

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

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HUMANA, INC.,	:	
	:	CIVIL ACTION
Plaintiff,	:	
	:	
v.	:	
	:	NO. 20-4602
INDIVIOR INC. f/k/a RECKITT	:	
BENCKISER PHARMACEUTICALS,	:	
INC., et al.,	:	
	:	
Defendants.	:	
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	:	
CENTENE CORPORATION, et al.	:	
	:	CIVIL ACTION
Plaintiffs,	:	
	:	
v.	:	
	:	NO. 20-5014
INDIVIOR INC. f/k/a RECKITT	:	
BENCKISER PHARMACEUTICALS,	:	
INC., et al.	:	
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Goldberg, J.

July 22, 2021

MEMORANDUM OPINION

In yet another chapter of the ongoing litigation relating to the marketing and distribution of the addiction treatment drug Suboxone®, Plaintiffs,¹ both healthcare providers, have filed lawsuits against Defendants Indivior Inc. f/k/a/ Reckitt Benckiser Pharmaceuticals, Inc. (“Indivior”) and

¹ One suit was brought by Humana, Inc. (“Humana”), and the other was brought by The Centene Company, WellCare Health Plans, Inc., New York Quality Healthcare Corporation d/b/a Fidelis Care, and Health Net LLC (the “Centene Plaintiffs”). I refer to all of these entities collectively as “Plaintiffs.”

several related entities.² The two Complaints set forth multiple claims under the Racketeering Influenced and Corrupt Organizations Act (“RICO”), state law common law fraud, state law antitrust laws, state unfair and deceptive trade practices laws, state insurance laws, and for unjust enrichment.

Defendants have moved to dismiss these Complaints. For the following reasons, I will grant these Motions and dismiss both Complaints against all Defendants.

I. FACTS IN THE COMPLAINTS

The following facts are taken from Plaintiffs’ Complaints.³

Suboxone® is a drug approved for use by recovering opioid addicts to avoid or reduce withdrawal symptoms while they undergo treatment for opioid-use disorder. Indivior—known at the time as Reckitt Benckiser Pharmaceuticals, Inc.—introduced Suboxone in tablet form in 2002 under an “orphan drug” designation by the Food and Drug Administration (“FDA”). Suboxone tablets soon reached annual United States sales of over \$1 billion. (Compl., Civ. A. No. 20-4602 (“Humana Compl.”), ¶ 1.)

In 2009, Indivior was facing the expiration of its regulatory exclusivity for Suboxone tablets and the impending entry of generic versions of Suboxone tablets. According to the Complaints,

² Aside from Indivior, Plaintiffs have sued Indivior Solutions, Inc. f/k/a Reckitt Benckiser Pharmaceuticals Solutions, Inc. (“Indivior Solutions”), Reckitt Benckiser Group plc (“RBG”), Reckitt Benckiser Healthcare (UK) Ltd. (“Reckitt UK”), and Aquestive Therapeutics, Inc. f/k/a MonoSol Rx, LLC (“Aquestive”). I refer to all of these entities collectively as “Defendants.”

³ In deciding a motion under Federal Rule of Civil Procedure 12(b)(6), the court must accept all factual allegations in the complaint as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading, the plaintiff may be entitled to relief. *Atiyeh v. Nat’l Fire Ins. Co. of Hartford*, 742 F. Supp. 2d 591, 596 (E.D. Pa. 2010).

The two Complaints before me here are substantially identical. As such, when discussing the relevant facts pled, I will cite only to the Humana Complaint in Civil Action No. 20-4602. To the extent there is a critical difference between the two Complaints, I will identify that distinction and cite to both Complaints.

Indivior undertook a “complex, sophisticated scheme” to “introduce a fraudulent new product in order to keep its Suboxone drug prices artificially high and unlawfully impede generic manufacturers from competing effectively.” (Id. ¶ 2.) The Complaints address the alleged impact of Defendants’ actions on Plaintiffs.

A. The Parties

Humana and the Centene Plaintiffs are providers of healthcare related services and insure risk for prescription drug costs for more than eight million members in all fifty states, the District of Columbia, and Puerto Rico. (Id. ¶ 11; Compl., Civ. A. No. 20-5014 (“Centene Compl.”), ¶¶ 11–14.)

Defendant Indivior is a wholly-owned subsidiary of Indivior plc and is engaged in the development, manufacture, and sale of Suboxone throughout the United States. Until December 12, 2014, Indivior was a wholly-owned subsidiary of RBG and was known as Reckitt Benckiser Pharmaceuticals. On December 23, 2014, Indivior plc acquired Indivior when Indivior plc was demerged from RBG. (Humana Compl. ¶ 12.)

Defendant Indivior Solutions employed the marketing and sales personnel for the Indivior group of companies. Defendant Indivior plc is a British corporation that, according to Plaintiffs, owned, controlled, managed, and operated Indivior. Defendant RBG is also a British corporation that manufactures and markets numerous consumer products and, according to the Complaints, was responsible for the initiation of the conduct at issue in this case. The Complaints allege that, in all relevant respects, Indivior plc is the successor to RBG and has continued RBG’s conduct. (Id. ¶¶ 13, 14, 15, 17.)

Reckitt UK is a British company that purportedly established the parameters for the timing of the launch and the formulation of Suboxone film and, according to the Complaints, was intricately involved with the alleged anticompetitive scheme. (Id. ¶ 16.)

Defendant Aquestive is a New Jersey-based corporation, which, during the relevant time period, was known as MonoSol. According to Plaintiffs, Aquestive was integral to the alleged anti-competitive and racketeering scheme through its development of the Suboxone film. (Id. ¶¶ 19–20.)

B. The Regulatory Structure for Approval and Substitution of Generic Drugs

The Hatch-Waxman Act provides regulatory exclusivity for new pharmaceuticals while providing a pathway for entry of low-priced generic drugs. A company seeking to market a new pharmaceutical product must file a New Drug Application (“NDA”) with the FDA demonstrating the safety and efficacy of the new product. These NDA-based products are referred to as “brand-name” or “branded” drugs, and they are entitled to regulatory exclusivity for a limited period of time. When regulatory exclusivity is about to expire, a generic drug company may submit an Abbreviated New Drug Application (“ANDA”) demonstrating that the generic version is essentially the same as a branded version. (Id. ¶ 25.)

A seven-year regulatory exclusivity period for an NDA approved drug can also be obtained by applying for orphan drug exclusivity with the FDA under 21 C.F.R. § 316, either (a) on the basis that a product is intended to treat a disease or condition that has a United States prevalence of less than 200,000 persons, or (b) where the sponsor can show that there is no reasonable expectation that the costs of developing and making the drug available will be recovered from United States sales, despite the fact that the disease or condition treated has a United States prevalence of more than 200,000 persons. (Id. ¶ 26.)

Generic drugs can be substituted at the pharmacy to fill a prescription for a branded drug. Both the federal government, through the Hatch-Waxman Act, and all fifty states provide drug substitution laws that encourage and facilitate this type of substitution. Thus, when a pharmacist fills a prescription for a branded drug, the laws allow or require that a less expensive generic version

be dispensed, unless a physician or patient directs otherwise. Such state substitution laws were enacted, in part, to correct a “disconnect” between payment obligations and product selections, *i.e.*, the doctor who selects the drug does not pay for it and, therefore, has no incentive to consider price. Due to these substitution laws, less-expensive generic drugs typically capture over 80% of a branded drug’s sales within six months. In turn, the lower cost generic drugs save consumers billions of dollars a year. (Id. ¶¶ 27–30.)

C. The Suboxone Hard Switch Scheme

Again, the following facts describing the alleged scheme are taken from Plaintiffs’ Complaints.

Indivior obtained FDA approval for Suboxone tablets in 2002. Subsequently, Indivior applied for and received orphan drug exclusivity for Suboxone based on Indivior’s claims that it was the first buprenorphine drug approved for the treatment of opioid addiction and Indivior would not recover the costs of developing the tablets. Nonetheless, during its seven-year period of exclusivity, Indivior earned over one billion dollars from marketing and selling Suboxone tablets in the United States. (Id. ¶¶ 33–34.)

As Indivior’s seven-year exclusivity was set to expire on October 8, 2009, it became aware that multiple generic manufacturers were seeking FDA approval to market generic versions of Suboxone, which would significantly deplete Indivior’s Suboxone sales. Accordingly, Indivior began to devise a strategy to develop a new dosage form of Suboxone and submit another NDA on this new form. (Id. ¶¶ 36–38.)

In connection with this strategy, Indivior discovered Aquestive, whose sole offering as a business is its development of a drug delivery formulation known as sublingual film or “PharmFilm.” Aquestive’s business model encourages companies to use its dosage form to extend a drug’s exclusivity on the market. In December 2006, Indivior and Aquestive executed an initial

contract that initiated a joint venture to create and manufacture Suboxone film using Aquestive's PharmFilm technology. Aquestive negotiated with Indivior to receive royalty payments on sales of Suboxone film. (*Id.* ¶¶ 39–40.)

Between December 2006 and March 2007, Indivior and others discussed additional ways to delay FDA approval of generic versions of Suboxone tablets by raising false safety concerns about Indivior's own Suboxone tablets, and then discontinuing tablets under the pretext of those safety concerns. Thereafter, in July 2007—more than two years before its orphan drug exclusivity expired—Indivior announced to the FDA that it planned to seek approval to market a sublingual film version of Suboxone. On October 20, 2008, Indivior submitted a new NDA to the FDA for its Suboxone sublingual film. (*Id.* ¶¶ 42–44.)

While awaiting FDA approval of Suboxone film, Indivior devised marketing plans for the drug, which included, in large, part, driving formulary support for Suboxone film through payors such as Plaintiffs. On June 9, 2009, Indivior's Medical Director told fellow Indivior medical personnel, "We need to develop a *story* about childhood exposures to set the stage for switching patients to" Suboxone film. This safety story became central to the Suboxone film. Subsequently, on October 5, 2009, Indivior sent a letter to the FDA asking whether the FDA agreed that Suboxone film's packaging would protect against diversion (e.g., illegal selling, sharing, and smuggling of Suboxone) and accidental child exposure (i.e., children taking Suboxone by accident). The FDA did not respond until March 29, 2010, at which time it rejected Indivior's claim that Suboxone film's packaging would protect against diversion and accidental child exposure. (*Id.* ¶¶ 45–48, 51.)

In the meantime, on November 24, 2009, Indivior resubmitted its NDA for Suboxone film to the FDA, including a revised Risk Evaluation Management Strategy ("REMS") to address safety concerns related to the film product. Aquestive remained active in the NDA-approval process. On

August 30, 2010, the FDA approved Indivior's application to market the film formulation. (Id. ¶¶ 49, 55.)

Thereafter, Indivior's Chief Executive Officer told its parent group, RBG, that "We will be making the most of every minute between now and generic approval to convert our tablet business to film," including a "Full Blitz campaign for salesforce through Thanksgiving." For the "Full Blitz" campaign, Indivior's salespeople planned to raise "diversion and misuse and pediatric safety" in sales presentations to physicians, even though there were no scientific studies to establish that Suboxone film was safer with regard to diversion, misuse, or pediatric safety. In fact, according to the Complaints, in many respects the film formulation had numerous drawbacks compared to the tablets. (Id. ¶¶ 55, 58.)

Plaintiffs allege that Indivior and Aquestive then focused its marketing campaign on the idea of selling Suboxone film in single-serving, or "unit-dose" packaging, and asserting that this packing made the product safer than tablets to prevent pediatric exposure. Indivior's CEO encouraged marketing personnel to convert patients from tablets to film using this story. Indivior Solutions employed the marketing and sales personnel of the Indivior group of companies and, on September 6, 2010, an Indivior Solutions national sales supervisor emailed approximately fifty Indivior salespeople, encouraging them to tell physicians that Suboxone film was "safer because of the packaging." Thereafter, and throughout the relevant time period, Indivior Solutions' sales representatives continued to make "false and fraudulent statements in order to induce and, in some cases, coerce, physicians, pharmacists, and other health care providers to prescribe and dispense Suboxone film and recommend the prescribing and dispensing of Suboxone film." According to Plaintiffs, however, Indivior's "child safety" rationale was a complete fabrication and designed solely to impair generic competition and maintain its monopolistic profits. Indeed, Plaintiffs allege that "[i]f Indivior really believed that unit-dose packaging was necessary to protect children from

accidental exposure to Suboxone, Indivior would have sold its Suboxone tablets in unit dose packages.” Notably, until FDA approval of generic Suboxone tablets was imminent, Indivior never told or suggested to the FDA that tablets in multi-unit bottles presented an undue safety concern for children. (*Id.* ¶¶ 63, 54, 55, 71–73, 75, 77, 80.)

According to the Complaints, the fraudulent marketing blitz would not work fast enough for Indivior to convert the patient population before generic drugs came onto the market. As such, starting in or about 2010, Indivior significantly raised the price of Suboxone tablets, but not the price of Suboxone film, thus creating an “artificial price difference to push patients to switch from the tablets to the film.” In addition, on September 14, 2012, Indivior began a public relations strategy to discontinue the Suboxone tablet, using a perception of discontinuation as a means for “blunting generic/competitive entry.” Indivior then sent a “Notice of Discontinuance” of the Suboxone tablet to the FDA, on September 18, 2012, stating the reason was “increasing concerns regarding pediatric exposure to” the Suboxone tablet. One week later, Indivior issued a press release advising the public and doctors that Indivior intended to withdraw the tablets from the market within the next six months “due to increasing concerns with pediatric exposure.” (*Id.* ¶¶ 84–86, 88–89.)

D. The Shared REMS Program and Indivior Citizen Petition

Plaintiffs also allege that, in order to give itself more time to switch the market from Suboxone tablets to film, Indivior used additional anticompetitive tactics to delay the FDA’s approval of competitors’ ANDAs for generic Suboxone tablets. (*Id.* ¶ 93.)

The first tactic involved the Single Shared REMS (“SSRS”) Program. On January 6, 2012, the FDA advised Indivior and the generic manufacturers that the generic Suboxone tablets would be subject to an SSRS program and that all ANDA filers would need to contact Indivior to collaborate on the creation and implementation of an SSRS program that addressed pediatric exposures. The FDA mandated compliance by May 6, 2012. Instead of coordinating its efforts and

resources with ANDA applicants, however, Indivior unilaterally retained the services of the Research Abuse, Diversion and Addiction-Related Surveillance System and Venebio Group, LLC to prepare a study on the risk of pediatric exposure to Suboxone tablets, but not Suboxone film. Plaintiffs allege that Indivior's goal in doing so was to ensure blocking, or at least delaying, ANDA applications. In addition, during the SSRS process, Indivior engaged in other delay tactics, flat refusals to participate, and pretextual conditions on participation. (Id. ¶¶ 94, 97, 98.)

On May 6, 2012, ANDA filers jointly requested a meeting with the FDA to discuss the delays created by Indivior. The FDA scheduled a meeting on June 18, 2012 and invited all ANDA filers and Indivior. At that time, the FDA asked the ANDA filers and Indivior to develop a new SSRS based upon the requirements set forth in the REMS Notification Letter without using any of Indivior's existing information. Indivior agreed to cooperate but failed to actually do so. (Id. ¶¶ 101–02.)

According to Plaintiffs, Indivior then engaged in a second delay tactic—the filing of a sham citizen petition with the FDA. On September 25, 2012, with FDA approval of generic Suboxone tablets imminent, Indivior announced its intent to permanently withdraw Suboxone tablets from the market for purported public safety reasons and, at the same time, filed a citizen petition with the FDA. The petition asked the FDA to withhold approval of general Suboxone tablet ANDAs unless: (1) the ANDA contained a targeted pediatric exposure education program; and (2) the ANDA product had child-resistant unit-dose packaging. It also asked that the FDA refrain from approving any generic Suboxone tablet ANDA until it determined whether Indivior discontinued the Suboxone brand tablet for safety reasons. Indivior's allegations were contrary to previous statements it had made to the FDA regarding the safety of its tablet packaging. As a result of the citizen petition, the FDA delayed approval of the generic Suboxone tablet ANDAs for five months while it investigated

the allegations. On February 22, 2012. The FDA denied the petition as baseless, finding that the data did not support any of Indivior's allegations. (Id. ¶¶ 104, 106, 107, 108, 110, 112.)

The FDA alerted the Federal Trade Commission ("FTC") to Indivior's conduct, and the FTC subsequently sued Indivior for its product hopping and abuse of the citizen petition process, alleging that in "September 2012, Indivior submitted a citizen petition requesting that the FDA reject any generic Suboxone tablet applications or subject them to additional requirements because it knew doing so could delay approval of generics while the FDA reviewed it. The petition misrepresented a study that Indivior had commissioned and falsely claimed that there was evidence that the packaging of Suboxone Film reduced the risk of pediatric exposures." (Id. ¶ 117.)

On the same day that the FDA rejected Indivior's citizen petition, it granted the generic pharmaceutical companies' ANDA applications. The damage caused by the delay, however, was already done. By the time generic manufacturers began selling generic Suboxone tablets in late February 2013, the prescription base for Suboxone tablets had already been destroyed and approximately 85% of Suboxone prescriptions were already being written for the film version of Suboxone. (Id. ¶¶ 115, 117.)

Defendants also filed patent litigation against generic film competitors. Once Defendants had been defeated in the first patent litigation, they filed new patent applications and then pursued successive patent litigation against generic competitors. (Id. ¶ 120.)

F. Procedural History

On September 18, 2020, Plaintiffs filed Complaints against Defendants alleging that, as a result of Defendants' conduct, Plaintiffs (a) reimbursed prescriptions for Suboxone that otherwise would not have been made and/or (b) paid the higher prices that resulted from the illegal conduct. (Id. ¶ 192.)

Both Complaints set forth the following causes of action: (a) violations of the Racketeer Influenced and Corrupt Organizations Act (“RICO”), 18 U.S.C. § 1962(c) against the Individual Defendants; (b) conspiracy to violate the RICO Act, 18 U.S.C. § 1962(d) against all Defendants; (c) fraud under state law against all Defendants; (d) monopolization and monopolistic scheme under various state laws against all Defendants except Reckitt UK; (e) attempted monopolization under state law against all Defendants except Reckitt UK; (f) unfair and deceptive trade practices under various state laws against all Defendants; (g) insurance fraud under state law against all Defendants; and (h) unjust enrichment against all Defendants.

On January 15, 2021, four Motions to Dismiss, under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), were filed by (1) Individual and Individual Solutions; (2) Individual plc; (3) RBG Group and Reckitt UK; and (4) Aquestive.

II. STANDARDS OF REVIEW

A. Rule 12(b)(1) Standard

Federal Rule of Civil Procedure 12(b)(1) permits a party to bring a motion to dismiss for lack of subject matter jurisdiction. See Fed. R. Civ. P. 12(b)(1). The burden of establishing federal jurisdiction rests with the party asserting its existence. DaimlerChrysler Corp. v. Cuno, 547 U.S. 332, 342 n.3 (2006). A district court must first determine “whether a Rule 12(b)(1) motion presents a ‘facial’ attack or a ‘factual’ attack on the claim at issue, because that distinction determines how the pleading must be reviewed.” Constitution Party of Pennsylvania v. Aichele, 757 F.3d 347, 357 (3d Cir. 2014).

A facial attack, as the adjective indicates, is an argument that considers a claim on its face and asserts that it is insufficient to invoke the subject matter jurisdiction of the court. Id. at 358. When evaluating a facial attack, like the one before me, courts apply the same standard of review

used when “considering a motion to dismiss under Rule 12(b)(6), i.e., construing the alleged facts in favor of the nonmoving party.” Aichele, 757 F.3d at 358.

B. Rule 12(b)(6) Standard

Under Federal Rule of Civil Procedure 12(b)(6), a defendant bears the burden of demonstrating that the plaintiff has not stated a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6); see also Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005). The United States Supreme Court has recognized that “a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions.” Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (quotations omitted). “[T]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice” and only a complaint that states a plausible claim for relief survives a motion to dismiss. Ashcroft v. Iqbal, 556 U.S. 662, 678–79 (2009). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” Id. at 678. A complaint does not show an entitlement to relief when the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct. Id. at 679.

The Court of Appeals has detailed a three-step process to determine whether a complaint meets the pleadings standard. Bistrrian v. Levi, 696 F.3d 352 (3d Cir. 2014). First, the court outlines the elements a plaintiff must plead to state a claim for relief. Id. at 365. Next, the court must “peel away those allegations that are no more than conclusions and thus not entitled to the assumption of truth.” Id. Finally, the court “look[s] for well-pled factual allegations, assume[s] their veracity, and then ‘determine[s] whether they plausibly give rise to an entitlement to relief.’” Id. (quoting Iqbal, 556 U.S. at 679). The last step is “‘a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.’” Id. (quoting Iqbal, 556 U.S. at 679).

Notably, claims of fraud are subject to a heightened pleading standard. Federal Rule of Civil Procedure 9(b) provides: “[i]n 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.” Fed. R. Civ. P. 9(b). This heightened pleading standard requires “plaintiffs to plead with particularity the ‘circumstances’ of the alleged fraud in order to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior.” Seville Indus. Mach. Corp. v. Southmost Mach. Corp., 742 F.2d 786, 791 (3d Cir. 1984). Stated differently, “Rule 9(b) requires, at a minimum, that plaintiffs support their allegations of . . . fraud with all of the essential background that would accompany the first paragraph of any newspaper story[,] that is, the who, what, when, where and how of the events at issue.” In re Rockefeller Ctr. Props., Inc. Sec. Litig., 311 F.3d 198, 217 (3d Cir. 2002) (citation and internal quotation marks omitted).

III. MOTION TO DISMISS BY DEFENDANTS INDIVIOR AND INDIVIOR SOLUTIONS

A. RICO Claims

The RICO statute, 18 U.S.C. § 1962(c) makes it “unlawful for any person employed by or associated with any enterprise . . . to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity.” Id. To plead a RICO claim under § 1962(c), “the plaintiff must allege (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity.” In re Ins. Brokerage Antitrust Litig., 618 F.3d 300, 362 (3d Cir. 2010) (quoting Lum v. Bank of Am., 361 F.3d 217, 223 (3d Cir. 2004)). An “enterprise” includes “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.” Id. at 362–63 (quoting 18 U.S.C. § 1961(4)). A “pattern of racketeering activity” requires at least two predicate acts of racketeering

within a ten-year period. Id. at 363. The predicate acts can include federal mail fraud or federal wire fraud. Id.

The RICO statute, 18 U.S.C. § 1962(d), also makes it unlawful for any person to conspire to violate the RICO statute. The essential elements of a § 1962(d) conspiracy include: (1) knowledge of the corrupt enterprise's activities and (2) agreement to facilitate those activities. Salinas v. U.S., 522 U.S. 52, 66 (1997). There is no requirement of an overt act and, thus, "a defendant may be held liable for conspiracy to violation section 1962(c) if he knowingly agrees to facilitate a scheme which includes the operation or management of a RICO enterprise." Smith v. Berg, 247 F.3d 532, 538 (3d Cir. 2001).

Indivior and Indivior Solutions (the "Indivior Defendants") seek to dismiss both the substantive RICO claim and the RICO conspiracy claim, contending that Plaintiffs lack statutory standing because Plaintiffs did not purchase Suboxone tablets or film directly from any Defendant. According to the Indivior Defendants, Plaintiffs are "end payors" or "indirect purchasers" in the distribution chain who pay for drugs purchased by a pharmacy, wholesaler, or their insured. Citing the "indirect purchaser" rule set forth by the United States Supreme Court in Illinois Brick Co. v. Illinois, the Indivior Defendants assert that Plaintiffs are barred from bringing RICO claims.

The United States Supreme Court originally developed the indirect purchaser rule in the antitrust context, holding that Clayton Act plaintiffs could not demonstrate injury by providing evidence of only indirect purchases. Illinois Brick Co. v. Illinois, 431 U.S. 720, 737 (1977). Underscoring this principle was the notion that allowing indirect purchasers to recover 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." Id. This "indirect purchaser rule" was intended to prevent defendants from being exposed to the "multiple liability" that would occur if both indirect and direct purchasers in the distribution chain could assert

claims arising out of a single overcharge. See McCarthy v. Recordex Serv., Inc., 80 F.3d 842, 851 (3d Cir. 1996).

Following Illinois Brick, the United States Court of Appeals for the Third Circuit, in McCarthy v. Recordex Serv., Inc., supra, addressed the question of indirect purchaser standing to bring RICO claims. In McCarthy, a group of indirect purchaser plaintiffs brought antitrust and RICO claims against the defendant sellers. Id. at 844. Recognizing that “all of the policy concerns expressed in Illinois Brick were implicated” in that case, the Third Circuit held that the “indirect purchaser” rule of Illinois Brick applied “equally to allegations of RICO violations” and, as such, indirect purchasers lack standing to pursue claims under RICO. Id. at 851, 855. Because the plaintiffs in McCarthy could not establish that they were direct purchasers in direct privity with the defendants, the Court found that the plaintiffs had no standing to assert any of their RICO claims.⁴ Id. at 855.

McCarthy’s bar on indirect purchaser standing in the RICO context has been cited with approval within the Third Circuit on multiple recent occasions. See Hu v. BMW of N. Am. LLC, No. 18-cv-4363, 2021 WL 1138123, at *2 (D.N.J. Mar. 24, 2021) (“Though McCarthy was decided twenty-five years ago, courts in this district continue to apply it to dismiss RICO claims.”) (citing cases); Minnesota by Ellison v. Sanofi-Aventis U.S. LLC, No. 18-14999, 2020 WL 2394155, at *8–9 (D.N.J. Mar. 31, 2020) (“Only the purchaser immediately downstream from the alleged [RICO

⁴ Both the Sixth and the Seventh Circuits have adopted the same stance on RICO standing and determined that the “indirect purchaser” rule bars end payors or indirect purchasers from pursuing RICO claims. See Trollinger v. Tyson Foods, Inc., 370 F.3d 602, 616 (6th Cir. 2004) (holding that plaintiffs who suffer derivative or “passed on” injuries lack standing to pursue RICO claims); Carter v. Berger, 777 F.2d 1173, 1177 (7th Cir. 1985) (holding that, under Illinois Brick, an end payor or indirect purchaser does not have standing to pursue RICO claims); see also In re Takata Airbag Prods. Lib. Litig., 15-md-2599, 2021 WL 908552, at *12 (S.D. Fl. Mar. 9, 2021) (recognizing that three Courts of Appeals have held that indirect purchasers cannot sue under RICO and predicting that the Eleventh Circuit would apply the direct purchaser rule to the RICO context).

violator] possesses standing to pursue an action.”); In re Insulin Pricing Litig., No. 17-cv-699, 2019 WL 643709, at *8 (D.N.J. Feb. 15, 2019) (reiterating McCarthy’s holding that “antitrust standing principles apply equally to allegations of RICO violations” and, thus, indirect purchasers were precluded from pursuing RICO violations, even when improper price inflation is passed along on a “dollar for dollar” basis); MSP Recovery Claims, Series, LLC v. Sanofi Aventis U.S. LLC, No. 18-cv-2211, 2019 WL 1418129, at *16 (D.N.J. Mar. 29, 2019) (finding, under McCarthy, that heightened coinsurance payments for insulin did not give RICO standing to plaintiff end payors because they failed to allege that they directly purchased insulin from defendants); see also In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132, 164–55 & n.55 (3d Cir. 2017) (favorably citing McCarthy’s application of the indirect purchaser rule to RICO standing); In re Zantac (Ranitidine) Prods. Liab. Litig., No. 20-md-2924, 2021 WL 2685640, at *7 (S.D. Fl. June 30, 2021) (reviewing nationwide case law and joining “prevailing view that the indirect purchaser rule applies to RICO claims”).

Bound by this clear Third Circuit precedent, I find that Plaintiffs here lack standing to pursue their RICO claims. Plaintiffs expressly allege that they are “end-payors” of Suboxone. (Humana Compl. ¶¶ 160 (“[T]he 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 Humana. Wholesalers and retailers passed on the inflated prices of Suboxone to Humana.”), 167; Centene Compl. ¶¶ 164 (“[T]he 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 Centene, WellCare, Fidelis, and Health Net.”), 168.) Indeed, Plaintiffs unequivocally admit that they did not directly purchase Suboxone from Defendants but rather reimbursed prescriptions for Suboxone that were already purchased. (Humana Compl. ¶¶ 192, 226,

238; Centene Compl. ¶¶ 198, 300, 342.) Accordingly, Plaintiffs have suffered only “passed on” injuries, thereby depriving them of standing to pursue their alleged RICO claims.

In an attempt to avoid the Third Circuit’s clear directives, Plaintiffs offer several arguments. First, Plaintiffs contend that McCarthy is no longer good law, having been effectively abrogated by more recent, binding Third Circuit jurisprudence permitting RICO claims to be brought by end-payors. In support, Plaintiffs rely on In re Avandia Mktg, Sales Practices & Prod. Liab. Litig., 804 F.3d 633 (3d Cir. 2015) and the Supreme Court case of Bridge v. Phoenix Bond & Indem. Co., 553 U.S. 639 (2008).

In Avandia, *supra*, the plaintiffs—third-party payors comprised of union health and welfare funds—alleged that a defendant drug manufacturer deliberately concealed the significant safety risks associated with the use of its drug and manipulated data and scientific data in order to increase sales. 804 F.3d at 636. The plaintiffs asserted that, in direct reliance on these misrepresentations made to them, they included the drug in their formularies⁵ and covered the drug at favorable rates. *Id.* The Third Circuit held that “[t]he conduct that allegedly caused plaintiffs’ injuries here is the same conduct forming the basis of the RICO scheme alleged in the complaint—the misrepresentation of the heart-related risks of taking Avandia that caused [third-party payors] and [pharmacy benefit managers] to place Avandia in the formulary.” *Id.* at 644. In turn, the Court concluded that such allegations were a sufficient basis on which the third-party payors could satisfy the proximate cause requirement of RICO and bring such claims against the drug manufacturer. *Id.* at 645.

⁵ A “formulary” is “[a] list of prescription drugs covered by a prescription drug plan or another insurance plan offering prescription drug benefits. Also called a drug list.” <https://www.healthcare.gov/glossary/formulary/>.

In Bridge, supra, bidders at a county's auctions of tax liens sued a competitor under RICO alleging that the competitor had engaged in a pattern of mail fraud by lying to the county about violating county's single simultaneous bidder rule. Id. at 644–45. The defendants argued that the plaintiffs had to show that they relied on the defendants' fraudulent misrepresentations, which they could not do because the alleged misrepresentations were made to the county, not to the plaintiffs. Id. at 648. The Supreme Court rejected this argument, finding that, under the RICO statute, "no showing of reliance is required to establish that a person has violated § 1962(c) by conducting the affairs of an enterprise through a pattern of racketeering activity consisting of acts of mail fraud." Id. at 649. It thus held that proximate causation element of a RICO claim did not necessitate first-party reliance on the alleged misrepresentations. Id.

In light of these holdings, Plaintiffs contend that they too relied on Indivior's misrepresentations and suffered economic harm as a direct result of the various conduct that is alleged to violate RICO. Accordingly, they posit that, as in Avandia, they have standing to pursue their RICO claims.

Plaintiffs' argument, however, conflates the distinct issues of (1) statutory standing under the indirect purchaser rule—addressed in McCarthy and its progeny—and (2) proximate causation as required to show RICO injury—addressed in Avandia and Bridge. The United States Court of Appeals for the Sixth Circuit, in Trollinger v. Tyson Foods, Inc., 370 F.3d 602 (6th Cir. 2004), discussed this distinction, explaining that "[s]tanding poses a threshold question involving constitutional, prudential and . . . statutory limitations on who may sue regardless of that person's claim. . . . Proximate cause poses a merits question involving common-law and prudential limitations on the consequences for which the law will hold a defendant accountable, regardless of the plaintiff's standing to sue." Id. at 612. The Sixth Circuit recognized that these concepts overlapped in the context of civil RICO claims, but were nonetheless distinct concepts with practical

significance. Id. at 613, 615. The Trollinger court emphasized that a plaintiff does not have standing to bring a RICO claim if the plaintiff suffers “derivative or passed-on injuries.” Id. at 614. It noted that “a RICO case with a derivative-injury problem [*i.e.*, direct purchaser versus end-payor] is better suited to dismissal on the pleadings than a RICO case with a traditional proximate-cause problem (*e.g.*, a weak or insubstantial causal link, a lack of foreseeability, or a speculative or illogical theory of damages).” Id. at 615. “[A] court often finds no need to look beyond the face of the complaint in order to determine that the plaintiff lacks standing because the injury was passed on by another party that had a more direct relationship with the defendant.” Id.

Courts within this Circuit have repeatedly recognized the distinction between concepts of standing under the indirect purchaser rule and proximate causation.⁶ Citing to McCarthy, these cases have held that both Avandia and Bridge addressed only the issue of proximate causation and did not touch on or undercut McCarthy’s conclusion that an indirect purchaser/end-payor lacks standing to pursue RICO claims. See, e.g., Hu, 2021 WL 1138123, at *3 (distinguishing Bridge and Avandia noting that they did not express disagreement with McCarthy but rather described proximate cause or separate RICO standing requirements without discussing the indirect purchaser rule); Rickman v. BMW of N. Am., No. 18-4363, 2020 WL 3468250, at *10 (D.N.J. June 25, 2020) (holding that plaintiffs, as indirect purchasers, did not have standing to pursue a RICO claim, and recognizing that Bridge and Avandia addressed distinct issues of proximate causation that had no

⁶ The McCarthy court recognized the distinction between these two concepts in the antitrust context. It remarked that standing deals whether a particular plaintiff who can trace an injury to a violation falls within the group of plaintiffs that Congress permitted to enforce the antitrust laws. Such a concept is a subject to “a bright line rule.” McCarthy, 80 F.3d at 851 n.14. By contrast, proximate causation is concerned with whether a particular plaintiff’s injury is too remote from an injury to warrant providing that plaintiff with a remedy. Id. The concept of proximate causation is “subtle and resists the use of hard -and-fast ‘black letter’ rules.” Id.

bearing on standing); In re Insulin, 2019 WL 643709, at *9–11 (declining to find that Bridge and Avandia preclude the application of the indirect purchaser rule to RICO claims).

Given this jurisprudence, Plaintiffs' contention that they reasonably relied upon and suffered harm as a direct result of Defendants' misrepresentations is insufficient to overcome their lack of standing to pursue RICO claims. While the Complaints have potentially alleged some reliance on Defendants' marketing materials in support of a proximate causation showing, Plaintiffs have not pled any facts to support that they are direct purchasers with standing to bring such RICO claims.

Plaintiffs' second argument contends that the allegations in their Complaints and those in Avandia are identical, meaning that to the extent the allegations in Avandia were sufficient to survive dismissal, Plaintiffs' claims must also be viable.

But, even assuming Avandia could be read to have overruled McCarthy, which it did not, the facts here are distinguishable. In Avandia, the plaintiffs were insurers who alleged RICO violations based on claims that they relied upon the manufacturer's misrepresentation and concealment of safety risks. The plaintiffs' alleged injury was based on their inclusion of the product at issue in their formulary decisions at favorable rates rather than covering the competitor's less expensive drugs. Id. at 636. In other words, the Avandia plaintiffs were not seeking recourse pursuant to payments made to third parties based on allegedly fraudulent prices set by a manufacturer or improperly inflated prices passed down to them through the distribution chain. Rather, the claimed damages in Avandia were based on favorable formulary placement resulting from direct reliance on misrepresentations of Avandia's heart-related risks. Id. at 644.

Repeatedly, other Courts of Appeals facing RICO claims by end payors in pharmaceutical marketing context have restricted Avandia to its facts and found, as a general rule, that representations to direct purchasers that affect the pricing of a drug do not support a claim by end payors. For example, in Sidney Hillman Health Ctr. of Rochester v. Abbott Labs., 873 F.3d 574

(7th Cir. 2017), the plaintiffs, two welfare benefit plans, brought RICO claims alleging that the defendant encouraged physicians and other intermediaries to use its drug for off-label purposes not approved by the FDA. Id. at 575. The plaintiffs alleged RICO injury because they paid for prescriptions filled for those off-label uses. Id. at 577. Distinguishing Avandia on its facts, the Seventh Circuit held that “representations made to physicians do not support a RICO claim by Payors, several levels removed in the causal sequence.” Id. at 578; see also UFCW Local 1776 v. Eli Lilly & Co., 620 F.3d 121 (2nd Cir. 2010) (finding that drug manufacturer’s alleged misrepresentations as to the efficacy and side effects of the drug, as a predicate RICO offense, was too attenuated to have required direct causal connection to the alleged excess prices that the third-party payors ultimately paid); accord United Food & Commercial Workers Health & Welfare Fund v. Amgen, Inc., 400 F. App’x 255 (9th Cir. 2010); Southeastern Laborers Health & Welfare Fund v. Bayer Corp., 444 F. App’x 401 (11th Cir. 2011).

Here, in alleging RICO injury, the Humana and Centene Complaints assert that Plaintiffs “suffered injuries when they reimbursed prescriptions for Suboxone that otherwise would not have been made and/or paid the higher prices that resulted from the illegal conduct.” (Humana Compl. ¶ 192; Centene Compl. ¶ 198.) Unlike in Avandia, the Humana and Centene Complaints do not clearly allege RICO injury resulting from Plaintiffs’ direct reliance on Defendants’ misrepresentations. Rather, these Complaints seek recourse for damages from artificially inflated prices paid by wholesalers and pharmacies before physicians prescribed Suboxone and consumers made their purchases from those intermediaries.⁷ Moreover, despite being able to precisely identify

⁷ (See Humana Compl. ¶ 162 (“[a]s a result of Defendants’ illegal conduct as alleged herein, Humana was compelled to pay, and did pay, artificially inflated prices for its Suboxone requirements. Humana paid prices for Suboxone that were substantially greater than the prices it would have paid absent the illegal conduct alleged herein.”); ¶ 163 (“Humana has sustained substantial losses and damage to its business and property in the form of overcharges.”); ¶ 192 (“Humana suffered [RICO] injuries when it reimbursed prescriptions for Suboxone that would not

various fraudulent communications sent through the mail and by wire, Plaintiffs identify no misrepresentations made to them upon which they acted. (Humana Compl. ¶¶ 55, 66–71, 91 125–131.) Plaintiffs boilerplate allegation within their RICO claims that “[f]alse representations were made to [Plaintiffs] for payment over the wires or by mail” (Humana Compl. ¶ 188) falls short of alleging facts that plausibly plead a claim under Rule 12(b)(6). And although the two Complaints each include a single allegation that Plaintiffs’ relied on Defendants’ statements and misrepresentations when including Suboxone film on their formularies, (Centene Compl. ¶ 213; Humana Compl. ¶ 207),⁸ those allegations⁹ do not contend, as in Avandia, that film was given a favorable rate on the formularies or that the inflated prices Plaintiffs paid for Suboxone were a direct result of the alleged misrepresentations. Stated simply, Plaintiffs here seek precisely what McCarthy precluded—to recover money spent on reimbursement of inflated Suboxone purchases passed downstream through the distribution chain, and not purchased directly from Defendants.¹⁰

have been made and/or paid the higher prices that resulted from the illegal conduct.”); see also Centene Compl. ¶¶ 166, 167, 198)

⁸ (See Humana Compl. ¶ 207 (“Humana reasonably relied on Indivior’s statements and misrepresentations—not knowing they were false statements or misrepresentations—and included Suboxone film on its formularies.”); Centene Compl. ¶ 213 (“Plaintiffs reasonably relied on Indivior’s statements and misrepresentations—not knowing they were false statements or misrepresentations—and included Suboxone film on their formularies. Plaintiffs rightfully relied on Indivior’s false statements and misrepresentations.”).)

⁹ Indeed, those allegations are included only as part of Plaintiffs’ cause of action for fraud and are not, under any plausible reading of the Complaints, at the heart of the RICO claims here.

¹⁰ See MSP Recovery Claims, Series LLC and MSPA Claims 1, LLC v. Abbott Labs., No. 10-cv-21607, 2021 WL 2177548, at *8 (D.N.J. May 28, 2021) (distinguishing Avandia and finding that mere allegation that plaintiffs included medical products on their formularies at favorable tier levels based on defendants’ fraudulent acts was insufficient to avoid indirect purchaser rule where actual injury alleged was for “inflated payments”).

Finally, Plaintiffs contend that McCarthy is not binding on district courts because the plaintiffs in McCarthy “conceded that if they lacked antitrust standing, they also lacked RICO standing” and instead argued that they were actually “direct purchasers.” McCarthy, 80 F.3d at 855. Plaintiffs reason that because McCarthy’s language regarding RICO standing was not necessary to the Court’s holding, it constitutes mere *dicta*.

The Third Circuit’s decision in McCarthy, however, spoke definitively on the fact that “[t]he precepts taught by Illinois Brick . . . apply to RICO claims, thereby denying RICO standing to indirect victims.” Id. at 855. Such a holding was crucial to the Court’s determination that if the plaintiffs were not “direct purchasers” then they did not have standing to pursue their RICO claims. See Romero v. Allstate Ins. Co., 1 F. Supp. 3d 319, 431–32 (E.D. Pa. 2014) (noting that *dicta* involves statements of law in the opinion “which could not logically be a major premise of the selected facts of the decision”).¹¹

Clear Third Circuit precedent holds that indirect purchasers of a product do not have standing to sue for artificially inflated prices. As Plaintiffs here are indirect purchasers of Suboxone alleging injury caused by downstream payments of inflated prices from the direct purchasers, their RICO claims must be dismissed. In turn, “if the pleadings do not state a substantive RICO claim upon which relief may be granted, then the conspiracy claim also fails.” Irish v. Ferguson, 970 F. Supp. 2d 317, 362 (M.D. Pa. 2013) (citing Kolar v. Preferred Real Estate Invs., Inc., 361 F. Appx. 354, 367 (3d Cir. 2010)). Accordingly, I will dismiss the RICO and RICO conspiracy claims with prejudice.

¹¹ Although I recognize that the United States District Court for the District of Kansas has suggested that McCarthy was wrongly decided, see In re EpiPen Mktg., Sales Practices & Antitrust Litig., 336 F. Supp. 3d 1256, 1324–25, 1324–25 (D. Kan. 2018), that disagreement is an insufficient basis on which I can disregard a precedential ruling from the Third Circuit. See Estate of Hake v. U.S., 234 F. Supp. 3d 626, 635 (M.D. Pa. 2017).

B. Remaining State Law Claims

Having dismissed the sole federal claims, Plaintiffs are left with a multitude of state law claims against the Individual Defendants. Defendants now urge that, upon dismissal of the RICO claims, the remaining claims should be dismissed for lack of subject matter jurisdiction. In response, Plaintiffs press that I should exercise supplemental jurisdiction pursuant to 28 U.S.C. § 1367.

District courts have supplemental jurisdiction over all other claims that are so related to claims within an action that are within original jurisdiction that they form part of the same case or controversy under Article III. 28 U.S.C. § 1367(a). Where a district has dismissed all claims over which it has original jurisdiction, it may decline to exercise supplemental jurisdiction. 28 U.S.C. § 1367(c)(3). “A district court’s decision whether to exercise that jurisdiction after dismissing every claim over which it had original jurisdiction is purely discretionary.” Carlsbad Tech., Inc. v. HIF Bio, Inc., 556 U.S. 635, 639 (2009). Although there is no bright line rule for determining whether a supplemental state law claim should be dismissed when the federal law claims have been eliminated before trial, the Supreme Court has emphasized that the district court should consider the balance of factors, *i.e.* judicial economy, convenience, fairness, and comity, in order to decide whether the case properly belongs in state court. Carnegie-Mellon Univ. v. Cohill, 484 U.S. 343, 350 (1988).

Plaintiffs posit that the relevant factors here weigh in favor of maintaining supplemental jurisdiction over the state law claims. They contend that they are putative members of the End-Payor Plaintiff class pending in the MDL. Plaintiffs further assert that many of the underlying facts raised in this litigation are familiar to this Court since that MDL has been pending here for more than seven years. Plaintiffs press that there is no potential inconvenience to the parties or concern of fairness by remaining in this Court because the parties here have all been involved in the MDL

in this Court for years, and that declining to exercise supplemental jurisdiction would result in significant judicial inefficiencies and the expenditure of many more judicial resources.

I disagree with Plaintiffs. While the factual background underlying these cases is almost identical to the one at issue in both the MDL case and the States Attorneys General case, the similarities stop there. Plaintiffs, through two separate Complaints, are pursuing entirely different theories of recovery that have not been fleshed out over the many years of discovery in the MDL cases. These theories will require that I apply the laws of various states, which would not only be cumbersome, but would reflect a lack of comity to the individual state courts who are adept at applying their own states' laws.

Finally, and not of minimal importance, the MDL case has been proceeding in this Court since 2013. Fact discovery has been completed, Daubert motions have been litigated, class certification has been granted, and summary judgment motions have been fully briefed and are ripe for consideration. Retaining supplemental jurisdiction over these state law claims based on the same underlying facts would require the Court and the parties to effectively hit the restart button on litigation. Considering the balance of factors, I decline to exercise supplemental jurisdiction over the remaining state law claims, and I will dismiss them without prejudice.¹²

¹² I note that Defendants RBG and Reckitt UK also move to dismiss the RICO claims against them but urge me to retain supplemental jurisdiction to dismiss the state law claims against them. They premise their argument on the sole assumption that the state law claims against them are meritless and should be dismissed. As such, they argue that they should not have to brief this issue a second time in state court.

RBG and Reckitt UK's argument, however, fails to consider the possible scenario that some of these claims may survive Rule 12(b)(6) scrutiny and would then have to be litigated here. Accordingly, I do not find the possibility that RBG and Reckitt UK will have to rebrief these issues in state court to weigh in favor of retaining supplemental jurisdiction.

III. MOTIONS TO DISMISS BY REMAINING DEFENDANTS

The remaining Defendants in this case—Indivior plc, RBG, Reckitt UK, and Aquestive—each bring separate Motions to Dismiss.

Defendant Indivior plc joins the arguments made by Indivior and Indivior Solutions and separately moves to dismiss all claims against it because it did not come into existence as a corporation until after the alleged improper conduct in this case.

Defendants RBG and Reckitt UK also incorporate by reference the arguments by Indivior and Indivior Solutions. They further contend that all claims against them are time barred and/or improperly pled against them.

Finally, Defendant Aquestive likewise joins the arguments made by Indivior and Indivior Solutions with respect to the RICO conspiracy claim against it. Aquestive also separately seeks to dismiss all claims against them as both time-barred and improperly pled.

Having already found that Plaintiffs do not have standing to bring RICO claims against Indivior and Indivior Solutions under the indirect purchaser rule, I find that the RICO/RICO conspiracy claims against Indivior Solutions, RBG, Reckitt UK, and Aquestive must also fail. Having declined to exercise supplemental jurisdiction over the remaining state law claims against Indivior and Indivior Solutions, I will likewise dismiss all of these claims against the other Defendants.

IV. CONCLUSION

For all of the foregoing reasons, I will grant all of the Motions to Dismiss and dismiss both the Humana and Centene Complaints in their entirety. An appropriate Order follows.