also suggests that the insurers, had they known of AstraZeneca's fraudulent scheme, could have limited their loss exposure under their policies in alternative fashions. They claim that, had they known of the fraud, they "could have excluded Seroquel altogether from their approved schedules [or] set a low scheduled value . . . or dissuaded doctors from prescribing Seroquel." Second Am. Consol. Compl. ¶ 276. In other words, had they known of the fraudulent conduct, they could have removed Seroquel, at least for off-label use, from their already approved formularies; adjusted their purchase price for the drug when prescribed off-label; or told plan doctors not to prescribe the medicine for off-label use.

This argument suggests that AstraZeneca's conduct not only defrauded the insurers indirectly—through the prescriptions written to their enrollees by doctors who relied on AstraZeneca's misrepresentations—but also directly through a fraud-by-omission based on AstraZeneca's failure to disclose to them its fraudulent marketing scheme. Thus, in essence, this direct fraud theory entails four steps: (1) Seroquel became available on the market and received FDA approval; (2) PBMs, based on Seroquel's approved uses, added the drug to the drug formularies of the insurers, whose policies required payment for all drugs listed on their formularies; (3) AstraZeneca initiated its fraudulent marketing scheme to dupe doctors into prescribing Seroquel for off-label uses by misrepresenting its efficacy and safety for off-label uses as superior to other treatments; and (4) the fraud was borne by the insurers because AstraZeneca did not inform them of its fraudulent conduct to allow the insurers to amend their existing business practices.

For such a theory based on nonfeasance to prove tenable, the insurers would need to establish that AstraZeneca owed them a legal duty of disclosure. No such duty exists, however, absent a special relationship between the parties. See United States v. Brown, 79 F.3d 1550, 1557 (11th Cir. 1996) ("[C]ertain people must always disclose facts where nondisclosure could result in harm. This circumstance exists when there is a special relationship of trust, such as a fiduciary relationship, between people." (citations omitted)), overruled on other grounds by United States v. Svete, 556 F.3d 1157 (11th Cir. 2009). The insurers have failed to allege the presence of a special relationship here—because none existed. Consequently, the insurers have asserted no cognizable fraud-by-omission claim against AstraZeneca.

voluntarily assumed the risk of paying for all prescriptions of Seroquel, including prescriptions for off-label uses that were medically unnecessary or inappropriate.

Their enrollees, however, we must infer from our common understanding of insurance practices—as well as common sense—did not receive this extensive prescription drug coverage for free. The insurers have pled no facts in the complaint that suggest the insurers established premiums in a way inconsistent with the insurance industry's conventional ratemaking procedures. We therefore must infer that the insurers do charge premiums established in that conventional manner. As a consequence, because the insurers consciously chose to assume the risk of paying for all medically unnecessary or inappropriate prescriptions of formulary-listed drugs—like Seroquel—we must further infer that they adjusted their premiums upward to reflect the projected value of claims for these prescriptions.[34] Such estimates, when calculated properly, take into account all known risks that might cause the insurers to pay for medically unnecessary or inappropriate prescriptions.

One such risk is fraud within the health care industry. Fraud is a well-known contributor to increased costs for health care services. See Furrow et al.,

[34] At oral argument, counsel for the plaintiffs specifically was asked by the court "if you pay more for drugs, then . . . you reflect that in the premium you charge to your clients?" In response, counsel for the plaintiffs stated, "We do, Your Honor."

supra, at 570 ("Fraud and abuse probably account for more than a trivial share of health care costs—aggressive enforcement of fraud and abuse laws appears to have played a role in decreasing Medicare costs in the late 1990s."); see also Nat'l Health Care Anti-Fraud Assoc., The Problem of Health Care Fraud, http://www.nhcaa.org/eweb/DynamicPage.aspx?webcode=anti_fraud_resource_centr&wpscode=TheProblemOfHCFraud (estimating "conservatively" that at least 3% of all health care spending—$68 billion—is lost to health care fraud annually). Thus, the risk that fraud—including fraudulent marketing by drug manufactures—might result in insurers paying for medically unnecessary or inappropriate prescriptions is just another cost to be factored into premiums.

As discussed generally in part II.B.1, supra, the insurers gambled that their estimates would prove sufficient to cover their payments for all medically unnecessary or inappropriate off-label Seroquel prescriptions. If their estimates exceeded the actual payments for these drugs, then the insurers paid nothing out of pocket to purchase Seroquel; instead, they earned a profit on their bargain. See, e.g., Int'l Bhd. of Teamsters Local 734 Health & Welfare Trust Fund v. Phillip Morris Inc., 196 F.3d 818, 823 (7th Cir. 1999) (declaring that similar insurers, "[h]aving collected extra money from [insured] smokers" based on premiums assessed by "actuaries whose life work is making accurate estimates of the costs of

smoking . . . and enabling the insurer to collect these in advance from insureds," cannot also recover that extra cost from tobacco manufacturers). If the insurers achieved this outcome, then their enrollees lost—having paid for more prescription drug coverage than they needed. If, however, the insurers' estimates fell short of actual payments, their own business mistakes caused their loss. AstraZeneca cannot be held to reinsure the insurers' sophisticated actuarial decisions.[35]

Either way, the insurers have not alleged facts suggesting that they plausibly suffered economic injury caused by AstraZeneca's false representations. Therefore, because they have not met their Twombly and Iqbal pleading burden, we affirm the district court and dismiss the entirety of the insurers' claims.

C.

We now address the allegations raised by the individual enrollee, Cheryl Martin, of whom we know very little from the complaint. In fact, the complaint discusses Martin only once, stating that, since 2003, she "has paid for a portion of

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[35] The Seventh Circuit illustrated this point well in Int'l Bhd. of Teamsters Local 734, stating:

> An auto insurer that charges male drivers under the age of 26 an extra premium to reflect the increased probability of dangerous driving can't also sue auto manufacturers for selling cars to these drivers and putting the youths in a position to cause accidents. Logically insurers could collect only for the net outlay produced by the risky activity; but there will be such a net outlay only if the insurers' actuaries are not calculating rates correctly.

196 F.3d at 824 (emphasis added).

her Seroquel prescription which was prescribed for her by her physician for an off-label use." Second Am. Consol. Compl. ¶ 26. Thus, unlike the insurers, Martin has paid out of her own pocket to purchase off-label Seroquel prescriptions. As a result, she potentially has viable claims against AstraZeneca based on her prescription of Seroquel in lieu of cheaper substitutes.[36]

Yet, as presented in part II.A.2, supra, allegations of out-of-pocket overpayment in the purchase of prescription drugs do not, alone, give rise to an actionable injury, notwithstanding the presence of underlying fraud. Rather, Martin, to meet her pleading burden under Twombly and Iqbal, must allege that she plausibly purchased medically unnecessary or inappropriate Seroquel prescriptions. Martin's bareboned allegations in the complaint, however, do not meet this burden. Nowhere in the complaint does she state the medical condition for which Seroquel was prescribed off-label, let alone whether Seroquel proved unsafe or ineffective in treating her condition.[37] Because Martin has failed to assert

[36] In fact, the allegations in the complaint suggest that Martin paid for the drugs in two ways: first, she paid her insurer's premium charges; then, she paid an escalated co-pay under her policy for each prescription and refill of the medication.

[37] The insurers' factual allegations, read in a light most favorable to the insurers, however, do adequately allege that Seroquel's off-label prescription may be medically unnecessary or inappropriate for treating certain conditions for which their enrollees were prescribed the drug. See, e.g., Second Am. Consol. Compl. ¶ 71, 73 (stating that AstraZeneca knew that Seroquel was "inferior" to Haldol, a cheaper alternative drug, in treating Tourette's Syndrome and dementia, conditions for which doctors prescribed Seroquel off-label).

We cannot, however, give the same benefit of the doubt to an individual enrollee like Martin. Martin has a specific condition for which she was prescribed Seroquel off-label.

these basic and essential facts, she has not pled a plausible actionable loss on account of AstraZeneca's fraud. As a consequence, we affirm the district court and dismiss her claims.

III.

To summarize, we affirm the judgment of the district court dismissing the entirety of the complaint for failing to state a claim upon which relief can be granted. We reach this conclusion, however, on different grounds: the insurers and Martin fail to allege sufficient facts suggesting they suffered a plausible injury from AstraZeneca's false representations regarding Seroquel's off-label benefits.

AFFIRMED.

Therefore, to plead a plausible claim, her portion of the complaint must allege her particular condition and that use of Seroquel to treat that condition was medically unnecessary or inappropriate.

MARTIN, Circuit Judge, concurring in the result:

I agree with the majority's conclusion that this action must be dismissed, but I concur specially to express my view that there is a much simpler reason why the appellees should prevail. As the Second Circuit explained in UFCW Local 1776 v. Eli Lilly & Co., 620 F.3d 121 (2d Cir. 2010), the independent decisions of the physicians and other intermediaries involved in Seroquel's allegedly increased usage and pricing eviscerates the chain of causation necessary to demonstrate a RICO violation. See id. at 134–36. I believe that these breaks in the chain of causation, which were conceded by the appellants in their complaint and at oral argument, dictate the result of this appeal. I therefore do not join the broader analysis of the majority opinion, and concur in the outcome only.