# United States Court of Appeals
## For the First Circuit

No. 24-1012

HUMANA INC.,

Plaintiff, Appellant,

v.

BIOGEN, INC. and ADVANCED CARE SCRIPTS, INC.,

Defendants, Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. F. Dennis Saylor IV, U.S. District Judge]

Before

Barron, Chief Judge,
Lynch and Thompson, Circuit Judges.

Robert E. Dunn, with whom Sarah H. Catalano, Scott C. Solberg, James W. Joseph, Benjamin E. Waldin, Gregory M. Schweizer, and Eimer Stahl LLP were on brief, for appellant.

Mark C. Fleming, with whom Mark A. Ford, Felicia H. Ellsworth, and Wilmer Cutler Pickering Hale and Dorr LLP were on brief, for appellee Biogen Inc.

Sarah M. Harris, with whom Farrah Bara, Erin M. Sielaff, and Williams & Connolly, LLP were on brief, for appellee Advanced Care Scripts, Inc.

January 17, 2025

**LYNCH, Circuit Judge.** Humana, a major health insurance company and Medicare Part C and Part D sponsor, filed suit in the District of Massachusetts on September 24, 2021 against the drug manufacturer Biogen and a specialty pharmacy, Advanced Care Scripts, Inc. ("ACS"), alleging that each defendant engaged in fraudulent schemes involving three Biogen-manufactured multiple sclerosis drugs and, inter alia, so violated the civil RICO statute. See 18 U.S.C. § 1964(c).

Humana alleged that Biogen constructed and implemented a scheme to "seed" the market of MS patients with these three drugs, funnel patients for whom the drugs were prescribed and administered into Medicare, and indirectly fund patient copays for the drugs through third-party patient-assistance programs ("PAPs"). As to ACS, Humana alleged that the pharmacy company ACS "aided and abetted" Biogen's scheme in that it "steered patients and acted as an information intermediary" between Biogen and the PAPs. Humana alleged that both defendants "caused the submission of false certifications to Humana" in furtherance of their scheme. The district court dismissed the case on the pleadings for reasons discussed below. See Humana v. Biogen, Inc., 666 F. Supp. 3d 135, 141 (D. Mass. 2023). Humana has appealed.

On appeal, Humana focuses on what it calls an "implied certification" theory: that the defendants caused the submission of claims for payment to Humana that were not "clean" under Centers

for Medicare and Medicaid Services ("CMS") regulations, 42 C.F.R. §§ 423.505(h)(1), 423.505(i)(3), and 423.505(k). Humana alleges that the CMS regulations generally require "downstream" entities that subcontract with Medicare Part D sponsors, like Humana, to comply with federal laws and regulations and to certify to Humana that claims data is true, accurate, and complete.[1] See 42 C.F.R. §§ 423.505(h)(1), 423.505(i), 423.505(k).

Humana alleges that through its insurance, it reimbursed the cost of the drugs prescribed to patients who use these MS drugs. Humana has also narrowed on appeal its claims of injury, abandoning its earlier argument that it paid more for these drugs than it would have paid absent the alleged scheme. Humana now only argues that its injury is that Humana covered prescriptions that it would not have covered absent the allegedly false certifications and that it covered more prescriptions for these drugs than it otherwise would have.

The district court dismissed the complaint in its entirety on two alternative grounds. First, the district court held that Humana lacked standing to bring RICO claims against each defendant because Congress intended that RICO incorporate the indirect purchaser rule from Illinois Brick Co. v. Illinois, 431

[1] Humana's cited language from 42 C.F.R. § 423.505(h)(1) describes only the Part D sponsor's, not the downstream entity's, obligation to comply with the law.

U.S. 720, 737 (1977), and both defendants were covered by that rule. The court secondly ruled that Humana's complaint failed to plead the RICO claims against each defendant with particularity, as required by Federal Rule of Civil Procedure 9(b).

After dismissal (and about a year after the motion to dismiss hearing), Humana moved for leave to amend its complaint. The district court denied the motion. Humana appealed both the dismissal and the denial of leave to amend.

We need not reach the first ground concerning whether the indirect purchaser rule applies to RICO claims or whether Humana is an indirect purchaser. We reach only the second ground of whether the pleadings meet the particularity rule for fraud under Rule 9(b). They do not, and we affirm on that ground. We also affirm the district court's denial of leave to amend.

**I.**

**A.**

When reviewing the allowance of a motion to dismiss, "'we recount the underlying facts as alleged in the complaint,' but 'disregard any conclusory allegations.'" Analog Techs., Inc. v. Analog Devices, Inc., 105 F.4th 13, 14 (1st Cir. 2024) (citation omitted) (first quoting Shash v. Biogen, Inc., 84 F.4th 1, 6 (1st Cir. 2023); then quoting Ponsa-Rabell v. Santander Sec. LLC, 35 F.4th 26, 30 n.2 (1st Cir. 2022)). We also note Humana's

concessions made in its briefs and at oral argument, as appropriate.

Biogen, Inc. manufactures Avonex, Tysabri, and Tecfidera, three drugs used to treat multiple sclerosis. ACS, a specialty pharmacy, filled prescriptions and provided patient drug management advice for those drugs. Humana, Inc. provided insurance coverage to patients for whom those drugs were prescribed, in part through Medicare.

Humana administers plans under Medicare Part C and Part D. Medicare Parts C and D both provide prescription drug benefits, and the government -- through CMS -- reimburses Humana for a portion of the prescription costs of Medicare-enrolled patients. Under Medicare Part C, Humana receives a capitated rate for each insured. While Humana does not submit claims directly to the government under Part C, Humana is subject to certain reporting requirements. Humana is also a Part D Sponsor, and under Medicare Part D, premiums are split between insureds and Medicare funds. Part D insureds are usually responsible to pay a portion of the cost of their prescription drugs via a copay or deductible.[2]

[2] Prior to 2023, Part D beneficiaries were responsible for 100% of an initial deductible. See Final CY 2025 Part D Redesign Program Instructions Fact Sheet, Ctrs. for Medicare & Medicaid Servs. (Apr. 1, 2024), https://www.cms.gov/newsroom/fact-sheets/final-cy-2025-part-d-redesign-program-instructions-fact-sheet [https://perma.cc/V78H-QCCU]. After satisfying that deductible, beneficiaries were responsible for 25% coinsurance payments until reaching the "catastrophic coverage" threshold, at

In practice, it is the pharmacy which provides the prescribed drug to the insured patient. The drug manufacturer typically provides the drugs to wholesalers, who provide the drugs to pharmacies. The insured patient usually pays a copay for the drug (or the whole price of a drug not covered by insurance). Citing 42 C.F.R. § 423.322, Humana alleges that the electronic record of the claim that the pharmacy submits to the insurer is called a Prescription Drug Event ("PDE"), and that generating and submitting PDE data is a condition of payment for CMS's provision of Medicare funds to Part D sponsors.

As described earlier, Humana alleged that CMS regulations require "downstream" or "related" entities that subcontract with Medicare Part D Plans -- including drug manufacturers and pharmacies -- to comply with "[f]ederal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. § 3729, et seq.) [], and the anti-kickback statute (§ 1127B(b) of the Act), [42 C.F.R.] § 423.505(h)(1)."

Humana alleged Biogen and ACS have engaged in a scheme to inflate the number of covered prescriptions for Avonex, Tysabri,

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which point they generally became responsible for 5% coinsurance payments. Id. The federal government also provides a subsidy to assist certain lower-income Medicare patients. Id.

and Tecfidera such that Humana was defrauded and overpaid in covering the drugs.[3] The alleged scheme had two major components. First, Biogen "seeded" the market by providing its MS drugs for free to patients who lacked insurance or whose insurance did not cover Biogen's MS drugs. Humana alleged Biogen then worked to funnel patients from the free-drug program into Medicare. Biogen's Patient Services Department or a third party contacted patients in the free-drug program who were eligible for Medicare and then obtained their consent to enroll them in Medicare. Once a patient starts a particular drug therapy, he or she is more likely to continue that therapy, including those free MS drugs, so Biogen ultimately profited from the free-drug program through insurance reimbursements.

Second, Humana alleged that Biogen coordinated with two non-profit organizations (not named as defendants), The Assistance

[3] In 2020, the Department of Justice intervened in a whistleblower suit against Biogen alleging that Biogen's conduct in connection with two of these drugs violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, and the False Claims Act, 31 U.S.C. §§ 3729-3733. See United States Notice of Intervention, United States ex rel. Paul Nee v. Biogen, Inc., No. 17-cv-10192 (D. Mass. Dec. 17, 2020), ECF No. 47. Biogen and the DOJ reached a $22 million settlement, without any admission of liability. See Biogen Agrees to Pay $22 Million to Resolve Alleged False Claims Act Liability for Paying Kickbacks, U.S. Dep't of Justice, Off. of Pub. Affs. (Dec. 17, 2020), https://www.justice.gov/opa/pr/biogen-agrees-pay-22-million-resolve-alleged-false-claims-act-liability-paying-kickbacks [https://perma.cc/SUA6-9Y6R]. ACS also "agreed to pay $1.4 million to resolve its role in the [same] conduct" without an admission of liability. Id.

Fund, Inc. ("TAF") and the Chronic Disease Fund, ("CDF"), to enroll patients using these MS drugs in TAF's and CDF's PAPs, which cover drug copayments for patients. Biogen allegedly made donations to CDF and TAF in exchange for the PAPs' commitments to cover specific patients' copays. After receiving Biogen's donations, the PAPs approved the patients' applications and covered their copay costs for the Biogen MS drugs. Biogen allegedly tracked every prescription and knew which ones were covered by a PAP. Humana alleged that ACS transferred patients who used these three Biogen MS drugs from the free-drug program to a PAP, and that it coordinated Biogen's payments to the PAPs. Humana alleged that ACS participated in the scheme because ACS derived revenue from transitioning patients to the PAPs and filling prescriptions of the MS drugs.

We describe later the precise allegations in the complaint as to the alleged fraud. In general, Humana alleged that through the scheme, both defendants "caused the submission of false certifications to Humana." Humana alleged without detail as to these certifications that the defendants represented to Humana that "they were complying with state and federal law, including laws related to kickbacks and false claims such as the AKS and the FCA," "as well as rules promulgated by government entities such as CMS."

Humana alleged it paid over $1.9 billion for these Biogen MS drugs between 2011 and 2019, with the drugs provided by ACS accounting for nearly $350 million of that spending. Humana alleged that it would have paid less absent Biogen and ACS's conduct because Humana would have paid for fewer MS drug prescriptions (including the costs of administering the drug). Humana further alleged that it suffered injuries every time Humana "reimbursed those prescriptions for the MS Drugs that otherwise would not have been filled, submitted, or reimbursed." At oral argument, Humana abandoned another theory of relief pled in the complaint -- that Humana paid an inflated price for the drugs -- and instead argued that Humana had overpaid in the sense that it would not have covered the prescriptions in which Biogen ultimately paid the copay.

**B.**

Humana's suit under 18 U.S.C. § 1964(c) against Biogen and ACS asserts ten counts based on the alleged Biogen-ACS scheme: one for violation of the civil RICO statute;[4] one for conspiracy

[4] To state a civil RICO claim,

> A plaintiff must allege "a violation of section 1962[c]" and an injury "by reason of" that violation. [18 U.S.C. § 1964(c)]. The underlying section 1962 violation in turn requires demonstrating: "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." Sedima, S.P.R.I. v. Imrex Co., 473 U.S. 479, 496, 105 S. Ct. 3275, 87 L.Ed.2d 346 (1985)(footnote omitted). The statute separately defines "pattern

to violate the civil RICO statute; and the remainder under various state laws. Humana alleged mail and wire fraud under, respectively, 18 U.S.C. § 1341 and 18 U.S.C. § 1343, as the predicate offenses for its core RICO claim. Biogen and ACS both moved to dismiss the complaint, arguing that the claims were time-barred and that Humana failed to state a claim upon which relief can be granted under Federal Rule of Civil Procedure 12(b)(6) for various reasons.

The district court took briefing and held a hearing on the motions to dismiss on April 7, 2022. Roughly a year later, on March 31, 2023, the district court dismissed the action. We turn to the second ground for dismissal and need not reach the first.[5]

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of racketeering activity" to require "at least two acts of racketeering activity." 18 U.S.C. § 1961(5).

Lerner v. Colman, 26 F.4th 71, 77 (1st Cir. 2022). A plaintiff may also allege an attendant conspiracy claim under 18 U.S.C. § 1962(d), which provides that "[i]t shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b), or (c) of this section." "[I]f the pleadings do not state a substantive RICO claim upon which relief may be granted, then the conspiracy claim also fails." Efron v. Embassy Suites (Puerto Rico), Inc., 223 F.3d 12, 21 (1st Cir. 2000).

[5] The court determined that Humana was an indirect purchaser, and reasoned that, under Supreme Court caselaw, "[a] plaintiff asserting a claim under the Clayton Act cannot demonstrate an actionable injury if it only made indirect purchases" (citing Illinois Brick Co. v. Illinois, 431 U.S. 720, 737 (1977)). The court further reasoned that after the Supreme Court's decision in Holmes v. Securities Investor Protection Corporation, 503 U.S. 258 (1992), "two circuits, following its reasoning, have concluded that the indirect purchaser rule applies in all civil RICO actions" as well as in the antitrust context. See Trollinger v. Tyson

The district court held that Humana failed to meet the pleading requirements under Rule 9(b) for its RICO claim. The court initially held that "[c]ivil RICO claims based on predicates of mail or wire fraud must meet the heightened pleading standard of Rule 9(b)." The plaintiff must "go beyond a showing of fraud and state the time, place and content of the alleged mail and wire communications perpetrating that fraud" (quoting Cordero-Hernandez v. Hernandez-Ballesteros, 449 F.3d 240, 244 (1st Cir. 2006)). The court held that the complaint failed to meet the 9(b) requirements and, more specifically, that the complaint was inadequate in meeting the particularity requirements on two grounds: failure to plead specific mail or wire communications and failure to plead fraudulent misrepresentations.

Humana relied on Exhibit A to the complaint, and the court rejected Humana's argument that Exhibit A provided the required specificity as to mail and wire communications. The court found "the absence of further detail in Exhibit A [] particularly puzzling, in that the communications in question were apparently

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Foods, Inc., 370 F.3d 602, 616 (6th Cir. 2004); McCarthy v. Recordex Serv., Inc., 80 F.3d 842, 855 (3d. Cir. 1996). Having determined that "[t]he First Circuit has yet to decide the issue," the court, "follow[ed] the lead of every circuit to have considered the issue," applied the indirect purchaser rule to Humana, and determined that it lacked standing to pursue a civil RICO claim. We express no view of the district court's analysis as to this issue.

made by a Humana subsidiary"[6] -- Humana's own specialty pharmacy, which filled the prescriptions -- "to Humana itself." Exhibit A, prepared by Humana, is a spreadsheet captioned "Examples of 100 Biogen Subsidized Copayments" with columns for "Rx Fill Date," "Copay Foundation," "Drug Cost," and "Copay Subsidy." Exhibit A did not purport to provide any information as to ACS. For example, one row representing one prescription has "1/7/2011" listed under "Rx Fill Date," "The Assistance Fund" listed under "Copay Foundation," "$6,982.21" listed under "Drug Cost," and "$997.30" listed under "Copay Subsidy." Humana alleged that Exhibit A constitutes a sample of claims for MS prescriptions filled through Humana's specialty pharmacy. As to the mail or wire fraud and interstate or foreign commerce elements of civil RICO, the district court concluded that neither the complaint nor Exhibit A itself "specifically identif[ied] which (if any) of the communications were made by mail, and which were made by wire." Further, Exhibit A "contain[ed] no detail as to who sent the communications" and "d[id] not even allege the technical requirement of the wire-fraud statute, that the communication be transmitted 'in interstate or foreign commerce'" (quoting 18 U.S.C. § 1343). Looking beyond

[6] The complaint alleges that Humana Pharmacy Inc. and Humana Pharmacy Solutions, Inc. are operating subsidiaries that "operate Humana's in-house pharmacy and manage Humana's pharmacy benefits, respectively." Humana alleged that the operating subsidiaries "have assigned the claims asserted here to Plaintiff Humana Inc. through written assignment agreements."

Exhibit A to all of the allegations, the court held that "the complaint does not allege a single specific instance of a mail or interstate wire communication -- at best, it only alleges that certain specific communications were sent by 'the wires or by mail'" (quoting Compl. ¶ 95).

The court also held that, independently, the complaint had failed to meet the Rule 9(b) requirements as to the "alleged falsehoods at issue." Those alleged falsehoods, the court noted, were "not that the prescriptions themselves were phony, or that the treatment was medically unnecessary; rather, it is the representation, in one or more 'certifications,' that defendants were in compliance with the law." The court ruled that "the complaint does not state when [the certifications] were made and how they were made, and does not provide the actual language of the misrepresentations at issue." The court observed that sections of the complaint "allege that Biogen and Humana entered into a contract with an effective date of January 1, 2006, that contained a provision in which Biogen agreed that it 'shall comply' with applicable federal laws."[7] Nonetheless, "[t]he complaint does not

[7] The complaint alleged that Biogen and Humana entered into a contract for Humana's private insurance business with an effective date of January 1, 2006 in which Biogen agreed that it "shall comply" with applicable federal laws. Defendants dispute that a 2006 contract has any relevance to a suit brought in 2021 and point out that there is no allegation in the complaint that ACS entered into any contract with Humana. We need not reach that issue.

include any allegations as to how Humana's contractual relationship with Biogen for its private commercial insurance business has any relevance to the alleged scheme at issue here." Accordingly, the court dismissed due to Humana's failure to plead its RICO claim with the specificity required by Rule 9(b). The court declined to exercise supplemental jurisdiction over the remaining state claims, and it noted that "there is no basis to permit Humana leave to amend, as may be the case when the critical information is not in the plaintiff's possession."

On April 28, 2023, Humana moved for reconsideration and for leave to file an amended complaint. The district court denied the motion after full briefing, concluding that "[t]here is no suggestion here that 'amendment would be anything other than futile'" and that seeking leave to amend after the case has been dismissed "is inefficient, unfair to defendants, and burdensome to the court" (first quoting Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc., 778 F.3d 228, 247 (1st Cir. 2015)).

**II.**

**A.**

We review the district court's dismissal order de novo, Douglas v. Hirshon, 63 F.4th 49, 54-55 (1st Cir. 2023), and we assume -- without deciding -- that the properly pleaded facts are true, Lerner v. Colman, 26 F.4th 71, 74 (1st Cir. 2022). "We do not credit legal labels or conclusory statements, but rather focus

on the complaint's non-conclusory, non-speculative factual allegations and ask whether they plausibly narrate a claim for relief." Cheng v. Neumann, 51 F.4th 438, 443 (1st Cir. 2022).

To state a civil RICO claim, a plaintiff must allege "(1) conduct, (2) of an enterprise, (3) through a pattern, (4) of racketeering activity." Kenda Corp. v. Pot O'Gold Money Leagues, Inc., 329 F.3d 216, 233 (1st Cir. 2003) (quoting Sedima, S.P.R.I. v. Imrex Co., 473 U.S. 479, 495 (1985)); see also Lerner, 26 F.4th at 77. "By statute, the 'pattern' element requires a plaintiff to show at least two predicate acts of 'racketeering activity,' which is defined to include violations of specified federal laws . . . ." Kenda, 329 F.3d at 233 (quoting Efron v. Embassy Suites (P.R.) Inc., 223 F.3d 12, 15 (1st Cir. 2000)). The predicate acts for Humana's RICO claim are mail and wire fraud.[8] "'RICO claims premised on mail or wire fraud must be particularly scrutinized' because of the ubiquity of the use of wires and mails" and the "ease" of pleading a pattern of fraud. Lerner, 26 F.4th at 85 (quoting Efron, 223 F.3d at 20). To state a claim for mail or wire fraud, Humana must plead: (1) "a scheme to defraud using false pretenses," (2) "the defendant's knowing and willing

[8] Humana does not challenge the district court's holding that the RICO conspiracy claim fails if the substantive RICO claim fails or the court's refusal to exercise supplemental jurisdiction over the remaining claims. Accordingly, we focus our analysis on the underlying RICO claim.

participation in the scheme with the intent to defraud," and (3) "the use of the mails [or wires] in furtherance of that scheme." United States v. Simon, 12 F.4th 1, 33 (1st Cir. 2021). Humana appeals the district court's determination that it failed to plead the first and third elements with particularity.

The district court correctly determined that Rule 9(b)'s pleading standard applies. Where, as here,

> a RICO complaint pleads mail and wire fraud as predicate acts, it adopts the heightened pleading requirement of Federal Rule of Civil Procedure 9(b), New England Data Servs., Inc. v. Becher, 829 F.2d 286, 290 (1st Cir. 1987), such that the plaintiff must "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b).

Lerner, 26 F.4th at 84; see also Ahmed v. Rosenblatt, 118 F.3d 886, 889 (1st Cir. 1997) ("RICO pleadings of mail and wire fraud must satisfy the particularity requirements of Rule 9(b)," under which "a pleader must state the time, place and content of the alleged mail and wire communications perpetrating that fraud."). We reject Humana's argument that an alternate, more plaintiff-friendly standard applies. Humana argues that the complaint need only "'contain[] enough factual detail to make it apparent that the plaintiff's claims' are not 'groundless' and to enable the defendant 'to file a responsive pleading.'" That is not the

standard.[9] Humana cites Dumont v. Reily Foods Co., 934 F.3d 35, 39 (1st Cir. 2019) and Foisie v. Worcester Polytechnic Inst., 967 F.3d 27, 51 (1st Cir. 2020) for the proposition that this court should apply a standard akin to a notice standard. But both Dumont and Foisie required particularity as to the "who," "what," "where," and "when" giving rise to the fraud. See Dumont, 934 F.3d at 39; Foisie, 967 F.3d at 50. Therefore, neither case supports Humana's contention that a lower standard applies.[10]

a. Fraudulent misrepresentations

Our RICO cases have made clear that it is insufficient to simply make conclusory allegations of fraud and to fail to describe the time, place, and content of the communications. See Feinstein v. Resol. Tr. Corp., 942 F.2d 34, 42 (1st Cir. 1991) ("It is not enough for a plaintiff to file a RICO claim, chant the statutory mantra, and leave the identification of predicate acts to the time of trial."). We hold that Humana failed to plead with the particularity required under Rule 9(b) what were the contents

[9] We also reject the argument that standard has been met here "[s]ince . . . Biogen and ACS reached multimillion dollar settlements with DOJ based on the same underlying conduct, [so] Biogen and ACS cannot plausibly be confused or underinformed about the wrongdoing underlying Humana's claims" without accepting the premise that would be adequate notice.

[10] Moreover, fraudulent conveyances -- which is what Foisie involved -- are an area where Rule 9(b)'s application is "a matter of some uncertainty." Foisie, 967 F.3d at 49-50.

of those "certifications," who made them to whom, where and when they were made, and even why they were fraudulent.

The RICO count relevantly alleges only that "[f]alse representations of compliance with federal and state laws were made to Humana for payment over the wires or by mail." The remaining paragraphs of the complaint allege that:

> 1. Defendants "caused the submission of false certifications to Humana."
>
> 2. "Defendants misrepresented to Humana that they were complying with state and federal law, including laws related to kickbacks and false claims such as the AKS and the FCA."
>
> 3. "Biogen and its agent ACS made such certifications and therefore directly misrepresented to Humana that they were not inducing Medicare patients to take Biogen's drugs by subsidizing copayments, and that Biogen and ACS were otherwise complying with federal law."
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> 4. "Humana's agreements with its providers include a provision that requires the provider to certify its compliance with state and federal law, as well as rules promulgated by government entities such as CMS."
>
> 5. "This underlying misconduct results in a further form of misconduct specifically directed to Humana: namely, specific misrepresentations that those participating in the deceptive scheme were complying with the very laws that they were in fact flouting."
>
> 6. "Biogen . . . certif[ied] to Humana that it was following federal law and CMS rules that prohibited such copayment subsidies for Medicare patients."

> 7. "False representations of compliance with federal and state laws were made to Humana for payment over the wires or by mail. These false representations were made directly to Humana and were a condition of reimbursement for all the MS Drugs claims submitted to Humana."

Humana also attached to its complaint Exhibit A, which purports to set out a list of 100 examples of claims submitted to Humana by Humana's own specialty pharmacy for MS drug prescriptions that it alleges were illegally subsidized by Biogen. The exhibit does not, however, provide any additional information about any certifications allegedly made in connection with those claims.

As the district court correctly concluded, none of these allegations plead with specificity "when the [alleged false certifications] occurred, where they took place, or what they contained." Feinstein, 942 F.2d at 42. Humana contends that additional detail is unnecessary because it identified in Exhibit A multiple specific claims submitted to it and because "the Complaint makes plain that Biogen submitted false certifications in connection with every claim." But even setting aside whether this fairly characterizes Humana's complaint, it is not enough to make conclusory assertions that fraudulent certifications were made, without identifying the fraudulent statement itself. And Humana's complaint does not identify what exactly was said -- or "certifi[ed]" -- to it in connection with each claim that was, in fact, false.

To the extent that Humana means to rely for the content of the alleged certifications on either its "agreements with its providers," or on federal regulations "requir[ing] 'downstream' entities . . . to certify that [claims] data is true, accurate, and complete," the complaint neither sets forth the content of any such agreements, nor alleges any specific instance in which either defendant expressly certified to it the certification set forth by regulation. Indeed, on appeal, Humana appears to disclaim any argument that the submitted claims were accompanied by an express certification by either defendant.

Likewise, Humana's contention that key information was in the defendants' hands, and therefore could not be pled with particularity, misses the mark. Even if Humana would not have been reasonably able to identify "exactly which claims were fraudulent," apart from claims submitted through its own specialty pharmacy, this does not explain Humana's failure to identify the content of the certification that it alleges was, in many instances, false.

We turn to Humana's "implied certification" theory, noting that it is not clear that such an argument was developed in front of the district court. We bypass this potential waiver by Humana because its argument fails in any event. To address this question, we turn to the Supreme Court's rulings in Universal Health Services, Inc. v. United States ex rel. Escobar, 579 U.S.

176 (2016). In Escobar, the plaintiffs' daughter received treatment at a mental health center and was prescribed medication by someone that the center had represented was a doctor. Id. at 183. The daughter died following an adverse reaction to the medication, and the plaintiffs discovered that of the five practitioners who had treated their daughter, only one was properly licensed. Id. One practitioner had been identified as a psychologist with a Ph.D., but that was false: her degree came from an unaccredited internet college, and the state had rejected her application to become licensed as a psychologist. Id. The practitioner who had prescribed medication, represented to be a psychiatrist, was a nurse who lacked authority to prescribe medication absent supervision. Id. The healthcare center submitted reimbursement claims to CMS using payment codes corresponding to services such as "Individual Therapy." Id. at 184. In its CMS claims, the center had used National Provider Identification numbers corresponding to and representing the provider had specific job titles in connection with those reimbursement claims, even though the providers lacked the credentials and licensing required for those titles. Id.

The Escobar plaintiffs filed a qui tam suit in federal court, alleging the center had violated the False Claims Act under an implied false certification theory of liability in that it "submitted reimbursement claims that made representations about

the specific services provided by specific types of professionals, but that failed to disclose serious violations of regulations pertaining to staff qualifications and licensing requirements for these services." Id. at 184-85. Reviewing the action at the motion to dismiss stage, the Supreme Court concluded that the plaintiffs had adequately pled actionable misrepresentations under the False Claims Act, holding that "the implied certification theory can be a basis for liability, at least where two conditions are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." Id. at 190.

Escobar does not support Humana's implied certification theory, as pled. Humana alleged the following:

> 1. "Any 'downstream' or 'related' entities that subcontract with Medicare Part D Plans (including pharmacies dispensing medication and manufacturers selling medication) are required to comply with '[f]ederal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. § 3729, *et seq.*) [the 'FCA'], and the anti-kickback statute (§ 1127B(b) of the Act),' id. § 423.505(h)(1), and all other federal laws, regulations, and CMS instructions, as well as any additional contractual obligations

> assumed by the Part D Plan. Id. § 423.505(i)(3)."
>
> 2. "CMS regulations require 'downstream' entities that generate and submit PDE claims data to certify that such data is true, accurate, and complete and that the PDE data is the basis for obtaining federal reimbursement for the healthcare products or services reflected therein. [42 C.F.R.] § 423.505(k). Congress has determined that any Medicare claim 'that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act].' 42 U.S.C. § 1320a-7b(g)."
>
> 3. "Humana's agreements with its providers include a provision that requires the provider to certify its compliance with state and federal law, as well as rules promulgated by government entities such as CMS."

The pleadings do not suffice. First, unlike in Escobar, Humana has not pled any specific claim for payment made to the plaintiff by either defendant. As to ACS, at most, Humana pled that ACS submitted some undefined set of claims to Humana, but that lacks any of the particulars required.

Humana argues that it could not have pled specific claims for payment from ACS because it does not know how copays were paid for non-Humana pharmacies and therefore could not know which claims were fraudulent. But Escobar did not address whether a mere request for payment could give rise to an implied certification. 579 U.S. at 188 ("We need not resolve whether all claims for payment implicitly represent that the billing party is legally

entitled to payment . . . [because] [t]he claims in this case do more than merely demand payment."). It merely approved an implied certification claim where the request for payment was accompanied by an affirmative, specific representation that amounted to a "misleading half-truth[]" about the good or services being provided. See id. at 190. And Humana has not developed any argument as to why the claims submitted to it in this case necessarily constitute misleading half-truths.

b. Use of the mail or wires

We agree with the district court that Humana failed to plead with particularity the separate elements of mail or wire fraud. The complaint alleged only the following with respect to defendants' use of the mail or wires:

> 1. Throughout the relevant period, Biogen, ACS, CDF, and TAF used thousands of mail and interstate wire communications to create and manage their scheme, which involved nationwide distribution of the MS Drugs through ACS at the direction of Biogen. Biogen communicated with ACS, US Bioservices, and the foundations through the mail and wires, causing thousands of reimbursement requests to be submitted to Humana over the wires or by mail, and used the wires and mail to effectuate their receipt of payments and contributions. For example, from 2011 through 2019, ACS submitted requests to Humana for reimbursement of more than 76,000 prescriptions worth nearly $350 million for the MS Drugs using the wires or the mail.
>
> 2. False representations of compliance with federal and state laws were made to Humana for payment over the wires or by mail. These false representations were made directly to Humana

> and were a condition of reimbursement for all the MS Drugs claims submitted to Humana. The illegally obtained payments were sought through, and sent over, the wires or by mail. The claims for reimbursement submitted for payment to Humana over the wires or by mail identified in Exhibit A attached to this Complaint are examples of the MS Drugs Enterprise's fraud on Humana.
>
> 3. Defendants and their co-conspirators have sought to and have engaged in the commission of overt acts, including the following unlawful racketeering predicate acts:
>
> a. Multiple instances of mail fraud in violation of 18 U.S.C. §§ 1341 and 1346; and
>
> b. Multiple instances of wire fraud in violation of 18 U.S.C. §§ 1343 and 1346.

We have repeatedly held that "conclusory allegations of mail and wire fraud . . . with no description of any time, place or content of the communication[s]" do not suffice. Becher, 829 F.2d at 292; accord Fleet Credit Corp. v. Sion, 893 F.2d 441, 445 (1st Cir. 1990); Feinstein, 942 F.2d at 42.

Exhibit A likewise fails to provide the necessary particularity. It does not provide the time, place and content of the alleged mail and wire communications perpetrating the fraud or the channel of transmission for the communications as required under 9(b), stating only that the communications detailed in Exhibit A were "submitted for payment to Humana over the wires or by mail." See Ahmed, 118 F.3d at 889. This disjunctive generalized allegation does not plead specific instances of mail

or wire fraud -- which are discrete offenses -- and therefore does not satisfy Rule 9(b)'s particularity requirement.

Humana attempts to excuse the failure, arguing that "the information the court believed was missing from the Complaint was exclusively in Defendants' possession" and the district court should have "given [Humana] the opportunity to investigate and supplement is allegations." Not so. This is not a situation where "the specific information as to use [of the mail or wires] is likely in the exclusive control of the defendant." Becher, 829 F.2d at 290. While Humana may not have "know[n] which members had their copays reimbursed by [the relevant PAPs]" for claims submitted by external pharmacies, it should have known the details of the communications with its own pharmacy. [11]

**B.**

This leaves Humana's appeal from the denial of leave to amend the complaint. We review this denial for abuse of discretion and find none. See Palmer v. Champion Mortg., 465 F.3d 24, 30 (1st Cir. 2006). Under this deferential standard, a district

[11] Humana also relies on a Central District of California case in which the court held that Humana adequately pled its claims. See Humana Inc. v. Mallinckrodt ARD LLC, No. 19-CV-06926, 2020 WL 3041309, at *10 (C.D. Cal. Mar. 9, 2020). This case, arising in a district court in another circuit, is neither authoritative nor relevant to our issue. The Mallinckrodt defendants merely "assert[ed] in conclusory fashion" that the allegations lacked sufficient particularity under Rule 9(b), and accordingly, the court offered no analysis supporting its conclusion.

court's decision will be affirmed "so long as the record evinces an adequate reason for the denial," such as "undue delay, bad faith, futility, [or] the absence of due diligence on the movant's part." Id. at 30 (quoting Aponte-Torres v. Univ. of P.R., 445 F.3d 50, 58 (1st Cir. 2006)). Undue delay justifies denying leave to amend "even standing alone." Kader v. Sarepta Therapeutics, Inc., 887 F.3d 48, 61 (1st Cir. 2018) (quoting Zullo v. Lombardo (In re Lombardo), 755 F.3d 1, 3 (1st Cir. 2014)). This court has stated that the "practice of seeking leave to amend after the case has been dismissed" is "discourage[d]." Abiomed, 778 F.3d at 247; see also Kader, 887 F.3d at 61 ("[W]e have explicitly condemned a 'wait and see' approach to pleading, whereby plaintiffs 'having the needed information, deliberately wait in the wings . . . with another amendment to a complaint should the court hold the first amended complaint was insufficient.'" (quoting ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 57 (1st Cir. 2008))).

Here, Humana waited nearly two years after filing the action before seeking leave to amend, despite the defendants' motions to dismiss in the interim. Humana also waited until after the court's dismissal before moving to amend. Humana attempts to justify its delay primarily by arguing that it could not have moved to amend earlier because its proposed amendments relied on "critical discovery [it obtained] in [separate RICO proceedings against ACS and Teva Pharmaceuticals] about the mechanics and

nature of Defendants' fraudulent scheme." This is not so for at least two reasons. As defendants point out, many of the proposed amended pleadings were not reliant on this discovery but were available much earlier, and as to the pleadings said to be reliant on this new discovery, defendants had them at least five months before they moved to amend. This plainly was not timely. Further, as we have pointed out, Humana had within its possession much of the information from its own files.[12] The district court did not abuse its discretion in denying Humana leave to amend and correctly stated that Humana's timing was "inefficient, unfair to defendants, and burdensome to the court."[13]

**III.**

For the foregoing reasons, we **affirm** the district court's dismissal of the complaint and denial of leave to amend.

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[12] Humana further argues that the district court should have granted leave to replead even if the complaint failed to plead interstate commerce, citing a decision of the United States District Court for the District of Massachusetts. See In re Lupron Mktg. & Sales Pracs. Litig., 295 F. Supp. 2d 148, 171 (D. Mass. 2003). Without endorsing that analysis, we note that the complaint there, unlike the complaint here, was "reasonably specific as to the nature of the materials that are alleged to have been distributed in furtherance of the scheme." Id. at 170. Here, Humana's deficiencies run deeper than just not "identify[ing] specific instances of mailings," and the district court was within its discretion in not granting leave to amend. Id.

[13] We have no need to further address the district court's futility point. See Kader, 887 F.3d at 61.