UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

United States of America, *ex rel.* Jeffrey Wilkerson and Larry Jackson, *et al.*, *Plaintiffs-Relators*, v. Allergan Limited f/k/a Allergan PLC, *et al.*, *Defendants*.	No. 22 CV 3013 Judge Lindsay C. Jenkins

MEMORANDUM OPINION AND ORDER

Relators Jeffrey Wilkerson and Larry Jackson were pharmaceutical sales representatives for Allergan USA, Inc. ("Allergan"),[1] the manufacturer of two gastrointestinal drugs, Linzess and Viberzi. They allege that while working for Allergan they learned that it was engaged in a nationwide scheme to provide illegal kickbacks to doctors in exchange for prescribing more Linzess and Viberzi. Relators filed this *qui tam* suit on behalf of the United States under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733; on behalf of several states under analogous statutes; and on behalf of two states under insurance fraud statutes. [Dkt. 173.] Relator

[1] The parties previously stipulated with respect to the Third Amended Complaint ("3AC") that Allergan, USA would accept service on behalf of Allergan Limited, obviating Allergan Limited's responsibility to answer the 3AC. [Dkt. 142.] While there is no equivalent stipulation on the docket with respect to Relators' Fourth Amended Complaint, based on the parties' prior representations and failure to raise this issue during the briefing of the motion to dismiss, the Court assumes Relators have agreed to excuse Allergan Limited from answering the complaint for the time being. However, both entities must timely answer the complaint in light of the partial denial of Allergan's motion to dismiss.

Jackson also brought a claim alleging that Allergan unlawfully terminated his employment in retaliation for reporting FCA violations.

Now on their Fourth Amended Complaint ("4AC"), Relators press two theories. The first is that Allergan's payment of kickbacks to doctors resulted in false claims for prescriptions being presented to the government for payment. The second theory is that Allergan violated the FCA by causing others to falsely certify compliance with the Anti-Kickback Statute ("AKS") in conjunction with Linzess and Viberzi prescriptions.

Allergan moves to dismiss the operative 4AC complaint for failure to state a claim upon which relief may be granted. [Dkt. 176]; Fed. R. Civ. P. 12(b)(6). For the reasons explained, its motion is granted in part and denied in part.

I. Background

A. Statutory Framework

The FCA, 31 U.S.C. §§ 3729-3733, prohibits the submission of false claims for payment to federal health care programs. As relevant here, a person violates the FCA when he:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> (C) conspires to commit a violation of [the FCA] ….

§ 3729(a)(1). The FCA defines "claim" as "any request or demand … for money … that … is presented to an officer, employee, or agent of the United States." § 3729(b)(2)((A). Relators' state statutory claims prohibit similar conduct. [Dkt. 173,

Counts V–XXXVI.]; *cf. Thulin v. Shopko Stores Operating Co.*, LLC, 771 F.3d 994, 996–97 (7th Cir. 2014).

The AKS prohibits soliciting, receiving, offering, or paying any "remuneration" in exchange for referring a patient for services that are reimbursed by a federal health care program, such as Medicare. 42 U.S.C. § 1320a–7b(b). In 2010, the AKS was amended to, among other things, provide that "a claim that includes items or services resulting from [an AKS violation] constitutes a false or fraudulent claim for purposes of [the FCA]." § 1320a–7b(g); § 3729(a)(1)(A). The Court refers to this theory of liability as the "false claim" theory.

The FCA can also be violated through express or implied false certifications of compliance. *United States v. Molina Healthcare of Illinois, Inc.*, 17 F.4th 732, 741 (7th Cir. 2021); *Universal Health Servs., Inc. v. Escobar*, 579 U.S. 176, 186-87 (2016). Entities, including doctors and pharmacies, seeking reimbursement from Medicare, must certify compliance with federal laws, including the AKS. If certifications, either express or implied, falsely represent compliance with the AKS in conjunction with a claim submitted for payment, the entity that submitted or caused the submission of the false certification may be liable under § 3729(a)(1)(B). *United States v. Walgreen Co.*, 417 F. Supp. 3d 1068, 1085 (N.D. Ill. 2019); *Escobar*, 579 U.S. 176, 186-87. This is Relators' "false certification" theory of liability.

B. Factual Overview[2]

Allergan, a pharmaceutical company headquartered in New Jersey, markets and sells the two drugs at issue: Linzess and Viberzi. [Dkt. 173 ¶ 22.] Relators worked for Allergan and its predecessor, Actavis Pharma, Inc., as sales representatives within the Gastroenterology Group—Jackson from 2013 to 2017 and Wilkerson from 2013 to 2016. [*Id.* ¶¶ 29–30.] Each Relator was responsible for a portion of Allergan's geographic territory: Jackson covered Tulsa, Oklahoma; Northwest Arkansas; and Southwest Missouri, while Wilkerson oversaw West Tennessee and North Mississippi. [*Id.*]

Linzess, a brand name for linaclotide, is a prescription medication that treats two chronic constipation disorders: irritable bowel syndrome with constipation ("IBS-C") and chronic idiopathic constipation. [*Id.* ¶ 107.] Linzess launched in the United States in December 2012. [*Id.* ¶ 108.] Actavis acquired the company that produced Linzess in July 2014; Allergan, in turn, acquired Actavis in March 2015. [*Id.* ¶¶ 108–09.] Viberzi is an opioid with the active ingredient eluxadoline which is used to treat irritable bowel syndrome with diarrhea ("IBS-D"). [*Id.* ¶ 112.] Allergan acquired eluxadoline in July 2014; the FDA approved Viberzi in May 2015, and it became available in December of that year. [*Id.* ¶ 113–15.]

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[2] The following factual allegations are taken from Relators' 4AC and are accepted as true for purposes of the motion to dismiss. *Smith v. First Hosp. Lab'ys, Inc.*, 77 F.4th 603, 607 (7th Cir. 2023). In setting forth the facts at the pleading stage, the Court does not vouch for their accuracy. *See Goldberg v. United States*, 881 F.3d 529, 531 (7th Cir. 2018).

Linzess and Viberzi are more expensive than over-the-counter alternatives. [*Id.* ¶¶ 110–11, 116–17.] Viberzi is allegedly "not a drug to be taken lightly" as it may cause serious side effects and is susceptible to "dangerous recreational use and abuse." [*Id.* ¶¶ 120–23.]

The federal government administers two subsidized health care programs that are relevant to this dispute: Medicare and Medicaid. Medicare is available to persons at least 65 years old and to disabled persons; Medicare Part D covers prescription drugs. [*Id.* ¶¶ 82–83.] Medicare contracts with private entities to provide Part D insurance. [*Id.* ¶ 83.] Claims submitted to Medicare are paid by the federal government. [*See id.* ¶¶ 37, 224, 285.]

Medicaid is a joint federal-state program that provides health care benefits primarily to poor and disabled persons; it also includes prescription drugs. [*Id.* ¶¶ 86–87.] Similar to Medicare, private companies administer the program. [*Id.* ¶ 87.] Payment for claims submitted to Medicaid are shared by the federal and state governments. [*See id.* ¶ 87–89.][3]

1. The False Claim Kickback Scheme

Relators allege that when Allergan launched Viberzi in late 2015, it "devised a scheme" to provide illegal kickbacks to physicians through a speaker program that Relators call the "Speaker Bureau." [*Id.* ¶¶ 29, 128–29.] The official purpose of the Speaker Bureau was to educate health care providers about Linzess and Viberzi. [*See id.* ¶¶ 226, 232.] According to Relators, its true "purpose and intent" "was to give

[3] The 4AC mentions other federal health care programs, [*id.* ¶¶ 91–93], but because the parties' briefs do not discuss them, neither does the Court.

physicians cash, food, alcohol, travel expenses, and other illegal remuneration to induce them to prescribe Allergan drugs, and to cause other physicians to prescribe those drugs." [*Id.* ¶ 129.][4] Relators allege that Allergan implemented its speaker scheme nationwide, causing millions of dollars in losses by the federal government and several states. [Dkt. 173 ¶ 130–31.]

Allergan held over 8,000 speaker events between 2015 and 2017. [*Id.* ¶¶ 142–44.] There were two types of events. For "in-office" events, a speaker physician and an Allergan sales representative would visit a health care provider's office, provide refreshments, and (ostensibly) present educational materials about Linzess and Viberzi. [*Id.* ¶¶ 161–62.] "Out-of-office" events were "dinner parties," often at "up-scale restaurants." [*Id.* ¶ 165.] Medical providers would join speaker physicians and sales representatives for meals paid for by Allergan, where the speakers purported to educate guests. [*Id.* ¶¶ 165–66.] Allergan required a minimum number of positive RSVPs to hold speaker events: two "prescribers" or "dispensers" for in-office events; four RSVPs, three of whom were prescribers or dispensers, for out-of-office events. [*Id.* ¶¶ 228–29.]

While Allergan's official policy imposed a $150 per person cap on food and alcohol for these events, Allergan routinely disregarded this limit and permitted speakers and attendees to spend far more. [*Id.* ¶ 167.] In addition to the food and alcohol budget, Allergan paid speakers $1,000-$3,500 per speaker event, plus reimbursement for travel and lodging. [*Id.* ¶¶ 163–66, 233.] If an event was cancelled

[4] Some of the speakers were not doctors. [*E.g.*, dkt. 65 ¶ 143.] Short-form references to speakers as "physicians" or "doctors" include all speakers.

shortly before being held, or if there were fewer attendees than the number of RSVPs required to schedule the event, Allergan still paid the speakers. [*Id.* ¶¶ 232, 237, 239, 241, 249.] Relators allege that Allergan's practice of paying speakers their full fee for cancelled events is inconsistent with other pharmaceutical companies. [*Id.* ¶17.]

Relators identify several features of the Speaker Bureau which they contend demonstrate its fraudulent purpose [*Id.* ¶ 232]:

- District and regional managers instructed sales representatives to focus on bringing high-volume prescribers into the Speaker Bureau; speakers were retained or removed based on prescription volume. [*Id.* ¶¶ 149–55.]
- Sales representatives' compensation was based on physicians' prescription volume; they were rewarded when they met or exceeded quotas and fired if they failed to meet quotas. [*Id.* ¶¶ 133–36, 138, 153.]
- Often, Speaker Bureau events had little or no educational content. [*Id.* ¶ 166.]
- Managers emphasized that the Speaker Bureau had an RSVP requirement, not an attendance requirement, encouraged sales representatives to consider noncommittal statements as positive RSVPs, and did not care if events were under-attended or cancelled. [*Id.* ¶¶ 231, 237, 239–41.]
- Allergan knew about the under-attendance problem because the number of attendees was reported through a platform called "IntraMed." [*Id.* ¶ 236.]
- Managers instructed salespeople to falsify attendance records. [*Id.* ¶ 234.]
- Allergan did not criticize or discipline salespeople who organized under-attended or cancelled events. [*Id.* ¶¶ 232, 237, 238–42, 248–49.]

In total, Relators allege there were over 2,000 "sham" events, which they define as events that were cancelled in advance or were unattended or under-attended, that is, attended only by the speaker and Allergan sales representative. [*Id.* ¶¶ 242–47.]

Relators offer more specific allegations about some speakers. The first is Dr. Paul Bierman, a gastroenterologist based in Memphis. The local district sales team identified Dr. Bierman as a "high-prescriber who could be guaranteed to produce a

high volume of Viberzi prescriptions." [*Id.* ¶ 152.] Relator Wilkerson and Dr. Bierman attended an in-office event in January 2016, at which "Dr. Bierman made no formal presentation and did not provide any educational information, but instead simply shook hands with Dr. Cary Finn and made small talk. Then, just before leaving, Dr. Bierman briefly stated that he thought Dr. Finn should prescribe Viberzi and Linzess." [*Id.* ¶ 164.] Wilkerson told his district manager Alan Foust, about the cursory nature of Dr. Bierman's in-office events including that "Dr. Bierman routinely declined to present the Allergan PowerPoint presentation." [*Id.*] Foust allegedly instructed Wilkerson to falsify documents to reflect that Dr. Bierman provided the required information and that Dr. Finn and his staff attended the presentation. [*Id.*]

Foust also told Wilkerson to convey to Dr. Bierman that the "payment of speaker fees was specifically conditioned upon Bierman increasing his prescription of Allergan drugs." Wilkerson and fellow sales representative Frank Adcock delivered this message in January 2016. [*Id.* ¶¶ 170–71.] Dr. Bierman acknowledged the *quid pro quo* and agreed to increase his prescriptions of Viberzi. [*Id.* ¶ 172.] Another sales representative, Will Fogelman, described Dr. Bierman as "the largest prescriber of Viberzi in the West Tennessee territory" and also referenced the *quid pro quo*. [*Id.* ¶ 177; *see also id.* ¶¶ 178–80.]

Relators allege that Allergan's payments to Dr. Bierman for nearly 100 Speaker Bureau events induced him to write approximately 517 prescriptions of Linzess and Viberzi for Medicare patents. [*Id.* ¶ 187.] Further, as Allergan knew would occur, Dr. Bierman's prescriptions for Linzess and Viberzi were presented to

pharmacies, claims for the prescriptions were submitted to Medicare and, as a result, Medicare paid approximately $269,000. [*Id.* ¶ 188.]

Relators also highlight the prescribing pattern of Nurse Practitioner Chantil Jeffreys. Jeffreys, from the Memphis area, was recruited as a speaker in 2017 after her Linzess prescriptions increased. [*Id.* ¶¶ 190–91.] Relators allege that "[t]his increase led Allergan to anticipate Ms. Jeffreys could be a valuable speaker-prescriber," so she was added to the Speaker Bureau. [*Id.* ¶ 191.] But when her Linzess prescription volume did not increase further, Allergan terminated her as a speaker. [*Id.*] Relators allege that Allergan terminated 136 speaker-physicians from the Speaker Bureau in 2016 because Allergan viewed them as "low-prescribers." [*Id.* ¶ 160.]

Another speaker, Dr. Daniel Kayal, joined the program in late 2015; he remained in the Speaker Bureau as he increased his Linzess prescriptions and began to prescribe Viberzi. [*Id.* ¶¶ 193–95.] Prior to being added to the Speaker Bureau, Kayal wrote 52 prescriptions for Linzess to Medicare Part D beneficiaries. [*Id.* ¶ 193.] In 2016, Allergan paid Kayal for 13 events, and his Linzess prescriptions rose to 103. [*Id.* ¶ 195.] In 2017, Allergan paid him for 9 events and he wrote 86 prescriptions; in 2018, Allergan paid Kayal for 5 events, and he wrote 44 prescriptions for Linzess and 20 for Viberzi. [*Id.*]

Dr. Joseph Hathaway, of Statesboro, Georgia wrote 36 Linzess prescriptions for Medicare Part D beneficiaries in 2015 before being added to the Speaker Bureau. [*Id.* ¶ 201.] In 2016, Allergan paid him for 24 Speaker Bureau events and he wrote

184 prescriptions for Linzess. [*Id.*] The pattern continued: in 2017, Allergan paid Hathaway for 27 events and his prescriptions rose to 395; in 2018, Hathaway was paid for 14 speaker events and his prescriptions for Linzess increased to 470. [*Id.*]

Relators offer another example: Dr. Jack Braha of Brooklyn, New York. [*Id.* ¶ 204.] In 2015, before Braha joined the Speaker Bureau, he wrote 23 Linzess prescriptions for Medicare Part D beneficiaries. [*Id.*] In 2016, Allergan paid Braha for 9 events, and he wrote 137 prescriptions for Linzess. [*Id.*] In 2017 and 2018, Allergan paid Braha for 11 and 9 events, respectively, and Braha wrote 158 prescriptions for Linzess each year. [*Id.*]

The prescription rate of Dr. Asif Quadri of Athens, Georga, also increased after he joined the Speaker Bureau. [*Id.* ¶ 208.] Before receiving payments from Allergan, he wrote 59 prescriptions for Linzess. [*Id.*] Once the Speaker Bureau payments began in 2016, his prescription rate increased to 144 prescriptions in 2016, 256 prescriptions in 2017, and 267 prescriptions in 2018. [*Id.*] Relators identify the same pattern for (1) Dr. Nikhil Agarwal of San Franscisco whose prescription rates for Linzess rose from 18 before joining the Speaker Bureau to 59 in 2016 and 172.5 in 2017 [*id.* ¶ 211]; (2) Dr. Jamal Qureshi of Milwaukee, Wisconsin whose prescription rates for Linzess rose from 107 before joining the Speaker Bureau to 262 in 2016 and 276 in 2017 [*id.* ¶ 214]; and (3) Dr. Thomas Tran of Dennison, Texas whose prescription rates for Linzess rose from 109 before joining the Speaker Bureau to 234 in 2016 and 320 in 2017 [*id.* ¶ 217].[5]

[5] Relators' 4AC includes similar allegations about other prescribers, aimed at showing that Allergan's payment of speaker fees caused an increase in these doctors' prescription

Relators contend that in 2016 and 2017 Allergan paid over $12 million to members of the Speaker Bureau. [*Id.* ¶ 284.] During the same time period, the federal government, through the Medicare Part D program, paid over $39 million for prescriptions of Viberzi and Linzess written by doctors receiving kickbacks from Allergan. [*Id.*]

The data Relators cite in their complaint comes from Centers for Medicare and Medicaid Services ("CMS") claims. [*Id.* ¶¶ 35–36.] CMS publishes Medicare Part D data which shows prescriptions written by each participating provider. [*Id.* ¶ 36.] The federal government also reports claims paid by Medicaid which includes the number of claims for each drug, the number of units paid for, and the amounts paid. [*Id.* ¶ 37.] Relators rely on that data as well, which purports to show, at the national-level, significant increases in amounts paid by Medicaid between 2016 and 2018 for Linzess and Viberzi. [*Id.*] That data reveals that the overall volume of claims paid by Medicare for Linzess increased in 2016 by 42%. [*Id.* ¶ 199.]

Relators also rely on a ProPublica 2019 study analyzing the CMS data and looking specifically at Allergan's payments to doctors for Linzess. [*Id.* ¶ 221.] Relators cite the results of the study: that doctors who received payments related to Linzess in 2016 wrote 45% more prescriptions for the drug, on average, than doctors who received no payments. [*Id.*] The study also found that the average number of Linzess prescriptions for Medicare beneficiaries submitted by doctors who took no money at all from Allergan was 26; in contrast, doctors who took any remuneration at all, even

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rates for Linzess and, therefore, resulted in claims paid by Medicare. [*Id.* ¶¶ 258, 261, 264, 267, 270, 273, 276, 279.]

just a free meal, prescribed an average of 49 prescriptions for Linzess. [*Id.*] Looking specifically at Speaker Bureau payments in 2016 though, Relators allege that Allergan documents and CMS data reveals that Speaker Bureau physicians averaged 69.56 prescriptions in 2016 which is 167% of the number written by doctors who received no remuneration at all from Allergan. [*Id.* ¶ 222.][6]

2. False Certification Theory

Relators' 4AC includes allegations concerning false certifications of compliance with the AKS. Relators allege that every recipient of Medicare payments, including pharmaceutical manufacturers, private insurance companies, doctors, and pharmacies, executes certifications of compliance with all applicable laws, including the AKS. [*Id.* ¶ 7.][7]

Part D sponsors—private insurance companies that contract to provide prescriptions to persons on Medicare and Medicaid— "must certify in their contracts that they agree to comply with all federal laws and regulations designed to prevent fraud, waste and abuse." [*Id.* ¶ 58.] Relators do not explain the content of any certification nor do they identify any private insurance companies that made certifications relevant to this dispute.

Physicians certify compliance for Medicare and Medicare Part D purposes through a provider agreement, Form 1500, and Form CMS-855O. [*Id.* ¶¶ 53, 56.] For

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[6] Relators also cite a "recent meta-study published in the Annals of Internal Medicine" purporting to show "a causal relationship … between receipt of a payment and an increase of prescriptions." [*Id.* ¶ 223.]

[7] Relators' only allegation regarding the certification made by pharmaceutical manufacturers concerns the Medicaid Rebate program. [*Id.* ¶ 53.] Because the Medicaid Rebate program is not at issue in this lawsuit, the Court does not consider it.

Medicaid, physicians certify compliance with the AKS via Form CMS-855I. [*Id.* ¶ 55.] Relators allege that these certifications are required in order for physicians to receive payment "for providing physician services." [*Id.* ¶ 56.] They also allege that physicians' certifications are necessary "to prescribe and have Medicare pay for prescriptions." [*Id.* ¶ 55.] However, Relators don't allege that physicians make any certification in conjunction with writing a prescription or that physicians receive any payment from Medicare or Medicaid for writing prescriptions. Further, Relators do not assert FCA liability for "physician services."

Pharmacies that dispense prescriptions also enter into Provider Agreements with CMS to establish their eligibility to seek payment through Form 885S. [*Id.* ¶¶ 54, 59.] Further, CMS regulations require that subcontracts between pharmacies and Part D sponsors contain certifications of compliance with the AKS. [*Id.* ¶ 60.]

According to Relators, Allergan's kickback payments caused prescribers' and pharmacies' certifications of compliance with the AKS to be materially false. [*Id.* ¶¶ 7, 9.] They contend that every physician who prescribed Linzess and Viberzi for Medicare patients—including those specifically identified—must have executed these required certifications to receive payment from Medicare. [*Id.* ¶¶ 19, 56.] Allergan was also allegedly aware that the pharmacies dispensing the at-issue medications were required to certify compliance with the AKS. [*Id.* ¶ 19.] Relators allege that compliance with the AKS is a material requirement to receive payment from government health care programs. [*Id.* ¶ 61.]

In addition to the express certifications discussed above, Relators allege that when a party submits a claim for payment they implicitly certify compliance with all conditions of payment. [*Id.* ¶ 67.] As a result, Relators assert that all claims for payment for Linzess and Viberzi prescriptions written while prescribing doctors were receiving kickbacks from Allergan are false because, in association with each prescription, the submitting party failed to disclose violation of the AKS. [*Id.* ¶ 68.] Relators do not explain which of the entities discussed submit claims for payment to the government, however. Relators also do not identify any implicitly false certification made in conjunction with a request for payment.

II. Legal Standards

A motion to dismiss under Rule 12(b)(6) challenges the sufficiency of the complaint. *See Camasta v. Jos. A. Bank Clothiers, Inc.*, 761 F.3d 732, 736 (7th Cir. 2014). The Court accepts well-pleaded factual allegations as true and draws all reasonable inferences in Relators' favor. *Smith*, 77 F.4th at 607. To survive a motion to dismiss, a complaint must contain sufficient factual information to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is facially plausible when "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* A claim lacks facial plausibility "if there is an 'obvious alternative explanation' for the complaint's factual allegations." *Alarm Detection Sys., Inc. v.*

Village of Schaumburg, 930 F.3d 812, 821 (7th Cir. 2019) (citations omitted) (quoting *Iqbal*, 556 U.S. at 682).

Rule 9(b)'s heightened pleading standard applies to fraud-based claims under the FCA and analogous state statutes. *United States ex rel. Berkowitz v. Automation Aids, Inc.*, 896 F.3d 834, 839 (7th Cir. 2018); *see Thulin*, 771 F.3d at 995. Rule 9(b) requires pleading with particularity, meaning that Relators "must describe the 'who, what, when, where, and how' of the fraud—the first paragraph of any newspaper story." *Berkowitz*, 896 F.3d at 839 (cleaned up). "What constitutes 'particularity' … may depend on the facts of a given case," but Relators must "use some … means of injecting precision and some measure of substantiation into their allegations of fraud." *Id.* at 839–40 (cleaned up). This means that pleading on "information and belief" will seldom suffice. *See Pirelli Armstrong Tire Corp. Retiree Med. Benefits Tr. v. Walgreen Co.*, 631 F.3d 436, 442–43 (7th Cir. 2011).

III. Count I: False Claim Theory

An FCA false claim theory based on an illegal kickback scheme requires a relator to allege violations of both the AKS and FCA.

A. AKS Violation

In its motion to dismiss Relators' 4CA, Allergan incorporates by reference the arguments made in its motion to dismiss Relators' 3AC. [Dkt. 177 at 8.][8] While it

[8] Citations to docket filings generally refer to the electronic pagination provided by CM/ECF, which may not be consistent with page numbers in the underlying documents.

maintains its disagreement with the Court's prior ruling, Allergan does not separately challenge it. [*Id.*]

As explained in the prior order granting Allergan's motion to dismiss Relators' 3AC, Relators alleged that Allergan engaged in illegal kickbacks through its Speaker Bureau program. [Dkt. 164 at 24, 30.] In brief, compensation in the form of speaker fees, food, drink, and travel qualify as "any remuneration," § 1320a–7b(b)(2), as long as any part of the remuneration was paid to induce the speaker doctors to write more prescriptions. *See United States v. Borrasi*, 639 F.3d 774, 780–82 (7th Cir. 2011) (rejecting the argument that the "primary motivation" of payment of remuneration must be to induce referrals and holding that "if part of the payment compensated past referrals or induced future referrals, that portion of the payment violates" the AKS); *United States v. Sorensen*,—F.4th—, 2025 WL 1099080, at *5 (7th Cir. Apr. 14, 2025).

Relators contend that Allergan knowingly and willfully offered remuneration in an effort to cause doctors in the Speaker Bureau to write more prescriptions for Linzess and Viberzi. [Dkt. 173 ¶¶ 29, 128–29.] The allegations in Relators' 4AC are sufficient to support the inference that Allergan operated the Speaker Bureau program at a national level and that the program operated, at least in part, as a system to funnel payments to physicians in exchange for prescriptions for Allergan drugs. [*Id.* ¶ 129.] As a result, Relators surpassed the first hurdle, stating an AKS violation.

B. FCA Violation

The 2010 Amendment to the AKS provides that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]." § 1320a-7b(g). Relators can state an FCA claim through this subsection by alleging that, as a result of Allergan's kickback scheme, a false claim was submitted to the government for payment. § 3729(a)(1)(A).

1. Causation

A circuit split exists on the meaning of "resulting from." Three circuits—the Eighth, Sixth, and First—hold that "resulting from" requires allegations (and eventually proof) of but-for causation. One—the Third Circuit—espouses a less demanding "exposed to" standard.

In their 3AC, Relators advocated for a taint theory: that every Linzess and Viberzi prescription written by physicians who received kickbacks are false claims because they are "tainted" by the illegal kickbacks. The Court disagreed with Relators' reading of *United Sates v. Teva Pharmaceuticals USA, Inc.*, 2019 WL 1245656, at *21 (S.D.N.Y. Feb. 27, 2019) as supporting that theory. Now, in their 4AC Relators focus on the Third Circuit's opinion in *Greenfield v. Medco Health Solutions* which held that "resulting from" requires some "link" but not "but for" causation. 880 F.3d 89, 98 (3d Cir. 2018).

After examining the context for the passage of the 2010 Amendment to the AKS, the *Greenfield* court concluded that it was most appropriate to "requir[e] something less than proof that the underlying medical care would not have been

provided but for a kickback." *Id.* at 96. Because "Congress passed § 1320a-7b(g) in 2010 as part of an overall effort to strengthen whistleblower actions … and … ensure that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil actions under the False Claims Act," the Third Circuit concluded that interpreting "resulting from" to require but-for causation would be "inconsistent with the drafters' intentions." *Id.* (cleaned up).

The *Greenfield* court was also concerned that requiring but-for causation "would lead to the incongruous result" where a defendant could be criminally convicted under the AKS but "insulated from civil False Claims Act liability for the exact same conduct." *Id.* (cleaned up). Still, at the summary judgment stage, *Greenfield* rejected the contention that "a temporal connection" between the AKS violation and submission of claims was sufficient to maintain an FCA claim based on the 2010 amendment. *Id.* at 98. The Court demanded "evidence of the actual submission of a false claim." *Id.*

On the other side of the divide, the Eight Circuit in *United States ex rel. Cairns v. D.S. Medical LLC*, performed an analysis that "both beg[an] and end[ed] with the [statutory] text." 42 F.4th 828, 834 (8th Cir. 2022). Leaning on the Supreme Court's decision in *Burrage v. United States*, 571 U.S. 204, 211 (2014), interpreting similar language in the Controlled Substances Act, as well as dictionary definitions, the *Cairns* court had "little trouble concluding" that "resulting from" demands but-for causation. *Id.* at 834–35. It rejected the government's proposed alternative causation standards—"taint" or "contributing factor"—as "hardly causal at all." *Id.* at 835. After

all, the court explained, "'taint' could occur without the illegal kickbacks motivating the inclusion of *any* of the 'items or services.'" *Id.* The upshot is that, at trial, "the government had to prove that the defendants would not have included particular 'items or services' absent the illegal kickbacks." *Id.*

The Sixth Circuit in *United States ex rel. Martin v. Hathaway* similarly rejected legislative history and concluded Congress's use of "resulting from" was "unambiguously causal." 63 F.4th 1043, 1053–54 (6th Cir. 2023), *cert. denied*, 144 S. Ct. 224 (2023). In reaching that conclusion, the Sixth Circuit also rejected the notion that "[t]emporal proximity by itself … show[s] causation." *Id.* at 1053. Just because the kickback scheme operated at the same time claims were submitted for reimbursement does not necessarily establish causation. *Id.* Ultimately, the Court concluded that, "[a] faithful interpretation of … 'resulting from' … still leaves plenty of room to target genuine corruption." *Id.* at 1055.

The First Circuit recently joined the Sixth and Eighth in holding that "resulting from" demands but-for causation. It also began with the *Burrage* decision, recognizing that "'resulting from' is read as calling for but-for causation in 'the usual course.'" (quoting *Univ. of Tex. Sw. Med. Ctr. v. Nassar*, 570 U.S. 338, 346 (2013)). Unlike *Greenfield*, the *Regeneron* court found nothing odd about a criminal AKS violation requiring a lesser causation standard than an FCA violation: "the mere fact that one liability is built on another says nothing about whether any additional elements are required to establish the subsequent liability." *Id.* at 331.

It also disagreed that "the addition of a causation element in the 2010 amendment [rendered] the AKS [] less able to pursue its 'animating principle.'" *Id.* at 331. Because criminal AKS liability exists "to protect patients from doctors whose medical judgments might be clouded by improper financial considerations … it makes sense for the AKS to criminalize even those kickbacks that do not ultimately cause a referral or purchase." *Id.* at 332. In contrast, since "the chief purpose" of civil FCA liability "is to provide restitution to the government of money taken from it by fraud," it makes sense that a claim is only "false" for FCA purposes "when a kickback is the cause of that claim's submission to the government." *Id.* (cleaned up). Finally, the First Circuit emphasized, contrary to *Greenfield*'s reasoning and in-line with the Sixth Circuit's, that even with but-for causation, the 2010 AKS amendment strengthened FCA claims by providing an additional pathway for liability that did not require proof of false certifications. *Id.* at 335.

While the Seventh Circuit has yet to address this precise issue, in resolving a challenge to a damages award in an FCA case, the Court recently interpreted "resulting from" and concluded that it "requires that there be some causal nexus between the allegedly false claims and the underlying kickback violation." *Stop Illinois Health Care Fraud, LLC v. Sayeed*, 100 F.4th 899, 908 (7th Cir. 2024), *reh'g denied*, 2024 WL 2785312 (7th Cir. May 30, 2024), and *cert. denied*, 145 S. Ct. 381 (2024). The Court did not need to establish what level of causation, "but-for causality or something less," § 1320a-7b(g) requires. But it expressly rejected the suggestion "that every claim for payment following an anti-kickback violation is automatically

false." *Id.* at 909. "It is not enough to show that a defendant both engaged in unlawful kickbacks and submitted false claims. The latter must 'result from' the former." *Id.* at 908 (cleaned up). The Seventh Circuit was clear that "resulting from" requires some level of "actual causality." *Regeneron Pharms., Inc.*, 128 F.4th at 331.

Relators argue that *Sayeed* endorsed *Greenfield* and, as a result, supports the conclusion that "resulting from" requires only some lesser level of causation. [Dkt. 180 at 20.] Specifically, Relators claim that they "need only show that the prescriptions written by speaker physicians while they were taking Allergan money violated the AKS, and thus claims paid for those prescriptions violate the FCA." [*Id.*] This rendition of Relators' burden confuses AKS and FCA requirements. As this Court previously explained "[t]he [AKS inquiry] concerns the defendant's conduct; the [FCA inquiry concerns] the conduct of the person who submits the allegedly false claims." [Dkt. 164 at 23.] The AKS violation does not depend on whether any prescriptions were written as result of the kickbacks; all that matters is Allergan's intent in paying the kickbacks. *See Borrasi*, 639 F.3d at 780–82. Consequently, it's inaccurate for Relators to suggest that an AKS violation rests on prescriptions written by doctors receiving kickbacks. The FCA, on the other hand, isn't violated unless corresponding claims are submitted for payment to federal health care programs. [Dkt. 164 at 26.]

In Relators' view, all claims resulting from prescriptions written by doctors while they received Allergan kickbacks are false claims. But that is nothing more than the causationless temporal standard rejected the Seventh Circuit in *Sayeed*:

"Th[e] broad suggestion … that every claim for payment following an anti-kickback violation is automatically false … is inconsistent with § 1320a-7b(g)'s directive." 100 F.4th at 909. *Sayeed* instructs that, at minimum, "some causal nexus between the allegedly false claims and the underlying kickback violation" must be shown. *Id.* at 908. Because Relators' proposed standard lacks any causal element, it doesn't pass muster under *Sayeed*. Even *Greenfield* (albeit at the summary judgment stage) explained "[i]t is not enough … to show temporal proximity between [the] alleged kickback plot and the submission of claims for reimbursement." *Greenfield*, 880 F.3d at 100.

There is also nothing inherently suspect, as the Government argues in its Statement of Interest, about an FCA violation premised on subsection (g) of the AKS requiring but-for causation while a criminal AKS violation does not. [Dkt. 187 at 6.] As the *Regeneron* court explained, "it is not unheard of for the same statute to impose different evidentiary burdens for related civil and criminal claims. 128 F.4th at 331–32. An example is civil and criminal RICO claims; "In civil RICO, each wrongful act that causes injury is a new cause of action …; in criminal RICO,… the defendant is being punished for his participation in the pattern as a whole." *Id.* (citing *McCool v. Strata Oil Co.*, 972 F.2d 1452, 1466 (7th Cir. 1992), *as amended on reh'g in part* (Oct. 26, 1992). Consequently, varying causation standards within a criminal and civil scheme is not a reason to reject the plain meaning of "resulting from." *Burrage*, 571 U.S. at 204.

Contrary to Relators' suggestion, *Greenfield* is not persuasive given the analytical misstep that pervades its reasoning. The relator in *Greenfield* styled his complaint as one concerning legal falsity due to false certification; his argument was that Accredo—the alleged FCA violator—falsely "certified compliance with the Anti-Kickback Statute" while paying kickbacks to two charities. 880 F.3d at 94. The Third Circuit explicitly recognized that Greenfield's theory was one of false certification: "Greenfield contends Accredo's claims were legally false because they were incorrectly certified as compliant with the Anti-Kickback Statutes." *Id.* However, without assessing the landscape of FCA claims post-2010 Amendment to the AKS, the Court assumed that the "resulting from" causation standard in § 1320a-7b(g) applied to all FCA kickback claims, including false certification claims running through § 3729(a)(1). Rather than interpreting subsection (g) as an *alternate* pathway to FCA liability, *Greenfield* assumed without analysis that it was the *only* pathway to FCA liability.

That assumption led the Court to reject the but-for causation standard. It reasoned that applying such a rigorous causation standard to all FCA claims "would dilute the FCA," defeating Congress's goal of the 2010 Amendment "strengthen[ing] whistleblower actions based on medical care kickbacks." *Id.* at 97 (cleaned up). It would make it more difficult to bring any type of FCA claim because, in addition to proving a false certification, the Relator would need to prove that the false certification was made because of the AKS violation. The Court's reasoning was also influenced by the language in the at-issue certification—CMS Form 855S. Observing

that the form included no causation requirement, the Court found it incongruous to require but-for causation. *Id.*

More will be said about this issue with respect to Relators' false certification claim, but *Greenfield*'s assumption is unsupported by the text of the statutes and was rejected by the *Regeneron* and *Cairns* courts. The concerns animating the *Greenfield* court decision are not persuasive when subsection (g) is properly viewed as an alternative pathway to FCA liability. Given these issues, Relators' reliance on *Greenfield* is unavailing. All the other Circuits to directly address the question point in one direction—holding that "resulting from" requires but-for causation for claims made under the 2010 Amendment. Examining the text of the statute, and in light of *Sayeed*'s guidance, this Court agrees that but-for causation is required. Ultimately though, no matter what causal standard is imposed, Relators' allegations are insufficient.

2. Sufficiency of Allegations

Next, the Court turns to the sufficiency of Relators' allegations. Rule 9(b) obligates Relators to "inject[] precision and some measure of substantiation into their allegations of fraud." *United States ex rel. Presser v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770, 776 (7th Cir. 2016) (citation and internal quotation marks omitted). By and large, courts require the identification of "an actual claim that was submitted to Medicare" to survive a motion to dismiss. *United States ex rel. Suarez v. AbbVie Inc.*, No. 15 C 8928, 2019 WL 4749967, at *10–11 (N.D. Ill. Sept. 30, 2019) (cleaned up). However, the Seventh Circuit explained that the minimum showing is

(1) "specific representative examples" of false submissions, *United States ex rel. Sibley v. Univ. of Chicago Med. Ctr.*, 44 F.4th 646, 656 (7th Cir. 2022), or (2) particularized factual allegations that give rise to a plausible inference of fraud," *United States ex rel. Mamalakis v. Anesthetix Mgmt. LLC*, 20 F.4th 295, 301 (7th Cir. 2021).

When courts excuse the relator from including "information concerning specific claims submitted to the government," they require that the particularized factual allegations "*necessarily* le[ad] one to the conclusion that the defendant … presented claims to the government." *Suarez*, 2019 WL 4749967, at *12 (citing *Presser*, 836 F.3d at 778). It is insufficient to "merely describe[e] [the] fraudulent or unlawful activity. *Id.* at *10. The facts alleged must overcome obvious alternative—and *legal*—explanations for the submission of claims. *Alarm Detection Sys., Inc.*, 930 F.3d at 821.

Last time around, the Court emphasized that "an uptick in prescriptions itself" does not imply the submission of false claims. [Dkt. 164 at 27.] It offered Relators some non-exclusive examples of how they could bulk up their allegations, including by identifying specific *quid pro quos* (similar to the allegations about Dr. Bierman) or comparing Speaker Bureau physicians' prescription rates against the prescription rates of doctors not receiving Allergan kickbacks or against the prescription rates of doctors who attended Speaker Bureau events but were not paid speakers. [*Id.* at 28–30.] In essence, Relators should present data that controls for other variables such that an increased number of prescriptions written by Speaker Bureau physicians is likely attributable to Allergan's payments.

Between the 3AC and 4AC, Relators' allegations changed only slightly. In the 3AC, Relators detailed the prescription habits of a few doctors but attached as an addendum additional information about 15 more. [Dkt. 177 at 9.] In their 4AC, Relators moved those allegations from the addendum into the main text and added one additional provider—Dr. Agarwal. In resolving the motion to dismiss the 3AC, the Court explained that even if it considered the information in the addendum, the complaint would not pass muster. [Dkt. 164 at 44.] Allegations "that a speaker physician was paid for an unattended, under-attended, or cancelled event and later increased his or her prescription volume" do not support the inference that "doctors submitted false claims resulting from kickbacks on a nationwide basis." [*Id.*]

Relators' new allegations concerning Dr. Agarwal follow the same deficient pattern. Before being paid by Allergan, Dr. Agarwal wrote 18 prescriptions, but in 2016, after being paid for 12 Speaker Bureau events, his prescription volume increased to 59 prescriptions. [Dkt. 173 ¶ 211.] Allergan paid Dr. Agarwal for five events in 2017, and he wrote 172 prescriptions. [*Id.*] The allegations for the other 15 speaker-physicians follow the same pattern, citing how much they were paid by Allergan and how many prescriptions they wrote, compared to a lesser amount before receiving kickbacks.

Regardless of whether the Court interprets "resulting from" as requiring but-for or some lesser causal relationship, Relators' allegations are not sufficient. As the Court previously explained, the fact that doctors' prescription rates for Linzess and Viberzi increased after they began receiving payments from Allergan does not, for

Rule 9(b) purposes, support an inference of causation. [Dkt. 164 at 2.] Relators urge the Court to make the "plausible" inference that "speakers did what Allergan expected by writing prescriptions once they entered the program and that the government paid claims for those prescriptions." [Dkt. 180 at 23.] But that is merely a temporal connection which the Seventh Circuit held is insufficient. *See Sayeed*, 100 F.4th at 908 ("It is not enough to show that a defendant both engaged in unlawful kickbacks and submitted false claims."). While inferences "are not forbidden in 9(b) territory, … this one is not supported by enough factual allegations." *RBG Plastic, LLC v. Webstaurant Store*, 2021 WL 4146899, at *4 (N.D. Ill. Sept. 13, 2021). Relators do not allege facts that "*necessarily* le[ad] one to the conclusion that" claims were presented to the government. *Suarez*, 2019 WL 4749967, at *12.

The fact that Allergan retained speaker-physicians who wrote more prescriptions and terminated speaker-physicians who wrote fewer prescriptions doesn't fit the bill either; that goes to Allergan's intent in paying kickbacks, which is relevant to an AKS claim but not an FCA one. [Dkt. 180 at 22.]

Allergan identifies variations in Speaker Bureau physicians' prescribing habits, including a few physicians, such as Dr. Kayal, who wrote fewer prescriptions while Allergan was paying them. [Dkt. 177 at 19.] Relators counter that Dr. Kayal's prescription rates "dropped in lockstep with reductions in his speaker fees" which supports the existence of a *quid pro quo* relationship. [Dkt. 180 at 25.] That theory is not borne out by Relators' examples. Dr. Agarwal was paid for substantially fewer events in 2017 compared to 2016 (5 vs. 12 events) but between those two years his

prescription rate jumped 192%. [Dkt. 173 ¶ 211.] The same is true for Dr. Hathaway, who was paid less in 2018 but increased his Linzess prescriptions. [*Id.* ¶ 201.] These examples only emphasize the difficulty in deriving any concrete relationship between payment for Speaker Bureau events and prescriptions written.

Faced with this difficulty, Relators assert that they "need not show never-ending growth in prescription volume," explaining that "among the hundreds of physicians in the program, some may have had different appetites for participating in Allergan's scheme"—in fact, Relators note, some physicians may have not "alter[ed] their prescribing patterns based on Allergan's payments." [Dkt. 180 at 24.]

This argument reveals cracks in Relators' claim. Supporting their theory that the Speaker Bureau was a conduit to trade cash for prescriptions are Relators' allegations about Nurse Practitioner Jeffreys who was allegedly axed from the Speaker Bureau after she failed to maintain or increase her prescription volume. [Dkt. 177 at 20.] While Relators allege Allergan terminated 136 speaker-physicians like Jeffreys for being "low-prescribers," they offer no details on their prescribing habits. [Dkt. 173 ¶ 160.] Meanwhile, Relators' allegations show there were other Speaker Bureau doctors like Dr. Tran who remained in the Speaker Bureau—and were paid for an increasing number of speaking events—despite their prescription volume dropping. [*Id.* ¶ 217.] Relators do not allege these doctors were cut from the program or disciplined in any way.

Relators ask the Court to agree that all claims resulting from prescriptions written by Speaker Bureau doctors are false claims. But they admit that some doctors

didn't change their prescribing habits in response to Allergan's payments. This inconsistency spotlights the risk of permitting a temporal connection to stand in for a causal one. The purpose of the FCA is "to provide restitution to the government of money taken from it by fraud" not to protect patients from doctors who may be making financially motivated treatment decisions. *Regeneron Pharms., Inc.*, 128 F.4th at 332. That problem falls to the AKS. *Id.* As *Sayeed* recognized, assuming that every prescription written by a doctor who received kickbacks resulted in the submission of a false claim would be overinclusive. 100 F.4th at 908. An FCA cause of action cannot be premised on claims that were not caused by the kickback scheme.

Responding to this Court's prior order, Relators attempt to identify a causal connection between kickbacks and claims by comparing the prescription rate of doctors in the Speaker Bureau with those who were not. They assert that "physicians who began accepting Allergan speaker payments … averaged 69.56 prescriptions in 2016 or 167% of the number of prescriptions written by doctors who received no remuneration from Allergan … during that same year." [Dkt. 173 ¶ 222.] On first blush, this statistic sounds compelling. But on closer review it falls short.

To plausibly allege a causal relationship between kickbacks and claims presented to the government for payment, what matters is not the number of prescriptions written during a particular year when doctors received remuneration but any change in prescription rate before and after the doctors began receiving kickbacks. To determine any impact of Allergan payments, that figure must be compared against any change in prescription rates for non-Speaker Bureau doctors

over the same period of time. Even drawing all reasonable inferences in their favor, from Relators' allegation there is no way to know if the doctors referenced wrote, on average, more prescriptions in 2016 or whether their average prescription rate stayed relatively flat. Put another way, any difference Relators allege between the two groups (Speaker and non-Speaker doctors) is not plausibly attributable to Allergan kickbacks. It just supports what Relators allege to be true: that Allergan recruited into the Speaker Bureau doctors who wrote lots of prescriptions for Allergan drugs. [*Id.* ¶¶ 149–55.]

A related problem with Relators' allegation is that using the average number of prescriptions written by Speaker Bureau doctors and non-Speaker Bureau doctors obscures the significant variation in prescription volume among doctors in general. Looking at the prescription habits alleged in the complaint, some doctors wrote relatively few prescriptions before being added to the Bureau—for example, Dr. Chiao wrote 23 prescriptions for Linzess in 2015 before he was paid. [*Id.* ¶ 264.] However, after beginning to receive payment from Allergan, he wrote 62 prescriptions, which is a 169% increase. [*Id.*] In contrast, another doctor, Dr. Chien, wrote 230 prescriptions of Linzess in 2015 before receiving any payment. [*Id.* ¶ 167.] In 2016, once Allergan began paying him, his volume increased to 337 prescriptions. [*Id.*] While that number is significant, Dr. Chiao's percentage increase was only 46%. Relying on average prescriptions written per year obscures the possibility that while Speaker doctors wrote more prescriptions in absolute terms that is merely because they were, in general, high prescribers. [*Id.* ¶¶ 149–55.]

Ultimately, Relators' assertion using average number of prescriptions does not help them allege a causal relationship between kickbacks and claims. All it shows is that in 2016 some collection of physicians in the Speaker Bureau wrote, on average, more prescriptions for Allergan drugs than physicians who did not receive remuneration.[9] Relators' assertion does not lead to the conclusion that Speaker Bureau doctors wrote more prescriptions that, in turn, resulted in more claims submitted to the government, because of Allergan kickbacks.

Dovetailing with the insufficiency of this assertion, Relators admit that CMS data shows that the overall prescription volume for Linzess in 2016—both by doctors paid by Allergan and those who were not—increased by 42% compared to 2015. [Dkt. 173 ¶ 199.] While they attribute this trend to the success of Allergan's Speaker Bureau program, they cite no data suggesting the increase in volume is due to paid speakers rather than the market at large. [*Id.*]

Relators also cite a 2019 ProPublica study, analyzing CMS data and Allergan's speaker fee payments for Linzess. [Dkt. 173 ¶¶ 35, 221.] Citing the article, they contend that "Doctors who received payments related to Linzess in 2016 wrote 45% more prescriptions for the drug, on average, than doctors who received no payments." [*Id.* ¶ 221.] Relators are not precise about whether this figure includes doctors who received other types of remuneration besides Speaker Bureau fees. The study's methodology suggests it does: 97% of doctors who received remuneration from Linzess

[9] Even viewing Relators' assertion generously, it is unclear to the Court whether the 69.56 figure is the average of all doctors in the Speaker Bureau in 2016 or some subset, such as only doctors who first began receiving remuneration in 2016.

received only free meals, not Speaker fees. *See* https://projects.propublica.org/graphics/d4dpartd-methodology (fig. "Promotional Spending on Open Payments"). This difference matters. Since the kickback Relators identify is Speaker Bureau payments—not receipt of free meals—statistics about claims resulting from doctors receiving that type of remuneration does not create an inference that false claims necessarily resulted from Speaker Bureau kickbacks. *Presser*, 836 F.3d at 778.

The new allegations in Relators' 4AC are unsuccessful in isolating for any effect Speaker Bureau payments had on prescription rates. They do not identify a specific patient or specific claim submitted to the government for payment. *Mamalakis*, 20 F.4th at 301; *Presser*, 836 F.3d at 777*; Sibley*, 44 F.4th at 656 ("[T]o defeat dismissal, 'specific representative examples' of false submissions are required."). Also missing are "particularized factual allegations," *Mamalakis*, 20 F.4th at 301, setting out "the requisite 'who, what, when, where, and how' of the fraud." *Sibley*, 44 F.4th at 657 (citation omitted). Relators' allegations do "*necessarily* le[ad] one to the conclusion that the defendant … presented claims to the government." *Suarez*, 2019 WL 4749967, at *12

The lack of rigor in Relators' pleading causes plausible, legal explanations for the rise in prescription volume to remain. *Id.* This time around, Relators allege that Linzess was not a new drug; as such, they argue that it is not a reasonable alternative explanation for the increase in prescriptions during the relevant period. Even so, Relators admit that after Allergan acquired Forest Laboratories and its drug,

Linzess, it engaged in aggressive marketing tactics, which allegedly included the speaker events. [Dkt. 173 ¶ 109.] The fact that, according to Relators, Linzess wasn't new doesn't make implausible that, due to Allergan's marketing efforts, many more physicians became aware of the drug (whether through lawful or unlawful marketing techniques).

Except for two doctors—Bierman and Kayal—Relators' allegations do not create the inference that doctors who received kickbacks wrote prescriptions out of that motivation, as opposed to their medical judgment concerning the efficacy of Allergan's products. Relators' allegations of Dr. Bierman's explicit *quid pro quo* with Allergan is sufficient to state a claim. With respect to Dr. Kayal, Relators allege that after he was added to the Speaker Bureau he "had 10 patients start on Viberzi." [Dkt. 173 ¶ 192.] Although not as specific as the allegations concerning Dr. Bierman, this is enough to make plausible that Dr. Kayal wrote ten prescriptions for Viberzi following an Allergan speaker event because of the kickback.[10]

* * * * *

When the Court ruled on Relators' 3AC it concluded that Relators also stated an FCA claim with respect to Nurse Practitioner Jeffries. [Dkt. 164 at 41 n.26.] Upon closer review, the Court is convinced that decision was error. Relators' allegations about Jeffreys go a long way to support an AKS violation. The fact that Allergan

[10] Allergan argues that Relators' allegations of a FCA kickback scheme with respect to Viberzi are thin; most allegations concern prescriptions for Linzess. [Dkt. 177 at 20–21.] True, however, Relators persuasively allege that the kickback scheme encompassed both drugs. In addition, since the Court is permitting only the FCA Kickback claims with respect to Dr. Bierman and Dr. Kayal to proceed, and both those doctors allegedly prescribed Viberzi, the Court need not splice the claim.

allegedly cut individuals like Jeffreys from the Speaker Bureau for failing to maintain or increase their prescription volume makes plausible that Allergan intended the Speaker Bureau to operate as a kickback. [Dkt. 173 ¶ 191.] With respect to an FCA violation, however, the fact that Jeffreys failed to increase her prescriptions makes it unlikely that any claims were submitted as a result of Allergan's kickbacks. [*Id.*] Quite the opposite, Relators' allegations suggest all the prescriptions she wrote were due to her medical expertise.

Consequently, for the remaining providers including Jeffreys, no matter what level of causation is required, Relators' allegations fail to connect kickback payments with false claims for payment presented to the government.[11]

IV. Count I: False Certification Theory

Relators' second FCA theory is false certification. A different flavor of this claim, referred to as a "false record" claim, was raised in Relators' 3AC and focused on doctored internal Allergan attendance records for Speaker Bureau events. [Dkt. 164 at 49.] Now Relators point to Medicare and Medicaid form certifications, which they allege failed to disclose the AKS violation.

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[11] Allergan offers an alternative view of the Medicare Part D data, arguing that "non-speakers' prescribing rates for Linzess grew 133% over the same time period" compared with a 76% growth rate for "all of the program speakers who appear in the Medicare Part D data." [Dkt. 177 at 18.] While the Court could consider this data without converting Allergan's motion into one for summary judgment, the deficiency of Relators' allegations make doing so unnecessary to the Court's resolution of the motion. *See Perkins v. Silverstein*, 939 F.2d 463, 469 n.4 (7th Cir. 1991) ("In determining the sufficiency of the complaint we must rely on the exhibits whenever the allegations of the complaint are materially inconsistent with those exhibits."); *Craig v. Rich Twp. High Sch. Dist. 227*, 736 F.3d 1110, 1113 (7th Cir. 2013) ("[A] court may also examine information from documents referenced in the complaint that the plaintiff relies upon to support its claim.").

A. Causation

The false certification theory arises under 31 U.S.C. § 3729(a)(1)(B) and applies where a person "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *U.S. ex rel. Ziebell v. Fox Valley Workforce Dev. Bd., Inc.*, 806 F.3d 946, 951 (7th Cir. 2015). "Claim" means a demand for payment presented to the federal government or its agent. *Id.* § 3729(b)(2)(A); *Olhausen v. Arriva Med., LLC*, 124 F.4th 851, 862 (11th Cir. 2024). Under this theory, a claim is made false through an express or implied false certification of compliance with a condition of payment that is material to the government's decision to pay the claim. *Molina Healthcare*, 17 F.4th at 741; *Escobar*, 579 U.S. at 186–87. Courts agree that AKS compliance is a material condition of payment. *United States v. Am. at Home Healthcare & Nursing Servs., Ltd.*, 2017 WL 2653070, at *9 (N.D. Ill. June 20, 2017). Relators assert both false express and implied certification theories, but by-and-large discuss them together.

A threshold question is whether false certification claims concerning AKS compliance must still satisfy 42 U.S.C. § 1320a-7b(g). The answer hinges on whether the 2010 AKS amendment—which added subsection (g)—applies to all FCA Kickback cases or just those where submission of false claims is at issue. This is the issue the *Greenfield* court missed when deciding that subsection (g) did not impose but-for causation.

Allergan argues, relying on Minnesota district court opinion, *United States ex rel. Louderback v. Sunovion Pharms., Inc.*, 703 F. Supp. 3d 961, 980 (D. Minn. 2023),

that all FCA cases premised on AKS violations must go through § 1320a-7b(g). [Dkt. 177 at 23.] It presses that the Seventh Circuit in *Sayeed* is in accord, as evidenced by its acknowledgement of the insufficiency of a purely temporal connection between kickback and submission of claim. [*Id.*] Allergan also cites this Court's prior conclusion that "Relators must allege claims submitted to the government that *resulted from* those kickbacks." [Dkt 184 at 9-10.]

Relators counter that false certification cases, which existed before the 2010 AKS amendment, run on a separate track from false-claim-style cases that implicate § 1320a-7b(g). Even *Cairns*—one of the principal cases supporting the but-for causation theory—cabins its analysis to cases based on the 2010 AKS amendment. 42 F.4th at 836 ("Our ruling today is narrow. We do not suggest that every case arising under the False Claim Act requires a showing of but-for causation[,] …" only "when a plaintiff seeks to establish falsity or fraud through the 2010 amendment …").

As discussed in section III.B.1, *supra*, the *Regeneron* court went further, holding that false certification cases "d[o] not require proof of causation to demonstrate falsity…; a material misrepresentation of compliance with the AKS [is] enough." 128 F.4th at 333 ("[T]here is nothing in the 2010 amendment that requires proof of but-for causation in a false-certification FCA case."). It explained that this cause of action predated the 2010 amendment and continues to be viable because the amendment "did not clearly intend to alter false-certification caselaw by imposing a but-for causation requirement." *Id.* ("[T]he 2010 amendment did not disturb alternative theories of FCA liability" such as false certification.). As for *Sayeed*,

Allergan's reading stretches its limited holding too far. 100 F.4th at 903, 908 (interpreting "resulting from" language in subsection (g) because Relator pursued a false claim, as opposed to false certification, theory).

These cases, principally *Regeneron* and *Cairns*, reject the rationale of the *Louderback* court when it comes to the animating purpose of the 2010 AKS amendment. *Louderback* was concerned that permitting some FCA claims based on AKS violations to skirt subsection (g) would result in the 2010 amendment having "little practical effect" because no "relator would go to the trouble of attempting to allege a claim under § 1320a-7b(g) and meet its but-for causation standard when a less demanding path" was available. 703 F. Supp. 3d at 980.

To begin with, the Court does not agree that establishing but-for causation is uniformly more difficult than proving false certification. As other courts recognize, the 2010 AKS amendment was intended to strengthen the government's ability to respond to fraud and "create[] a different pathway to establish falsity in FCA actions based on AKS violations." *Regeneron*, 128 F.4th at 335 (cleaned up). Requiring all FCA claims stemming from AKS violations to pass muster under subsection (g) and allege but-for causation would work against the goal of the amendment. Ultimately, the Court sides with the First Circuit in *Regeneron* and finds that a cause of action for falsely certifying compliance with the AKS exists and does not require alleging but-for causation.

B. Failure to State a Claim

Relators argue that Allergan caused both express and implied certifications to falsely indicate compliance with the AKS. [Dkt. 180 at 12.]

"Under an express false certification theory, a plaintiff must allege that [the] defendant[] falsely and specifically certified that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds." *Walgreen Co.*, 417 F. Supp. 3d at 1085 (cleaned up). The statute expressly requires that any false record or statement be material to a claim for payment. § 3729(a)(1)(B); § 3729(b)(2)(A).

The Supreme Court in *Escobar* recognized the implied certification theory as a basis for liability but with two conditions. 579 U.S. at 190. First, the claim cannot "merely request payment"; it must "make[] specific representations about the goods and services provided." *Id.* Second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements [must] make[] those representations misleading half-truths." *Id.*

Under either theory, FCA liability extends to a defendant who "knowingly … causes" the creation or use of a "false record or statement material to a false or fraudulent claim." § 3729(a)(1)(B). The Seventh Circuit recently clarified, albeit not in an AKS violation context, that FCA liability can result even where an innocent intermediary submits the false certification. *Sibley*, 44 F.4th at 659; *see also United States ex rel. Kroening v. Forest Pharms., Inc.*, 155 F. Supp. 3d 882, 887 (E.D. Wis. 2016) (same conclusion in a pre-*Escobar* FCA Kickback case).

Cases from within the Seventh Circuit in the express false certification context indicate that the "documents [comprising the false certification must] ha[ve] an[] apparent nexus to federal payments." *Ziebell*, 806 F.3d at 951. Put another way, the alleged false certification must have been made "in connection with the claim for payment of federal funds." *United States v. UnitedHealthcare Ins. Co.*, 2018 WL 2933674, at *4 (N.D. Ill. June 12, 2018). The nature of the connection required is opaque—must the certification accompany the request for payment or is it sufficient if the certification influences the request for payment (for example, if payment would not be made absent the certification)? Further complicating matters is the Seventh Circuit's holding that "[p]romises of future compliance" with federal laws are not a basis for FCA liability unless the promise was "made with intent not to perform." *Ziebell*, 806 F.3d at 951; *see also United States ex rel. Cieszyski v. LifeWatch Servs., Inc.*, 2015 WL 6153937, at *8 (N.D. Ill. Oct. 19, 2015).

Taken together with *Sibley*, these cases indicate that FCA liability cannot result where an innocent third party makes future representations of compliance. 44 F.4th at 659. Since the third party is unaware of any violation, it would be unlikely that they previously certified compliance "with intent not to perform." *Ziebell*, 806 F.3d at 951. Consequently, where a case involves an innocent third-party certifier, this case law suggests that liability only lies where the certification manifests current compliance in conjunction with a claim for payment.

To be sure, another possibility is that *Ziebell*'s holding regarding future promises is simply inapplicable to cases involving third-party certifiers. 806 F.3d at

951. Or, perhaps, *Ziebell* and similar cases like *UnitedHealthcare* mistook the statute's materiality requirement (certification being material to a claim for payment) for a timing requirement (narrowing scope of FCA liability except where certifications accompany requests for payment of a specific claim). These issues are for another court to resolve. The dearth of allegations in this case make resolving the precise contours of the cause of action unnecessary. Regardless of how § 3729(a)(1)(B) claims apply where innocent third parties submit prospective certifications of compliance, Relators' allegations fall short of Rule 9(b).

Relators' complaint is vague about what entities submit claims for payment, referring only to "a party that submits a claim for payment." [Dkt. 173 ¶ 67.] Instead, Relators cite a variety of form certifications (provider agreements, certifications of compliance, enrollment forms) and argue Allergan's kickbacks caused them all to be false. [*Id.* ¶¶ 53–56.] They broadly assert that "[e]very physician who prescribed … Linzess and Viberzi for Medicare patients alleged herein must have executed these required certifications in order to receive payment from Medicare for providing physician services to these Medicare patients." [*Id.* ¶56.] They contend that physicians complete a few standard forms: Form 1500, Form CMS-855O, and Form CMS855I. These certifications, Realtors argue, are necessary for physicians to be paid "for providing physician services" and "to prescribe and have Medicare pay for prescriptions." [*Id.* ¶¶ 53–56.]

Absent from Relators' 4AC, though, are allegations connecting "physician services" to claims for reimbursement for prescriptions. Similarly missing are

allegations that physicians submitted *any* certification or received *any* payment in conjunction with writing a prescription that eventually wound its way to the government for payment. So, that doesn't suffice for an express false certification theory.

Relators allege that pharmacies make prospective certifications of compliance through Form 855S and through subcontracts with Medicare Part D sponsors. [*Id.* ¶ 60.] Relators do not allege that pharmacies submitted any claims in conjunction with Viberzi or Linzess prescriptions. The closest they come is alleging that "Dr. Bierman's prescriptions for Viberzi and Linzess were presented to pharmacies that filled them and claims for the medication were submitted to the Medicare Program." [Dkt. 173 ¶ 188.][12]

Far from identifying any specific false certification, Relators don't explain the claim submission and certification process or identify any false claim submitted in conjunction with a false certification. Rule 9(b) requires Relators to explain "the 'who, what, when, where, and how'" of their false certification theory. *Berkowitz*, 896 F.3d at 839 (cleaned up). Instead of doing so, they ask the Court to agree that unnamed and unknown pharmacies completed certifications and some unspecified entity

[12] By way of comparison, in another false certification case, *United States ex rel. Lisitza v. Par Pharmaceutical Companies, Inc.*, the relators' allegations concerning the claim-submission process were clear: "pharmacies submitted reimbursement claims to Medicare after filling prescriptions," and completed a "standard form" indicating "a provider number, a total amount billed, the name of [the] patient, the National Drug Code … the prescription number, and the date filled." 276 F. Supp. 3d 779, 785 (N.D. Ill. 2017). Also included was a certification form attesting to the accuracy of the information being provided, including that falsification of claims could be a violation of federal and state law. *Id.* In contrast, Relators' allegations here do not even sketch the process by which claims are submitted for payment.

subsequently submitted claims for prescriptions written by Speaker Bureau doctors. Relators do not identify any representative claims or identify any certifications completed by any pharmacies. Their "complaint fails to allege … any specific facts demonstrating what occurred at the individualized transactional level." *United States ex rel. Berkowitz v. Automation Aids, Inc.*, 896 F.3d 834, 841 (7th Cir. 2018).

Sometimes courts relax the Rule 9(b) requirement that Relators identify a specific false claim submitted to the government where relators are not "in a position to obtain" such information. *Suarez*, 2019 WL 4749967, at *12. Here, Relators allegations confirm that is not the case. Relators allege that, in particular with respect to Dr. Bierman, Allergan had sales representatives, including Relator Wilkerson, "chase" prescriptions written by doctors to ensure pharmacies filled them and that the prescription was "paid for by the relevant federal or state payor." [Dkt. 173 ¶ 174.] This allegation suggests that Relators were aware of specific pharmacies that dispensed Allergan medication in response to specific prescriptions written by Speaker Bureau doctors. Consequently, Relators could have included particularized allegations concerning certifications submitted by those pharmacies. The decision not to is fatal to their claim.

Relators' implied false certification claim fails for the same reason. To state a claim for implied false certification Relators must identify a claim for payment submitted where the submitter did "not merely request payment, but also ma[de] specific representations about the goods or services provided." *Escobar*, 579 U.S. at 190. Relators failed to identify any request made for payment from the government

or its agent or any language making specific representations about what was provided. While Relators identify forms pharmacies complete to participate in the Medicare program, *see* dkt. 173 ¶ 55, none include a request for payment or any specific representations.

Relators contend that every "'claim' submitted for payment by a dispensing pharmacy" represented that the "doctor had prescribed Linzess or Viberzi" but failed to disclose the AKS violation. [Dkt. 180 at 13.] They argue that "if a party pays a kickback to induce prescriptions, it renders false the claim submitter's implied certification of compliance with the AKS." [*Id.*] But, again, this is a repackaged taint theory which is insufficient under *Escobar*. In *Escobar*, the defendants made specific representations about the goods provided, including payment codes and identification numbers that represented that services had been provided by health providers with certain job titles and corresponding qualifications. *Escobar*, 579 U.S. at 189–90. Relators do not identify anything similar here, because, as explained, they isolate no false claims to begin with. As a result, Relators' implied false certification claim fails as a matter of law.

V. Count II: FCA False Record Claim

The second count of Relators' complaint asserts a claim under § 3729(a)(1)(B) but this overlaps in large part with their false certification theory. With respect to

false certifications through Medicare and Medicaid forms, that claim is dismissed for failure to state a claim for the reasons discussed.

In support of Count II, Relators also allege that Allergan falsified Speaker Bureau attendance records. [Dkt. 173 ¶ 317.] Relators contend that they were directed by Allergan managers to falsify records of who attended speaker events, and Allergan was aware of this practice and encouraged it. [*Id.* ¶¶ 167, 236.]

As the Court explained when dismissing Relators' 3AC, Relators did not allege that Allergan fabricated these attendance records "in order to receive money from the government." *Lanahan v. Cnty. of Cook*, 41 F.4th 854, 862 (7th Cir. 2022). Relators did not allege that the attendance records were submitted or used in any way to obtain payment from governmental entities. Also missing from Relators' complaint were allegations connecting record falsification to high-level Allergan employees. [Dkt. 164 at 50.] Instead, Relators vaguely alleged that "Allergan instructed sales representatives to manipulate speaker event attendance records" declining to specify who, when, or how. *Lanahan*, 41 F.4th at 862; [Dkt. 173 ¶ 167.] Between the 3AC and 4AC Relators' allegations did not materially change. [*See generally*, dkt. 173-2 (redline comparison of 3AC and 4AC).] So, Count II is dismissed for failure to state a claim for the same reasons previously explained.

VI. Count III: FCA Conspiracy Claim

Relators allege, as they did in their 3AC, that Allergan conspired with Speaker Bureau physicians "to commit violations of the FCA and the AKS." § 3729(a)(1)(C). [Dkt. 173 ¶¶ 321–322.] "A civil conspiracy is a combination of two or more persons

acting in concert to commit an unlawful act, or to commit a lawful act by unlawful means." *Beaman v. Freesmeyer*, 776 F.3d 500, 510 (7th Cir. 2015) (cleaned up). "As long as there was a common goal, a conspiracy can be proved without respect to whether the goal was ever accomplished." *United States ex rel. Lisitza v. Par Pharm. Companies, Inc.*, 276 F. Supp. 3d 779, 807 (N.D. Ill. 2017). What matters is whether there was an "agreement to commit an unlawful act," not that "the conspiracy succeed in its illicit aim." *Id.* (quoting *United States v. Vallone*, 752 F.3d 690, 697–98 (7th Cir. 2014)). Since a corporation like Allergan cannot conspire with its employees, *United States ex rel. McCarthy v. Marathon Techs., Inc.*, 2014 WL 4924445, at *3 (N.D. Ill. Sept. 30, 2014), Relators must allege "an agreement or meeting of the minds," *United States ex rel. Lisitza v. Par Pharm. Companies, Inc.*, 276 F. Supp. 3d 779, 806 (N.D. Ill. 2017), between Allergan and doctors in the Speaker Bureau program.

It is not enough for Relators "to show that the alleged conspirators agreed upon a fraud scheme" that would violate the FCA; 'it must be shown that the conspirators intended to defraud the Government." *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672–73 (2008) (cleaned up). Because the FCA is not "a general anti-conspiracy statute," "[t]he object of the conspiracy must be to make false or fraudulent claims." *Lisitza*, 276 F. Supp. 3d at 809 (holding that conspiracy to violate Medicaid law is not sufficient for a claim under § 3729(a)(1)(C)). While speaker physicians "need not have agreed on the details of the conspiratorial scheme," Relators must allege that they "understood the general objectives of the scheme,

accept[ed] them, and agree[d], either explicitly or implicitly, to do [their] part to further them." *Jones v. City of Chicago*, 856 F.2d 985, 992 (7th Cir. 1988).

The Court previously dismissed this count of Relators' 3AC, explaining that Relators' allegations were too scant to establish an agreement. [Dkt. 164 at 47–48.] Citing knowledge-attribution principles, Relators now argue that there is no requirement that they allege a conspiracy between doctors and high-level Allergan employees because all employees' knowledge is attributed to the corporation. [Dkt. 180 at 27.] This misses the mark. The *United States v. Anchor Mortgage Corporation* case Relators cite discussed the knowledge requirement in § 3729(a)(1)(A), ("knowingly presents, or causes to be presented …), not agreement for purposes of a conspiracy claim. 711 F.3d 745, 747 (7th Cir. 2013). Agency principles control whether actions of employees in agreeing with a third-party to commit an unlawful act are attributable to the employee's employer. *United States v. Ganos*, 2019 WL 2178605, at *5 (E.D. Wis. 2019).

In this case, regardless of whether low-, mid-, or high-level Allergan employees are considered, Relators failed to allege sufficient facts about any agreement. Most of Relators' detailed allegations concern the *quid pro quo* with Dr. Bierman. According to Relators, Allergan District Manager Foust directed sales representatives, including Relator Wilkerson, to inform Dr. Bierman that if he wanted to continue to receive speaking fees, he had to increase his prescriptions of Viberzi. [Dkt. 173 ¶ 170–71.] In response, Dr. Bierman agreed to increase his prescriptions so he could continue to receive speaker fees. [*Id.* ¶ 172.] However, Relators do not allege any

explicit or implicit agreement with Allergan to defraud the government by submitting false or fraudulent claims. The allegations only concern Dr. Bierman's agreement to continue writing more prescriptions for Allergan drugs in order to continue receiving Speaker Bureau fees. [Dkt. 173 ¶ 171–72.] That's just evidence of an agreement to engage in a scheme that would violate the FCA; not "inten[t] to defraud the Government." *Allison Engine Co.*, 553 U.S. at 672–73.

Relators do not include allegations outlining any meeting of the minds between any Allergan employee and any Speaker Bureau doctor with respect to an agreement aimed at defrauding the government. In their Opposition brief they direct the Court to allegations about "Dr. Adam Levy, Dr. Asif Qadri, and other HCPs." [Dkt. 180 at 27.] Relators' allegations concerning Dr. Qadri mirror the allegations about other providers: before Quadri was added to the Speaker Bureau he wrote relatively few prescriptions for Allergan drugs; after being paid, he increased his prescriptions and continued to do so while Allergan paid him. [Dkt. 173 ¶¶ 208–210.] There are no allegations that Qadri agreed with anyone at Allergan to defraud the government. The same goes for the other Speaker Bureau prescribers. As for Adam Levy, Relators' complaint includes no allegations about him at all. Even for Dr. Kayal, Relators do not allege any agreement. [Dkt. 173 ¶ 192–197.]

When ruling on Relators' 3AC, the Court recognized that Allergan admitted the existence of an unlawful agreement with Dr. Bierman and found that admission constituted waiver on the conspiracy claim at the pleading stage. [Dkt. 164 at 48.] The Court holds Allergan to its waiver but emphasizes, as it did before, that

agreement with a single physician does not establish a nationwide conspiracy. Count III may proceed only with respect to an alleged conspiracy between Allergan and Dr. Bierman.

VII. Count IV: Reverse FCA Claim

Relators allege what is commonly referred to as a "reverse FCA claim" under § 3729(a)(1)(G), arguing that Allergan "knowingly and improperly avoid[ed] … an obligation or pay or transmit money or property to the government. [Dkt. 173 ¶¶ 325–27.] The Court previously dismissed an identical version of this claim in Relators' 3AC, explaining that the claim is redundant because the only alleged obligation to repay the government flows from Allergan's alleged violation of § 3729(a)(1)(A). [Dkt. 164 at 51.] Relators now argue that redundancy is not a valid reason to dismiss the claim at the motion to dismiss stage, but do not provide any new allegations with respect to this claim. [Dkt. 180 at 27–28.]

Courts in this Circuit—and elsewhere—regularly dismiss reverse FCA causes of action when faced with identical circumstances. Where the relator "alleged that the Defendant[] received money from the government through false claims and records" but does "not allege[] that Defendant[] had an obligation to pay money … to the government separate from the money [it] received via fraudulent statements and records," the reverse FCA claims should be dismissed as redundant. *United States ex rel. Myers v. Am.'s Disabled Homebound, Inc.*, 2018 WL 1427171, at *3 (N.D. Ill. Mar. 22, 2018) (collecting cases). Otherwise, under Relators' theory, "just about *any* traditional false statement or presentment action would give rise to a reverse false

claim action" since "any false statement actionable under sections 3729(a)(1)(A) or 3729(a)(1)(B) could theoretically trigger an obligation to repay the fraudulently obtained money." *Pencheng Si v. Laogai Rsch. Found.*, 71 F. Supp. 3d 73, 97 (D.D.C. 2014) (citing *United States ex rel. Taylor v. Gabelli*, 345 F.Supp.2d 313, 338 (S.D.N.Y. 2004)). Count IV is dismissed for failure to state a claim.[13]

VIII. Counts V–XXXVIII: State Law Claims

Relators' state law claims mirror their federal ones. [Dkt. 180 at 28 ("Because Relators have pled FCA related to [sic] Medicare claims, Relators respectfully submit that their state law claims should not be dismissed."). In dismissing Relators' 3AC, the Court emphasized that when re-pleading they could "allege facts and make legal arguments" that "some states' FCA analogues are more permissive than the federal statute." [Dkt. 164 at 53 n.31.] Relators did not take that opportunity. Because most of Relators' FCA claims are deficient as a matter of law, so too are their state law claims.

The only exception is Count XXXI, Relators' Tennessee Medicaid FCA claim. Tennessee's version of the FCA is "substantially the same" as the federal FCA, so "the federal FCA analysis" applies to that claim. *United States v. Walgreen Co.*, 591 F. Supp. 3d 297, 304 (E.D. Tenn. 2022) (cleaned up) (citation omitted). Because the

[13] Relators' citation to *United States ex rel. Wallace v. Exactech, Inc.*, does not persuade the Court otherwise for several reasons, not the least of which is that, in that case, relators alleged that the defendant took steps to conceal the obligation for surgeons to repay the money they'd received from the government. 2020 WL 4500493, at *21 (N.D. Ala. Aug. 5, 2020). There are no similar allegations in this case supporting a stand-alone violation of subsection (g).

Court concluded that Relators stated a claim with respect to Dr. Bierman and Dr. Kayal under federal law, and because Relators allege that both doctors practiced in Tennessee, *see* dkt. 173 ¶¶ 152, 192, Relators' Tennessee FCA claims may proceed only with respect to those two prescribers.

IX. Count XXXIX: Relator Jackson's FCA Retaliation Claim

A. Allegations of Retaliation against Relator Jackson

Relator Jackson alleges that Allergan retaliated against him in violation of the FCA by terminating him after he reported potential violations of the FCA. 31 U.S.C. § 3730(h)(1). According to the 4AC, Allergan instructed its sales force, including Relators, to aggressively promote Viberzi to patients who did not have IBS-D, but "had loose, runny or watery stools, and belly pain" or who simply wanted to "eat whatever they wanted without fear of diarrhea." [*Id.* ¶ 287.] Jackson viewed this effort as illegal "off label" marketing. [*Id.* ¶ 288.] His supervisor, Foust, coached Jackson to promote Viberzi to non-IBS-D patients and downplay potential side effects of the drug. [*Id.* ¶ 289] Jackson observed Foust downplay the risks of Viberzi during meetings with doctors, specifically the potential negative side effects for patients who drank more than three alcoholic beverages per day. [*Id.*] Jackson also learned that sales representatives who were not aware of Viberzi's risks and addictive characteristics aggressively marketed the drug to primary care physicians. [*Id.* ¶ 290.]

Jackson refused to participate in this off-label marking but observed Viberzi's growth once sales representatives followed Allergan's directive. [*Id.* ¶ 293.] Foust

reprimanded Jackson for describing Viberzi's contraindications, limiting his marketing pitches to approved uses, and objecting to making false representations to health care providers about Viberzi's side effects. [*Id.* ¶¶ 296, 298.] Foust told Jackson that he would fill out a negative coaching report—an internal Allergan report—in response to Jackson's conduct. [*Id.* ¶ 298.]

This pattern continued through 2016, with Foust writing Jackson two negative performance reviews in addition to the coaching report. [*Id.* ¶ 299.] Jackson reported to Allergan managers and HR that Foust was directing him to lie about Viberzi's addictive qualities and to recommend the drug to patients who did not meet its profile. [*Id.* ¶ 301.] In addition, he explained Foust was retaliating and discriminating against him for not participating in off-label marketing. [*Id.* ¶¶ 301–02.] Allergan regional manager Jimmy Martin, who supervised Foust, took no action in response to Jackson's reports. [*Id.* ¶¶ 303–04.]

In January 2017, after Foust again reprimanded Jackson on the same basis, Foust and Allergan HR fired Jackson for not meeting expectations. [*Id.* ¶ 307.] During the same time, however, Jackson met and exceeded several performance-related measures showing he was a capable and productive sales representative. [*Id.* ¶ 309.]

B. Analysis

Because an FCA termination "claim does not allege fraud," but is instead more akin to discrimination statutes like Title VII, Rule 9(b) does not apply. *Sibley*, 44 F.4th at 662. Jackson just needs to offer "a short and plain statement" showing that he is entitled to relief. Fed. R. Civ. P. 8(a). "[T]he court asks only whether the plaintiff

has pleaded a facially plausible claim by alleging factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Sibley*, 44 F.4th at 662 (citation and internal quotation marks omitted).

Since its amendment in 2009, § 3730(h)(1) has prohibited "employers from terminating employment for conduct that is in furtherance of an action under this section" as well as for "undertaking other efforts to stop violations of the Act, such as reporting suspected misconduct to internal supervisors." *Halasa v. ITT Educ. Servs., Inc.*, 690 F.3d 844, 848 (7th Cir. 2012) (citations and internal quotation marks omitted). That includes violations of § 3729. *Makela v. Apex Hospice & Palliative Care, Inc.*, 2025 WL 343464, at *3 (N.D. Ill. Jan. 30, 2025).

To state a claim, Jackson must allege that he "engaged in protected conduct and was fired because of that conduct." *Sibley*, 44 F.4th at 661. To assess whether Jackson's conduct was protected under the statute, courts examine "whether (1) the employee in good faith believes, and (2) a reasonable employee in the same or similar circumstances might believe, that the employer is committing fraud against the government." *United States ex rel. Uhlig v. Fluor Corp.*, 839 F.3d 628, 635 (7th Cir. 2016) (citation and internal quotation marks omitted).

Jackson alleges that "Allergan management" and his supervisor instructed him (and other sales representatives) to promote Viberzi "off label" to patients who did not have IBS-D and to downplay the drug's side effects. [Dkt. 173 ¶¶ 287–89, 296–98.] When Jackson refused to participate in off-label marketing of Viberzi, he was reprimanded by his supervisor multiple times. [*Id.* ¶¶ 293, 296, 298.] Jackson

reported to Allergan managers and HR that his supervisor was directing him to market Viberzi off-label to patients who did not meet its profile and was retaliating against him for not doing so. [*Id.* ¶¶ 301–02.] Jackson knew what off-label marketing was, having attended compliance training, and was aware off-label marketing could result in FCA liability. [*Id.* ¶ 300.] Jimmy Martin, the manager to whom Jackson reported these issues, had also attended compliance training concerning off-label marketing and was aware of the risks, but took no action in response to Jackson's report. [*Id.* ¶¶ 304, 306.] Although Jackson met and exceeded several performance-related metrics, he was fired for not meeting expectations. [*Id.* ¶¶ 307, 309.]

These facts adequately allege an FCA retaliation claim. Jackson believed promoting Viberzi to patients who did not meet its profile—that is, did not have IBS-D—constituted off-label marketing which, he knew from experience, could result in FCA liability. This is sufficient to support the inference that "it was objectively reasonable for [Jackson] to believe" Allergan was committing fraud against the government. *Sibley*, 44 F.4th at 662.

His allegations also support the inference that reasonable employees in his position would reach the same conclusion. He contends that others, including Martin, were aware of past settlements for violation of the FCA's prohibition on off-label marketing and had attended compliance training. Jackson also alleges first-hand knowledge of Allergan encouraging off-label promotion of Viberzi. *Id.* at 663. Because he was on the front-line of Allergan's alleged illegal marketing efforts, it is plausible that a reasonable employee in his position would know the scope of legal marketing

and know that exceeding that scope by "aggressively market[ing] the drug to doctors to treat patients who were not suffering from IBS-D" could violate the FCA. [Dkt. 173 ¶ 293.]

"Refusing to engage in a fraudulent scheme, which was intended and reasonably could be expected to prevent the submission of a false claim to the government, can constitute protected activity under the statute." *Makela* 2025 WL 343464, at *3 (citing *United States ex rel. Chorches for Bankr. Est. of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 96 (2d Cir. 2017)) (cleaned up) (finding FCA retaliation claim where relator repeatedly opposed employer's efforts to violate federal law and refused to participate in aiding employer in billing for services provided in violation of federal law). Jackson's actions qualify as an "effort[] to stop" violations of the FCA. *Halasa*, 690 F.3d at 848. The same goes for Jackson's more informal reports to his supervisors and Allergan's HR department. *Id.* at 847–48; *Sibley*, 44 F.4th at 664.

Given the Rule 8(a) standard and need to view allegations in the light most favorable to Jackson, he has sufficiently alleged an FCA retaliation claim.

X. Conclusion

Allergan's motion to dismiss is granted in part and denied in part. Relators' FCA claim concerning Dr. Bierman and Dr. Kayal, their Tennessee Medicaid FCA claim concerning Dr. Bierman and Dr. Kayal, their FCA conspiracy claim as to Dr. Bierman, and Jackson's FCA retaliation claim may all proceed. Allergan's motion to dismiss is otherwise granted. Relators have been afforded one prior opportunity to

amend their complaint following adversarial testing of their claims, so dismissal of the remaining claims is with prejudice. *Zimmerman v. Bornick*, 25 F.4th 491, 494 (7th Cir. 2022); *Circle Block Partners, LLC v. Fireman's Fund Insurance Company*, 44 F.4th 1014, 1018 (7th Cir. 2022) ("Ordinarily, a plaintiff whose complaint is dismissed under Rule 12(b)(6) should be given at least one opportunity to try to amend her complaint before the entire action is dismissed.")

Enter: 22 CV 3013
Date: April 23, 2025

Lindsay C. Jenkins