UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

HUMANA, INC.,	)	
	)	
Plaintiff,	)	Case No. 6:21-cv-00072-CEM-DCI
	)	
v.	)	DISPOSITIVE MOTION
	)	
TEVA PHARMACEUTICALS USA INC., TEVA NEUROSCIENCE, INC., ADVANCED CARE SCRIPTS, INC., and ASSISTRX, Inc.,	)	
	)	
Defendants.	)	

MOTION OF DEFENDANT ADVANCED CARE SCRIPTS, INC. TO DISMISS THE COMPLANT PURSUANT TO F.R.C.P. 9(B) AND 12(B)(6) AND INCORPORATED MEMORANDUM IN SUPPORT

Defendant Advanced Care Scripts, Inc. ("ACS") hereby moves, pursuant to Federal Rules of Civil Procedure ("F.R.C.P.") 9(b) and 12(b)(6), to dismiss the Complaint (ECF No. 1) filed by Plaintiff Humana, Inc. ("Humana").

I. PRELIMINARY STATEMENT

In this lawsuit, Humana alleges that Teva, which manufactured Copaxone, a drug used to treat multiple sclerosis ("MS"), orchestrated a fraudulent scheme to increase its profits from the sale of Copaxone by subsidizing copay obligations for Medicare Part D patients. As alleged, ACS and later, Defendant AssistRx, two specialty pharmacies that filled prescriptions for Copaxone, arranged for patients to receive copay assistance from two charities, the Chronic Disease Foundation, Inc.

("CDF") and the Assistance Fund, Inc. ("TAF") (collectively, the "Foundations"), and Teva then used information from ACS and AssistRx to time donations to the Foundations so that Teva's funds would only cover copays for Copaxone patients. Humana now alleges that Defendants' conduct violated RICO and approximately three dozen state fraud statutes. Although the Complaint does not lack for soundbites, it is patently deficient under Rules 9(b) and 12(b)(6) and, therefore, cannot survive this motion to dismiss.

First, the claims against ACS, which exited the alleged scheme in 2015, are time-barred because: (i) national press reports in 2005 and 2013 highlighted concerns about drug manufacturers' use of patient assistance programs ("PAPs") and charities, including Teva and CDF; (ii) Humana's own records showed that from 2011 to 2015 its specialty pharmacy received more than $1.6 million in copay funding from CDF and TAF for Copaxone prescriptions, and that Copaxone's price increased by about 500% during that time; and (iii) guidance issued by the Department of Health and Human Services, Office of Inspector General ("OIG") in 2014 left no doubt that insurers like Humana had an obligation to conduct due diligence with regard to PAPs. This so-called scheme, therefore, was open and notorious by 2014, giving Humana until 2018 to file this lawsuit. This Complaint, filed in 2021, comes too late.

Second, Humana's theory for why it suffered a RICO injury was roundly rejected by the Eleventh Circuit in Ironworkers.[1] The court there upheld the dismissal

[1] See Ironworkers Loc. Union 68 v. AstraZeneca Pharm., LP, 634 F.3d 1352 (11th Cir. 2011).

of fraud-based RICO claims alleging that a drug company fraudulently induced physicians to prescribe a drug for off-label use, thereby increasing the price of the drug to the plaintiffs' detriment. In its affirmance, the court held that plaintiffs' allegation that they had merely paid for more expensive drugs did not allege a cognizable RICO injury. Instead, the court explained, "to assert an economic injury, the plaintiff must allege that her payments were the product of a physician's medically unnecessary or inappropriate prescriptions." Humana makes no such claim, nor could they.

Third, Humana's vague allegations in support of its RICO and state law fraud claims that ACS made misrepresentations to Humana do not even come close to meeting the particularity required under F.R.C.P. 9(b). The allegations of fraud also fail under the F.R.C.P. 12(b)(6) plausibility standard.

II. ARGUMENT

A. Humana's Claims Against ACS are Time-Barred

1. Humana's RICO Claims Are Untimely and Must be Dismissed

The statute of limitations for a federal civil RICO action is four years, see Agency Holding Corp. v. Malley-Duff & Assocs., Inc., 483 U.S. 143, 156 (1987), and begins to run when the injury was or should have been discovered, "regardless of whether or when the injury is discovered to be part of a pattern of racketeering." Lehman v. Lucom, 727 F.3d 1326, 1330 (11th Cir. 2013) (internal citation and quotation marks omitted). The Supreme Court has "been at pains to explain that discovery of the injury, not discovery of the other elements of a claim, is what starts the clock." Rotella v. Wood, 528 U.S. 549, 555 (2000). Because Humana had notice

of its alleged injury by 2014, at the latest, the limitations period for the RICO and RICO conspiracy claims (Counts I and II), expired roughly three years before Humana filed the Complaint. Those claims are therefore time-barred and must be dismissed.[2]

At the heart of Humana's RICO claims are allegations that Teva "engineered" a scheme to violate the Anti-Kickback Statute ("AKS"). As alleged: (i) Teva "routed" to ACS patients who had Medicare Part D copay obligations for their Copaxone prescriptions; (ii) ACS arranged for those patients to obtain copay assistance from the Foundations; and (iii) Teva used data from ACS to donate funds to the Foundations in a manner that would guarantee those funds would subsidize copays only for Copaxone patients (¶¶ 5, 50-53, 82).[3] Humana alleges that Teva induced patients to take Copaxone by subsidizing patients' copays, and that Teva's donations were kickbacks in violation of the AKS (¶¶ 4, 6-7, 31-32).

Critically, though, judicially noticeable sources establish that the conduct that Humana claims is a blatant AKS violation—Teva donating to copay assistance charities to increase Teva's drug sales and profits—has long been a matter of public record.[4] Indeed, a front-page article published in the *Wall Street Journal* in 2005 drew

[2] A court can dismiss a claim on a F.R.C.P. 12(b)(6) motion where it is apparent from the face of the complaint that the plaintiff's claim is time-barred. See, e.g., Bruce v. U.S. Bank Nat'l Ass'n, 770 F. App'x 960, 965 (11th Cir. 2019).

[3] Unless otherwise indicated, citations preceded only by "¶" refer to the Complaint (ECF No. 1.)

[4] A court is permitted to take judicial notice "at any stage of the proceeding," Federal Rule of Evidence 201(d), including on a motion to dismiss, see Universal Express, Inc. v. U.S. S.E.C., 177 F. App'x 52, 53 (11th Cir. 2006); Duldulao v. La Creperia Cafe, Inc., No. 8:11-CV-1413-T-23TBM, 2011 WL 6840585, at *1 n.1 (M.D. Fla. Dec. 29, 2011). Courts are permitted to take judicial notice of newspapers and other publications for the purpose of determining the statements contained in the publication. See, e.g., U.S. ex rel. Osheroff v. Humana Inc., 776 F.3d 805, 811 n.4 (11th Cir. 2015). It is also proper for courts to take judicial notice of government documents published in the Federal

attention to criticisms that, by subsidizing copays for patients, drug companies were "shifting" the price of expensive medicines "to the patients' insurers" and "appropriat[ing] most of the gain" from the donations.[5] As is particularly relevant here, the article highlighted Teva selling an MS drug costing $18,000 per year. A Teva executive, told the *Journal* that Teva did not explicitly calculate the profits from its donations, "but from a common-sense perspective, you can get there." Thus, more than 15 years ago, a national newspaper reported that Teva saw donations to copay assistance charities as a means to profit.

CDF, now dubbed a "co-conspirator" by Humana, drew particular public scrutiny. The Complaint states that "[o]ver 2,800 claims for Copaxone prescriptions filled directly through Humana's own specialty pharmacy received more than $1.6 million in copayment funding through either CDF or TAF between 2011 and 2015" (¶73). Based on its own records, therefore, Humana would have clearly known from 2011 onwards that CDF was providing copay assistance to Copaxone patients. Furthermore, as noted in the Complaint, in 2013, the President of CDF resigned and the charity's entire board was replaced following an internal investigation conducted by an outside law firm (¶49). In October of 2013, an article in *Barron's* reported that: from 2009 to 2012, CDF received more than $900 million in donations, "mostly from

Register. See Longo v. Seminole Indian Casino-Immokalee, 813 F.3d 1348, 1349 n.2 (11th Cir. 2016) (citing 44 U.S.C. § 1507).

[5] See April 2, 2021 Declaration of Mariellen Dugan ("Dugan Decl."), Ex. A (Geeta Anand, *Through Charities, Drug Makers Help People – and Themselves*, WALL ST. J. at A1 (Dec. 1, 2005), available at https://www.wsj.com/articles/SB113339802749110822).

drug companies;" CDF's president and founder had become a "rich man" as a result; and, given the nature of the relationship between CDF and the drug manufacturer Questcor, it was a "fair question" as to whether CDF "abided" to commitments that drug company donors would not "influence the charity's choice of targeted diseases and a drug maker's contributions weren't earmarked for its own products."[6]

In December 2013, the *New York Times* reported that CDF was in "turmoil" following an internal investigation resulting in the president's resignation and the replacement of CDF's entire board, and that CDF would implement new policies that could "eliminate co-payment assistance for certain drugs."[7] The *Times* explained that it had "long been an open secret" that the "bulk of the contributions to these charities come from the pharmaceutical companies. The foundations not only help hundreds of thousands of patients a year, they also raise drug company sales and profits." Drug makers sought clarity from the government regarding the legality of their donations to PAPs, which were also the subject of litigation brought by health insurers.[8]

In May of 2014, OIG supplemented its 2005 guidance concerning PAPs based on experience it had gained in the years since and the industry "practices and trends"

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[6] See Dugan Decl., Ex. B (Bill Alpert, *Too Close for Comfort?* BARRON'S (Oct. 19, 2013), available at https://www.barrons.com/articles/SB50001424053111904462504579137163650125276).
[7] See Dugan Decl., Ex. C (Andrew Pollack, *Drug Maker's Donations to Co-Pay Charity Face Scrutiny*, N.Y. TIMES at B1 (Dec. 18, 2013), available at https://www.nytimes.com/2013/12/19/business/shake-up-at-big-co-pay-fund-raises-scrutiny-on-similar-charities.html).
[8] See Dugan Decl., Ex. D (David Howard, Ph.D., *Drug Companies' Patient Assistance Programs – Helping Patients or Profits?*, 371 N. ENGL. J. MED. 97 (2014), available at https://www.nejm.org/doi/full/10.1056/NEJMp1401658).

it had observed.[9] At the outset, OIG stressed that many PAPs "present a risk of fraud, waste, and abuse with respect to Medicare[,] and it highlighted "problematic features of PAPs with respect to the [AKS]." Dugan Decl., Ex. F at 31,120-21. To that end, OIG noted its concern regarding PAPs "establishing narrowly designed disease funds and covering a limited number of drugs within those funds" and seeking to cover copays only for "expensive or specialty drugs." Id. at 31,121-22. In OIG's view, both practices could result in "steering" patients to certain drugs and increase the likelihood that donors could use PAPs "as improper conduits to provide a subsidy to patients who use the donors' own products," which would potentially increase federal health care costs when cheaper alternative drugs were available and "encourage manufacturers to increase prices[.]" Id. at 31,122. OIG pointed out that actions by donors to "correlate" funding of PAPs with "support for their own products" may indicate the donor's intent to "channel its financial support to copayment of its own products," implicating the AKS. Id. at 31,123. In closing, OIG warned that "Independent Charity PAPs raise serious risks of fraud, waste, and abuse if they are not sufficiently independent from donors." Id.

Coinciding with these public reports concerning copay assistance fraud was a 500% increase in the price of Copaxone from "$18,000 per year to more than $90,000 per year," a rate that significantly exceeded inflation (¶¶ 7, 59). The Complaint also

[9] See Dugan Decl., Ex. E (Publication of Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623 (Nov. 22, 2005)); Ex. F (Supplemental Special Advisory Bulletin: Independent Charity Assistance Programs, 79 Fed. Reg. 31,120, 31,123 (May 30, 2014)).

alleges, no doubt from Humana's own records, that Humana's Copaxone expenditures more than quadrupled between 2008 and 2014, from less than $50 million per year to more than $200 million per year (¶70). Humana claims it was injured by "overpayments for Copaxone," either because it covered too many Copaxone prescriptions or paid too much for each prescription (¶¶ 3, 71). Humana was obviously aware that its expenditures on Copaxone were increasing sharply year-over-year.

Clearly, based upon publicly available information in 2014, Humana would have known that: (i) Teva sought to profit from its donations to charities providing copay assistance to patients who took Teva's expensive MS drugs; (ii) the entire leadership of CDF, one of the charities providing copay assistance to Copaxone patients insured by Humana, was replaced because of improprieties related to donations from drug manufacturers; and (iii) OIG had warned of the dangers of fraud associated with patient assistance foundations and the risk that drug manufacturers, such as Teva, could use donations to charities to subsidize copays for their own products and thereby increase profits and medication costs. Humana, therefore, should have discovered its alleged injury as early as 2005, but no later than 2014. The RICO statute of limitations, therefore, expired in 2018, and Humana's RICO claims, raised for the first time in 2021, should be dismissed as untimely. See, e.g., see also Youngblood-W. v. Aflac Inc., 796 F. App'x 985, 991 (11th Cir. 2019) (affirming dismissal of complaint as untimely where the plaintiff "had long since known of or could have discovered her injuries" and "failed to act on the information she

possessed"); Lehman, 727 F.3d at 1332-33 (affirming dismissal of RICO claim where the plaintiff knew of his injuries at least four years prior to his RICO claim).

Given the nature of the allegations, there would be no basis here to apply the "separate accrual rule" and conclude that the statute of limitations reset on the basis of conduct after 2014. Once the limitations period has started to run, a later predicate act does not cause it to restart. Klehr v. A.O. Smith Corp., 521 U.S. 179, 187-90 (1997). As the Eleventh Circuit has explained, under the separate accrual rule, "if a new RICO predicate act gives rise to a new and independent injury, the statute of limitations clock will start over for the damages caused by the new act." Lehman, 727 F.3d at 1331. However, when an injury is a "'continuation of [an] initial injury,' it 'is not *new and independent*.'" Id. (internal citation omitted) (emphasis in original). In this case, the alleged injury to Humana—overpayment for Copaxone prescriptions—was the same throughout rather than being new and independent. See Ward v. Dickinson Fin. Corp. II, No. 7:14-CV-8 HL, 2015 WL 1020151, at *11 (M.D. Ga. Mar. 9, 2015).

Even assuming that the separate accrual rule could be properly applied here, that would not bring Humana's claims against ACS within the statute of limitations. According to the Complaint, ACS's role in the alleged RICO scheme ended in 2015 when AssistRx "took over the role of ACS" (¶¶24, 62). If the statute of limitations clock started over because of RICO predicate acts by ACS in 2015 giving rise to a new and independent injury to Humana, then Humana had until the end of 2019 to bring its RICO claim. As Humana did not meet that deadline, its present RICO claims are barred by the four-year statute of limitations.

Humana contends that "fraudulent concealment" prevented it from discovering Defendants' conduct until the Department of Justice "brought these acts to light" through investigations, actions, or settlements, the first of which was in November of 2019 (¶¶9, 75). Humana's cursory allegations of fraudulent concealment are insufficient to toll the statute of limitations. First, Humana cannot establish fraudulent concealment based on its generalized allegations that Teva "concealed its arrangements with CDF and TAF," that CDF and TAF "took steps to disguise the source of funds they received," and that Teva and ACS certified that they were complying with federal law (¶¶ 32, 74). See Pocahontas Supreme Coal Co. v. Bethlehem Steel Corp., 828 F.2d 211, 218-19 (4th Cir. 1987) ("To permit a claim of fraudulent concealment to rest on no more than an alleged failure to own up to illegal conduct upon this sort of timid inquiry would effectively nullify the statute of limitations in these cases."); Speier-Roche v. Volksw Agen Grp. of Am. Inc., No. 14-20107-CIV, 2014 WL 1745050, at *7 (S.D. Fla. Apr. 30, 2014) (under Florida law, plaintiff seeking to rely on fraudulent concealment to toll statute of limitations had to allege more than "mere 'nondisclosure'"). In addition, the time at which the Department of Justice announced its actions does not control when Humana's injury occurred. Cf. Curtis Inv. Co., LLC v. Bayerische Hypo-Und Vereinsbank, No. 1:06-CV-2752WSD, 2007 WL 4564133, at *11 (N.D. Ga. Dec. 20, 2007) ("The fact that the IRS did not discover [plaintiff's] tax liability until 2005 does not affect the date on which the injury occurred, and does not toll the limitations period"). Additionally, the allegations relating to "fraudulent concealment" fail because the Complaint is

silent as to when and how Humana discovered that it was allegedly injured. See Hall v. Burger King Corp., 912 F. Supp. 1509, 1536 (S.D. Fla. 1995) ("a plaintiff seeking to avoid the statute of limitations by alleging 'fraudulent concealment' must make 'distinct averments as to the time when the fraud, mistake, concealment or misrepresentation was discovered'") (internal citation omitted). Nowhere in the Complaint does Humana allege these facts. Furthermore, Humana cannot merely rely upon the fraudulent conduct alleged as RICO predicates here to save its claims from the statute of limitations. See Pacific Harbor Capital, Inc. v. Barnett Bank, N.A., 252 F.3d 1246, 1251-52 (11th Cir. 2001).

Another flaw with Humana's fraudulent concealment allegations is that the Complaint is devoid of any facts showing due diligence by Humana. See Hill v. Texaco, Inc., 825 F.2d 333, 335 (11th Cir. 1987) (a plaintiff relying on the doctrine of fraudulent concealment must show "that he exercised diligence to discover his cause of action within the limitations period"). Humana alleges that the pattern of racketeering conduct began in "at least late 2006" (¶79), but it did not file the Complaint until almost 15 years had passed. In fact, the Complaint indicates that, in spite of Humana's rapidly increasing expenditures on Copaxone and the public reports concerning copay assistance fraud and CDF, in particular, Humana did nothing until 2021. If, as Humana seemingly contends, the statute limitations did not start to run until November of 2019, then Humana could bring suit up until 2023, approximately seventeen years after the first alleged predicate act. The Eleventh Circuit has previously remarked that a gap of twelve years between the first RICO predicate act

and the filing of a complaint was "too long for a RICO suit to hang in the air." Pac. Harbor Cap., 252 F.3d at 1252. The gap here is even larger and should not be excused. The prospect that Humana could have recovered triple damages by proving its RICO claims should have been more than enough incentive for Humana to investigate whether its increasing expenditures on Copaxone were in any way connected to fraud. See id. (the reward of triple damages for a RICO plaintiff is "meant to stimulate its vigilance as a private attorney general").

2. Humana's State Law Claims are Untimely

Humana alleges that ACS committed fraud (Count VII), conspired to commit fraud (Count VIII), and that it violated more than 30 different state statutes prohibiting unfair competition (Count III), consumer fraud (Count IV), and insurance fraud (Count V). Humana bases these claims on the same allegations as its RICO claims. Because Humana was on notice of facts supporting these claims by 2014, at the latest, they are likewise barred by the applicable statutes of limitations set forth in the chart incorporated into this memorandum.[10] Humana's tortious interference with contract and unjust enrichment claims are similarly time-barred. See, e.g., ERMC LTD v. Town of Redington Shores, No. 8:19-CV-688-T-60AAS, 2020 WL 1974224, at *3 (M.D. Fla. Apr. 24, 2020) (tortious interference has four-year statute of limitations and "delayed discovery doctrine" does not apply); Flatirons Bank v. Alan W. Steinberg

[10] To the extent that any of Humana's claims under state law have six-year statutes of limitations that did not begin to run when Humana could have reasonably discovered the alleged fraud, which was before 2015, those claims must be dismissed for failure to state a claim under F.R.C.P. 9(b) and 12(b)(6).

Ltd. P'ship, 233 So. 3d 1207, 1213 (Fla. 3d DCA 2017) (unjust enrichment has four-year statute of limitations and "delayed discovery doctrine" does not apply").[11]

B. Humana's Complaint Should be Dismissed for Failure to State a Claim

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual context that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. at 663. A plaintiff's "[f]actual allegations must be enough to raise a right to relief above the speculative level." Twombly, 550 U.S. at 555. If plaintiffs have not "nudged their claims across the line from conceivable to plausible, their complaint must be dismissed." Id. at 570.

For a RICO claim to survive a motion to dismiss, the plaintiff "'must allege facts sufficient to support each of the statutory elements for at least two of the pleaded predicate acts.'" Rogers v. Nacchio, 241 F. App'x 602, 607 (11th Cir. 2007) (internal citation omitted). Moreover, civil RICO cases, "which are essentially a breed of fraud claims, must be pled with an increased level of specificity" pursuant to F.R.C.P. 9(b). Ambrosia Coal & Constr. Co. v. Pages Morales, 482 F.3d 1309, 1316 (11th Cir. 2007).

1. Humana's RICO Claims Should be Dismissed

a. Humana Has Not Plausibly Alleged a RICO Injury

[11] See Am. United Life Ins. Co. v. Martinez, 480 F.3d 1043, 1059 (11th Cir. 2007) ("Federal courts adjudicating state law claims apply the substantive law of the state where they render decisions.").

To prove a RICO violation under 18 U.S.C. § 1962(c), a plaintiff must show: (1) conduct; (2) of an enterprise; (3) through a pattern; (4) of racketeering activities. See Sedima, S.P.R.L. v. Imrex Co., Inc., 473 U.S. 479, 496 (1985). A civil RICO plaintiff must additionally establish that "the defendant committed at least two predicate acts proximately causing the alleged injury to his business or property." Maiz v. Virani, 253 F.3d 641, 671 (11th Cir. 2001); see also 18 U.S.C. § 1964(c). This requires the plaintiff do more than simply allege "'an act of racketeering occurred and that he lost money.'" Maiz, 253 F.3d at 672 (internal citation omitted). Instead, a plaintiff must prove that the defendant's RICO violation was both the "but for" and the proximate cause of plaintiff's injury, that is, "whether the alleged violation led directly to the plaintiff's injury." Se. Laborers Health & Welfare Fund v. Bayer Corp., 444 F. App'x 401, 409 (11th Cir. 2011) (internal citation omitted).

Here, the facts alleged do not suggest that Humana suffered economic injury caused by ACS in violation of the RICO statute. Humana's claimed economic injury was its increased expenditures on, or "overpayments" for, Copaxone (¶¶3, 72). Humana alleges that, as a result of Teva's copay assistance through the Foundations, patients took Copaxone instead of "cheaper alternatives" and filled Copaxone prescriptions they would have forgone if required to make copays themselves (¶¶1, 39, 71). This is rank speculation on Humana's part. It is not a plausible allegation of causation. Despite claiming as damages an estimated $1 billion worth of Copaxone purchased by Humana between 2006 and 2018, including the $500 million claimed to have been purchased from ACS up until 2015 (¶¶24, 72, 79), Humana has not alleged

that any patient was prescribed Copaxone when the drug was medically unnecessary or was not, in the doctor's opinion, the best available treatment for the patient.

Underscoring that Humana's allegations of economic injury caused by the copay assistance are simply speculation is that Humana claims that "cheaper alternatives" were available for the MS patients it insured who took Copaxone (¶1), but the Complaint does not identify, or even provide a basis to infer the existence of, any other MS treatment which was (i) as safe, suitable, and effective for MS patients as Copaxone, (ii) available to the Humana insureds during the time period at issue in the Complaint, and (iii) actually cheaper than Copaxone for Humana or the patients.

Ironworkers, 634 F.3d at 1352, makes plain that Humana has not plausibly alleged causation. In that case, the Eleventh Circuit affirmed dismissal of RICO and fraud-based claims brought by health insurers alleging that AstraZeneca fraudulently induced physicians to prescribe Seroquel for off-label uses, which caused the insurers to pay for medically unnecessary prescriptions or to unnecessarily pay more for Seroquel than alternative drugs. Id. at 1357-58, 1360. The court concluded that the insurers had not pled cognizable RICO injury, and that "in the context of prescription drug purchases, the fact that the payer merely paid for more expensive drugs does not suffice." Id. at 1360. Instead, the Eleventh Circuit explained, "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." Id. at 1363.

With respect to the insurers, the Ironworkers court determined that, "under the terms of their insurance policies, [they] 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." Id. at 1360. Given that exposure, a "rational insurer" would have charged higher premiums to enrollees than if its policies offered less extensive prescription coverage, and those premiums would compensate the insurer for the increased number of prescription payments, including "payments for medically unnecessary or inappropriate prescriptions." Id. Because the insurers failed to plead facts suggesting that they established premiums "in a manner distinct from this conventional understanding," the court concluded that the insurers' claims had to be dismissed for a failure to "allege plausibly" that AstraZeneca's false representations caused them economic injury. Id.

The same deficiencies are present here. First, Humana has not alleged that it made a single payment for Copaxone that was the result of a doctor's medically unnecessary or inappropriate prescription. See id. at 1363. Humana also failed to allege facts to suggest that it established premiums in a non-conventional manner such that it did not address the risk of increasing numbers of payments for Copaxone prescriptions by increasing the premiums charged to its customers. See id. at 1360. The Complaint notes that the premiums for Humana's Part D plans are split between the individual insureds and Medicare funds using taxpayer money (¶26). Assuming that Humana is a "rational insurer," it would have simply increased the premium charges to those two groups to address its increased costs for Copaxone.

At the same time, the independent decisions by doctors to prescribe Copaxone as treatment for MS breaks the chain of causation necessary to demonstrate a RICO

violation. See, e.g., Sidney Hillman Health Ctr. of Rochester v. Abbott Lab'ys & Abbvie Inc., 192 F. Supp. 3d 963, 971 (N.D. Ill. 2016) ("[I]ntervening events between the alleged misrepresentations and the Funds' alleged overpayments for Depakote—doctors' independent medical decisions to prescribe Depakote over other medications and patients' decisions to fill those prescriptions, for example—make the causal chain too attenuated to establish the required proximate causation."), aff'd sub nom. Sidney Hillman Health Ctr. of Rochester v. Abbott Lab'ys, 873 F.3d 574 (7th Cir. 2017); Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi–Aventis U.S. LLP, 20 F.Supp.3d 305, 323, 327 (E.D.N.Y.2014) (finding chain of causation in RICO case was "interrupted" by the prescribing decisions of physicians, which are based on such factors as "the patient's diagnosis, past and current medications being taken by the patient, the physician's (and the patient's) experience with a particular antibiotic, and the physician's knowledge of the side effects of the antibiotics"), aff'd, 806 F.3d 71 (2d Cir. 2015).[12]

b. The "Racketeering Activity" Allegations are Deficient

[12] The general nature of the allegations here mean that, even if Humana could prove its claims, assessing damages would be an almost impossible task. The court would have to inquire into a vast number of individual prescriptions and the associated interactions between the patient and doctor to determine whether there was an "overpayment" caused by allegedly improper copay assistance or whether the patient filled a Copaxone prescription in reliance on the doctor's independent medical judgment. This is the "type of speculative damages analysis the direct proximate cause requirement is intended to prevent." In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig., No. 3:09-CV-20071-DRH, 2010 WL 3119499, at *7 (S.D. Ill. Aug. 5, 2010).

Even the most cursory review of the Complaint reveals that beneath the noisy rhetoric claiming a billion-dollar fraud that lasted for more than a decade, Humana's allegations are deficient in several critical respects.

A pattern of racketeering activity requires at least two predicate acts, each of which must be a violation of the state or federal laws identified in 18 U.S.C. § 1961(1). Crawford's Auto Ctr., Inc. v. State Farm Mut. Auto. Ins. Co., 945 F.3d 1150, 1158 (11th Cir. 2019). Here, Humana alleges that Defendants engaged in mail fraud under 18 U.S.C. § 1341, wire fraud under 18 U.S.C. § 1343, and "use of interstate facilities to conduct unlawful activity" in violation of 18 U.S.C. § 1952 (¶¶ 83-86). "Mail and wire fraud are analytically identical save for the method of execution." United States v. Bradley, 644 F.3d 1213, 1238 (11th Cir. 2011). Both crimes require that a person: "(1) intentionally participates in a scheme or artifice to defraud another of money or property, and (2) uses or 'causes' the use of the mails or wires for the purpose of executing the scheme or artifice." Id. (internal citation and quotation marks omitted).

Where RICO cases allege predicate acts of mail and wire fraud, the plaintiff must satisfy the Twombly and Iqbal plausibility standard, as well as Rule 9(b)'s heightened requirements. Am. Dental Ass'n v. Cigna Corp., 605 F.3d 1283, 1291 (11th Cir. 2010). The plaintiff must thus allege "(1) 'precisely what statements were made in what documents . . . or what omissions were made;' (2) 'the time and place of each such statement and the person responsible for making (or, in the case of omissions, not making)' each statement; (3) 'the content of such statements and the manner in which they misled the plaintiff;' and (4) 'what the defendants obtained as a

consequence of the fraud.'" Crawford's Auto Center, Inc., 945 F.3d at 1159 (internal citation omitted). Humana's Complaint is fatally flawed when compared with this rigorous standard.

Humana alleges that Defendants made misrepresentations when they certified that they were in compliance with federal and state law, including the AKS and False Claims Act, and that Defendants omitted to tell Humana (presumably in such certifications) that they were inducing Medicare patients to take Teva's drug by subsidizing copays. Nowhere in the Complaint, however, does Humana refer to a single one of these certifications. Similarly, Humana broadly alleges that Teva used the mail and wires to: (i) communicate with ACS, AssistRx, and the Foundations; (ii) submit more than 140,000 thousand reimbursement requests for Copaxone to Humana; and (iii) receive payments and make contributions. See (¶¶30-32, 67, 83). Again, Humana fails to aver to even one such communication, reimbursement request, payment or contribution. Instead, Exhibit A to the Complaint purports to provide "examples" of the fraud on Humana (¶83). However, Exhibit A identifies Copaxone prescriptions filled through Humana's specialty pharmacy, **not ACS** (¶73). Remarkably, Humana fails to identify a single prescription filled by ACS.

Humana has utterly failed to allege "precisely what statements were made in what documents," "the time and place" of each false statement, "the person responsible for making it," or the specific contents of the alleged false statements. See Crawford's Auto Center, Inc., 945 F.3d at 1159. Having failed to identify a single specific false statement by ACS, Humana's RICO counts must be dismissed. Id; see,

e.g., Brooks v. Blue Cross & Blue Shield of Fla., Inc., 116 F.3d 1364, 1381 (11th Cir. 1997) (RICO claims alleging mail and wire fraud as predicate acts were subject to dismissal where the complaint "fail[ed] to set forth the time, place, and manner in which any specific predicate act occurred"); Bray & Gillespie Mgmt. LLC v. Lexington Ins. Co., 527 F. Supp. 2d 1355, 1363 (M.D. Fla. 2007) (dismissing civil RICO claim where the plaintiff failed to allege the precise misrepresentations made, or the time and place of the misrepresentations, or the person responsible, and instead "assert[ed] a series of general allegations which claim that Defendants engaged multiple instances of mail and wire fraud").

Moreover, the Complaint is entirely devoid of allegations that Defendants violated the Travel Act, 18 U.S.C. § 1952. But, if Humana contends that same conduct that constituted mail and wire fraud also violated the Travel Act, then the allegation would suffer from the deficiencies discussed above. In any event, the commission of a single predicate act is insufficient for liability under RICO. Further, because Humana failed to plead sufficient facts alleging a RICO violation, the RICO conspiracy claim must also be dismissed. See Rogers, 241 F. App'x at 609 ("where a plaintiff fails to state a RICO claim and the conspiracy count does not contain additional allegations, the conspiracy claim necessarily fails").

3. Humana's State Law Fraud Claims Fraud Should be Dismissed

Humana's claims, in Counts III through V, VII and VIII, alleging various types of fraud, should also be dismissed. First, Humana's fraud claims are deficient under F.R.C.P. 9(b) because Humana has not adequately identified a single false

representation made by ACS. See, e.g., In re Horizon Organic Milk Plus DHA Omega-3 Mktg. & Sales Prac. Litig., 955 F. Supp. 2d 1311, 1323 n.8 (S.D. Fla. 2013) ("most courts" recognize that Rule 9(b) applies to claims brought under states' consumer fraud statutes). And, as in Ironworkers, 634 F.3d at 1361-69, Humana has not alleged that its payments were "the product of a physician's medically unnecessary or inappropriate prescriptions" and thus has failed to allege facts to plausibly suggest it suffered economic injury caused by false representations by ACS.

Beyond that, Humana's state fraud claims do not even satisfy the Twombly standard. Humana catalogues more than 30 statutes it claims were violated by Defendants, without differentiating among the Defendants in any way or elaborating on how the alleged conduct would satisfy the different elements of those statutes. Because the Complaint provides no reasonable basis to infer that ACS is liable for violating any of these laws, the state law fraud claims must be dismissed. See Ezekoye v. Ocwen Federal Bank FSB, 179 Fed. Appx. 111, 113 n.3 (3d Cir. 2006) ("Although [plaintiff] lists in his complaint numerous other statutes that he contends have been violated, their mere mention is insufficient to state a claim for relief").[13]

[13] See also Chavez v. Wal-Mart Stores, Inc., No. CV-13-6429-GHK(PJWx), 2014 WL 12591244, at *4 (C.D. Cal. Mar. 3, 2014) ("[Plaintiff's] cursory listing of the other states' statutes is insufficient to satisfy Twombly and Iqbal's pleading requirements, much less the heightened pleading requirements of Rule 9(b)"); McCalley v. Samsung Elecs. Am., Inc., No. CIV.A. 07-2141 (JAG), 2008 WL 878402, at *9 (D.N.J. Mar. 31, 2008) (dismissing claim alleging violation of unfair and deceptive acts statutes of 44 states where the plaintiff "fail[ed] to allege even the elements of the various statutes, or facts permitting this Court to draw inferences that the elements exist").

Additionally, Humana cannot properly recover damages under many of the state fraud statutes alleged in the Complaint. See, e.g., Buetow v. A.L.S. Enters., Inc., 888 F. Supp. 2d 956, 961-62 (D. Minn. 2012) (monetary damages to private plaintiff do not benefit public as required to proceed under Minnesota's private attorney general statute); Cent. Reg'l Emps. Ben. Fund v. Cephalon, Inc., No. CIV.A. 09-3418 MLC, 2009 WL 3245485, at *3 (D.N.J. Oct. 7, 2009) (third-party payors who do not themselves consume prescription medications are not "consumers" under New Jersey Consumer Fraud Act); Duronio v. Merck & Co., No. 267003, 2006 WL 1628516, at *6 (Mich. Ct. App. June 13, 2006) (Michigan Consumer Protection Act does not apply to regulated transactions or conduct).

4. Humana's Tortious Interference with Contractual Relations and Unjust Enrichment Claims Should be Dismissed

In Count VII of the Complaint, Humana has failed to state a claim for tortious interference with contractual relations because there was no breach of contract by Humana's insureds. In 2005, OIG explained that copay assistance provided by a PAP would count towards the true out-of-pocket costs of a Medicare Part D enrollee, "even if the PAP does not comply with fraud and abuse laws," an approach which "relieves beneficiaries of the financial risk of accepting assistance from an entity that may be improperly structured or operated." Dugan Decl. Ex. E at 70,625. Thus, even accepting the dubious proposition that Humana's contracts with its insureds prohibit anyone other than the insureds to make copays for prescription drugs, any such provision would be unenforceable.

Finally, contrary to Count IX, ACS was not "unjustly enriched" as a result of payments made by Humana for Copaxone. As discussed throughout, Humana has not alleged that a single Copaxone prescription filled by ACS was improperly issued by a doctor or medically unnecessary for the patient. Thus, even assuming that an unjust enrichment claim can properly be brought by Humana here, it would not be inequitable for ACS to retain the payments it received for Copaxone.

III. CONCLUSION

For all the reasons above, the Court should dismiss the Complaint against ACS.

LOCAL RULE 3.01(g) Certification

Counsel for Movant certifies that they have conferred with counsel for Plaintiff by telephone, and Plaintiff opposes the relief requested herein.

Dated April 2, 2021.

Respectfully submitted,

/s/ Mariellen Dugan

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STATUTES OF LIMITATION APPLICABLE TO COUNTS III & IV	
Statute	**Limitations Period**
Ak. Stat. § 45.50.471(a), *et seq.*	2 years after a person discovers or reasonably should have discovered the unlawful act, Alaska Stat. § 45.50.531(f)
Ariz. Rev. Stat. § 44-1521, *et seq.*	1 year after the cause of action accrues, Ariz. Rev. Stat. § 12-541(5)
Ark. Code. § 4-88-101, *et. seq.*	5 years from occurrence of violation, Ark. Code Ann. § 4-88-115
Cal. Bus. & Prof. Code § 17200, *et seq.*	4 years after the cause of action accrues, Cal. Bus. & Prof. Code § 17208
Colo. Rev. Stat. § 6-1-101, *et seq.*	3 years from the unlawful act or after a person discovers or should have discovered it, Colo. Rev. Stat. § 6-1-115
Conn. Gen. Stat. § 42-110a, *et seq.*	3 years after the violation, Conn. Gen. Stat. § 42-110g(f)
Fl. Stat. § 501.201, *et seq.*	4 years from occurrence of actual damages, Fla. Stat. § 95.11(3)(f)
Ga. Code § 10-1-390, *et seq.*	2 years after a person knew or should have known of the occurrence of the violation, Ga. Code § 10-1-401(a)
Idaho Code § 48-601, *et seq.*	2 years after the cause of action accrues, Idaho Code § 48-619
815 Ill. Comp. Stat. 505/1, *et seq.*	3 years after the cause of action accrues, 815 Ill. Comp. Stat. 505/10a(e)
Ind. Code § 24-5-0.5-1, *et. seq.*	2 years after the occurrence of the deceptive act, Ind. Code § 24-5-0.5-5
La. Rev. Stat. § 51:1401, *et seq.*	1 year from the unlawful act, La. Rev. Stat. § 51:1409
Md. Code., Com. Law § 13-101, *et. seq.*	3 years after the cause of action accrues, Md. Code, Cts. & Jud. Proc. § 5-101
Mass. Gen. Laws Ch. 93A, §1, *et seq.*	4 years after the cause of action accrues, Mass. Gen. Laws Ch. 260, § 5A
Mich. Comp. Laws. § 445.901, *et seq.*	6 years after the occurrence or one year after the last payment in transaction involving unlawful act, Mich. Comp. Laws § 445.911(7)
Minn. Stat. § 325F.68, *et seq.*	6 years from the discovery of the facts constituting the fraud, Minn. Stat. § 541.05, subd. 1(6)
Neb. Rev. Stat. § 59-1601, *et seq.*	4 years after the cause of action accrues, Neb. Rev. Stat. § 59-1612
Nev. Rev. Stat. § 41.600, *et seq.*	4 years after the even which would constitute consumer fraud, Nev. Rev. Stat. § 11.190(d)(2)

N.H. Rev. Stat. § 358-A:1, *et seq.*	3 years from the time the plaintiff knew, or reasonably should have known, of the unlawful conduct, N.H. Rev. Stat. § 358-A:3(IV-a)
N.J.S.A. § 56:8-1, *et seq.*	6 years after cause of action accrues, N.J.S.A. § 2A:14-1
N.M. Stat. § 57-12-1, *et seq.*	4 years from the time the plaintiff sustains actual injury and discovers, or should have discovered through reasonable diligence, the facts essential to the cause of action, N.M. Stat. § 37-1-4
N.C. Gen. Stat. § 75-1.1, *et seq.*	4 years after the cause of action accrues, N.C. Gen. Stat. § 75-16.2
N.D. Cent. Code § 51-15-01, *et seq.*	6 years after the cause of action accrues, N.D. Cent. Code, § 28-01-16
Or. Rev. Stat. 646.607, *et seq.*	1 year from the discovery of the unlawful method, act or practice, Or. Rev. Stat. § 646.638
S.C. Code § 39-5-10, *et seq.*	3 years after discovery of the unlawful conduct, S.C. Code Ann. § 39-5-150
Tenn. Code § 47-18-101, *et seq.*	1 year from discovery of unlawful act or practice, but no more than 5 years after the consumer transaction giving rise to the claim, Tenn. Code § 47-18-110
Wash. Rev. Code § 19.86.010, *et seq.*	4 years after the cause of action accrues, Wash. Rev. Code § 19.86.120
Wis. Stat. § 100.18, *et seq.*	3 years after the occurrence of the unlawful act or practice, Wis. Stat. § 100.18
Wyo. Stat. Ann. § 40-12-101, *et seq.*	1 year after the required written notice is furnished to the alleged violator (which must be furnished either within 1 year after the unlawful deceptive trade practice or within 2 years following the consumer transaction, whichever occurs first), Wyo. Stat. Ann. § 40-12-109
STATUTES OF LIMITATION APPLICABLE TO COUNT V	
720 Ill. Comp. Stat. 5/17-10.5	5 years after the cause of action accrued, 735 Ill. Comp. Stat. 5/13-205
Ky. Rev. Stat. § 304.47-010, *et seq.*	5 years from when the cause of action accrued, Ky. Rev. Stat. § 413.120(11)
18 Pa. Cons. Stat. § 4117, *et seq.*	2 years from when the injured party knew, or in the exercise of reasonable diligence, should have known of the injury, 42 Pa. Cons. Stat. § 5524(7)
N.J.S.A. § 17:33A, *et seq.*	6 years after the action accrued, N.J.S.A. § 17:33A-7(e)
Tenn. Code § 56-53-101, *et seq.*	Within 3 years of the violation if treble damages are sought, Tenn. Code. § 56-53-107(c), or within five years of when the plaintiff discovered, or, with reasonable diligence, could have discovered the acts constituting the violation, Tenn. Code. § 56-53-107(e)

CERTIFICATE OF SERVICE

I hereby certify that on April 2, 2021, the foregoing was electronically filed with the Clerk of the Court through the CM/ECF system, which will send a notice of electronic filing to counsel for all parties of record.

/s/ Mariellen Dugan
Mariellen Dugan