Recent Cases Clarify FCA Kickback Pleading Standards

By **Li Yu, Ellen London and Gregg Shapiro** (March 10, 2025)

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In January, the U.S. Department of Justice obtained a $59.7 million settlement from Pfizer Inc., resolving allegations that one of its subsidiaries caused false Medicare claims by paying kickbacks to physicians to induce prescriptions of migraine drug Nurtec ODT.[1]

And on Dec. 27, 2024, the U.S. Court of Appeals for the Second Circuit issued a decision reversing the dismissal of a qui tam case, U.S. ex rel. Camburn v. Novartis Pharmaceuticals Corp.,[2] which alleged that Novartis' use of speaker programs for its multiple sclerosis drug, Gilenya, violated the Anti-Kickback Statue and the FCA.

Manufacturer-sponsored speaker programs, where a physician makes a speech or presentation to other healthcare providers about a drug or a disease state, are a common prescription drug marketing tool.[3]

Despite their prevalence, speaker programs have been the focus of repeated False Claims Act investigations and settlements. A 2020 special fraud alert from the U.S. Department of Health and Human Services, Office of Inspector General, found that between 2017 and 2019, for example, "drug and device companies ... reported paying nearly $2 billion" for speaker programs.[4] The HHS OIG also raised concerns about the educational value of such programs.[5]

The Second Circuit's Camburn decision clarified a key AKS element — whether a defendant violates the AKS when at least one purpose but not necessarily the sole or primary purpose of its remuneration is to induce a prescription or order. Camburn also adopted a framework that district courts and the HHS OIG have articulated to help identify sham speaker programs.

Finally, Camburn addressed a third common issue in qui tam litigation — how to apply the plausibility standard articulated by the U.S. Supreme Court in Bell Atlantic Corp. v. Twombly in FCA cases.

Here, we begin with a summary of the key allegations in Camburn and how other courts and the HHS OIG have addressed speaker programs under the AKS.

We then analyze the Second Circuit's three main holdings and how they may affect ongoing and future AKS-based FCA cases, whether or not these cases involve speaker programs.

Finally, we offer some practical suggestions for whistleblower and defense counsel involved in cases alleging sham speaker programs.

Allegations in Camburn and How Speaker Programs May Implicate AKS

Camburn was brought by a former Novartis employee alleging that the company's Gilenya

speaker programs "did not actually educate [healthcare providers] or patients but instead were a pretext for payments to high-prescribing physician speakers."[6]

Specifically, the relator alleged, as relevant here, three practices: (1) Novartis paid physician-speakers to give Gilenya presentations "solely to other Novartis speakers or to members of their own practice" over "lavish" meals; (2) Novartis repeatedly paid physician-speakers "for canceled events;" and (3) Novartis managers encouraged its sales staff "to offer speaking engagements to certain physicians" in order to "incentivize prescription-writing."[7]

In 2022, the U.S. District Court for the Southern District of New York dismissed those allegations with prejudice, holding that the relator failed to plead the existence of a kickback scheme with the particularity required by Rule 9(b).[8]

As the Second Circuit noted in Camburn, similar speaker program allegations had been litigated in prior AKS-based FCA cases.

In U.S. ex rel. Bilotta v. Novartis, for example, the DOJ alleged that speaker events were a sham because Novartis "repeatedly invited the same participants to attend events concerning the same drug or topic in a short span of time," paid doctors "thousands of dollars … [for] events [that] did not take place," and paid for programs at inappropriate venues like "crowded sports bars and restaurants."[9] In 2014, the district court found that those allegations sufficiently stated AKS and FCA violations.

Similarly, in 2019, in U.S. ex rel. Arnstein v. Teva Pharmaceutical USA Inc., the district court denied a motion for summary judgment because the relator offered evidence that "speaker programs were regularly given without legitimate attendees" and "speakers were chosen for their potential to prescribe more" medications."[10]

Further, in its 2020 special fraud alert, the HHS OIG raised concerns "about the educational value" of speaker programs. According to the HHS OIG, prior investigations and published studies showed that physicians receiving remuneration from a company "are more likely to prescribe or order that company's products."[11] This may "skew [the physicians'] clinical decision making" away from the "best interests" of their patients.[12]

To help identify sham speaker programs, the inspector general's special fraud alert provides a "list of suspect characteristics," which includes programs with "little or no substantive information," programs that involve alcohol or lavish meals, programs offered when "no new medical or scientific information" about a product has appeared for a long time, programs attended mainly by other speakers or staff from "the speaker's own medical practice," selection of speakers based on past or expected revenue, and paying speakers above fair market value.[13]

While Camburn, Bilotta and Arnstein relate to events a decade or more ago, several of the characteristics of suspect or sham speaker programs also were at issue in the DOJ's recent settlement with Pfizer in U.S. v. Biohaven Pharmaceuticals Holding Company Ltd.

There, the DOJ alleged that from March 1, 2020, through Sept. 30, 2022, Biohaven Pharmaceuticals, a company that Pfizer acquired in October 2022, paid for programs "attended by individuals with no educational need," and for prescribers to attend "multiple programs on the same topic."[14]

Three Key Holdings in Camburn

The Second Circuit began its Camburn decision with a discussion of Rule 9(b), which requires a plaintiff in an AKS-based FCA case to "plead the factual basis that gives rise to a strong inference of fraudulent intent."[15]

Construing this standard in an AKS-based FCA case, the Camburn court adopted the at-least-one-purpose rule, which provides that the plaintiff need only plead that "at least one (rather than the primary or sole) purpose of the remuneration [the defendant] provides is to induce purchase of a federally reimbursable healthcare product."[16]

Thus, the Second Circuit joined the First, Third, Fourth, Fifth, Seventh, Ninth and Tenth Circuits in construing the AKS to apply when just one purpose of the remuneration was inducement.[17]

Significantly, the Second Circuit went on to hold that, as a corollary to the one-purpose rule, it is not necessary to "state a quid pro quo exchange" to plead "an AKS violation as a predicate to an FCA claim."[18] In short, there is no need to allege "a cause-and-effect relationship (a quid pro quo) between the payments and the physicians' prescribing."[19]

This corollary that Camburn drew to the one-purpose rule follows prior decisions in AKS-based FCA cases like Teva, which emphasized that the core of the AKS analysis is the drug manufacturer's intent in offering and paying kickbacks, instead of the effect of the kickbacks.[20]

While the Second Circuit did not further opine on causation or express a view on whether a plaintiff in an AKS-based FCA case must make a showing of but-for causation, this holding suggests that false claims could result from a kickback even if the recipient of the kickback did not knowingly agree to participate in a quid pro quo exchange.

In other words, if a drug company knowingly pays a kickback to induce a physician to prescribe its drug, the absence of a quid pro quo exchange requirement implies that subsequent claims emanating from that physician's prescriptions of the drug could be false claims even if the evidence does not show that the physician knowingly accepted a bribe.

Applying these principles to the relator's complaint in Camburn, and under Twombly's pleading requirement of plausibility, not merely possibility, the Second Circuit found that the relator "stated a sufficient AKS violation" as to the three types of speaker programs discussed above.

With respect to the first category of events, the Second Circuit held that their "exclusive attendance by individuals attached to practices already familiar with Gilenya, via their respective physician-speakers, 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."[21]

The Second Circuit also found the one-purpose standard satisfied where the relator provided examples of Novartis paying physician speakers substantial sums — e.g., $20,000 to $22,500 — for events that the company canceled.[22] Allegations of such remuneration in these circumstances "give rise to a strong inference that the payments constituted, at least in part, unlawful remuneration."[23]

Finally, as to allegations about Novartis managers encouraging sales staff "to offer speaking engagements to certain physicians" based, in part, on the likelihood of the physicians

increasing their prescribing of Gilenya, the Second Circuit held that these allegations plausibly and strongly suggested that "Novartis operated its speaker program at least in part to remunerate certain physicians to prescribe Gilenya."[24]

And, in keeping with its holding that a quid pro quo exchange is not necessary, the Second Circuit did not require any allegation that the physicians knowingly had agreed to increase their prescribing of Gilenya in exchange for Novartis' speaker payments.[25]

Camburn is significant because it adopts a framework that enables courts to identify sham speaker programs based on discernible evidentiary criteria. The Second Circuit, in effect, accepted several of the "suspect characteristics" identified by the HHS OIG in its 2020 special fraud alert on speaker programs.

Specifically, by recognizing that efforts to link speaker-event offers to physicians' prescribing levels may be sufficient for an inference of improper remuneration, Camburn allows plaintiffs in FCA cases to plead kickback schemes organized by corporate managers without having to offer voluminous details about individual sham events.

Finally, Camburn's adoption of the one-purpose rule may have significance beyond just speaker program FCA cases. This legal standard also could apply to cases that allege improper inducements to government program beneficiaries in the forms of subsidized housing or drug co-pay waivers,[26] to hospitals in the form of free services from device manufacturers,[27] to pharmacies in the form of bonus rebates or patient referrals[28] and to health insurance brokers in the form of marketing payments tied to steering beneficiaries toward a Medicare or Medicaid managed care plan.[29]

Suggestions for FCA Practitioners

The Second Circuit's Camburn decision makes it clear that those who are involved in speaker program FCA cases should be thinking through the implications of the one-purpose rule and the fact that proving higher prescription rates may not be required to survive a motion to dismiss. Practitioners also should familiarize themselves with the factors set forth in the HHS OIG's speaker programs special fraud alert, discussed above.

Counsel for FCA defendants should note that, as the special fraud alert states, "the lawfulness of any remunerative arrangement, including speaker program arrangements, under the anti-kickback statute depends on the facts and circumstances and intent of the parties."

While the Camburn opinion may make it more difficult to defeat a case on a motion to dismiss, a plaintiff ultimately will not be able to prevail in an FCA case without proof of more than just the appearance of fraud, even when the speaker programs at issue may look questionable on their face.

For whistleblower attorneys, the Camburn decision and the January Pfizer settlement underscore the viability of FCA cases with tangible evidence that a drug manufacturer picked speakers to reward past prescriptions or to influence future prescriptions. Specifically, relator counsel can note that the case law is increasingly in line with the special fraud alert's emphasis on the risks inherent to these types of programs.

Further, at the pleading stage, Camburn may help whistleblower attorneys overcome Rule 9(b) motions that attack the qui tam complaints for failing to particularize the impact of the alleged improper programs on the speakers' prescription patterns. This data is often not

available prediscovery. Under Camburn, however, a relator does not need to plead, let alone detail, the specifics of a quid pro quo exchange.

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[1] https://www.justice.gov/opa/pr/pfizer-agrees-pay-nearly-60m-resolve-false-claims-allegations-relating-improper-physician.

[2] 124 F.4th 129 (2d Cir. 2024).

[3] See Special Fraud Alert: Speaker Programs at 1 (available at: https://oig.hhs.gov/documents/special-fraud-alerts/865/SpecialFraudAlertSpeakerPrograms.pdf).

[4] Id.

[5] See generally Special Fraud Alert: Speaker Programs, https://oig.hhs.gov/documents/special-fraud-alerts/865/SpecialFraudAlertSpeakerPrograms.pdf.

[6] U.S. ex rel. Camburn v. Novartis Pharms. Corp., 2022 U.S. Dist. LEXIS 165383, at *28–29 (S.D.N.Y. Sept. 13, 2022).

[7] 124 F.4th at 137-38. Relator also alleged other forms of kickbacks, including "Novartis's DVD initiative, 'entertainment rooms,' visual aids for billing codes, and one-on-one physician dinners." Id. at 139.

[8] 2022 U.S. Dist. LEXIS 165383, at *28–29.

[9] 50 F. Supp. 3d 497, 515 (S.D.N.Y. 2014).

[10] 2019 U.S. Dist. LEXIS 35148, at *47-55 (S.D.N.Y. Feb. 27, 2019).

[11] Special Fraud Alert: Speaker Programs at 3.

[12] Id. at 3-4.

[13] See id. at 5-6.

[14] https://www.justice.gov/opa/pr/pfizer-agrees-pay-nearly-60m-resolve-false-claims-allegations-relating-improper-physician.

[15] 124 F.4th at 135 (internal quotation marks omitted).

[16] Id. at 136.

[17] 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); 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).

[18] 124 F.4th at 136-37.

[19] Id. at 137.

[20] See Teva, 2019 WL 1245656, at *10 (S.D.N.Y. Feb. 27, 2019) ("[T]he [AKS] does not require evidence of a 'quid pro quo' in the sense that each bribe must successfully generate referrals."); see also U.S. ex rel. Parikh v. Citizens Med. Ctr., 977 F. Supp. 2d 654, 665 (S.D. Tex. 2013) (The AKS "makes it unlawful for a defendant to pay a kickback with the intent to induce a referral, whether or not a particular referral results."); U.S. ex rel. Witkin v. Medtronic, Inc., No.1:11-cv-10790-IT, 2024 U.S. Dist. LEXIS 81710, at *39 (D. Mass. Mar. 31, 2024) (same).

[21] Id. at 137-38.

[22] Id. at 138.

[23] Id.

[24] Id. at 139 (quoting U.S. ex rel. Hart v. McKesson Corp., 96 F.4th 145, 153 (2d Cir. 2024)).

[25] As for other allegations of kickbacks, including "Novartis's DVD initiative, 'entertainment rooms,' visual aids for billing codes, and one-on-one physician dinners," the Second Circuit found that relator did not provide enough detail to show that Novartis intended these to induce prescribing of Gilenya. Thus, relator did not satisfy Twombly's requirement that he nudge his "'claims across the line from conceivable to plausible.'" Id. (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007), at 570).

[26] See, e.g., United States v. Narco Freedom, 95 F. Supp. 3d 747 (S.D.N.Y. 2015); United States v. Teva Pharms. USA, Inc., 682 F. Supp. 3d 142 (D. Mass. 2023).

[27] See, e.g., United States v. Medtronic PLC, 2024 U.S. Dist. LEXIS 56949 (D. Minn. Mar. 28, 2024).

[28] See, e.g., U.S. ex rel. Kester v. Novartis Pharms. Corp., 41 F. Supp. 3d 323 (S.D.N.Y.

2014).

[29] See Special Fraud Alert: Suspect Payments in Marketing Arrangements Related to Medicare Advantage and Providers (Dec. 12, 2024) at 2 n.3 (available at: https://oig.hhs.gov/documents/special-fraud-alerts/10092/Special%20Fraud%20Alert:%20Suspect%20Payments%20in%20Marketing%20Arrangements%20Related%20to%20Medicare%20Advantage%20and%20P.pdf).