United States of America ex rel. Steven M. Camburn et al. v. Novartis Pharmaceuticals Corporation Doc. 93

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WASHINGTON and WISCONSIN, the DISTRICT OF COLUMBIA, THE CITY OF CHICAGO and THE CITY OF NEW YORK *ex rel.* STEVEN M. CAMBURN,

Plaintiffs and Relator,

-against-

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant.

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13-CV-3700 (KMW)

OPINION & ORDER

KIMBA M. WOOD, United States District Judge:

In this *qui tam* action, Relator Steven Camburn ("Relator") alleges that Defendant Novartis Pharmaceuticals Corporation ("Novartis") violated the Anti-Kickback Statute ("AKS") and the False Claims Act ("FCA") by operating a nationwide kickback scheme in which Novartis improperly induced physicians to prescribe Gilenya, a drug used to treat multiple sclerosis. Novartis has moved to dismiss Relator's Third Amended Complaint ("TAC") pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure. For the reasons stated below, Novartis' motion is GRANTED, and the TAC is dismissed, with prejudice.

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BACKGROUND

Relator brings a *qui tam* action against Novartis for violations of the AKS and FCA, alleging that Novartis operated a kickback scheme with a purpose of bribing physicians to prescribe Gilenya. Much of the procedural history of this action was reviewed in the Court's prior ruling on the Amended Complaint ("AC") and does not bear repeating in detail. (*See* Op. & Order, ECF No. 44.)[1] Only the pertinent portions of this history and facts from the TAC are summarized below.

I. Procedural History

Relator initiated this lawsuit on behalf of the United States and several states and municipalities on May 31, 2013. (Compl., ECF No. 16.) Those governments subsequently declined to intervene, and the complaint was unsealed. (ECF Nos. 15, 18.) On September 10, 2018, Relator filed the AC, which Novartis moved to dismiss. (ECF Nos. 27–28.) On March 24, 2020, the Court dismissed the AC, holding that Relator had "not adequately pl[ed] the existence of a kickback scheme with sufficient particularity," but granted Relator leave to amend his complaint. (Op. & Order at 13.)

Relator filed a Second Amended Complaint ("SAC") on May 15, 2020, which added, *inter alia*, statements from confidential witnesses. (ECF No. 47.) After Novartis' discovery into these statements, Novartis informed Relator that there were mischaracterizations relating to the statements. (*See* Gruenstein Decl. ¶¶ 11–12, ECF No. 88; Miller Decl. ¶ 3, ECF No. 90.) On August 8, 2021 Novartis served Relator with a Rule 11 Notice of Motion for Sanctions. (Gruenstein Decl. ¶ 12.) Following extensive discussions, the parties agreed that Relator would

[1] *United States ex rel. Camburn v. Novartis Pharmaceuticals Corp.*, No. 13-CV-3700, 2020 WL 1436706 (S.D.N.Y. Mar. 24, 2020) (Wood, J.).

file a TAC to address Novartis' concerns, with the understanding that Novartis would move to dismiss. (*See* Gruenstein Decl. ¶¶ 13–15; Miller Decl. ¶¶ 4–6.) Relator filed the instant TAC on November 19, 2021. (ECF No. 77.) Novartis moved to dismiss on January 3, 2022. (ECF No. 86.)

II. TAC Allegations

Novartis manufactures Gilenya, a drug that was approved to treat multiple sclerosis in September 2010. (TAC ¶ 5.) When it approved Gilenya, the Food and Drug Administration ("FDA") imposed a First Dose Observation ("FDO") requirement, in which a physician had to monitor a person for potential heart problems for at least six hours after drug administration. (TAC ¶ 152.) To promote Gilenya, Novartis sales representatives organized speaker programs. (TAC ¶¶ 7, 165.) At these programs, Novartis-paid speakers addressed other healthcare professionals ("HCPs") or potential patients about Gilenya. (*Id.*) Relator alleges that these speaker programs did not actually educate HCPs or patients but instead were a pretext for payments to high-prescribing physician speakers. (TAC ¶¶ 162, 166, 216.)

Relator alleges that the speaker programs were "shams" and "provide[d] little, if any educational value" for several reasons. (TAC ¶¶ 7, 166.) First, he alleges that the content of speakers' presentations was constantly recycled and simply repeated the drug package label insert information or information sales representatives already provided to physicians. (TAC ¶ 166.) Second, he alleges that Novartis conducted an excessive number of speaker programs, which were not informed by a needs assessment. (TAC ¶¶ 168, 190.) Third, Relator alleges that the speaker programs were poorly attended, or had no "legitimate Attendees," and were regularly conducted at high-end restaurants. (*See* TAC ¶¶ 186–217.) In support of this allegation, he provides a series of tables that identify events for which Novartis paid speakers but where there were "no legitimate Attendees" or too few HCP Attendees. (TAC ¶¶ 221–25.) Fourth, Relator

alleges that Novartis paid speakers for cancelled events, conduct that often benefitted high prescribers. (TAC ¶¶ 236, 241.) In support of this allegation, he provides a list of 282 cancelled programs between 2010 and 2013 for which speakers were still paid. (TAC ¶ 238, Ex. C.) Finally, according to Relator, Novartis selected physician speakers based on their prescribing potential and removed physicians who did not prescribe enough Gilenya as speakers. (TAC ¶¶ 270, 276, 280.)

Relator also alleges that Novartis found other ways to provide kickbacks to physicians. He alleges that Novartis produced DVDs and flyers that included information such as physicians' names, contact information, photos, and credentials, which were intended to be distributed at speaker programs. (TAC ¶¶ 320–27.) Additionally, Relator alleges that Novartis improperly outfitted medical offices with "entertainment centers" to "appease physicians regarding their resistance to the FDO requirement." (TAC ¶ 335–36.) According to Relator, Novartis also provided improper billing assistance by suggesting billing codes that physicians could use to bill for their time overseeing the FDOs. (TAC ¶ 340.) He alleges that one nurse educator "worked with physicians to explain how they could bill for 23 hours of time with respect to the 6 hour FDO period." (TAC ¶ 342.) Finally, Relator alleges that Novartis "wined and dined" speakers with an eye toward "relationship building" and with the intent of influencing prescription-writing. (TAC ¶¶ 344–49, 353.)

LEGAL STANDARD

"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)). In assessing the plausibility of a plaintiff's claim for relief, a court "must construe [the complaint]

liberally, accepting all factual allegations therein as true and drawing all reasonable inferences in the plaintiffs' favor," but "disregard[ing] conclusory allegations, such as 'formulaic recitation[s] of the elements of a cause of action.'" *Sacerdote v. N.Y. Univ.*, 9 F.4th 95, 106–7 (2d Cir. 2021) (quoting *Twombly*, 550 U.S. at 555), *cert. denied sub nom. N.Y. Univ. v. Sacerdote*, 142 S. Ct. 1112 (2022) (mem.). If a plaintiff has not "nudged [its] claims across the line from conceivable to plausible, [the] complaint must be dismissed." *Twombly*, 550 U.S. at 570.

In cases involving fraud, a plaintiff must also comply with Rule 9(b)'s requirement that claims be pled "with particularity." Fed. R. Civ. P. 9(b). Generally, to comply with Rule 9(b), a complaint "must: (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Lerner v. Fleet Bank, N.A.*, 459 F.3d 273, 290 (2d Cir. 2006) (quoting *Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1175 (2d Cir. 1993)). Importantly, the "adequacy of particularized allegations under Rule 9(b) is . . . case- and context-specific." *United States ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 81 (2d Cir. 2017) (internal quotations and citations omitted).

In addition, "where the alleged fraudulent scheme involved numerous transactions that occurred over a long period of time, courts have found it impractical to require the plaintiff to plead the specifics with respect to each and every instance of fraudulent conduct." *United States v. Wells Fargo Bank, N.A.*, 972 F. Supp. 2d 593, 616 (S.D.N.Y. 2013) (Furman, J.) (quoting *In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 333 (D. Conn. 2004)). Therefore, "where a relator pleads a complex and far-reaching fraudulent scheme with particularity, and provides examples of specific false claims submitted to the government pursuant to that scheme, a relator may proceed to discovery on the entire fraudulent scheme." *United States ex rel. Tessler v. City*

of New York, No. 14-CV-6455, 2016 WL 7335654, at *2 (S.D.N.Y. Dec. 2016) (Furman, J.) (quoting *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 510 (6th Cir. 2007)). But these examples "will support more generalized allegations of fraud only to the extent that [they] are representative samples of the broader class of claims." *Id.*

Plaintiffs alleging FCA claims premised on violations of the AKS must plead both the FCA violation and the underlying kickback scheme in compliance with Rule 9(b). *See United States ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 617–18 (2d Cir. 2016); *United States ex rel. Bilotta v. Novartis Pharm. Corp.*, 50 F. Supp. 3d 497, 513–14 (S.D.N.Y. 2014) (Gardephe, J.). Claims pled under FCA-analogous state and municipal laws must also be pled in compliance with Rule 9(b). *See United States ex rel. Arnstein v. TEVA Pharms. USA, Inc.*, No. 13-CV-3702, 2016 WL 750720, at *11 (S.D.N.Y. Feb. 22, 2016) (McMahon, J.).

DISCUSSION

The Court previously dismissed Relator's Amended Complaint because Relator had "fail[ed] to plead the existence of a kickback scheme with adequate particularity." (Op. & Order at 5.) Accordingly, the Court begins here by considering whether Relator has cured the deficiencies in his complaint relating to the alleged kickback scheme and thus meets the Rule 9(b) standard. The Court holds that he has not.

I. Relator Has Not Sufficiently Pled the Existence of a Kickback Scheme

Relator's central allegation is that Novartis violated the AKS, and by extension the FCA, by operating a nationwide kickback scheme in which Novartis improperly induced physicians to prescribe Gilenya. (TAC ¶ 162.) The FCA imposes liability on "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). A claim that results from a violation of the AKS "constitutes a false or

fraudulent claim for the purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). Therefore, any person who violates the AKS by "knowingly and willfully offer[ing] or pay[ing] any remuneration" to induce a person to submit a claim to a federal health care program is also liable under the FCA. 42 U.S.C. § 1320a-7b(b)(2).

In support of this central allegation, Relator describes certain events and conduct that, he asserts, demonstrate Novartis had an improper purpose to bribe prescribers. Relator alleges several features of the speaker events that he claims establish the existence of a kickback scheme, namely that: (1) they lacked educational value, (2) they were poorly attended, (3) speakers were paid for cancelled events, and (4) speakers were chosen on the basis of their prescription potential. Relator also describes other Novartis conduct he alleges constitute kickbacks: (1) provision of "promotional materials" to physicians, (2) outfitting of medical offices for FDOs, (3) conduct regarding billing codes, and (4) "wining and dining" speakers. The Court addresses each of these two broad categories of conduct in turn.

A. Novartis' Allegedly "Sham" Speaker Events

To promote Gilenya, Novartis held speaker programs around the country. At these events, a healthcare professional, typically a physician, was paid to educate an audience about Gilenya. Relator alleges these speaker events did not serve an educational purpose and were instead a pretext for Novartis to provide compensation to physician speakers for prescribing Gilenya.

1. Speaker Events Had No Educational Value

Relator has not cured the deficiencies the Court identified in the AC regarding his allegations about the educational value of the speaker events. He argues that these events lacked educational value because they were thin on substance, were largely social in nature, and were conducted so frequently that "the repeated content left nothing new to learn." (Pl.'s Mem. in

Opp'n at 9, ECF No. 89.)

With respect to content, Relator alleges that the slide decks presented at speaker events "provide[d] little, if any, educational value, as the content [was] rudimentary, overly simplistic and repetitive." (TAC ¶ 166.) He further alleges that "the slide deck content repeat[ed] the drug package label insert information, and also repeat[ed] the information that sales representatives provide to each doctor during weekly office visits . . . ." (*Id.*) But Relator's allegations remain essentially unchanged from the AC, which the Court found insufficiently pled. (*See* Op. & Order at 9.)[2] Relator has not provided additional information that the Court identified in its prior order, for example "whether events at which the slide deck was partially or fully presented served an educational purpose." (*Id.*)

Relator also alleges that the speaker events were "largely social events" and thus not educational in nature. (TAC ¶ 206.) In support of this assertion, Relator alleges that the speaker events occurred at "high-end restaurants" and often went over budget. (TAC ¶¶ 213, 215–17.) Additionally, he details efforts by some sales representatives to conceal this excessive spending, and he identifies locations of some events and the amounts spent. (TAC ¶¶ 211–218.) He does not, however, explain "why sales personnel concealed the excessive spending . . . or what role the falsification played in the alleged kickback scheme." (Op. & Order at 9.) Instead, Relator concludes without explanation that meal limits were "being exceeded as part of its campaign to bribe." (TAC ¶ 218.) Accordingly, Relator has not provided sufficient information from which

[2] In his AC, Relator alleged: "Novartis gives the speakers a slide deck to present to attendees. However, these slide decks provide little, if any, educational value, as the content is rudimentary, overly simplistic and repetitive. In fact, the slide deck content repeats the drug package label insert information, and also repeats the information that sales representatives provide to each doctor during their weekly office visits when they 'detail' the physicians. Unsurprisingly, based on Plaintiff-Relator's experience . . . only approximately 10% of the Peer-to-Peer speakers and 20-30% of the patient program speakers present the entire slide deck . . . . In addition, because the slide deck material is so rudimentary and repetitive . . . there is usually no substantive discussion among the attendees . . . ." (AC ¶ 96.)

the Court could reasonably infer that that speaker events were improper social events that amounted to bribes.

As for frequency, Relator alleges that the speaker events were so numerous that they should be considered "shams." In support of this allegation, Relator points to several witness statements to emphasize that the speaker events were excessive in number. (*See* TAC ¶¶ 167–185, 303, 306.) He also alleges that Novartis failed to conduct a needs assessment "to legitimately determine the appropriate number of [speakers or programs] . . . to legitimately promote Gilenya." (TAC ¶ 190.) But Relator does not provide a sufficient basis for the Court to infer that the speaker events lacked educational value *because* they were excessive in number. Relator does not explain, for example, why a given number of events was excessive for a particular area, or why conducting a large number of events indicates that the events themselves were shams.[3] His allegation that sales representatives' compensation was based in part on the number of events they conducted does no more to establish a sufficient link between frequency and improper purpose. Accordingly, Relator's allegations regarding the speaking events' lack of educational value have not been sufficiently pled to support the inference that the events were a "sham."

2. Attendance at Speaker Events

Relator alleges that many speaker events lacked "legitimate Attendees"[4] and thus

[3] For example, Relator alleges that sales representatives in the Philadelphia region were "required to schedule 96 Patient Events and 32 Peer-to-Peer programs in 2012." (TAC ¶ 303.) He then compares these figures to the number of "similar events conducted by competitors, which normally would not exceed five per annum for either event in the same geographical region." (*Id.*) First, Relator seems to compare Novartis' allegedly target number with competitors' actual number of events. Second, the fact that Novartis purportedly conducted more events than competitors in a given area does not by itself demonstrate that the events were excessive in number. More is required for the Court to reasonably infer that Relator's allegations establish an improper purpose.

[4] Relator does not clearly define "legitimate Attendee." He defines "Attendee" as someone who is an "attendee[] at . . . [Speaker] Programs." (TAC ¶ 39.) Elsewhere in the TAC, Relator alleges that "Speaker Programs must have at least three HCPs [healthcare providers] in attendance, that at least one Novartis sales representative must be present at every Speaker Program, and that doctors or other practitioners from the Speaker's

amounted to payments to physicians for "attending dinners with Novartis sales representatives" and underscoring the "fraudulent nature of [Novartis'] Speaker Programs." (TAC ¶ 197, 220.) He also alleges that many speaker events had repeat attendees, in some cases up to "80 to 90 percent." (TAC ¶ 256.)

a. Few or No "Legitimate Attendees"

In support of his allegations regarding "legitimate Attendees," Relator provides several tables that list events at which there were allegedly no legitimate attendees or not enough legitimate attendees. (*See* TAC ¶¶ 221–25.) With respect to this information, Novartis argues that Relator "has failed to provide the details required to address th[e] Court's criticisms of the AC." (Def.'s Reply Supp. Mot. to Dismiss at 5, ECF No. 91.) Two of the tables include the date of the event, the speaker's initials, the program code, and the territory. (TAC ¶ 221, 224.) Another two of the tables include only the date, program code, and territory. (TAC ¶ 222, 225.) Although he has added more detail, Relator still has not provided a basis on which to reasonably infer that these events were fraudulent. For example, Relator does not specify the content of these events or who else was in the audience. His assertion that the events had no legitimate attendees, or not enough of them, suggests that he is familiar with the composition of the audience at these events. Yet he does not provide that detail in his TAC.

Relator also alleges that several speaker programs included other Novartis speakers in the audience, thus undermining the programs' educational purpose. (TAC ¶ 228.) Although he

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own practice cannot be included in determining whether a Program has at least the minimum three attendees." (TAC ¶ 57.) Further in the TAC, Relator alleges that "non-prescribers, such as office managers, receptionists and secretaries do not qualify as HCPs and, therefore, would not be legitimate attends [sic] at Speaker Programs[.]" (TAC ¶ 197.) Relator also appears to use "legitimate Attendee" and "legitimate HCP Attendee[]" interchangeably. (*See, e.g.*, TAC ¶ 197.) Additionally, he equates "illegitimate Attendees" with "Speakers." (TAC ¶ 229.) Therefore, it seems that "legitimate Attendee" means: a prescriber of Gilenya who does not work with the physician who is speaking at an event. But Relator does not adequately explain why only speaker events to audiences of these attendees can be legitimate and thus not "shams."

provides names, dates, and locations, he does not specify who else attended those events. The fact that another physician speaker was in the audience does not automatically render a speaker event illegitimate. Without more detail as to the composition of the audience at these events, and the content covered, Relator's claim that they are "shams" is merely a "conclusory allegation."[5] *See Sacerdote*, 9 F.4th at 107. Relator provides only a single example of an event at which "[t]he *only* attendees were Gilenya speakers." (TAC ¶ 228(n) (emphasis added).) But he has not shown that this event is a representative example. To the contrary, Relator's other alleged instances of physician speaker attendance, for which Relator does not detail who else attended, suggest this single example is not representative. Therefore, Relator has not adequately explained why the events with few or no "legitimate Attendees" were fraudulent and has not "nudged [these] claims across the line from conceivable to plausible." *See Twombly*, 550 U.S. at 570.

b. Repeat Attendees

Relator alleges that the many repeat attendees at speaker programs for potential patients undermine the legitimacy of these programs. Specifically, he argues, "[t]here was little educational value in the programs for repeat attendees who would hear the same presentation over again." (Pl.'s Mem. in Opp'n at 11.) In support of this contention, Relator provides several witness statements regarding repeat attendees. (*See, e.g.*, TAC ¶¶ 254–264.) Witnesses describe their experience with patient programs and allege that repeat attendance could be as low as "10 to 15 percent" and as high as "90 . . . to 100 percent." (TAC ¶¶ 258, 298.) Others allege that repeat attendance "averaged 30-40 percent" or "70 to 80 percent." (*Id.* at ¶ 261–62.)

[5] By contrast, in *Bilotta*, the complaint alleged that "groups of the same doctors would repeatedly attend speaker events on the same topic within a short period of time, with the doctors taking turns in the roles of attendees and 'speakers.' For example, one doctor attended the same presentation ten times between July 2010 and October 2011, and the same three doctors were consistently present at nine of those events." *Bilotta*, 50 F. Supp. 3d at 502.

These allegations suffer from a lack of particularity. Relator does not provide the type of concrete details regarding the allegedly repeat attendees, or the content of speakers' presentations at events with repeat attendees, that the Court previously indicated could substantiate his allegations. (*See* Op. & Order at 9.) Notwithstanding Relator's allegation that "no attendance lists are maintained with respect to patient[]" programs, he also alleges that sales representatives received "RSVPs for Patient Programs." (TAC ¶ 252, 263.) Based on these facts, the composition of the audience at patient programs seems at least somewhat knowable. Moreover, it is difficult to conclude that witnesses' alleged estimates of repeat attendance, which range from 10 to 100 percent, are consistent enough to constitute "representative samples of the broader class of claims." *See Bledsoe*, 501 F.3d at 510. Therefore, Relator's allegations regarding repeat attendees have not been sufficiently pled with particularity.

3. Payment for Cancelled Events

Relator alleges that Novartis had a "deliberate practice of scheduling and then cancelling Speaker Programs." (TAC ¶ 236.) Because speakers were paid for these programs, nonetheless, Relator alleges that this practice facilitated "illegal payments to doctors." (*Id.*) In support of these allegations, Relator provides an exhibit listing speaker programs between 2010 and 2013 in which "Novartis paid doctors approximately $1,000,000 in connection with four hundred and sixty-nine (469) [6] Speaker Programs that were cancelled . . . [constituting an] excess of 10 percent of Programs scheduled during this period[.]" (*Id.*; *see also* TAC Ex. C.) Although that exhibit identifies specific events, Relator does not "identify . . . the circumstances or timing of the cancellation" for any of these events. (Op. & Order at 10.) Moreover, the information

[6] Relator appears to correct this number to 282 in his memorandum in opposition to Defendant's motion to dismiss. (Pl.'s Mem. in Opp'n at 12.)

regarding the three doctors who allegedly had received payments for cancelled events is unchanged from the AC. (*See* TAC ¶ 241; AC ¶ 99.) The Court previously concluded that this information was insufficient to evaluate the legitimacy of the alleged cancellations. (*See* Op. & Order at 10.) Therefore, it is not reasonable to infer, on the basis of the information Relator now provides, that the events he identifies were improperly cancelled and thus were a means of providing kickbacks to Gilenya prescribers.

4. ROI Analysis and Physicians' Prescription Potential

Relator alleges that Novartis "performed return on investment [ROI] analysis with respect to Speakers' prescribing habits" and prioritized physicians for speaking engagements based on their prescribing potential. (TAC ¶¶ 290, 300, 351.) He argues that "Novartis only wanted to pay speakers who would reciprocate by writing prescriptions" and therefore "us[ed] the Speaker Programs as a tool to increase prescriptions." (Pl.'s Mem. in Opp'n at 13.) But Relator's allegations do not link the ROI analysis and speaker prioritization to physicians' actual prescribing habits, and thus it is not reasonable to infer that a speaker's receipt of large payments was contingent on the number of prescriptions the speaker/physician wrote. *Cf. Arnstein*, 2016 WL 750720, at *17 (holding that the complaint's allegations supported the inference that physicians could become speakers and remain speakers only if they generated sufficient prescriptions).

In addition, Relator alleges that Novartis tracked whether speakers' prescriptions increased after participation in speaking events. (*See* TAC ¶¶ 286, 290, 293.) But Relator provides only one example of a speaker, Dr. A.O., whose prescribing allegedly "increase[d] after she was made a speaker." (TAC ¶ 300.) Notably, Relator does not list Dr. A.O. in any of the

exhibits that he alleges are evidence of Novartis' fraudulent inducement.[7] Finally, alleging that a physician's prescriptions merely "increase[d]," without more detail, is not enough. *Cf. Bilotta*, 50 F. Supp. 3d at 517–18 (court denied motion to dismiss because, *inter alia*, complaint described the change in the *number* of prescriptions doctors wrote compared to their earlier prescription-writing).

Relator also alleges that Novartis employees "frequently made comments about the prescribing habits of Speakers," and nominated speakers based on their prescribing potential. (TAC ¶¶ 270–71, 279.) But he does not provide specific examples of speakers who were selected on that basis.[8] Relator gives three examples of speakers who allegedly "were removed from the [speaking] bureau" because they "did not write sufficient amounts of Gilenya." (TAC ¶ 276.) These examples, however, do not demonstrate that Novartis selected speakers because of their prescribing potential.

In one example, Relator's witness alleges that, although the "official reason" Dr. C.R. was removed as a speaker was because s/he "had not conducted enough programs," the "real reason was that Dr. C.R. was not writing enough Gilenya prescriptions." (TAC ¶ 276.) These reasons, which the Court assumes to be true, are in conflict. Relator has not provided additional facts that would allow the Court to conclude that the alleged official reason should be ignored. Accordingly, it is not reasonable to infer, based on these allegations, that Dr. C.R. was removed because s/he was not prescribing enough Gilenya.

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[7] Exhibits C and D list physicians who allegedly were paid for cancelled events and physicians who allegedly submitted false claims, respectively. (*See* ECF No. 77.)

[8] Relator seems to suggest that the Court should conclude that speakers were selected on the basis of their prescribing habits because, for example, a witness alleged that Novartis employees "frequently made comments about the prescribing habits of Speakers . . . [and were] tracking the prescriptions of Speakers." (TAC ¶ 270.) That same witness, however, specifically stated that the "[Area Business Manager] never stated that individuals were being chosen as Speakers or Scheduled as speakers to influence their prescribing habits" and that the Area Business Manager never "explicitly link[ed] Speaking and prescribing." (*Id.*)

In a second example, Relator alleges that Dr. E.F. was removed as a speaker "for presenting off-label material regarding Gilenya, after which he completely stopped writing prescriptions for Gilenya." (TAC ¶ 280.) Relator's allegation regarding Dr. E.F. plainly states that Dr. E.F. was removed for a reason unconnected to his prescribing activity. (*Id.*) Therefore, Relator's claims do not support the conclusion that Dr. E.F. was removed as a speaker *because* he stopped prescribing Gilenya.

Finally, Relator alleges that a witness was "told to cease using Dr. J.H." because Dr. J.H. "wrote less and less Gilenya . . . after a competitor to Gilenya came to market." (TAC ¶ 302.) Unlike in *Bilotta*, in which plaintiffs alleged that "Novartis invited doctors to be speakers . . . based on the number of prescriptions they wrote for Novartis drugs, and that the doctors were aware of this practice," 50 F. Supp. 3d at 516, there is no indication here that Dr. J.H. was invited to be a speaker because of his prescribing habits or that he was aware of the reason for his purported removal. Moreover, Relator's witness conceded that s/he "was not completely certain if" Dr. J.H. was actually removed. (TAC ¶ 302.) Accordingly, these three examples do not reasonably support the inference that the speaker programs were "a tool to increase prescriptions." (Pl.'s Mem. in Opp'n at 13.)

B. Novartis' Other Alleged Conduct

In addition to the allegedly "sham" speaker programs, Relator alleges that Novartis engaged in other activities that were designed to reward physicians who prescribed Gilenya or induce them to increase their prescriptions. Specifically, Relator alleges that Novartis improperly: provided promotional materials to physicians, outfitted medical offices for FDOs, provided billing assistance, and "wined and dined" speakers. The Court considers each of these activities in turn.

1. Promotional Materials

Relator alleges that Novartis "provide[d] illegal remuneration to its Speakers by providing them with marketing materials and services to promote their medical practices and attract patients." (TAC ¶ 319.) These materials included DVDs that "contained doctors' names, contact information and professionally-rendered photos of each doctor." (TAC ¶ 320.) Although Relator alleges that they were "designed to be handed out to patients at Speaker Programs . . . to help the Speakers build their practices," Relator also alleges, inconsistently, that they were "provided to the doctor for distribution to their patient base as an educational tool." (TAC ¶¶ 320, 324.) Novartis allegedly compensated the physicians featured in these DVDs for their time. (TAC ¶ 319.)

Relator has failed to connect the DVD initiative to changes in physician prescribing behavior. *Cf.*, *Bilotta*, 50 F. Supp. 3d at 517–18 ("The Amended Complaint identifies at least ten doctors . . . and the change in their prescribing of Novartis cardiovascular drugs during [the relevant] time periods"; "Complaint also describes . . . the change in the number of prescriptions for Novartis drugs these doctors wrote compared to their earlier prescription-writing"; "During the time period that these doctors were being paid as 'speakers' . . . they wrote more prescriptions for Novartis's cardiovascular division drugs."). In the several paragraphs Relator devotes to describing the DVD initiative, he does not provide an example of a physician who changed his or her prescribing behavior while they participated in the initiative. (*See* TAC ¶ 319–33.) Relator identifies six examples of physicians who prescribed Gilenya and were featured in DVDs.[9] But the concurrence of these alleged facts does not automatically create an

[9] Drs. L.H. and J.S. "in the Philadelphia territories" (TAC ¶ 320) and Drs. T.S., E.M., J.S.S., and K.D. (locations unspecified, TAC ¶ 330).

inference that a purpose of the DVD initiative was to induce more prescriptions. Relator has not provided enough information to support that inference. Accordingly, Relator's allegations regarding the promotional materials are not sufficiently pled. [10]

2. Outfitting Medical Offices for FDOs

The FDA imposed an FDO requirement that any patient receiving Gilenya for the first time be observed for six hours thereafter because the drug can affect a person's heart rate. (TAC ¶ 152.) Relator alleges that, because "it was challenging to market Gilenya at the time of launch due to the FDO requirement," Novartis outfitted medical offices with "entertainment rooms," for the use of patients being observed.[11] (TAC ¶¶ 337, 339.) Relator argues that these rooms were "*quid pro quo* exchanges" to benefit Gilenya prescribers. (Pl.'s Mem. in Opp'n at 35.)

Relator's allegations regarding the "entertainment rooms" do not establish that the rooms were part of a campaign to bribe prescribers. Relator does not allege evidence of prescriber behavior in response to Novartis' provision of the rooms—the other side of the *quid pro quo* he seeks to establish. Accordingly, he has not provided sufficient information to infer that "the only reason that Novartis would have to facilitate the FDO . . . was to increase prescriptions . . . ." (TAC ¶ 337.)

3. Conduct Regarding Billing Codes

Relator alleges that Novartis "taught physicians how to defraud the government by overbilling for the FDO." (TAC ¶ 340.) Novartis allegedly did this by providing "visual aid[s]" that listed billing codes physicians could use to bill for their time spend administering the FDO.

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[10] Relator also alleges that "Novartis created flyers to invite attendees to the Speaker Programs." (TAC ¶ 325, 327.) Those allegations lack sufficient detail and suffer from the same deficiency as explained regarding the DVD initiative.

[11] Relator alleges that these rooms benefitted both physicians and their patients; by making patients more comfortable during the six-hour observation period, Novartis made it easier to convince physicians to prescribe Gilenya for first-time patients. (TAC ¶ 336–38.)

(*Id.*) One witness stated that a "nurse educator in his/her area worked with physicians to explain how they could bill for 23 hours of time with respect to the 6 hour FDO period." (TAC ¶ 342.) But Relator has not demonstrated that this example of allegedly fraudulent billing conduct is representative of activity on a broader scale.

Importantly, Relator does not allege that physicians' billing for FDO time was improper. Instead, he argues that Novartis was "improperly detailing physicians on billing codes as a service for those who were hesitant to spend long hours on FDOs without proper compensation." (Pl.'s Mem. in Opp'n at 36.) That is, "[a]lthough medical practices typically hire medical billing and coding specialists, Novartis took it upon itself to provide such assistance in order to induce prescription writing of [Gilenya]." (*Id.*)

Relator's allegations here fail in two key respects. First, they do not connect Novartis' alleged billing conduct to physician prescription activity. The fact that Novartis provided billing assistance for FDOs, for which physicians could properly bill their time, does not create a reasonable inference of fraudulent inducement. Second, Relator's allegations do not support an inference that Novartis "eliminate[d] an expense that the physician would have otherwise incurred." (*See id.*) The TAC does not provide examples of physicians who did not have to hire billing and coding staff because the physician effectively outsourced those functions to Novartis. Accordingly, Relator has not pled facts sufficient to infer a fraudulent scheme to generate Gilenya prescriptions.

4. "Wining and Dining" Speakers

Relator's allegations regarding Novartis' "schmoozing" scheme do not provide a coherent basis on which to infer improper inducement. (TAC ¶ 348.) Relator alleges that Novartis "bribed its Speakers and other high prescribers of Gilenya directly by having Key Account Managers throughout the United States 'wine and dine' these physicians for purposes of

influencing their prescription writing . . . ." (TAC ¶ 353.) These account managers allegedly focused their efforts on "one-on-one" dinners with physicians to "build . . . relationship[s]." (TAC ¶¶ 344, 349–50.) But it is not clear from Relator's allegations how this conduct was supposed to "get them [physicians] to prescribe Gilenya." (*See* TAC ¶ 348.)

The witness anecdotes in the relevant portion of the TAC lack particularity and are largely contentions that, when cobbled together, allegedly amount to some form of impropriety. Exactly what form is unclear. For example, Relator alleges that account managers could not "provide any greater information at these dinners to physicians regarding Gilenya than the information that sales representatives provided," without explaining why this is significant. (TAC ¶ 345.) In another example, Relator alleges that a witness "arranged meetings between key Speakers and potential Speakers . . . as part of his duties of cultivating relationships between [Novartis] and high prescribers who were targeted as potential speakers." (TAC ¶ 351.) In a third example, Relator alleges that an account manager provided "training [to] secretaries and other medical office staff at physician offices," including at one medical practice "which had doctors who were high prescribers of Gilenya." (TAC ¶ 352.) Relator then concludes that Novartis did these things "to convince [physicians] to become Speakers . . . . There can be no other explanation for these interactions." (Pl.'s Mem. in Opp'n at 37.) But Relator does not adequately explain why these interactions amount to improper inducement. Accordingly, these allegations are insufficient to plead a fraudulent kickback scheme.

II. Relator's Allegations Regarding False Claims

A claim that results from a violation of the AKS "constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). Novartis argues that the TAC should be dismissed because Relator has not pled the existence of false claims with particularity. (Def.'s Mem. Supp. Mot. to Dismiss at 43.) As noted in the Court's prior ruling on Novartis' motion to

dismiss the AC, "[t]he Court cannot productively address" this argument "until (and if) Relator sufficiently alleges the existence of the kickback scheme upon which the falsity of the alleged claims is premised." (Op. & Order at 14.) As explained above, Relator has failed to sufficiently plead a kickback scheme in his TAC. Therefore, he has not established the alleged AKS violations on which his FCA-related claims are premised. Accordingly, the Court does not address Relator's claims regarding the FCA.

III. No Leave to Amend

Taken together, the allegations in the TAC do not adequately plead the existence of a kickback scheme with sufficient particularity.[12] Because the Court previously granted Relator leave to amend his Complaint, the question arises whether the Court should do so again here.

The Court declines to grant leave to amend. Relator has not cured the deficiencies identified in the AC, even after the Court provided specific guidance as to how Plaintiffs could comply with Rule 9(b)'s particularity requirement. (*See* Op. & Order at 6–13.) Relator has had four opportunities to plead his claims. Nothing suggests he will be successful if given a fifth. *See, e.g.*, *De Jesus v. Sears, Roebuck & Co., Inc.*, 87 F.3d 65, 71–72 (2d Cir. 1996) (upholding

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[12] Plaintiff submits as supplemental authority *U.S. ex rel. Travis v. Gilead Sciences, Inc.*, No. 17-1183, 2022 WL 991382 (E.D. Pa. Apr. 1, 2022), in which a court denied defendant Gilead's motion to dismiss with respect to plaintiffs' allegations that defendant had used physician speaker programs to compensate high prescribers. (*See* ECF No. 92.) While there are some similarities between the complaint at issue in *Travis* and Plaintiffs' TAC, the *Travis* complaint provides the type of explanatory detail that is absent here. For example, "[i]n most cases, the physician speaker would simply sit with the Gilead sales representative in the provider's office and chat with the physician, nurses, and office staff as they at lunch." (Gilead Third Am. Compl. ¶¶ 103–104 [hereinafter Gilead TAC], ECF No. 49.) In another example, "the physician speaker did not put on a presentation, but rather just sat in the lunch area, without ever speaking or giving a presentation . . . [and] was still paid." (Gilead TAC ¶ 105.)

By contrast, Relator does not allege that physicians neglected to make their presentations. Although he alleges physician speakers were often more interested in socializing, he still acknowledges that speakers made their presentations, even if for "15 to 20 minutes . . . to run through a slide deck." (TAC ¶ 286.) But he does not allege that these events were fraudulent because the deck was only partially presented. Even had he alleged partial presentation, his TAC does not "explain whether events at which the slide deck was partially or fully presented served an educational purpose." (Op. & Order at 9.) The Gilead TAC also describes a key feature of the Gilead speaker program—namely using "less well-known speakers and some who were completely unqualified to give such educational presentations"—that is not central to this case. (*See* Gilead TAC ¶ 109 *et seq.*) Furthermore, *Travis* does not bind this Court.

district court decision to dismiss complaint alleging fraud without leave to replead a fifth time because plaintiffs had not cured complaint's deficiency); *Decker v. Massey-Ferguson, Ltd.*, 681 F.2d 111, 115 (2d Cir. 1982) (holding that district court did not abuse its discretion in refusing plaintiff a third attempt to restate defective fraud allegations); *Weinstein v. Appelbaum*, 193 F. Supp. 2d 774, 782 (S.D.N.Y. 2002) (McMahon, J.) (dismissing with prejudice plaintiffs' amended complaint, their fourth attempt overall, after holding that plaintiffs had not pled fraud with particularity). The Court therefore dismisses the TAC, with prejudice.

CONCLUSION

For the foregoing reasons, the Court GRANTS Novartis' motion to dismiss pursuant to Rules 12(b)(6) and 9(b), and the TAC is dismissed with prejudice.

The Clerk is respectfully directed to close ECF No. 86 and to close the case.

SO ORDERED.

Dated: New York, New York
September 13, 2022

/s/ Kimba M. Wood
KIMBA M. WOOD
United States District Judge