NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

Nos. 21-2573 & 21-2574

HUMANA, INC.,

Appellant in 21-2573

v.

INDIVIOR, INC., f/k/a Reckitt Benckiser Pharmaceuticals, Inc.;
INDIVIOR SOLUTIONS, INC., f/k/a Reckitt Benckiser Pharmaceuticals Solutions, Inc.;
INDIVIOR PLC; RECKITT BENCKISER HEALTHCARE (UK) LTD.;
RECKITT BENCKISER GROUP PLC;
AQUESTIVE THERAPEUTICS, INC., f/k/a
Monosol RX, LLC

CENTENE CORPORATION; WELLCARE HEALTH PLANS, INC.; NEW YORK QUALITY HEALTHCARE CORPORATION doing business as Fidelis Care; HEALTH NET, LLC,

Appellants in 21-2574

v.

INDIVIOR, INC., f/k/a Reckitt Benckiser Pharmaceuticals, Inc.; INDIVIOR SOLUTIONS, INC., f/k/a Reckitt Benckiser Pharmaceuticals Solutions, Inc.; INDIVIOR PLC; RECKITT BENCKISER GROUP, PLC; RECKITT BENCKISER HEALTHCARE (UK) LTD; AQUESTIVE THERAPEUTICS, INC., f/k/a Monosol RX, LLC

On Appeal from the United States District Court for the Eastern District of Pennsylvania (D. C. Nos. 2-20-cv-04602 & 2-20-cv-05014) District Judge: Honorable Mitchell S. Goldberg

Argued on March 31, 2022

Before: RESTREPO, ROTH, and FUENTES, Circuit Judges

(Opinion filed: December 15, 2022)

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OPINION*

ROTH, Circuit Judge.

Humana, Inc., and Centene Corporation (Insurers) are health benefit program insurers that provide their members with insurance to cover prescription drug costs. They maintain approved lists of medications covered by their members' health insurance plans. These lists are known as formularies. Defendants are companies that are involved in the development, manufacture, and sale of Suboxone and Suboxone film, two forms of a drug used to treat opioid addiction. According to Insurers, defendants engaged in a nationwide racketeering effort to convince Insurers to place Suboxone film on their formularies. As a result of this effort and the alleged misrepresentations made by defendants in connection with it, Insurers did place Suboxone film on their formularies. Insurers have now brought suits in federal court, alleging substantive and conspiracy offenses in violation of the

^{*} This disposition is not an opinion of the full Court and under I.O.P. 5.7 does not constitute binding precedent.

¹ The Insurers' complaints consist of substantially the same allegations. Although appellants in these appeals brought two separate lawsuits by filing similar complaints, those lawsuits were consolidated in the District Court, and this Court consolidated the appeals for all purposes.

Racketeer Influenced and Corrupt Organizations Act (RICO), as well as numerous statelaw claims. ²

The District Court dismissed Insurers' complaints with prejudice, reasoning that the Insurers had alleged their RICO claims based on a theory of injury caused by their downstream reimbursements for Suboxone film,³ a theory foreclosed by the indirect-purchaser rule.⁴ The court held that, because Insurers merely reimbursed the purchase of Suboxone film, they were indirect purchasers of the drug and therefore lacked standing under the indirect-purchaser rule, first articulated in *Illinois Brick Co. v. Illinois*,⁵ and subsequently applied by this Court to RICO cases in *McCarthy v. Recordex Service, Inc.*⁶ Insurers appealed, asserting that the indirect-purchaser rule did not apply to them. They allege that they have stated a claim for relief of a direct injury under *In re Avandia Marketing, Sales Practices & Product Liability Litigation*.⁷ Defendants assert that *Avandia* is not applicable in this case.

For the reasons set out below, we will affirm the judgment of the District Court.

I.8

² The viability of the state-law claims in federal court turns on whether the complaints successfully invoke supplemental jurisdiction. Thus, if the RICO claims cannot be sustained, then the state-law claims cannot independently proceed in federal court.

³ JA23–24.

⁴ JA23–24.

⁵ 431 U.S. 720 (1977).

⁶ 80 F.3d 842 (3d Cir. 1996).

⁷ 804 F.3d 633 (3d Cir. 2015).

⁸ These facts are taken from the complaints and treated as true because, in reviewing a denial of a motion under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), we accept as true all well-pleaded allegations and construe the complaints in the light most favorable to the plaintiffs. *See Lewis v. Atlas Van Lines, Inc.*, 542 F.3d 403, 405 (3d Cir. 2008).

Insurers sell insurance plans that cover drug costs. Defendants have developed, manufactured, and sold Suboxone, a drug used to treat opioid addiction, and the related Suboxone film, which is the drug at issue here. In 2009, Invidior's exclusivity on Suboxone tablets was about to expire. Generic pharmaceutical companies would then be able to produce less expensive versions of the tablets and Invidior would lose a great deal of business. To avoid this, Invidior and Aquestive Therapeutics, Inc., developed a sublingual film version of Suboxone. When the film was approved by the FDA, defendants started a campaign to induce physicians, patients and health plans to switch from Suboxone tablets to Suboxone film. In this way, by the time generic tablets entered the market, a majority of patients had already switched to Suboxone film and Invidior and Aquisitive now had exclusivity on the film.

According to Insurers, defendants' scheme caused Insurers to "continue[] to pay higher prices for treatment of [their] insureds." Specifically, they allege that defendants "designed and coordinated" their scheme to "charge and maintain inflated prices for Suboxone, the Suboxone market, and to defraud payors like" Insurers. In addition, Insurers claim that they "paid hundreds of millions of dollars for Suboxone film, as well as higher prices for Suboxone tablets, due to the mail and wire fraud, and pattern of racketeering activity alleged" in the complaints. 12

⁹ JA69–70; JA290.

¹⁰ JA70; JA290.

¹¹ JA114; JA336.

¹² JA340.

Insurers specifically admit that they made "indirect purchases of Suboxone" but claim that they "suffered injuries when [they] reimbursed prescriptions for Suboxone." Insurers also allege that "the institutional structure of pricing and regulation in the pharmaceutical drug industry assures that overcharges at the higher level of distribution are passed on to end-payors like" them. Hous, "[w]holesalers and retailers passed on the inflated prices of Suboxone to" the Insurers. This characterization, however, fits the description of a "third-party payor" who is barred from recovery in a RICO action by the indirect-purchaser rule.

Insurers, nonetheless, attempt to invoke their theory of direct injury. They allege that defendants fraudulently induced them to include Suboxone film on their formularies, and thus defendants' scheme directly injured them. They allege that "[d]riving formulary support for Suboxone film through payors—like [the Insurers]—was a key goal of the Suboxone Scheme because third-party payors like [the Insurers] were the ultimate source of [defendants'] profits." The Insurers claim that they "reasonably relied on [defendants'] statements and misrepresentations—not knowing they were false statements or misrepresentations—and included Suboxone film on [their] formularies. [The Insurers] rightfully relied on [defendants'] false statements and misrepresentations." 17 18

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¹³ JA130; JA353.

¹⁴ JA124; JA346.

¹⁵ JA124; JA346.

¹⁶ JA84; JA305.

¹⁷ JA133; JA355–56.

¹⁸ We note, however, that the above allegations are not directly connected in the complaints to the Insurers' RICO claims. The complaints make only passing reference to the formularies. They do not define formularies. Nor do they describe the misrepresentations,

The District Court dismissed the Insurers' complaints because it found that the Insurers' RICO claims turned on an indirect injury that they suffered from being end-payors. The court concluded that the Insurers do not have RICO standing to assert their primary theory: that the Insurers "suffered injuries when [they] reimbursed prescriptions for Suboxone." For that reason, they suffered no direct injury from defendants' alleged RICO scheme. Thus, the District Court held that the Insurers lacked RICO standing under the indirect-purchaser rule.

As mentioned above, this characterization of the Insurers' position aligns with the definition of a "third-party payor," which comprises those who are barred from recovery in a RICO action by the indirect-purchaser rule. The Supreme Court first recognized that plaintiffs, asserting Clayton Act violations, cannot demonstrate an injury by providing

who made them, to whom they were made, or which statements the Insurers relied on when they placed Suboxone film on their formularies. In fact, in support of their state-law claims (not of their RICO claims), the Insurers merely make the conclusory allegation only that they "reasonably relied on [defendants'] statements and misrepresentations . . . and included Suboxone film on [their] formularies." JA133; JA355–56.

¹⁹ This Court has appellate jurisdiction over the District Court's final decision pursuant to 28 U.S.C. § 1291. "Whether the District Court had jurisdiction is the issue before us. We exercise plenary review over all jurisdictional questions, including those related to standing." *Const. Party of Pa. v. Aichele*, 757 F.3d 347, 356 n.12 (3d Cir. 2014) (citing *Belitskus v. Pizzingrilli*, 343 F.3d 632, 639 (3d Cir.2003)).

²⁰ As the District Court correctly noted, cases involving allegations of fraud are subject to a heightened pleading standard in lieu of the traditional pleading standard enumerated by Fed. R. Civ. P. 8(a)(2). Under Fed. R. Civ. P. 9(b), "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally."

²¹ JA130; JA353.

evidence of being an "indirect purchaser."²² The Court instituted the indirect-purchaser rule because pecuniary recoveries by indirect purchasers would "transform treble-damages actions into massive multiparty litigations involving many levels of distribution and including large classes of ultimate consumers remote from the defendant."²³ We later recognized in *McCarthy* that the same policy concerns apply to RICO cases.²⁴ Thus, the indirect-purchaser rule is applicable here.

The main theory advanced in the Insurers' complaints is a textbook indirect-purchaser theory: They seek redress for injuries suffered because their insureds purchased Suboxone film and the Insurers reimbursed those purchases. In their complaints, the Insurers allege that defendants "marketed, sold, purchased, or provided Suboxone film to thousands of individuals" and that the Insurers "suffered injuries when [they] reimbursed prescriptions for Suboxone [film] that otherwise would not have been made and/or paid the higher prices that resulted from illegal conduct." In that way, based on the Insurers' complaints, the injury that the Insurers purportedly suffered came from the "reimbursed prescriptions." Such a claim is barred by the indirect-purchaser rule.

On appeal, however, the Insurers contend that the District Court's analysis did not address their theory of direct, cognizable injury, a theory based on the contention that defendants fraudulently induced them to include Suboxone film on their formularies. But

²² Illinois Brick Co. v. Illinois, 431 U.S. 720, 737 (1977).

²³ *Id*.

²⁴ McCarthy v. Rocordex Serv., Inc., 80 F.3d 842, 851 (3d Cir. 1996) (recognizing that "all of the policy concerns expressed in *Illinois Brick* were implicated" in RICO cases).

²⁵ JA130; JA353.

²⁶ JA130; JA353.

even if we were to take the Insurers' claim at face value, they still fail to satisfy the Rule 9(b) standard of particularity. Because the Insurers' claim is one of fraud, it must comply with Fed. R. Civ. P. 9(b). As mentioned above, "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." "The purpose of Rule 9(b) is to provide notice of the 'precise misconduct' with which the defendants are charged and to prevent false or unsubstantiated charges." "Although Rule 9(b) falls short of requiring every material detail of the fraud such as date, location, and time, plaintiffs must use 'alternative means of injecting precision and some measure of substantiation into their allegations of fraud." One such alternative measure would have been through satisfaction of the standard set forth by the RICO statute, which "requires (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity. The plaintiff must, of course, allege each of these elements to state a claim."

And yet, there is no specific allegation of injury or pattern other than the expense of the drug involved. The Insurers' complaints make only passing references to formularies. They fail to specify, for example: which of Defendants' misrepresentations Insurers relied

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²⁷ Fed. R. Civ. P. 9(b).

²⁸ Rolo v. City Investing Co. Liquidating Gr., 155 F.3d 644, 658 (3d Cir. 1998), abrogation on other grounds recognized by Forbes v. Eagleson, 228 F.3d 471 (3d Cir. 2000).

²⁹ *In re Rockefeller Ctr. Properties, Inc. Sec. Litig.*, 311 F.3d 198, 216 (3d Cir. 2002) (citing *In re Nice Systems*, 135 F.Supp.2d 551, 577 (D.N.J. 2001)).

³⁰ Sedima, S.P.R.L. v. Imrex Co., 473 U.S. 479, 496 (1985); see also Lum v. Bank of Am., 361 F.3d 217, 223 (3d Cir. 2004) ("Where, as here, plaintiffs rely on mail and wire fraud as a basis for a RICO violation, the allegations of fraud must comply with Federal Rule of Civil Procedure 9(b), which requires that allegations of fraud be pled with specificity."), abrogation on other grounds recognized by In re Ins. Brokerage Antitrust Litig., 618 F.3d 300, 323 n.22 (3d Cir. 2010).

on when they placed Suboxone film on their formularies; to whom or by whom those misrepresentations were made; or when they were made. At most, the Insurers state the conclusory allegation that they "reasonably relied on [defendants'] statements and misrepresentations . . . and included Suboxone film on [their] formularies."³¹

To comply with Rule 9(b), Insurers' must at least describe, with particularity, how they were induced by Defendants. Instead, they merely claim that they were induced without pointing to which misrepresentations caused their induction. In other words, under Rule 9(b), there is no indication which "circumstances constitute[ed] the fraud" they complain of. If this Court cannot say how defendants' fraud caused Insurers' injury, it cannot say that Fed. R. Civ. P. 9(b) was satisfied.³²

III.

For the reasons stated above, we will affirm the District Court's order, dismissing the Insurers' complaints.

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³¹ JA133; JA355–56.

³² We also agree with defendants that *Avandia* is not applicable here. The Insurers here did not overcome the heightened pleading standard. Thus, this Court need not contrast this matter with *Avandia* any further.