In the
United States Court of Appeals
for the Second Circuit

August Term 2023
Argued: October 18, 2023
Decided: December 27, 2024

No. 22-2708

UNITED STATES OF AMERICA ex rel. STEVEN M. CAMBURN, STATE OF CALIFORNIA ex rel. STEVEN M. CAMBURN, STATE OF CONNECTICUT ex rel. STEVEN M. CAMBURN, STATE OF COLORADO ex rel. STEVEN M. CAMBURN, STATE OF DELAWARE ex rel. STEVEN M. CAMBURN, STATE OF FLORIDA ex rel. STEVEN M. CAMBURN, STATE OF GEORGIA ex rel. STEVEN M. CAMBURN, STATE OF HAWAII ex rel. STEVEN M. CAMBURN, STATE OF ILLINOIS ex rel. STEVEN M. CAMBURN, STATE OF INDIANA ex rel. STEVEN M. CAMBURN, STATE OF IOWA ex rel. STEVEN M. CAMBURN, STATE OF LOUISIANA ex rel. STEVEN M. CAMBURN, STATE OF MARYLAND ex rel. STEVEN M. CAMBURN, STATE OF MASSACHUSETTS ex rel. STEVEN M. CAMBURN, STATE OF MICHIGAN ex rel. STEVEN M. CAMBURN, STATE OF MINNESOTA ex rel. STEVEN M. CAMBURN, STATE OF MONTANA ex rel. STEVEN M. CAMBURN, STATE OF NEVADA ex rel. STEVEN M. CAMBURN, STATE OF NEW HAMPSHIRE ex rel. STEVEN M. CAMBURN, STATE OF NEW JERSEY ex rel. STEVEN M. CAMBURN, STATE OF NEW MEXICO ex rel. STEVEN M. CAMBURN, STATE OF NEW YORK ex rel. STEVEN M. CAMBURN, STATE OF NORTH CAROLINA ex rel. STEVEN M. CAMBURN, STATE OF OKLAHOMA ex rel. STEVEN M. CAMBURN, STATE OF RHODE ISLAND ex rel. STEVEN M. CAMBURN, STATE OF TENNESSEE ex rel. STEVEN M. CAMBURN, STATE OF TEXAS ex rel. STEVEN M. CAMBURN, STATE OF VIRGINIA ex rel. STEVEN M. CAMBURN, STATE OF WASHINGTON ex rel. STEVEN M. CAMBURN, STATE OF WISCONSIN ex rel. STEVEN M. CAMBURN, DISTRICT OF COLUMBIA ex rel. STEVEN M. CAMBURN, CITY OF CHICAGO ex rel. STEVEN M. CAMBURN, CITY OF NEW YORK ex rel. STEVEN M. CAMBURN,
Plaintiffs-Appellants,
v.
NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant-Appellee.*

Appeal from the United States District Court for the Southern District of New York

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Before: KEARSE, CARNEY, AND PÉREZ, *Circuit Judges*.

On appeal from a judgment of the United States District Court for the Southern District of New York (Wood, *J.*).

A private plaintiff can, on behalf of the United States, bring a False Claims Act ("FCA") claim predicated upon an Anti-Kickback Statute ("AKS") violation. This appeal asks us to resolve whether the plaintiff has adequately stated an AKS-based FCA claim under Federal Rule of Civil Procedure 9(b)'s heightened pleading standard and under Rule 12(b)(6) to survive a motion to dismiss.

Relator-Appellant Steven M. Camburn alleged that Appellee Novartis Pharmaceuticals Corporation ("Novartis") offered remuneration to certain physicians to induce their prescribing of its drug Gilenya, which treats multiple sclerosis, through its peer-to-peer speaker program for physicians and by offering other forms of illicit remuneration. We hold as a matter of first impression in this Circuit that a plaintiff states an AKS violation so long as she alleges with the requisite particularity that at least one purpose of the purported scheme was to induce fraudulent conduct. Applying that rule, we conduct the case-specific inquiry that Rules 9(b) and 12(b)(6) require and conclude that here, Camburn has adequately pleaded certain categories of factual allegations that give rise to a strong inference of an AKS violation. Specifically, Appellant stated an AKS violation with respect to his allegations that Novartis (1) held certain "sham" speaker events with no legitimate attendees; (2) excessively compensated physician speakers for canceled events; and (3) selected and retained speakers to incentivize prescription-writing. However, Appellant has not adequately pleaded his other factual allegations with the requisite specificity to support a strong inference of fraudulent conduct. For those categories of allegations, Camburn's suit may not go forward. Accordingly, we affirm the district court in part, and

* The Clerk of Court is respectfully directed to amend the official caption as set forth above.

vacate the judgment and remand in part, for proceedings consistent with this opinion.

AFFIRMED IN PART, AND VACATED AND REMANDED IN PART.

JAMES E. MILLER (Laurie Rubinow, Anna K. D'Agostino, Miller Shah LLP, New York, NY; Bruce D. Parke, Eric L. Young, John C. Roberts, Miller Shah LLP, Philadelphia, PA; Nathan Zipperian, Miller Shah LLP, Fort Lauderdale, FL; Steven A. Schwartz, Timothy N. Mathews, Chimicles Schwartz Kriner & Donaldson-Smith LLP, Haverford, PA, *on the briefs*), Miller Shah LLP, Chester, CT, *for Plaintiffs-Appellants*.

BENJAMIN GRUENSTEIN (Evan R. Chesler, Damaris Hernández), Cravath, Swaine & Moore LLP, New York, NY, *for Defendant-Appellee.*

MYRNA PÉREZ, *Circuit Judge*:

This appeal asks us to consider whether Relator-Appellant Steven M. Camburn's factual allegations are sufficiently particular, on a motion to dismiss, to give rise to a strong inference that Appellee Novartis Pharmaceuticals Corporation ("Novartis") crossed the line between permissibly promoting its drug and illicitly remunerating physicians to prescribe it in violation of federal law. Rule 9(b) requires, in cases sounding in fraud, that plaintiffs "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b).

While applying this heightened pleading standard is always a context-specific inquiry, we illustrate here the level of particularity that district courts should credit and what sorts of allegations, taken together, are enough to give rise to the strong inference of fraud that the Rule requires. We also hold for the first time in this Circuit that a plaintiff adequately pleads an Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, violation when she states with the requisite particularity that at least one purpose of the alleged scheme was to induce fraudulent conduct (the "at-least-one-purpose" rule).

Novartis employed Camburn in sales for its drug Gilenya, which is indicated to treat multiple sclerosis ("MS"). Novartis fired Camburn shortly after he filed the instant qui tam suit in May 2013 under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729–3733, and its equivalent state and municipal laws.[1]

Since Gilenya's approval in September 2010, the FDA has imposed a first-dose observation requirement for new patients, who must be monitored by a doctor while attached to an electrocardiogram machine for six hours. Because the

[1] "Qui tam is short for 'qui tam pro domino rege quam pro se ipso in hac parte sequitur,' which means 'who pursues this action on our Lord the King's behalf as well as his own.'" *United States v. Quest Diagnostics Inc.*, 734 F.3d 154, 158 n.2 (2d Cir. 2013) (altered italics) (quoting *Rockwell Int'l. Corp. v. United States*, 549 U.S. 457, 463 n. 2 (2007)). Under the FCA's qui tam provision, "a private plaintiff, known as a relator," may "bring[ ] suit on behalf of the [g]overnment to recover a remedy for a harm done to the [g]overnment." *Id.* (quoting *Woods v. Empire Health Choice, Inc.*, 574 F.3d 92, 97 (2d Cir. 2009)); *see* 31 U.S.C. § 3730(b).

first-dose observation is burdensome for physicians, Novartis sought to widen Gilenya's appeal to the market through, among other activities, operating a peer-to-peer speaker program during which physicians, theoretically, shared insights about Gilenya with other healthcare professionals. Camburn alleged that these programs, in actuality, obfuscated a scheme by which Novartis offered remuneration to physicians in exchange for their prescribing Gilenya to patients.

The district court ultimately dismissed Camburn's operative Third Amended Complaint ("TAC") with prejudice. The court concluded that Camburn had not pleaded his factual allegations with the adequate particularity under Rule 9(b) to support a strong inference of an AKS-based FCA violation. *See United States ex rel. Steven M. Camburn v. Novartis Pharms. Corp.*, No. 13-CV-3700 (KMW), 2022 U.S. Dist. LEXIS 165383, at *28–29 (S.D.N.Y. Sept. 13, 2022).

Evaluating the sufficiency of pleadings under the heightened Rule 9(b) standard, which applies to fraud-based claims, is always a "context-specific" exercise. *United States ex rel. Chorches for Bankr. Est. of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 81 (2d Cir. 2017) (citation omitted). Applying the at-least-one-purpose rule, we affirm the judgment of the district court in large part, but we vacate and remand with respect to three categories of allegations related to

Novartis's operation of its speaker program: (1) speaker programs with no legitimate attendees; (2) excessive compensation of speakers for canceled events; and (3) the selection and retention of certain speakers deliberately to induce a higher volume of prescriptions of Gilenya.

BACKGROUND

This appeal centers around Novartis's marketing of a drug used to treat MS. We begin with a recitation of the factual allegations contained in the operative TAC, which we construe as true for purposes of this appeal. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007).

The FDA approved Gilenya in September 2010. The drug's label specifies that it is "indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability." J. App'x 306 (TAC ¶ 120). Gilenya can cause a patient's heart rate to slow, resulting in dizziness, tiredness, and an irregular heartbeat. Therefore, after receiving her first dose, a patient requires at least six hours of physician monitoring while attached to an electrocardiogram machine.

Novartis operated a marketing campaign for Gilenya targeted at physicians. The TAC alleges that various aspects of this campaign functioned as a pretext for

Novartis to remunerate physicians in order to influence their prescribing practices. Specifically, Camburn alleged that Novartis convened "sham" speaker and patient programs, professionally produced promotional materials for doctors, outfitted medical offices for first-dose observations, "taught physicians how to defraud the government by overbilling for the [first-dose observations]," and "wined and dined" physician speakers at one-on-one dinners at high-end restaurants. J. App'x 263, 268, 279–80, 389 (altered capitalization). The theory of Camburn's case is that Novartis caused pharmacies and physicians to submit false claims to the government and to the states for healthcare reimbursement under programs including Medicare Part D, Medicaid, and TRICARE.

Camburn began working for Novartis in August 2010 as an executive sales specialist. In that role, he aided Novartis in launching Gilenya in the Philadelphia area. The complaint states that Camburn "excel[led]" in his role, ranking highly within his sales team and earning praise from his manager. In July 2013, shortly after he filed suit, Novartis terminated his employment.

I. Procedural History

Camburn filed this qui tam action against Novartis in May 2013 on behalf of the United States, 29 states ("States"), the District of Columbia ("D.C."), and the

City of Chicago and the City of New York ("Cities"). He alleged civil liability under the FCA and equivalent state and municipal laws.

After the government, the States and D.C., and the Cities declined to intervene, Novartis moved to dismiss, and Camburn elected to file an Amended Complaint in lieu of responding. The district court granted Novartis's motion to dismiss in March 2020 after concluding that the Amended Complaint had not pleaded the existence of the kickback scheme with the particularity that Rule 9(b) requires. The court granted Camburn leave to amend.

In May 2020, Camburn filed a Second Amended Complaint containing additional factual allegations. He illustrated his claims with the statements of 21 newly identified confidential witnesses, who worked in sales or as nurse educators across 21 states. Following a period of contested discovery, the parties stipulated to Camburn's filing the TAC, which is the subject of this appeal. While the substance of Camburn's allegations remained the same across the complaints, the TAC, among other changes, recharacterizes some of the confidential witnesses' statements in light of their deposition testimony.

The district court dismissed the TAC with prejudice. *See Novartis Pharms. Corp.*, 2022 U.S. Dist. LEXIS 165383, at *29–30. The court analyzed each broad

grouping of alleged misconduct—holding "sham" speaker and patient programs, providing promotion materials to physicians, outfitting medical offices, coaching physicians to bill improperly, and wining and dining physician speakers—in turn. *Id*. at *9–28. The district court concluded that Camburn still had not "adequately plead[ed] the existence of a kickback scheme with sufficient particularity." *Id*. at *29. Because Camburn's FCA claim was predicated on his establishing a violation of the AKS, the court dismissed the FCA claim after it determined that Camburn alleged no AKS violation. *Id*. at *29–30. Camburn timely appealed.

STANDARD OF REVIEW

We review de novo the grant of a Rule 12(b)(6) motion to dismiss, "accepting," as the district court also must, "all factual allegations as true and drawing all reasonable inferences in favor of the plaintiff." *Trs. of Upstate N.Y. Eng'rs Pension Fund v. Ivy Asset Mgmt.*, 843 F.3d 561, 566 (2d Cir. 2016). In evaluating whether a claim to relief is "plausible on its face," a court "disregard[s] conclusory allegations, such as 'formulaic recitation[s] of the elements of a cause of action.'" *Sacerdote v. New York Univ.*, 9 F.4th 95, 106–07 (2d Cir. 2021) (quoting *Twombly*, 550 U.S. at 555, 570).

Claims sounding in fraud, including the AKS-based FCA claim Camburn brought, must also meet the heightened pleading requirements of Federal Rule of Civil Procedure 9(b). *United States ex rel. Hart v. McKesson Corp.*, 96 F.4th 145, 153 (2d Cir. 2024); *Chorches*, 865 F.3d at 81 (citing *United States ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 26 (2d Cir. 2016)); *United States ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 617–18 (2d Cir. 2016). Rule 9(b) provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. Pro. 9(b). Under this standard, Camburn was obligated to "plead the factual basis" that "gives rise to a strong inference of fraudulent intent." *Hart*, 96 F.4th at 153 (quoting *United States v. Strock*, 982 F.3d 51, 66 (2d Cir. 2020)). Ultimately, the "adequacy of particularized allegations under Rule 9(b) is . . . case- and context-specific." *Chorches*, 865 F.3d at 81 (internal quotation marks and citations omitted).

DISCUSSION

The district court erred in holding that no part of the TAC stated a cognizable violation of the AKS. Camburn set forth with adequate particularity certain factual allegations related to (1) Novartis's organization of speaker events, (2) its compensation structure for them, and (3) its selection of speakers, as

specified below. These allegations regarding the alleged "sham" speaker program, J. App'x 266 (TAC ¶ 7), give rise to a "strong inference" that at least one purpose of Novartis's conduct was to induce fraud. *Hart*, 96 F.4th at 153. In concluding otherwise for these portions of the TAC, the district court drew inferences against Camburn in contravention of the Rule 12(b)(6) standard.

I. Relevant Law

The AKS prohibits individuals from "knowingly and willfully offer[ing] or pay[ing] any remuneration . . . to induce" an individual to purchase a federally reimbursable healthcare product. 42 U.S.C. § 1320a-7b(b)(2)(B); *see Pfizer, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 42 F.4th 67, 72 (2d Cir. 2022), *cert. denied*, 143 S. Ct. 626 (2023). While the AKS sets forth a criminal prohibition, it can supply the predicate, in a relator-initiated action, for civil liability under the FCA. The FCA proscribes individuals from "knowingly . . . caus[ing] to be presented[] a false or fraudulent claim for payment or approval" or "knowingly . . . caus[ing] to be made or used[] a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)–(B). The AKS provides that a claim "resulting from a violation" of the AKS "constitutes a false or fraudulent claim" for purposes of the FCA. 42 U.S.C. § 1320a-7b(g).

We hold as a matter of first impression that, in relator-initiated actions, a defendant violates the AKS when at least one (rather than the primary or sole) purpose of the remuneration she provides is to induce purchase of a federally reimbursable healthcare product. This rule aligns with that of our sister circuits. *See Guilfoile v. Shields*, 913 F.3d 178, 189 (1st Cir. 2019); *United States v. Greber*, 760 F.2d 68, 69, 72 (3d Cir. 1985); *United States v. Mallory*, 988 F.3d 730, 741 (4th Cir. 2021); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); *United States v. Borrasi*, 639 F.3d 774, 781-82 (7th Cir. 2011); *See United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989); *United States v. McClatchey*, 217 F.3d 823, 834–35 (10th Cir. 2000).[2] And as a corollary, a plaintiff pleading an AKS violation as a predicate to an FCA claim need not state a quid pro quo exchange.

[2] We have approved the at-least-one-purpose rule only in an unpublished opinion. *See Dhaliwal v. Salix Pharms., Ltd.*, 752 F. App'x 99, 100 (2d Cir. 2019). Lower courts in this Circuit have also applied this rule. *See, e.g.*, *Pfizer Inc. v. U.S. Dep't of Health & Hum. Servs.*, No. 1:20-CV-4920 (MKV), 2021 U.S. Dist. LEXIS 189381, at *40–45 (S.D.N.Y. Sept. 30, 2021), *aff'd*, 42 F.4th 67 (2d Cir. 2022); *United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 806 (S.D.N.Y. 2017), *rev'd and remanded on other grounds*, 899 F.3d 163 (2d Cir. 2018); *United States v. Teva Pharmaceuticals USA, Inc.*, 2016 U.S. Dist. LEXIS 22554, at *50–51 (S.D.N.Y. Feb. 22, 2016).

We note, too, that the district court explained, following the lead of its peers in the Circuit, that because Camburn alleged a complex fraudulent scheme, he could satisfy Rules 9(b) and 12(b) without alleging every instance of fraudulent conduct, so long as he alleged a "representative sample[]" with particularity. *Novartis Pharms. Corp.*, 2022 U.S. Dist. LEXIS 165383, at *8 (quoting *United States ex rel. Tessler v. City of New York*, No. 14-CV-6455, 2016 U.S. Dist. LEXIS 174013, at *8 (S.D.N.Y. Dec. 16, 2016)). No party disputes this standard, and we do not pass on it.

So, here, Camburn needed only to allege that at least one purpose of the remuneration was to induce prescriptions, without alleging a cause-and-effect relationship (a quid pro quo) between the payments and the physicians' prescribing habits. We turn to evaluating the adequacy of Camburn's pleadings with these principles in mind.

II. Analysis

We hold that Camburn has sufficiently pleaded factual allegations in support of an AKS violation in the three categories set forth below. But we affirm the district court in concluding that Camburn did not plead his remaining factual claims with the requisite particularity to allege that one of the purposes of Novartis's conduct was to induce physicians to prescribe Gilenya at a higher volume. *See Novartis Pharms. Corp.*, 2022 U.S. Dist. LEXIS 165383, at *18–28.

A. The District Court Erroneously Dismissed Three Categories of Factual Allegations

Camburn has stated a sufficient AKS violation with regard to three narrow categories of factual allegations involving (1) speaker events with few or no legitimate attendees, J. App'x 345–47 (TAC ¶¶ 228(n), 232, 233); (2) excessive compensation of speakers for canceled events, *id*. at 349–50 (TAC ¶ 241); and (3) the selection of speakers to reward and influence high prescribers, *id.* at 370–71,

373, 377–78 (TAC ¶¶ 296, 300, 314). The district court, treating these allegations as "representative samples," *see Novartis Pharms. Corp.*, 2022 U.S. Dist. LEXIS 165383, at *8 (citation omitted), should have credited their specificity and drawn all plausible inferences in Camburn's favor. Together, these allegations give rise to a strong inference that one purpose of Novartis's conduct was to illicitly compensate physicians in order to induce them to write a higher volume of prescriptions for Gilenya. We describe each category in turn.

1. Camburn Stated an AKS Violation with Respect to Speaker Events with No Legitimate Attendees

Camburn provided "illustrative examples" of physician-speakers giving presentations solely to other Novartis speakers or to members of their own practice. J. App'x 346 (TAC ¶ 229). Specifically, on April 11, 2013, one speaker allegedly presented to two other Novartis speakers over a "lavish" steak dinner at a Florida restaurant. *Id*. at 345 (TAC ¶ 228(n)). The tab totaled an alleged $1,080 by the end of the night. *Id*. (TAC ¶ 228(n)). Elsewhere, the TAC chronicles similarly "extravagant" events hosted at "a Zagat-rated bistro, 211 York" and "a high-end steakhouse, CHOPS II." *Id*. at 346–47 (TAC ¶¶ 232, 233). At these, speakers allegedly presented only to colleagues and staff from their own practices. *Id*. (TAC ¶¶ 232, 233). Importantly, in each case, Camburn identified with

particularity the doctors and attendees involved. He specified the dates on and venues at which the alleged events took place. These details satisfy Rule 9(b).

We agree with Camburn that these events give rise to a strong inference of fraudulent conduct. Their exclusive attendance by individuals attached to practices already familiar, via their respective physician-speakers, with Gilenya, in combination with their upscale settings, support a strong inference that at least one purpose of this aspect of the speaker program was to provide kickbacks to prescribers.

We note, too, that though we are not bound by rulings of district courts, at least three in this Circuit have found similar allegations sufficient. *See, e.g.*, *United States ex rel. Bilotta v. Novartis Pharms. Corp.*, 50 F. Supp. 3d 497, 515 (S.D.N.Y. 2014) (ruling that the government had sufficiently pleaded AKS violations against Novartis for speaking events that "constituted upscale, all-expense paid social outings for the doctors" "in venues that were not appropriate for their purported 'educational' purpose" to push other drugs); *United States v. Teva Pharms. USA, Inc.*, No. 13 Civ. 3702 (CM), 2016 U.S. Dist. LEXIS 22554, at *51 (S.D.N.Y. Feb. 22, 2016) (finding relators had sufficiently "pleaded that . . . speaking programs were sham" when they alleged that the programs "provided useless information, and

that the few persons in attendance were both familiar with the material already (indeed, most of them are alleged to have been presenters) and were paid to be there").

We conclude that Camburn's allegations here, even without more, support a claim of an AKS violation.

2. Camburn Stated an AKS Violation with Respect to Compensation of Speakers for Canceled Events

The TAC also identifies, by name and location, three physicians whom Novartis paid for canceled events. J. App'x 349–50 (TAC ¶ 241). It describes exactly how much each speaker was paid for canceled events (from $20,000 to $22,500) in a two-year period and details the volume and dollar value of claims (from $1 to $1.7 million) each allegedly submitted to Medicare Part D in the same period. *Id*. (TAC ¶ 241).

Here, too, Camburn's claims resemble those that district courts in our Circuit have found sufficient. *See, e.g.*, *Bilotta*, 50 F. Supp. 3d at 515 (explaining that signs of sham speaking programs include the fact that "doctors were paid thousands of dollars to 'speak' at these events, even when Novartis drugs were not discussed or the events did not take place"); *accord Teva*, 2016 U.S. Dist. LEXIS 22554, at *48–49 (echoing *Bilotta*'s admonition that the compensation of physicians

for speaking engagements that did not take place can support the sufficiency of relators' FCA allegations).

We think that Camburn's factual allegations here are set forth with enough particularity to give rise to a strong inference that the payments constituted, at least in part, unlawful remuneration.

3. Camburn Stated an AKS Violation with Respect to the Selection and Retention of Speakers

Finally, the TAC recounts the testimony of two Novartis sales representatives who outlined how their managers encouraged them to offer speaking engagements to certain physicians. J. App'x 370–71, 373 (TAC ¶¶ 296, 300). One identified Chicago-based physician's nurse allegedly informed Witness 18 that the physician would not prescribe Gilenya without speaking engagements. *Id*. (TAC ¶ 296). Thereafter, Witness 18's district manager instructed Witness 18 to facilitate this quid pro quo. *Id*. (TAC ¶ 296). And according to the TAC, when the physician's prescriptions declined, the district manager explained to Witness 18 that Novartis "ha[d] to use" the physician as a speaker because his prescriptions of Gilenya were "down." *Id*. 370–71 (TAC ¶ 296). The TAC also describes a similar interaction between Witness 19 and Witness 19's account manager. *Id*. at 373 (TAC ¶ 300). The manager allegedly commented that a certain identified physician had

the potential for a "huge volume" of prescriptions and instructed Witness 19 to select that physician for the speaker program. *Id*. (TAC ¶ 300). According to the TAC, "Dr. A.O.'s prescriptions did increase after she was made a [s]peaker." *Id*. (TAC ¶ 300).

Lastly, Camburn alleged that in 2013, "there were weekly conference calls concerning Dr. J.S.[,] a young, high-volume Gilenya writing physician based in the State of Delaware." J. App'x 377–78 (TAC ¶ 314). The TAC asserts that a strategic account manager "led these calls," and that during them, he "explicitly stated that he was extremely concerned that, since Patient Programs had decreased in 2013, Novartis needed to find additional ways to 'show [Dr. J.S.] love and keep him happy.'" *Id*. (TAC ¶ 314). The manager allegedly began searching for other opportunities for Dr. J.S. to speak or otherwise earn compensation from Novartis. *Id*. (TAC ¶ 314).

Taken as true, all three categories of activities detailed above—(1) lavish speaker events with no legitimate attendees; (2) excessive compensation of speakers for canceled events; and (3) the selection of speakers to incentivize prescription-writing—plausibly and "strong[ly]" suggest Novartis operated its speaker program at least in part to remunerate certain physicians to prescribe

Gilenya. *See Hart*, 96 F.4th at 153 (citation omitted). Further proceedings upon remand will reveal how meritorious Camburn's claims actually are. But at the motion to dismiss stage under Rules 9(b) and 12(b)(6), we are satisfied that on these three grounds, Camburn has stated a claim of an AKS violation.

B. The District Court Correctly Dismissed the Remaining Factual Allegations

The district court properly dismissed the remainder of Camburn's allegations, which fail to support the conclusion that at least one purpose of the alleged remuneration Novartis provided was to induce higher prescriptions. *See Novartis Pharms. Corp.*, 2022 U.S. Dist. LEXIS 165383, at *18–28. Camburn was required to supply enough color in his TAC to "nudge[] [his] claims across the line from conceivable to plausible," *Twombly*, 550 U.S. at 570, under Rule 9(b)'s "strong inference" standard. *See Hart*, 96 F.4th at 153 (citation omitted). But outside of those facts discussed above, pp. 13–19, other aspects of his allegations regarding the supposed "sham" speaker program, J. App'x 266 (TAC ¶ 7), provide few specific details to satisfy the at-least-one-purpose rule. Similarly, we agree that Camburn failed to link Novartis's DVD initiative, "entertainment rooms," visual aids for billing codes, and one-on-one physician dinners with a strong inference

that Novartis used these tools, at least in part, to induce higher prescription-writing.

We conclude with a reminder that our analysis is necessarily context-specific. *See Chorches*, 865 F.3d at 81. A future AKS-based FCA action involving different parties may feature a complaint that pleads similar facts in substance, but that substantiates them with greater particularity such that a strong inference of fraud may be drawn.

CONCLUSION

We hold that a complaint states a viable AKS claim when it alleges with the requisite particularity that at least one purpose of the alleged scheme was to induce fraudulent conduct. Here, for the foregoing reasons, for three categories of factual allegations related to Novartis's speaker program, we conclude that Camburn has stated an AKS violation.

We therefore **AFFIRM** the district court's dismissal order in part, and **VACATE** the judgment and **REMAND** in part for proceedings consistent with this opinion. On remand, the district court is instructed to evaluate whether, given Camburn has stated a predicate AKS violation with respect to (1) speaker events with no legitimate attendees; (2) excessive fees paid to speakers for

canceled events; and (3) the selection of speakers to induce them to prescribe Gilenya, Camburn has therefore stated all the elements of an FCA claim with respect to these allegations. The district court is additionally instructed to assess, as appropriate, the adequacy of Camburn's claims under state and municipal law in a manner consistent with this opinion.