### 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,

No. 22 CV 3013

v.

Judge Lindsay C. Jenkins

Allergan Limited f/k/a Allergan PLC, et al.,

Defendants.

### MEMORANDUM OPINION AND ORDER

Relators Jeffrey Wilkerson and Larry Jackson were pharmaceutical sales representatives for Allergan USA, Inc. ("Allergan"),<sup>1</sup> which manufactures Linzess and Viberzi. Relators allege that while working for Allergan, they discovered that Allergan was engaged in a nationwide scheme to provide illegal kickbacks to doctors in exchange prescribing more Linzess and Viberzi. Relators filed this *qui tam* action<sup>2</sup> 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. 65.] Relators' theory is that Allergan violated these statutes by asking government entities to pay for prescriptions written by doctors to whom Allergan paid illegal kickbacks. Jackson also alleges that Allergan terminated his employment in retaliation for reporting distinct FCA violations.

<sup>&</sup>lt;sup>1</sup> The Court uses "Allergan" to refer to the U.S. entity only; Relators also name the parent company, Allergan Limited f/k/a Allergan PLC, as a Defendant, but this Order does not apply to Allergan Limited. [See Dkt. 65 ¶ 13; Dkt. 142.]

<sup>&</sup>lt;sup>2</sup> Qui tam is short for a Latin phrase meaning "who [qui] sues in this matter for the king as well as [tam] for himself." United States ex rel. Bogina v. Medline Indus., Inc., 809 F.3d 365, 368 (7th Cir. 2016) (alterations in original).

Allergan moves to dismiss the operative Third Amended Complaint (the "Operative Complaint") [Dkt. 65] for failure to state a claim upon which relief may be granted. [Dkt. 132.] Fed. R. Civ. P. 12(b)(6). The motion is granted; while Relators come close to stating viable claims, a few key facts are missing. Despite being the fourth pleading in this case, the Operative Complaint is the first that has been subject to adversarial testing. Thus, the Court will give Relators one final chance to amend.

### I. Background

### A. Statutory Framework

The Court begins with the federal statutory backdrop of this case, the False Claims Act and the Anti-Kickback Statute ("AKS"). 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 state statutes under which Relators seek to recover prohibit similar conduct. [See Dkt. 65 ¶¶ 35–38; 225–399; Dkt. 133 at 21–22.] Cf. Thulin v. Shopko Stores Operating Co., LLC, 771 F.3d 994, 995 (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). A claim that includes items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for FCA purposes. § 1320a–7b(g). The Court refers to violations of the FCA that involve the submission of claims resulting from kickbacks prohibited by the AKS as "FCA kickback schemes" or simply "kickback schemes."

# **B.** Factual Overview

Allergan, headquartered in New Jersey, markets and sells pharmaceutical products including the two drugs at issue in this case, Linzess and Viberzi. [Dkt. 65 ¶ 13.] Relators worked for Allergan and its predecessor Actavis Pharma, Inc. as sales representatives, Jackson from 2013 to 2017 and Wilkerson from 2013 to 2016. [*Id.* ¶¶ 20–21.]<sup>3</sup> Jackson and Wilkerson worked in Allergan's gastroenterology group, which promoted Linzess and Viberzi. [*Id.*] Each Relator was responsible 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 and chronic idiopathic constipation. [*Id.* ¶ 66.] Linzess launched in the United States in December 2012. [*Id.* ¶ 67.] Actavis acquired the company that produced Linzess in July 2014; Allergan in turn acquired Actavis in March 2015 and continued marketing Linzess. [*Id.* ¶ 68.] Viberzi is an opioid-based drug with the active ingredient eluxadoline used to treat irritable bowel syndrome with diarrhea ("IBS-D"). [*Id.* ¶ 71.] Allergan acquired eluxadoline in July 2014; the FDA approved Viberzi in May 2015,

<sup>&</sup>lt;sup>3</sup> For the sake of conciseness, the Court often uses generic descriptive terms, such as "sales representative," instead of formal titles, such as "Senior Professional Sales Specialist."

and it became available in December of that year. [*Id.* ¶¶ 72–74.] Relators allege that Linzess and Viberzi are more expensive than over-the-counter alternatives. [*Id.* ¶¶ 69–70, 75–76.] Viberzi allegedly "is not a drug to be taken lightly"; it may cause serious side effects and it has the potential for addiction and abuse. [*Id.* ¶¶ 79–85.]

The federal government administers two subsidized health care programs that are relevant here, Medicare and Medicaid. Medicare is available to persons at least 65 years old and disabled persons; Medicare Part D covers prescription drugs. [Id. ¶¶ 44–45.] Medicare contracts with private entities to provide Part D insurance; as a condition of participation, those entities must certify that they agree to comply with applicable federal laws, including the AKS, as must doctors who prescribe drugs to Medicare patients and subcontracting pharmacies. [Id. ¶¶ 46–49.] Claims submitted to Medicare are paid by the federal government. [See id. ¶ 44.] Medicaid, which provides health care benefits primarily to poor and disabled persons, requires similar certifications for private parties that states contract with to implement the Medicaid program. [Id. ¶¶ 50–54.] Payment for claims submitted to Medicaid are shared by the federal and state governments. [See id. ¶ 50.]<sup>4</sup>

### C. The Alleged 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.* ¶¶ 87–88.] The official purpose of the Speaker Bureau was to educate health care providers about Linzess and Viberzi. [*See* 

<sup>&</sup>lt;sup>4</sup> The Operative Complaint mentions other federal health care programs [Dkt. 65  $\P\P$  55–57], but because the parties' briefs do not discuss them, neither does the Court.

*id.* ¶¶ 116, 120; Dkt. 133 at 6–7.] Relators allege, however, that the true "purpose and intent" of the Speaker Bureau "was to give 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." [Dkt. 65 ¶ 88.] Relators allege that the scheme operated nationwide: Allergan paid kickbacks to doctors throughout the United States, causing millions of dollars in losses by the federal government and several states. [*Id.* ¶¶ 89–90.]<sup>5</sup>

Allergan allegedly held over 8,000 speaker events between 2015 and 2017. [Id.  $\P\P$  101–03.]<sup>6</sup> These events fell into two categories. 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.  $\P\P$  116–17.] "Out-of-office" events were "dinner parties," often at "up-scale restaurants." [Id.  $\P$  119.] Medical providers would join speaker physicians and sales representatives for meals paid for by Allergan, again where the speakers purported to educate guests. [Id.  $\P\P$  119–20.] Allergan required a minimum number of positive RSVPs to hold speaker events: two "prescribers" or "dispensers" for in-office events; four attendees, three of whom were prescribers or dispensers, for out-of-office events. [Id.  $\P\P$  162–63.] It also imposed a \$150-per-person cap for food and drink for out-of-office events. [Id.  $\P$  121.] Allergan paid speakers \$1,000–\$3,500

<sup>&</sup>lt;sup>5</sup> Some of the speakers were not doctors. [*E.g.*, Dkt. 65 ¶ 143.] Short-form references to speakers as "physicians" or "doctors" include all speakers.

<sup>&</sup>lt;sup>6</sup> The Operative Complaint often specifies that these were "gastrointestinal" speaker events. [See, e.g., Dkt. 65 ¶¶ 101–03.] Because there are no other types of speaker events at issue here, the Court often omits this qualifier.

per speaker event, plus reimbursement for travel and lodging. [*Id.* ¶¶ 117, 120.] If an event was cancelled 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.* ¶¶ 175–82.]

Relators allege that the purpose of the Speaker Bureau was not to educate medical providers about Linzess and Viberzi, but to induce speaker physicians to prescribe more of these drugs. They identify several facets of how the Speaker Bureau allegedly operated in practice that they believe demonstrate its fraudulent purpose<sup>7</sup>:

- 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.* ¶¶ 105–10.]
- 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.* ¶¶ 91–94.]
- Often, events had little or no educational content. [*Id.* ¶¶ 116–20.]
- Managers emphasized that the Speaker Bureau had an RSVP requirement, not an attendance requirement, encouraged sales representatives to consider noncommittal statements positive RSVPs, and did not care if events were under-attended or cancelled outright. [*Id.* ¶¶ 164–66.]
- Allergan knew about the under-attendance problem because the number of attendees was reported through a platform called "IntraMed." [*Id.* ¶ 169.]
- Managers instructed sales people to falsify attendance records. [Id.  $\P$  121.]
- Allergan paid speaker physicians full fees for under-attended or cancelled events and did not criticize or discipline salespeople who organized such events. [*Id.* ¶¶ 164, 166, 181–83.]

<sup>&</sup>lt;sup>7</sup> The Operative Complaint asserts that Allergan's speaker program presents "[a]lmost all of the characteristics of speaker's programs" that the Department of Health and Human Services, Office of the Inspector General classified as suggestive of fraud in a November 2020 special fraud alert. [Dkt. 65 ¶¶ 58–65.] Allergan points out that the alleged fraud Relators identify predated the release of the alert. [Dkt. 133 at 7–8, 18.] Because the alert had not been issued at the time of Allergan's alleged fraud, the Court does not address it further. To the extent that the practices the alert identifies as suggestive of fraud support an inference of kickbacks, alleging those practices themselves will help Relators state an FCA claim.

In total, Relators allege that there were over 2,000 "sham" events, which they define as events that were cancelled in advance or were unattended or under-attended except by the speaker and the sales representative. [*Id.* ¶¶ 175–80.]<sup>8</sup>

Relators offer more specific allegations about several speakers, primarily Dr. Paul Bierman, a doctor 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. ¶ 111.] 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. ¶ 118.] Wilkerson told his district manager, Alan Foust, about "the cursory nature of Dr. Bierman's inoffice" events, including apparently that "Dr. Bierman routinely declined to present the Allergan PowerPoint" presentation." [Id.] Foust allegedly told Wilkerson to falsify documents to reflect that Dr. Bierman provided the required information and that Dr. Finn and his staff attended. [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

<sup>&</sup>lt;sup>8</sup> Relators allege additional details, such as that out-of-office events routinely exceeded the \$150-per-person cap, that non-medical guests such as attendees' and speaker-physicians' spouses and dates attended events, and that sales representatives engaged in aggressive sales tactics. [See, e.g., Dkt. 65 ¶¶ 95–98, 119, 121, 128.] Because these allegations do not impact the Court's analysis below, it does not focus on them. Similarly, Relators' allegations that Allergan is a "recidivist violator of the AKS and the FCA" does not impact the Court's analysis, so it does not address those allegations. [See, e.g., id. ¶ 14.]

Allergan drugs"; Wilkerson and fellow sales representative Frank Adcock delivered this message in January 2016. [*Id.* ¶ 125.] Dr. Bierman expressly acknowledged the *quid pro quo* and agreed to increase his prescriptions of Viberzi. [*Id.* ¶¶ 126, 128.] Another sales representative, Will Fogelman, described Dr. Bierman as "the largest prescriber of Viberzi in the West Tennessee territory" and also expressly referenced the *quid pro quo*. [*Id.* ¶ 131; *see also id.* ¶¶ 132–35 (similar allegations).]

Relators discuss several other speakers too. One, nurse practitioner Chantil Jeffreys from the Memphis area was recruited as a speaker in 2017 after her Linzess prescriptions increased. [*Id.* ¶¶ 143–44.] Relators allege that "[t]his increase led Allergan to anticipate Ms. Jeffreys could be a valuable speaker-provider," so she was added to the Speaker Bureau. [*Id.* ¶ 144.] When her Linzess prescription volume did not increase further, Allergan terminated her as a speaker. [*Id.*] Another speaker, Dr. Daniel Kayal, joined the program in early 2016; he remained in the Speaker Bureau as he increased his Linzess prescriptions and began to prescribe Viberzi. [*Id.* ¶¶ 145– 48.] The addendum to the Operative Complaint contains further allegations about speakers in other states being paid for "sham" speaker events and subsequently prescribing more Linzess and Viberzi. [*Id.* addendum 1.]<sup>9</sup>

## D. Jackson's Termination

Allergan terminated Jackson's employment in January 2017, which he alleges was in retaliation for his reporting FCA violations unrelated to kickbacks and the Speaker Bureau. [*Id.* ¶¶ 192–208.] Jackson alleges that he "was concerned that

<sup>&</sup>lt;sup>9</sup> Allergan asserts that one physician's prescription volume did not increase. [Dkt. 133 at 17 n.10.]

Allergan was illegally promoting Viberzi and other drugs, including through the use of solicitation of confidential patient information in violation of" the Health Insurance Portability and Accountability Act ("HIPAA"), a practice that Jackson worried "was not only unlawful but was resulting in harm to patients." [*Id.* ¶ 192.] Jackson had received "compliance training instructing against off-label marketing and AKS violations," and when he raised his concerns with his supervisor, Foust, Foust told Jackson "not to raise the contraindications and potential dangers associated with Viberzi and to minimize the potential risks of the drug to particular patients." [*Id.* ¶¶ 193–94; *see also id.* ¶¶ 195–99 (alleging similar interactions with Foust).]

Jackson informed other managers and Allergan's human resources ("HR") department about Foust's instructions and that he believed Foust was retaliating against him. [Id. ¶ 200.] An HR employee informed Jackson "that Allergan took [his] allegations very seriously and that she was documenting his concerns." [Id. ¶ 201.] Jackson then met with Foust's supervisor, regional manager Jimmy Martin. Jackson told Martin that "Foust was consistently encouraging sales representatives to promote Viberzi for off-label purposes and for patients who do not exhibit IBS-D symptoms," which Viberzi is intended to treat; Jackson also told Martin about Foust's retaliation. [Id. ¶ 202.] Jackson alleges that in spite of the "detailed information" he gave Martin about "potential FCA violations in his territory," Martin ignored his concerns. [Id. ¶ 203.] On January 19, 2017, Foust's reprimands continued. Foust told Jackson that "we are going to make some decisions tonight and will let you know something in the morning." [Id.  $\P$  204.] The next day, Foust and a different HR employee told Jackson he was being terminated for not meeting expectations. [Id.]

# E. Procedural History

Relators filed this case under seal on December 20, 2017 in the Eastern District of Washington. [17-cv-427 (E.D. Wash.), Dkt. 1.] They amended the complaint twice while the case remained under seal. [17-cv-427 (E.D. Wash.), Dkt. 14, 18.] In August 2021, the government declined to take the case, the case was unsealed, and on Relators' motion the case was transferred to the Middle District of Georgia. [17-cv-427 (E.D. Wash.), Dkt. 45, 46, 48.] Within days, Relators filed a notice that they were preparing the Operative Complaint, which they then filed. [21-cv-306 (M.D. Ga.), Dkt. 54, 65.] Allergan appeared and moved to transfer the case to this Court in January 2022; that motion was granted in June 2022. [21-cv-306 (M.D. Ga.), Dkt. 75, 100.] Before this Court, Allergan moved to dismiss the Operative Complaint. [Dkt. 132.]

The Operative Complaint asserts 39 claims, but central to the parties' briefs and the Court's decision is Count I, which alleges a nationwide FCA kickback scheme in violation of 31 U.S.C. § 3729(a)(1)(A). [Dkt. 65 ¶¶ 209–12.] Counts II through IV allege FCA violations under § 3279(a)(1)(B), (C), and (G), respectively. [Id. ¶¶ 213– 24.] Counts V through XXXVI allege that Allergan violated state statutes analogous to the FCA. [Id. ¶¶ 225–399.] Counts XXXVII and XXXVIII allege that Allergan violated California and Illinois insurance fraud statutes. [Id. ¶¶ 400–419.] Finally, Count XXXIX alleges that Allergan terminated Jackson in retaliation for activity protected by the FCA. [Id. ¶¶ 420–423.]

# 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 v. First Hosp. Lab'ys, Inc., 77 F.4th 603, 607 (7th Cir. 2023). 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. Further, a claim might lack 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: The Kickback Scheme

The Court begins with Relators' primary claim, that Allergan engaged in an illegal kickback scheme in violation of the AKS and FCA by using its Speaker Bureau to induce doctors to write more prescriptions for its drugs, claims for which were then submitted to the federal government.

# A. The "Specific Patient" Rule

The Court begins with a threshold issue: Allergan's argument that Relators' FCA claims fail because they do not identify a specific patient to whom a doctor allegedly prescribed Linzess or Viberzi in exchange for a kickback. [Dkt. 133 at 10–11.] As Allergan reads Seventh Circuit precedent, a relator must necessarily identify at least one such patient to state a claim under the AKS. [*Id.*] This requirement, it argues, derives from *United States ex rel. Grenadyor v. Ukrainian Village Pharmacy*, 772 F.3d 1102 (7th Cir. 2014), as recognized by several district court opinions. [Dkt. 133 at 10–11; Dkt. 141 at 2–4.] Relators disagree; they argue that the Seventh Circuit imposes no such requirement and that the cases Allergan cites are distinguishable. [Dkt. 137 at 12–15.] The Court agrees with Relators.

# 1. Grenadyor

The origin of the supposed specific patient rule is *Grenadyor*. There, the alleged kickback scheme involved inducing customers to patronize the defendant pharmacy in two ways: first, by giving customers small gifts and, second, by waiving copays

without reducing the reimbursement amount requested from the government. 772 F.3d at 1104–05. Relators' claims involved an implied certification claim, the concept

of which *Grenadyor* described as follows:

This theory does not depend on a defendant's having intended to make illegal kickbacks at the time it signed the form for enrolling in the Medicare program. It requires only that the government, had it known the defendant was billing Medicare or Medicaid for drugs on which it had given kickbacks, would not have reimbursed it for any part of the cost of those sales. The theory treats a bill submitted to the government as an implicit assurance that the bill is a lawful claim for payment, an assurance that's false if the firm submitting the bill knows that it's not entitled to payment.

*Id.* at 1106.<sup>10</sup> This passage makes no mention of a rule that a relator must name a

specific patient who received a kickback, a logical omission because the false claim is

the bill to the government, not the kickback itself. See 42 U.S.C. § 1320a-7b(b), (g).

*Grenadyor* then turned to the sufficiency of the relator's allegations:

[T]he complaint fails to allege facts sufficient to show that the pharmacy waived copays for other than "dual eligibles"—persons who being enrolled in both Medicare and Medicaid are allowed to be given such waivers provided that the pharmacy does not advertise the practice. No waiver mentioned in the complaint exceeded the maximum copays that pharmacies are permitted to charge their dual-eligible customers. ... And Grenadyor alleged no facts that would support his allegation that the waivers were advertised.

772 F.3d at 1106 (citation omitted). Again, there is no indication that a relator must

name a patient who has been prescribed medications in a kickback scheme. The first

mention of specific patients came later, after a brief digression into various types of

<sup>&</sup>lt;sup>10</sup> Grenadyor assumed without deciding that such a theory was viable, 772 F.3d at 1106, but implied certification claims are now recognized, United States ex rel. Prose v. Molina Healthcare of Ill., Inc., 17 F.4th 732, 742–43 (7th Cir.), as amended (Nov. 15, 2021).

caviar. The opinion noted the allegation that a confidential witness had seen customers being given gifts, then explained why this allegation was insufficient:

[I]t is not enough to allege, or even prove, that the pharmacy engaged in a practice that violated a federal regulation. Violating a regulation is not synonymous with filing a false claim. To comply with Rule 9(b) Grenadyor would have had to allege either that the pharmacy submitted a claim to Medicare (or Medicaid) on behalf of a specific patient who had received a kickback, or at least name a Medicare patient who had received a kickback (presumably if the pharmacy provided a drug to a Medicare patient it billed Medicare for the cost of the drug minus the copay). The complaint contains no such allegations. Similarly, by failing to identify a single patient who received multiple gift bags over the course of the year the complaint fails to allege with the requisite particularity that any customer received more than \$50 worth of these goodies, the permissible amount before the anti-kickback rules kick in, or that those customers who did receive more were not Medicare or Medicaid recipients and so cost the government nothing.

Id. at 1107 (citations omitted).<sup>11</sup>

Reading the opinion as a whole, the Court does not understand *Grenadyor* to hold that naming a specific patient is a legal prerequisite in an FCA kickback case. First, *Grenadyor*'s analysis turned on Rule 9(b)'s pleading standard, and the Seventh Circuit has explained—albeit not in a kickback case—that Rule 9(b) does not impose rigid pleading requirements; rather, "the precise details that must be included in a complaint 'may vary on the facts of a given case." *United States ex rel. Presser v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770, 776 (7th Cir. 2016) (quoting *Pirelli*, 631 F.3d at 442); accord, e.g., Prose, 17 F.4th at 739. A categorical specific patient

<sup>&</sup>lt;sup>11</sup> Allergan argues that the sentence beginning "To comply with Rule 9(b)" "set[s] forth a clear pleading standard for FCA cases premised on violations of the AKS." [Dkt. 141 at 2.] As the Court has explained, it does not believe *Grenadyor* was making a sweeping comment about FCA kickback cases but rather applying Rule 9(b) to the facts of the case before it. In the passage in question, the Court takes *Grenadyor* to be explaining what Grenadyor himself would have needed to allege in order to satisfy Rule 9(b)'s particularity requirement.

rule in FCA kickback cases would be inconsistent with how Rule 9(b) operates in other contexts. Second, the language Allergan argues creates the specific patient rule appears in a section of *Grenadyor* that analyzes a particular theory, rather than in a section that describes the nature of and pleading requirements for an FCA kickback claim. This suggests that *Grenadyor* was applying the governing standard to that claim—which flunked Rule 9(b) because it did not name a specific patient—and not announcing a new legal test. Third and relatedly, the Court is hesitant to read language in an opinion as adopting a new, categorical test without the Seventh Circuit expressly stating or at least implying it should do so. *Cf. Ortiz v. Werner Enters., Inc.*, 834 F.3d 760, 764–66 (7th Cir. 2016) (discussing how erroneous and imprecise application of Seventh Circuit Title VII cases gave rise to a "rat's nest of surplus 'tests," and "removing ... [those] 'tests' from the law of the circuit").

### 2. District Court Opinions

Allergan also relies on district court opinions to support its argument that *Grenadyor* created the specific patient rule. It identifies three cases in which two district judges have interpreted *Grenadyor* to impose such a requirement: *United States ex rel. Kalec v. NuWave Monitoring LLC*, 84 F. Supp. 3d 793 (N.D. Ill. 2015) (Ellis, J.), *United States ex rel. Stop Illinois Marketing Fraud, LLC v. Addus Homecare Corp.*, 2018 WL 1411124 (N.D. Ill. Mar. 21, 2018) (Pallmeyer, J.), and *United States ex rel. Suarez v. AbbVie, Inc.*, 2019 WL 4749967 (N.D. Ill. Sept. 30, 2019) (Pallmeyer, C.J.). [Dkt. 141 at 2–3.] *Kalec*, 84 F. Supp. 3d at 807, and *Addus*,

2018 WL 1411124, at \*4, did not analyze this issue at length,<sup>12</sup> so the Court focuses on Chief Judge Pallmeyer's thorough treatment in *Suarez*. As explained below, *Suarez*'s analysis is sound with respect to kickback schemes like the one at issue there, but Allergan's alleged scheme differs in important respects.

Suarez concerned a scheme in which the relator alleged that the defendant, the maker of the autoimmune drug Humira, made nurses available at no cost to serve as "Ambassadors." 2019 WL 4749967, at \*1–2. The complaint alleged that these Ambassadors provided valuable services to doctors and Humira patients, easing the substantial administrative burdens related to Humira prescription for both doctors and patients. *Id.* at \*2–3. The relator alleged that these services were kickbacks that induced doctors to prescribe Humira to patients they otherwise would not have. *Id.* at \*3–4. The court held that the relator had not plausibly alleged an FCA kickback scheme under Rule 9(b) in part because he failed to name a patient to whom a doctor prescribed Humira in exchange for a kickback. *Id.* at \*10–11.

The court cited the specific patient rule it—and *Addus* and *Kalec*—drew from *Grenadyor*, *id*. at \*10, and rebuffed the relator's counterarguments. First, the court rejected the argument that the specific patient rule is applicable only when "the alleged fraud [is] aimed at patients rather than doctors," reasoning that

*Grenadyor* did not limit its conclusion to circumstances in which the alleged fraud targets patients .... And the *Grenadyor* court explained that the purpose of requiring relators to link a kickback with a patient and a submitted claim is to ensure that relators allege the actual "filing of a false claim"—not merely a "violation of a regulation." In fact, Relator

<sup>&</sup>lt;sup>12</sup> The *Addus* court relied on a previous opinion from the same litigation, which read *Grenadyor* to impose a specific patient requirement without a lengthy discussion. 2017 WL 467673, at \*10 (N.D. Ill. Feb. 3, 2017).

himself admits that a plaintiff asserting an FCA claim must allege "representative examples" of fraudulent transactions.

Id. at \*11 (cleaned up). The court distinguished the district court opinions the relator relied on, noting that both preceded *Grenadyor* and that in one, the relator had access to patient names but did not include them to protect their confidentiality, while the other "had nothing to do with referring patients for services or prescribing drugs to patients in exchange for kickbacks," but rather "concerned double-billing Medicare for physician services provided by unsupervised resident doctors—and it was pleaded with particularity because the complaint identified the particular hospitals, university, and residents allegedly engaged in the fraud." Id. (citation omitted). Second, the court noted that Kalec had expressly found that Grenadyor adopted this requirement. Id. at \*12. Third, the court rejected the relator's argument that it could apply Rule 9(b) flexibly because his allegations did not "necessarily [lead] one to the conclusion that the defendant had presented claims to the Government." Id. at \*12– 13 (citations omitted) (quoting Presser, 836 F.3d at 778). Thus, as Allergan points out, Suarez rejected the argument that the specific patient rule applies only to when the kickbacks are given to patients. [Dkt. 141 at 4.]

Suarez's reasoning is persuasive on its facts, but its analysis leaves open the possibility that under some circumstances a relator can plead the existence of an FCA kickback scheme that satisfies Rule 9(b)'s requirements without naming a specific patient. As noted above, while interpreting *Grenadyor* to establish the rule that a relator must name a patient to plausibly allege an FCA kickback scheme, *Suarez* also recognized that Rule 9(b) is flexible when a relator cannot allege every aspect of the

scheme with particularity, but his allegations necessarily lead to the inference that a false claim has been submitted. 2019 WL 4749967, at \*12–13; *see Presser*, 836 F.3d at 777–78. The fact that *Suarez* found the allegations insufficient to meet the *Presser* standard does not change the bottom-line conclusion that even *Suarez* interprets *Grenadyor* to sometimes allow a relator's claim to proceed past the motion to dismiss stage without naming a specific patient.<sup>13</sup>

More importantly, the scheme alleged in *Suarez* depended on the identities of specific patients. The alleged kickbacks were the free services Ambassadors provided to doctors and patients, which incentivized prescribing Humira to those patients. 2019 WL 4749967, at \*3.<sup>14</sup> Unless the defendant submitted a claim to the government for a prescription that had been induced by the Ambassadors' services, there could be no kickback and therefore no FCA violation; because the alleged kickbacks applied only to specific patients, it was essential to name at least one to state a plausible FCA claim. *See id.* at \*11 ("It is undisputed that Relator does not name a specific patient for whom a doctor prescribed Humira in exchange for a kickback. Likewise, Relator does not allege that a claim was submitted to a government health care program for any such patient."). Here, though, the alleged kickbacks flowed to doctors in exchange for prescribing more Linzess and Viberzi overall, not to specific patients. In such a scheme, the identities of specific patients are irrelevant. If Relators can plausibly

<sup>&</sup>lt;sup>13</sup> Thus, the Court disagrees that *Suarez* stands for the proposition that *Presser* does not apply in kickback cases; *Suarez* applied *Presser*. [*See* Dkt. 137 at 13; *contra* Dkt. 141 at 4–5.] <sup>14</sup> The court also held that the relator had not plausibly alleged that the Ambassadors' services were "remuneration" within the meaning of the statute, 2019 WL 4749967, at \*5– 10, but this point does not impact the Court's analysis.

allege that Allergan's speaker program induced doctors to prescribe more Linzess and Viberzi with the level of particularity required by Rule 9(b)—a question the Court takes up below—then they will have sufficiently pleaded an FCA kickback claim, despite not naming any specific patient.

Decisions from other district courts support the conclusion that *Grenadyor* does not impose a categorical requirement that a relator identify a specific patient who has received a prescription. First, United States v. Walgreen Co. suggests that to the extent there is a specific patient rule, it applies more narrowly than Allergan argues. See 417 F. Supp. 3d 1068, 1101 (N.D. Ill. 2019) (Blakey, J.) ("As Grenadyor made abundantly clear with respect to copayment-related AKS claims, to 'comply with Rule 9(b) Grenadyor would have had to allege either that the pharmacy submitted a claim to Medicare (or Medicaid) on behalf of a specific patient who had received a kickback, or at least name a Medicare patient who had received a kickback." (emphases added and omitted) (quoting Grenadyor, 772 F.3d at 1107)). Second, Stop Illinois Health Care Fraud, LLC v. Sayeed indicates that as an alternative to identifying a specific patient, a relator may "at least name the individual who had received a kickback" (presumably in conjunction with identifying a specific fraudulent claim), which here would be a doctor. 2016 WL 4479542, at \*4 (N.D. Ill. Aug. 25, 2016) (Coleman, J.). Third, United States ex rel. Dustman v. Advocate Health & Hospitals Corp. reads Grenadyor and other Seventh Circuit cases to require "representative examples of claims, bills, or transactions," not the identities of specific patients. 2023 WL 2799699, at \*9 (C.D. Ill. Apr. 5, 2023) (McDade, J.).

### 3. Violation of Both Statutes

At oral argument, Allergan argued that *Grenadyor* stands for the proposition that a relator must allege with particularity not only the kickback scheme but also at least one false claim, because an FCA kickback scheme depends on violations of both statutes. [See Dkt. 160 at 7–9.] To state a plausible FCA kickback claim, a relator needs more than "the particularized allegation of a kickback scheme"; he must also "link the kickback scheme to claims that actually resulted from" the scheme. [*Id.* at 8:22–:25.] "You can certainly have a standalone violation of the AKS that does not then morph into or result in a violation of the FCA. ... [T]hat linkage is what establishes falsity." [*Id.* at 9:1–:4.] The Court agrees with Allergan's reading of the statutes, but not its conclusion that naming a specific patient is always necessary.

Allergan's arguments about why a relator must identify a specific patient bear more on Rule 8's plausibility standard and Rule 9(b)'s particularity requirement than the legal requirements of an FCA kickback claim. Allergan argued that Relators' allegations were insufficient to plausibly allege a nationwide kickback scheme. [*Id.* at 9:5–10:7.] And it argued that alleging an increase in the number of Linzess and Viberzi prescriptions written by a speaker would not plausibly allege a violation of the FCA because of the obvious alternative explanation that the doctor was exercising medical judgment. [*Id.* at 11:4–20.] These are serious Rule 8 arguments, and the Court considers them below, but they do not convince the Court that naming a specific patient is necessary to comply with Rule 9(b). *See Iqbal*, 556 U.S. at 680–82 (discussing obvious alternative explanations in the context of Rule 8, not Rule 9(b). The bottom line, in the Court's view, is that it must carefully consider the specific facts alleged and determine whether Relators have "inject[ed] precision and some measure of substantiation into their allegations of fraud," without "tak[ing] an overly rigid view" of how an FCA claim must be pleaded. *Presser*, 836 F.3d at 776 (cleaned up). The Court does not doubt that the failure to name a specific patient in connection with a kickback scheme will often mean that a relator's allegations are not particularized under Rule 9(b), his claim is not plausible under Rule 8, or both. Indeed, courts in this district have regularly held as much. But "often" and "always" are not synonyms, so the Court cannot agree with Allergan that *Grenadyor* adopted a rule that a relator alleging an FCA kickback scheme must identify a specific patient.

\* \* \*

The combination of *Grenadyor*'s failure to announce that it was creating a new rule for FCA kickback cases; the flexibility of the specific patient rule, if it exists, that *Suarez* recognized; and other district courts' varying interpretations of *Grenadyor* persuade this Court that *Grenadyor* did not establish a rule that a relator must name a specific patient to bring an FCA kickback claim. Of course, Rule 9(b)'s heightened pleading standard still applies. Recognizing that FCA kickback claims do not require a plaintiff to identify a specific patient does not change the fact that he still must allege representative examples of false claims, *see United States ex rel. Sibley v. Univ. of Chi. Med. Ctr.*, 44 F.4th 646, 656 (7th Cir. 2022), or facts that necessarily lead to an inference of false claims, *see Presser*, 836 F.3d at 777–78.

# B. Pleading an FCA Kickback Scheme

Allergan's briefs in support of its motion to dismiss focus on whether Relators have plausibly alleged a nationwide FCA kickback scheme with particularity. Before turning to that question, the Court considers how to allege an FCA kickback scheme in the abstract and how to allege the type of scheme Relators advance here.

# 1. Pleading a Kickback Scheme Generally

Allergan correctly noted at oral argument that alleging an FCA claim based on an illegal kickback scheme requires a relator to allege violations of both the AKS and the FCA. [*See* Dkt. 160 at 7–9.] The AKS prohibits:

knowingly and willfully offer[ing] or pay[ing] any remuneration ... directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing ... of any ... for which payment may be made in whole or in part under a Federal health care program ....

42 U.S.C. § 1320a–7b(b)(2). The AKS further provides that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of" the FCA. § 1320a–7b(g). Put differently, a relator must allege (1) that the defendant paid illegal kickbacks (the AKS component) and (2) that claims "resulting from" the defendant's violation of the AKS were submitted to the government (the FCA component).<sup>15</sup>

<sup>&</sup>lt;sup>15</sup> The parties disagree about whether the "resulting from" language requires a relator to establish that the kickbacks were a but-for cause of the false claims. [*See* Dkt. 141 at 3 n.2; Dkt. 143.] Because the Court rules on other grounds, it does not address the causation issue.

These are distinct requirements. The former concerns the defendant's conduct; the latter the conduct of the person who submits the allegedly false claims. A relator who satisfies his pleading burden with respect to one statute might not do so with respect to the other. *See Grenadyor*, 772 F.3d at 1104, 1107 (explaining how waiving copays for patients could constitute kickbacks, but holding that the relator had insufficiently alleged that false claims were submitted on behalf of any such patient). Further, both statutory violations must be pleaded with particularity under Rule 9(b). *See id.* at 1106–07 (explaining that the Rule 9(b) standard was not met as to kickbacks because "the complaint fail[ed] to allege facts sufficient to show that the pharmacy waived copays for other than ... persons ... allowed to be given such waivers" and not met as to false claims when the complaint did not "allege either that the pharmacy submitted a claim ... on behalf of a specific patient who had received a kickback, or at least name a ... patient who had received a kickback").

### 2. Allergan's Alleged Kickback Scheme

Relators' theory is that Allergan, through its Speaker Bureau, paid kickbacks to doctors to induce them to write additional prescriptions for Linzess and Viberzi. The kickbacks took the form of speaker fees, plus reimbursement for travel, lodging, and high-end meals and alcohol. [Dkt. 65 ¶ 3.] The ostensible purpose of Allergan's speaker events was to promote and to educate medical providers about Linzess and Viberzi, but Relators allege that the true purpose was to induce the doctors prescribe more Linzess and Viberzi. [*Id.* ¶¶ 3, 5.] If plausibly and particularly alleged, this is a viable theory for an FCA kickback claim. Start with kickbacks. Fees, food and drink, travel, and lodging qualify as "any remuneration," § 1320a–7b(b)(2); *cf. Grenadyor*, 772 F.3d at 1106–07 (cheap caviar and TV guides could be kickbacks), as long as any part of the remuneration was paid to induce the speakers 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); *see also* § 1320a–7b(b)(3)(B) (excluding from anti-kickback provisions "any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services"). Thus, if Allergan paid speaker physicians in part to induce them to write more prescriptions, it violated the AKS.

The false claim portion of Relators' claim presents a more difficult analytical issue. Relators must allege facts with particularity that make it plausible that false claims "resulting from" Allergan's kickbacks were submitted to the government. *See* § 1320a–7b(g). This task would be straightforward if Relators alleged that individual physicians submitted false claims on behalf of specific patients, but they do not name specific patients. Instead, they contend that

when one purpose of a drug company's payments is to induce doctors to write prescriptions, and the doctors prescribe the drugs at issue any resulting claims submitted to Medicare or another federal health care program for those prescriptions are tainted claims that violate the AKS and false claims under the FCA.

[Dkt. 137 at 2 (cleaned up).] That is, every Linzess or Viberzi prescription written for a Medicare or Medicaid patient by a speaker physician is a false claim resulting from a kickback. [See Dkt. 65 ¶¶ 137–41 (alleging that Dr. Bierman was responsible for at least 517 false claims).] Allergan balks at this theory, noting that it would result in sweeping FCA liability "because *every* claim paid by Medicare for a prescription written by a physician who ever spoke at a program for Linzess or Viberzi [would] necessarily [be] false." [Dkt. 141 at 5.]<sup>16</sup>

The Court disagrees with Relators' sweeping theory that every prescription submitted the government by a doctor who has received a kickback is necessarily "false" under the FCA. Relators rely on *United States v. Teva Pharmaceuticals USA*, *Inc.*, which held that a nationwide claim against a company could proceed on a "taint theory" if the relators could offer evidence "that the speaker program had a universal and improper purpose." 2019 WL 1245656, at \*21 (S.D.N.Y. Feb. 27, 2019) (cleaned up). [See Dkt. 137 at 2.] But as Allergan notes, if Relators read *Teva* to endorse the idea that kickbacks like those alleged here necessarily convert prescriptions by doctors who received kickbacks into false claims, Relators overread the opinion. [*See* Dkt. 141 at 6 n.5.] As *Teva* acknowledged, the existence of a speaker program that induces doctors to write prescriptions "raise[s] an inference of causation," but the court qualified that observation:

Of course, this is not a theory against which there can be no defense. Defendants may call witnesses—likely, doctors—who will testify that, for some portion of the damages period, their patients were not "exposed to" an illegal referral from Teva, either because the witnesses' relationships with Teva ended well before the prescriptions at issue, or because the witnesses' sound medical judgment broke the chain of

<sup>&</sup>lt;sup>16</sup> Allergan made this point in the context of arguing in favor of the specific patient rule. The Court disagrees with Allergan on that front, but the overall point applies more broadly.

causation, such that Teva's speaker payments played no part in their decision to prescribe [the drugs at issue].

2019 WL 1245656, at \*27.

The Court agrees with *Teva*'s analysis, as limited by its context. As Allergan put it at oral argument, to plead an FCA violation based on a kickback, relator must allege violations of the AKS and FCA. [Dkt. 160 at 7–9.] A speaker program intended to induce physicians to write prescriptions violates the AKS but does not violate the FCA unless physicians submit claims to federal health care programs. Relators may be correct that kickbacks in the form of a speaker program taint all later prescriptions written by doctors who participated, but "taint" is not the standard for FCA liability; the claims at issue must have "result[ed] from a violation of" the AKS. § 1320a–7b(g). At the pleading stage, therefore, Relators must allege with sufficient plausibility and particularity more than illegal kickbacks and tainted prescriptions. They must allege claims submitted to the government that resulted from those kickbacks and that, as a result, were false claims within the meaning of the FCA.

Because not every Linzess and Viberzi prescription written by a physician who received kickbacks is automatically a false claim, Relators must do more than allege that such physicians continued to write Linzess or Viberzi prescriptions. In doing so, their allegations must not be susceptible to such an obvious alternative explanation not involving illegal conduct that it undermines their allegations' plausibility. *See Alarm Detection Sys.*, 930 F.3d at 821. Relators' answer is that they have plausibly alleged false claims because speaker physicians wrote more Linzess and Viberzi prescriptions to Medicare patients after Allergan provided kickbacks to them. [Dkt. 137 at 5–6.] Allergan offers two alternative explanations. First, doctors' exercise of "sound medical judgment may [have] br[oken] the chain of causation such that [Allergan's] speaker payments played no part in their decision to prescribe." [Dkt. 141 at 6 n.5 (cleaned up).] Second, Linzess and Viberzi were new drugs, so one would expect to see prescriptions increase in the years after their launch. [Dkt. 133 at 18.]

Relators could defeat these alternative explanations with respect to a given doctor by alleging (with sufficient particularity) that he or she prescribed Linzess or Viberzi as a result of kickbacks, but with some exceptions discussed below, they do not do so. Moreover, Relators make no allegations about specific patients, so the only way for their allegations to support a reasonable inference of an FCA violation is if an uptick in prescriptions itself implies the submission of false claims. The Court is not convinced that it does. If, as Allergan suggests,<sup>17</sup> physicians generally wrote more prescriptions for Linzess and Viberzi because they were relatively new drugs, then it might not be meaningful that speaker physicians increased their prescription counts after joining the Speaker Bureau. *See Alarm Detection Sys.*, 930 F.3d at 821 (allegations might not rise to the level of plausibility if there is an obvious alternative explanation); *United States ex rel. Integra Med Analytics, L.L.C. v. Baylor Scott & White Health*, 816 F. App'x 892, 897 (5th Cir. 2020) (per curiam) (rejecting a data-

<sup>&</sup>lt;sup>17</sup> According to Allergan: "[A] mere increase in prescriptions of Linzess and Viberzi by speakers does not give rise to an inference of fraud. Not only do Relators not deny this last point, their [brief] cites to data showing that prescriptions for all doctors (not just speakers for Allergan) nearly doubled between 2016 and 2018 for Linzess and nearly tripled during that same period for Viberzi, which is not surprising given that Viberzi did not enter the market until December 2015 and Linzess had a new dose approved by the FDA in 2017." [Dkt. 141 at 8 (citations omitted)).]

based argument when nonfraudulent activity was also consistent with the relator's allegations and some allegations corroborated the nonfraudulent explanation).

The upshot is that Relators' allegations that speaker physicians prescribed Linzess and Viberzi to Medicare patients more frequently after Allergan gave them kickbacks does not, by itself, support an inference that false claims were submitted as a result of these kickbacks. The Court has outlined how Relators could try to plead FCA violations without naming specific patients whose prescriptions are false claims, and in the next section, the Court will discuss whether Relators' allegations suffice to state a plausible claim. But before that, the Court emphasizes that its analysis in this section is limited in several respects.

First, Rule 8 and Rule 9(b)—and the underlying substantive law—remain the guiding stars for pleading FCA claims. The Court has analyzed the allegations and arguments currently before it and has considered how the allegations here might be bolstered or attacked. The Court takes no position on how new or reframed factual allegations or legal arguments may fare in the future. Likewise, the parties should not take the Court's analysis on these points as set in stone. These are complex issues, and additional briefing may reveal further nuance that changes the Court's view.

Second, finding useful data about other physicians' prescription practices may be difficult.<sup>18</sup> The Court envisions potential issues with representativeness and scope. Cherry-picking a few non-speakers whose Linzess and Viberzi prescription numbers

<sup>&</sup>lt;sup>18</sup> If the database the parties cite [Dkt. 137 at 8; Dkt. 141 at 9] makes it easy to assess complete data, however, it may be appropriate to analyze all physicians' data. The parties have not addressed this specific issue, so the Court takes no firm position on it here.

remained constant might be insufficient to overcome an alternative explanation for speaker physicians' rising prescription numbers, but on the other hand, it may not be feasible for Relators to conduct a nationwide analysis of every doctor who prescribed these drugs to Medicare patients during the relevant time period. If it is necessary to find some middle ground, it might make sense to compare speakers' prescription numbers to the numbers for physicians who attended Allergan's promotional events but were not in the Speaker Bureau. These physicians would have been exposed to information about Linzess and Viberzi but would not have received kickbacks, perhaps making them superior comparators. To be clear, the Court does not mean to suggest that only such physicians can be considered comparators.

Third, the Court clarifies that its analysis here bears on the issue of whether Relators have plausibly alleged a violation of the FCA—that is, false claims being submitted to the government—not the underlying AKS violation, which depends on whether Allergan illegally used its Speaker Bureau to induce physicians to prescribe more Linzess and Viberzi. It is possible to have the latter without the former. Paying lucrative speaker fees to induce prescriptions violates the AKS whether or not false claims are ultimately submitted, but the FCA is violated only if a speaker physician submits a false claim "resulting from" the kickbacks. § 1320a–7b(g). Thus, allegations about Allergan's conduct do not help Relators establish the FCA portion of their claims unless that conduct supports (or helps support) a reasonable inference that a physician has submitted a false claim to the government. Fourth, the above discussion does not limit Relators in how they may attempt to plausibly allege the existence of FCA violations. The Court has addressed only Relators' theory that doctors prescribing more Linzess and Viberzi alone supports an inference of the submission of false claims. Relators may attempt to establish the existence of false claims through particularized allegations about specific physicians around the country, similar to their allegations about Dr. Bierman.<sup>19</sup>

# C. Sufficiency of Relators' Allegations

With those limitations in mind, the Court turns to Relators' allegations. It first addresses the AKS component of Relators' claim, whether they have plausibly alleged with particularity that Allergan undertook a nationwide kickback scheme. Then, the Court considers the FCA component, whether Relators have plausibly alleged with particularity that false claims were submitted to the government as a result of that scheme. Allergan argues that Relators fail on both fronts. [*See* Dkt. 160 at 7:17–:20 ("[T]he relator must do more than merely lay out what the Anti-Kickback scheme is. Now, we don't think the relators did that either, but they have to do more than lay out the Anti-Kickback scheme with particularity.").] The Court holds that Relators have plausibly alleged that Allergan violated the AKS, but their allegations that false claims were submitted on a nationwide basis resulting from kickbacks fall short.

#### 1. AKS Allegations: Allergan's Alleged Kickbacks

A pharmaceutical company violates the AKS if it "knowingly and willfully offers or pays any remuneration" to a physician "to induce" that physician to prescribe

<sup>&</sup>lt;sup>19</sup> As the Court explains below, Relators' allegations are sufficient to state a plausible claim that Dr. Bierman submitted false claims to the government in exchange for kickbacks.

drugs that will be paid "in whole or in part" by "a Federal health care program," such as Medicare. 42 U.S.C. § 1320a–7b(b)(2)(A). Relators satisfy their pleading burden if they allege facts with particularity that make it plausible that Allergan paid such kickbacks. That is, they must plead "who, what, when, where, and how" of Allergan's kickback scheme. *See Berkowitz*, 896 F.3d at 839 (cleaned up). If Relators are not able to allege the answers to all the newspaper questions, they can still state a plausible claim if the particularized allegations they do make "necessarily [lead] one to the conclusion that" Allergan paid kickbacks. *See Presser*, 836 F.3d at 777–78.

Allergan argues that Relators' allegations are not particularized in many respects and that their particularized allegations do not support a plausible inference that Allergan paid kickbacks on a nationwide scale. [Dkt. 133 at 11–20.] Specifically, it challenges Relators' allegations on the who, what, where, and how. [*Id.* at 11.]

# i. Who

Allergan asserts that "[b]eyond a vague reference to 'the highest level of management,' Relators never even try to explain who 'devised' or 'implemented' Allergan's alleged nationwide scheme." [*Id.* at 12 (citation omitted).] Allergan argues that it is significant that the specific employees Relators name did not "possess[] nationwide policymaking or management authority," and that Relators do not allege that the highest-ranking of these individuals "orchestrat[ed] a kickback scheme." [*Id.* at 12 & n.6.] Relators argue that their allegations are sufficient because they allege facts "based on their personal knowledge about the scheme's involving Allergan's national headquarters and regional managers"; they allege "data showing speaker payments and submitted claims from at least eleven states where Allergan paid doctors"; and they allege that "Allergan's national office communicated about" the Speaker Bureau. [Dkt. 137 at 16 (citations omitted).]

The Court agrees with Relators that their allegations pass Rule 9(b) muster. Although they do not name specific high-level Allergan employees who implemented and oversaw the Speaker Bureau, construing Relators' particularized allegations in their favor necessarily implies that Allergan operated the program at a national level.

See Presser, 836 F.3d at 777–78. For example, Relators allege:

- Sales representatives' compensation depended on prescription volume; if they exceeded sales' quotas, they were eligible for rewards including membership in the "President's Club," stock options, and vacations. [Dkt. 65 ¶¶ 92–94.]
- Sales representatives who did not meet their quotas were fired. [*Id.* ¶ 92.]
- Sales representatives received instruction about the Speaker Bureau program at a national sales conference in Florida in October 2016. [*Id.* ¶ 97.]
- Sales managers and representatives selected physicians to join the Speaker Bureau in their territory, but annually an employee at Allergan's headquarters contacted salespeople, through district and regional managers, for input about who should be added to or removed from the Speaker Bureau. [*Id.* ¶¶ 105, 108.]
- District managers passed other information and gave direction to salespeople through regional managers. [*Id.* ¶¶ 106, 109.]
- A senior manager circulated a list of speaker physicians slated to be removed from the Speaker Bureau in December 2017. [*Id.* ¶ 113.]
- Allergan held hundreds or thousands of speaker events for Linzess or Linzess and Viberzi in 2015, 2016, and 2017. [*Id.* ¶¶ 101–03.]

These allegations, if true, strongly suggest that Allergan's speaker program operated at a companywide scale. Direction and communication about the program came—at least to some extent—from employees at Allergan's headquarters or at nationwide events. Organizing salespeople into districts and regions and sales representatives' compensation model, especially the "President's Club" and stock options, bolster the inference because this structure suggests direction from the top. The large number of speaker events further supports the Speaker Bureau being a nationwide project. Relators' failure to name the individuals responsible for the Speaker Bureau or allegedly fraudulent conduct related to the Speaker Bureau does not undermine their allegations on the "who" of the kickback scheme. Relators were regional salesmen, not employees at Allergan's headquarters, where they might have been privy to high-level marketing decisions. *Cf. Presser*, 836 F.3d at 778 ("Considering Ms. Presser's position as a nurse practitioner, a position that does not appear to include regular access to medical bills, we do not see how she would have been able to plead more facts pertaining to the billing process." (citation omitted)). Therefore, with respect to Relators' allegations about who at Allergan headquarters directed the Speaker Bureau, "for now, an inference is enough." *Id.* (cleaned up).

### ii. How

Skipping ahead to the "how" inquiry, Allergan argues that Relators "fail to allege with particularity how Allergan's policies and practices facilitated the alleged national scheme." [*Id.* at 14.] The two main policies Relators focus on—planning events based on RSVP numbers and paying speaker physicians even if events are cancelled or poorly attended—it argues, "are fully consistent with non-fraudulent explanations" and do not support an inference of fraud. [*Id.* (citation omitted).] Allergan is correct on this point—a company with no fraudulent intent would adopt these or similar policies. [*See* Dkt. 141 at 8–9 (noting that Relators do not suggest alternative policies).] But even so, the fact that Allergan had these policies does not insulate it from an FCA claim where additional allegations support an inference of fraud. Relators' allegations raise such an inference. Relators allege, and Allergan does not dispute, that if speaker events are not a kickback to the speaker, then their purpose must be "for a speaker to educate and inform others"; thus, "those others must be in attendance to hear the speaker." [Dkt. 65 ¶¶ 160–61; *cf.* Dkt. 133 at 6–7 (characterizing the speaker events as educational).] Yet Allergan held events based on required numbers of RSVPs, not required numbers of attendees. [Dkt. 65 ¶¶ 162–63.] Further, Allergan paid speaker physicians fees and reimbursed them for expenses, even if events were under-attended or canceled, which Relators allege routinely occurred. [*Id.* ¶¶ 172–75, 181.]

Allergan protests that these practices are exactly what one would expect from an honest company. It is correct. Allergan "only controls the number and identity of the invitees"; it "cannot control either how many people RSVP or, critically, how many confirmed attendees actually end up attending." [Dkt. 133 at 15.] Similarly, there is nothing "unusual about Allergan paying the scheduled speaker" if an event "had low attendance or [was] canceled shortly before scheduled to take place" because that doctor had already committed his or her time to the event. [*Id.*] Indeed, the Court cannot see "how Allergan could justify refusing to pay" speakers who presented at under-attended events or when there was a late cancellation. [*Id.*] To the extent that Allergan's Speaker Bureau operated in this way, it does not suggest fraud—the fact that a company not paying kickbacks would act the same way is an obvious alternative explanation that would render Relators' allegations not sufficiently plausible. *See Alarm Detection Sys.*, 930 F.3d at 821. But Relators allege more. They allege that, in practice, the Speaker Bureau

operated as a system to funnel payments and benefits to physicians, with little or no

regard for the content or attendance of the speaker events. Their allegations include:

- Sales representatives counted uncertain RSVPs as positive RSVPs and held events even when prospective attendees informed representatives that they would no longer attend. [Dkt.  $65 \P\P$  163–65.]
- Regional manager Foust emphasized that speaker events had an RSVP requirement, not an attendance requirement. [Id.  $\P$  164.]
- Foust instructed Wilkerson to falsify documentation about the instructional content of an in-office presentation. [Id.  $\P$  118.]
- Richard Uhles, a primary care manager who oversaw sales representatives in Oklahoma, "instructed sales representatives to add false attendees to speaker program documentation, often after the event took place," to disguise the fact that there was insufficient attendance. [*Id.* ¶ 167.]
- "On many other occasions," sales representatives reported through IntraMed, Allergan's platform "designed and used to record speaker event attendance," that events were under-attended or attended by no one besides the speaker and a sales representative. [*Id.* ¶ 169.]
- At one event in 2015, Jackson collected the requisite number of RSVPs, but no one attended, so he and the speaker physician "simply ate a very nice meal," and Allergan paid the physician \$1,500. Jackson reported the non-attendance through the IntraMed platform, but "he was surprised to find that Allergan did not care. Because Allergan's focus was on positive RSVPs, not actual attendees, Allergan did not discipline or criticize" Jackson. [*Id.* ¶¶ 170–71.]
- In July 2016, Chris Sweeney, a vice president of sales "responsible for all GI sales managers and sales representatives in the Western United States" told "all Regional and District Managers" that salespeople were not complying with RSVP requirements. Among 93 events scheduled for an upcoming week, only six satisfied the RSVP requirements; after Sweeney's message, more events received the requisite RSVPs, but 12 went "totally unattended," 17 were "under-attended," and three were cancelled for lack of RSVPs. [*Id.* ¶¶ 173–74.]
- There were 2,129 unattended, under-attended, or cancelled events for which the speaker physicians were paid between 2015 and May 2018, the lion's share of which occurred in 2016 and 2017. [*Id.* ¶¶ 175–82.]<sup>20</sup>

<sup>&</sup>lt;sup>20</sup> The allegations about the number of events that were unattended, under-attended, and cancelled are unclear. Sometimes Relators appear to break these three categories out separately, but not always. For example, for 2015, they identify 11 events with no attendees, 28 events with fewer attendees than the requisite number of RSVPs, and 19 events that were cancelled in advance. [Dkt. 165 ¶¶ 176, 182.] For 2016, they state that 507 events had no

While not all of these allegations are particularized, Relators' allegations go beyond pleading based on information and belief, *cf. Pirelli*, 631 F.3d at 442–43; they "inject[] precision and some measure of substantiation into their allegations of fraud," *see Berkowitz*, 896 F.3d at 839–40 (cleaned up).<sup>21</sup>

Allergan argues that it had no reasonable alternative to paying physicians for events even if they were poorly attended or cancelled in advance. [*See e.g.*, Dkt. 133 at 15 ("Even when a program is canceled, the scheduled speaker is still required to block off his or her schedule and forego other activities while also preparing for the presentation.").] It is correct as to each individual event—Relators' allegations do not support an inference that Allergan could have done anything besides pay speakers what it had agreed to under these circumstances. In the aggregate, however, Allergan could have taken different steps, and it is reasonable to infer that it would have, if its purpose in operating the Speaker Bureau was not fraudulent.

As Relators note, the purpose of the Speaker Bureau—if not to pay kickbacks to doctors—was to raise awareness and educate physicians about Linzess and Viberzi.

attendees other than the speaker and sales representative, but they also allege that there were "494 under-attended or non-attended events." [*Id.* ¶¶ 177–78.] The Court suspects this is an error and Relators mean that the 494 events were under-attended, not unattended *or* under-attended, but clarification would be beneficial. For 2017, Relators cite the number of unattended (425) and cancelled (69) events, but not the number of under-attended events. [*Id.* ¶¶ 179, 182.] It may be that the Court could subtract the sum of the other categories from the 2,129 total to learn the number of under-attended 2017 events, but the Court cannot know for sure.

<sup>&</sup>lt;sup>21</sup> The Court agrees with Allergan that Relators' particularized allegations about the lack of educational materials at events they personally attended are insufficient to support an inference of a nationwide kickback scheme and that the allegations about events Relators did not attend are too conclusory. [*See* Dkt. 133 at 16.] These allegations do not contribute to the Court's conclusion that Relators have met their burden of pleading the "how" of the fraud.

[See Dkt. 65 ¶ 160.] It is reasonable to infer that a company with this nonfraudulent motive would want to hold well-attended educational events, not poorly attended or even cancelled events that still impacted the company's bottom line. "Particularly during the explosion of speaker fees paid in 2016 and 2017," however, there were "so many speaker events ... that sales representatives had difficulty getting physicians to show up to the events." [Id. ¶ 172.] It seems that 1,001 speaker events were under-attended or unattended in 2016 alone, and 93 were cancelled. [Id. ¶¶ 177–78, 182.]

If Allergan knew about so many cancelled or unattended events, one would expect it to have raised the RSVP thresholds for holding events, limited the number of events, or both. Relators' allegations permit the inference that high-level Allergan employees learned about the attendance issues via IntraMed, its reporting platform. [*See id.* ¶¶ 169, 171.] Assuming that most sales representatives honestly reported the attendance levels and cancellation rates of events,<sup>22</sup> then it is reasonable to infer that Allergan did not care that it was paying for expensive events that yielded little or no legitimate educational benefit to the company.

Relators do not mention any policy change in response to the cancellations and lack of attendance [*cf. id.* ¶ 163 (discussing RSVP requirements)], and hundreds of events continued to be cancelled or under-attended in 2017 [*id.* ¶¶ 179, 182]. Relators

<sup>&</sup>lt;sup>22</sup> If falsifying reports on the IntraMed platform was so commonplace that high-level employees might never have learned about how ill-attended so many speaker events were, it would raise a different inference of fraud. To achieve so much concealment, it is reasonable to infer either that instructions to falsify records came from the top [*see, e.g.*, Dkt. 65 ¶¶ 118, 167 (alleging that Allergan told employees to fabricate records)] or that falsification by lowerlevel employees was so rampant that it infected all or most of the gastrointestinal division of Allergan. Whether due to orders from the top or organic grassroots fabrication, this level of institutional falsification would support an inference of companywide fraud.

do not include specific allegations about many cancelled or under-attended events, and many of their allegations about events they do mention are not particularized.<sup>23</sup> Even so, the Operative Complaint contains enough specifics to support the inference that the pattern of under-attended events existed nationwide. They allege that Uhles in Oklahoma and Foust in Tennessee instructed sales representatives to falsify records. [Id. ¶¶ 118, 167.]<sup>24</sup> They allege that Sweeney, responsible for the Western United States, sent a nationwide message that salespeople were not meeting the RSVP requirements for events approximately two weeks in the future. [Id. ¶ 173.]<sup>25</sup> More than one-third of those events were cancelled or under-attended, which the Court infers Allergan learned about when salespeople submitted the attendance records of the events afterward. [See id. ¶¶ 169, 171, 174.] Together, these allegations support the inference that Allergan was aware that its speaker events were going unattended and underattended at high rates in 2016 on a national scale, but Allergan did not change its policies. While there are reasons other than fraud that Allergan might have continued its practices-for example, perhaps Linzess and Viberzi were so profitable that Allergan was willing to lose money to poorly attended events to

The Court discusses these allegations in connection with the FCA portion of this claim. Allergan notes that the incident with Foust involved Wilkerson himself falsifying the records [Dkt. 133 at 16], but Relators allege that this was done at Foust's direction, which the Court must take as true at this stage. Allergan cites no authority for the proposition that if a relator's allegations involve his own bad acts, it changes the pleading standard.

<sup>&</sup>lt;sup>25</sup> The Court infers that the 93 events scheduled for the week of August 8, 2016 were all events in the country, not only those events in Sweeney's geographic territory. There were a total of 4,435 speaker events held in 2016. [Dkt. 65 ¶ 102.] The 90 events that were held constituted about 2% of the total events held that year, a proportion consistent with there being 93 events scheduled in the entire country that week, not a subset of the country. That means that Sweeney was communicating to a nationwide audience, further supporting the inference that Allergan implemented the Speaker Bureau through companywide policy.

ensure that its Speaker Program reached the largest possible audience—they are not so obvious that they render Relators' theory implausible. *Cf. Alarm Detection Sys.*, 930 F.3d at 821. Therefore, Relators have adequately plead the "how" of the fraud.

#### iii. What and Where

Allergan argues that Relators fall short on the "what" of the fraud because they "fail to explain what role national management played in the supposed scheme." [Dkt. 133 at 13–14.] Similarly, Allergan contends that although Relators "assert[] that [its] scheme operated 'nationwide," the Operative Complaint "is almost entirely devoid of allegations concerning employees at Allergan's U.S. headquarters." [*Id.* at 12–13.]

Above, the Court explained why Relators' allegations are sufficient to support the inferences that high-level Allergan officials organized a kickback scheme to induce physicians to prescribe more Linzess and Viberzi and that Allergan made payments to speakers at least in part to induce such prescriptions. The allegations that imply the involvement of high-level Allergan employees—for example, sharing instructions about the Speaker Bureau at a national conference and passing input and information up and down the Allergan corporate ladder [Dkt. 65 ¶¶ 97, 105–06, 108–09]—also raise the necessary inference that high-level employees were taking action or making statements in furtherance of the kickback scheme (the "what") from Allergan's headquarters (the "where"). See Presser, 836 F.3d at 777–78. As regional sales representatives, Relators were not in a position to know everything that the relevant Allergan employees said and where they were at the time, allowing them to rely on inference for the time being. See id. at 778.

\* \* \*

Relators' allegations are thin in places, but ultimately the Court concludes that when construed in their favor, Relators have alleged facts with enough particularity to make plausible that Allergan's Speaker Bureau violated the AKS.

### 2. FCA Allegations: False Claims Resulting from Kickbacks

Relators' job is not finished yet. They also must allege facts with particularity that, if true, make it plausible that false claims were submitted on a nationwide basis resulting from the alleged kickbacks. 42 U.S.C. § 1320a–7b(g). As the Court explained above, it is insufficient to allege that Allergan paid illegal kickbacks to doctors who then wrote more Linzess and Viberzi prescriptions. While conceding that Relators have pleaded illegal *quid pro quo* relationships with a small number of physicians with the requisite particularity, Allergan argues that their allegations of nationwide false claims do not pass muster. [Dkt. 133 at 17–20.] The Court agrees.

The Court begins with Relators' strongest allegations, about Dr. Bierman, a Memphis-based physician who was "a high-prescriber who could be guaranteed to produce a high volume of Viberzi prescriptions." [Dkt. 65 ¶ 111.] Relators allege that Dr. Bierman and Allergan employees entered an explicit *quid pro quo* arrangement whereby Dr. Bierman would prescribe more Viberzi in exchange for more speaker fees. Their allegations are undoubtedly particularized, including:

- In January 2016, Foust "was not satisfied" with "Bierman's initial prescribing levels" and "demanded of his sales team that all speaker-physicians needed to 'get on board' with prescribing Viberzi to continue receiving speaker fee payments." [*Id.* ¶ 124.]
- That month, at Foust's direction, Wilkerson and fellow sales representative Adcock told Dr. Bierman that if he "wanted to continue receiving thousands of dollars in speaker fees from Allergan, he had to prescribe more Viberzi." Dr. Bierman agreed. [Id. ¶¶ 125–26; id. ¶ 134 (Dr. Bierman saying he needs more money, for which he knows he needs to write more prescriptions).]

- Dr. Bierman, Wilkerson, and Adcock told Dr. Bierman's head nurse the steps she needed to take to facilitate additional prescriptions for Viberzi. [*Id.* ¶ 128.]
- Thereafter, more speaker events for Dr. Bierman were scheduled. [*Id.* ¶ 129.]
- In March 2017, Wilkerson spoke to fellow sales representative Fogelman, who expressed joy that Dr. Bierman prescribed the most Viberzi in Allergan's West Tennessee territory, which Fogelman said was because Allergan was "paying him." [*Id.* ¶ 131.]
- In September 2017, Adcock was falling behind on his Viberzi quota and said that he "needed Allergan to pay Dr. Bierman more speaker fees so Adcock could reach his sales quota"; Adcock then arranged more events with Dr. Bierman, and Dr. Bierman in turn wrote more prescriptions. [*Id.* ¶ 132.]
- In February 2018, Adcock arranged five more speaker events for Dr. Bierman, to which Foust responded that these events would be Dr. Bierman's last unless he wrote more prescriptions. [*Id.* ¶ 133.]

Relators also allege that other speakers in the area were retained or terminated based on their prescription volume. [See id. ¶¶ 143-44 (Jeffreys was added to the Speaker Bureau in 2018 because of Fogelman's knowledge of the success with Dr. Bierman, but she was terminated as a speaker when her Linzess prescription volume "remained relatively constant"), ¶¶ 145-48 (Dr. Kayal was added to the Speaker Bureau, and a sales representative said that he "had 10 patients start on Viberzi" after the event, and his prescription volume grew).]<sup>26</sup> These allegations support the inference that Allergan sales representatives and managers, and at least Dr. Bierman, understood the Speaker Bureau program to be a kickback scheme whereby speakers were induced to prescribe more Linzess and Viberzi. As a result, Relators have plausibly alleged that Dr. Bierman submitted false claims that resulted from kickbacks. § 1320a-7b(g).

<sup>&</sup>lt;sup>26</sup> The Court disagrees with Allergan that the allegations about Jeffreys and Dr. Kayal are not particularized. [Dkt. 133 at 17 n.15.] Relators provide enough detail based on events that they observed or that were related to them personally to satisfy Rule 9(b).

Allergan argues that beyond the allegations about Tennessee and Dr. Bierman, the Operative Complaint lacks sufficient particularity to show that false claims were submitted on a nationwide scale. [Dkt. 133 at 17.] These allegations take two forms: information about speaker physicians' prescription volume and an addendum to the Operative Complaint providing examples of sham speaker events attended by doctors in various states and resulting prescriptions submitted to Medicare. [See Dkt. 65  $\P\P$  155–58; *id.* addendum 1.] The Court has explained why alleging an increase in prescription volume for Linzess and Viberzi is, by itself, insufficient to state a plausible claim that those prescriptions resulted from illegal kickbacks, so the Court focuses on the allegations in the addendum. These allegations raise two issues: first, whether the Court can consider them at all and, second, whether they support an inference of nationwide false claims.

As to the first question, Rule 9(b) does not by its terms prohibit pleading based on information a party obtained from another source, rather than observed firsthand, but the particularity standard does demand "some means of injecting precision and some measure of substantiation into ... allegations of fraud." *Presser*, 836 F.3d at 776 (cleaned up). When a relator pleads fraud based on information learned secondhand, it will likely be necessary to allege how the relator obtained that information and to allege facts indicating the information is reliable. *Cf. Grenadyor*, 772 F.3d at 1107– 08 (explaining that "Grenadyor trips over Rule 9(b)" because "[m]issing" from his complaint "is any allegation that indicates how [he], a pharmacist working for just one of the defendant pharmacies, obtained such information about a large number of pharmacies scattered over a number of states," and explaining that the allegation that a confidential witness in one other state "observed the practice" is inadequate); United States ex rel. Kroening v. Forest Pharms., Inc., 155 F. Supp. 3d 882, 897 (E.D. Wis. 2016) (holding that alleging that the relator "spoke with sales representatives from other states" was insufficient to "allege[] the existence of a nationwide scheme" when the complaint "lacks any details regarding alleged false claims" in other states, "even purported hearsay from other sales representatives"). To be clear, the Court does not interpret *Grenadyor* to foreclose the use of secondhand information to plead fraud, provided a relator can supply enough detail to make his allegations particular and plausible. Nor does the Court understand Allergan to be advancing this sort of categorical argument. [See Dkt. 133 at 19–20.]

At oral argument, Relators indicated that the allegations in the addendum were "information developed as the government corroborated [their] allegations of a company-wide, i.e., national, program." [Dkt. 160 at 55:8–:10; *see id.* at 53–55.] Since Relators did not put this information in the Operative Complaint, it is beyond the scope of the current motion to dismiss, but the Court clarifies that Relators assertions at oral argument, if incorporated into a pleading, would be insufficient support for the allegations in the addendum because they are general statements about how Relators gained that information, rather than being tied to specific allegations. That is not to say that Relators cannot bring these allegations up to snuff by adding detail, but they must do more than cite a government investigation that corroborated their allegations of nationwide fraud. On the second issue, even if the Court were to consider these allegations, it would agree with Allergan that these allegations do not make it plausible that doctors submitted false claims resulting from kickbacks on a nationwide basis.<sup>27</sup> As Allergan notes, the allegations in the addendum "follow the same template" of alleging that a speaker physician was paid for an unattended, under-attended, or cancelled event and later increased his or her prescription volume for Linzess or Viberzi. [Dkt. 133 at 18; *see* Dkt. 65 addendum 1.] While the allegations about the events might be particularized for Rule 9(b) purposes if Relators add detail about how they obtained the relevant information, Relators allege no details about the speakers' prescription practices. That is, setting aside the sourcing issue, the detail in these allegations does not address the issue of false claims. Allergan may have paid these doctors kickbacks, but unless false claims resulted from those kickbacks, Relators' claim fails because particularized allegations about doctors in one state are insufficient to plausibly allege a "top-down nationwide scheme." [Dkt. 133 at 19 (citation omitted).]

<sup>27</sup> The "manifold" deficiencies Allergan enumerates [Dkt. 133 at 17–18] largely do not relate to the specific question about whether the addendum suffices to allege false claims on a nationwide scale. Its first, second, and fourth points relate to the allegations about Allergan's own behavior—the AKS component of an FCA kickback claim. While the Court agrees with Allergan on some of these points, Relators' allegations nevertheless make it plausible that Allergan violated the AKS. Its third and sixth points are relevant to the issue of whether an increase in prescription volume itself suggests false claims, which the Court considered and rejected above. As to Allergan's fifth point, that Relators do not allege that these physicians were asked or agreed to write more Linzess and Viberzi prescriptions in exchange for kickbacks, the Court agrees with Relators that the physicians' state of mind is irrelevant. [Dkt. 137 at 1–2.] Allergan is the Defendant here, so the question is whether it "knowingly and willfully" paid kickbacks to induce additional prescriptions, not whether the physicians knowingly and willfully wrote such prescriptions. See 42 U.S.C. § 1320a-7b(b)(2). FCA liability attaches for AKS violations not based on a mental state but a causal question: whether claims were submitted "resulting from" an illegal kickback. § 1320a-7b(g).

Relators' counterarguments are unavailing. First, they argue that they have properly alleged "a nationwide Allergan scheme of using speaker events to induce speakers to prescribe Linzess and Viberzi from coast to coast, and to cut off payments to speakers who prescribe too little." [Dkt. 137 at 11–12 (emphasis omitted).] But these allegations relate to the AKS component of Allergan's claim, which the Court agrees has been sufficiently alleged. Second, Relators argue that the scope of their allegations in the addendum, covering 11 states, is sufficient to support an inference of a nationwide scheme. [Dkt. 137 at 15–17.] The Court agrees, but the geographic scope of Relators' allegations on this topic is not the problem; the lack of detail about prescriptions is. Third, Relators note that they "have alleged hard data establishing ... the submission and payment of many Medicare claims for prescriptions written by doctors after they accepted Allergan's payments." [*Id.* at 11.] Again, the Court agrees, but as it has explained, the submission of claims in connection with Linzess or Viberzi prescriptions is not, by itself, sufficient to support an inference of false claims.

Relators can attempt to bring their allegations about the FCA component of their claim up to the Rule 8 and Rule 9(b) standards in at least two ways. First, they can add allegations about specific speakers' prescribing patterns, akin to their allegations about Dr. Bierman, Dr. Kayal, and Jeffreys. Those speakers would have to be based in sufficiently diverse geographic locations to support an inference of nationwide fraud. Second, Relators can provide more convincing data showing that speakers' Linzess and Viberzi prescription volume increased disproportionately to non-speakers' prescription volume, which could make it plausible that at least some of those claims resulted from kickbacks. *Cf. Integra*, 816 F. App'x at 897 (holding that statistical data were insufficient when those data were consistent with an obvious nonfraudulent explanation). Because the Operative Complaint does not plead facts to support either theory, Relators have failed to plausibly allege the FCA component of their claim. Without both the AKS and FCA pieces, an FCA claim predicated on an illegal nationwide kickback scheme necessarily fails. Therefore, the Court grants Allergan's motion to dismiss Count I.

# **IV.** Other Claims

## A. Other FCA Fraud Claims

In Counts II through IV, Relators raise other fraud-based FCA claims. Allergan argues that each should be dismissed. [Dkt. 133 at 20–21.] The Court agrees with Allergan about two claims, but not the third.

#### 1. Count III: Conspiracy

Taking the claims out of order, in Count III, Relators allege that Allergan conspired with physicians, including Dr. Bierman, "to commit violations of the FCA and the AKS." [Dkt. 65 ¶ 219.] "[G]eneral civil conspiracy principles apply" to FCA conspiracy claims. United States ex rel. Durcholz v. FKW, Inc., 189 F.3d 542, 545 n.3 (7th Cir. 1999) (citation omitted). "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). Because "a corporation 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) (citing *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 771 (1984)), the conspiracy must be between Allergan and one or more doctors.

The Court is skeptical that Relators have properly alleged a conspiracy to violate the FCA as to any doctor. As explained above, Relators' allegations make it plausible that high-level Allergan employees intended the Speaker Bureau at least in part to pay kickbacks to doctors, but Relators' pleading burden for a conspiracy claim is different. "[A]s with any conspiracy, the core burden is to prove an agreement or meeting of the minds." United States ex rel. Lisitza v. Par Pharma. Cos., Inc., 276 F. Supp. 3d 779, 806 (N.D. Ill. 2017) (citing *Durcholz*, 189 F.3d at 545–46). Thus, they must allege particular facts that support a reasonable inference of an *agreement* on Allergan's part. Cf. Cincinnati Life Ins. Co. v. Beyrer, 722 F.3d 939, 948-49 (7th Cir. 2013) (analyzing an FCA conspiracy claim under Rule 9(b)). The Operative Complaint and Relators' brief are light on details about specific statements high-level Allergan employees made; while for other FCA claims it was sufficient to infer that such employees established the Speaker Bureau at least in part to pay kickbacks to doctors, an FCA conspiracy claim requires alleging facts about the agreement. Even for Dr. Bierman, as to whom Relators alleged a *quid pro quo* of speaker fees for prescriptions, the only alleged statements suggesting a meeting of the minds were with sales representatives or low-level managers. The Court is unconvinced that these allegations suggest an agreement that is attributable to Allergan.

However, Allergan concedes that Relators have plausibly alleged a conspiracy between it and Dr. Bierman. Its opening brief states: "Relators nowhere allege—let alone with particularity—that any doctor other than Dr. Bierman had an express quid pro quo or other unlawful agreement with Allergan." [Dkt. 133 at 20 (emphasis added); see Dkt. 137 at 18 (noting the concession); Dkt. 141 at 13 n.10 (arguing that Relators' broader conspiracy claims still fail).] This assertion is not an assumption for the sake of argument that the alleged conspiracy between Allergan and Dr. Bierman is adequately alleged; it argues that Relators have not alleged a quid pro quo arrangement with "any doctor other than Dr. Bierman." [Dkt. 133 at 20.] Cf. Walker v. Baldwin, 74 F.4th 878, 881 (7th Cir. 2023) (unconditionally conceding a point was waiver because "[a]dvocates know how to phrase a limited waiver" (quotation omitted)); Bradley v. Village of University Park, 59 F.4th 887, 898–99 (7th Cir. 2023) (finding waiver where a party said it was not contesting a point "in this case," rather than "in this appeal"). In light of this concession, Allergan has waived its right to contest the sufficiency of Relators' allegation of conspiracy with Dr. Bierman at the pleading stage.<sup>28</sup>

Allergan accurately notes that an agreement with a single physician cannot establish a nationwide conspiracy [Dkt. 141 at 13 n.10.] Although the Court will allow this claim to proceed at least as to a conspiracy with Dr. Bierman, it will dismiss the entire claim at this time, to allow Relators to attempt to replead the nationwide claim. If they cannot or decline to do so, this claim will proceed as to a conspiracy between Allergan and Dr. Bierman only.

<sup>&</sup>lt;sup>28</sup> To be clear, because Allergan's concession only related to Relators' allegations, it will have no effect at the summary judgment stage or beyond.

# 2. Count II: False Record

Count II alleges that Allergan violated the FCA when it "created or used false speaker attendance records, caused to be made or used false Medicare enrollment certifications, and false Medicare billing certifications." [Dkt. 65 ¶ 214.] The FCA imposes liability on a defendant who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B). Relators must allege that Allergan "(1) made a statement in order to receive money from the government, (2) the statement was false, (3) [Allergan] knew the statement was false at the time it made the statement, and (4) the statement was material to the government's decision to give [Allergan] money." *Lanahan v. County of Cook*, 41 F.4th 854, 862 (7th Cir. 2022) (citation omitted).

There are several problems with this claim as alleged. The allegedly false records are the "falsified attendance records at ... speaker events, including at events involving Dr. Bierman." [Dkt. 137 at 18 (citation omitted).]<sup>29</sup> But Relators allege no

<sup>&</sup>lt;sup>29</sup> Relators also suggest that a tainted prescription is "itself a false or fraudulent record or statement." [Dkt. 137 at 18.] They cite no legal authority supporting their reading of the statute, and the Court disagrees with it. In the context of an FCA kickback claim, what makes a claim false is that it resulted from an illegal kickback. 42 U.S.C. § 1320a–7b(g). The claim is not false in the sense that it is fabricated—a doctor actually prescribed a patient the drug in question. Interpreting 31 U.S.C. § 3729(a)(1)(B) to mean that a prescription tainted by a kickback is a "false record or statement" not only duplicates § 3729(a)(1)(A) (which prohibits presenting "a false or fraudulent claim for payment or approval" without reference to records) but also renders the language of § 3729(a)(1)(B) distinguishing between "a false record or statement" and "a false or fraudulent claim" superfluous. In the absence of authority to the contrary, the Court declines to read the statute in this manner.

This theory also largely fails for an independent reason. While Relators contend that Allergan violates § 3729(a)(1)(B) whenever a doctor submits a prescription resulting from a kickback [Dkt. 137 at 18], the only possible way a doctor's action could be attributable to Allergan is if they were acting in concert. Because the conspiracy claim fails (except as to Dr. Bierman), Relators cannot impute doctors' submission of prescriptions to Allergan.

facts that suggest that any falsification is attributable to high-level Allergan employees. Like the FCA conspiracy claim, Relators face a different pleading burden on this claim than on their § 3729(a)(1)(A) claim. Separately, even if falsified records are attributable to Allergan, Relators do not allege facts showing that the fabricator did so "in order to receive money from the government." *Lanahan*, 41 F.4th at 862 (citation omitted). These records were an internal record-keeping function Allergan required; they were not related to the submission of prescriptions for reimbursement. Relatedly, it is unclear why fabricated attendance records would be material to the government's decision to pay the claim. *See id.* If Allergan falsified records to conceal violations of the AKS, the purpose of the fabrication would be the concealment, not to receive money from the government, and what would be material to the decision to reimburse Allergan or not would be the kickback, not the falsification. *See id.* 

Perhaps Relators can salvage this claim by alleging more facts about the false records and how their creation can be attributed to Allergan. As currently pleaded, however, the Court agrees with Allergan that Count II fails.

#### 3. Count IV: Reverse FCA

Count IV alleges that Allergan committed a so-called "reverse" FCA violation by "knowingly and improperly avoid[ing] ... an obligation to pay or transmit money or property to the Government" in violation of 31 U.S.C. § 3729(a)(1)(G). [Dkt. 65 ¶¶ 222–24.] Allergan argues that this claim is redundant because Relators' only theory of FCA violations is that doctors submitted claims to the government that were tainted by illegal kickbacks. [Dkt. 133 at 21.] Allergan submits that "Relators' theory that Allergan incurred such an obligation by causing the submission of a false claim ignores the distinction between Sections 3729(a)(1)(A) and (G) by turning any false claim for payment *from* the government into avoidance of an obligation to make payment *to* the government." [*Id.*] Relators respond, without elaboration, that their claim is not "redundant" and that in any event it would be premature to dismiss this claim because it is at least conceivably possible that a jury could find that Allergan violated § 3729(a)(1)(G) but not § 3729(a)(1)(A). [Dkt. 137 at 18–19 & n.4.]<sup>30</sup>

The Court agrees with Allergan that if the obligation to pay the government is only the obligation to make the government whole because it violated § 3729(a)(1)(A), then the claims are duplicative and there is no reason for Relators to maintain both. *See, e.g., Myers,* 2018 WL 1427171, at \*3 (dismissing such a claim). Relators' scant briefing on this claim prevents the Court from determining whether there is a way to read the claims as factually distinct or whether there is a legal obligation distinct from Allergan's alleged FCA violations that gives rise to an obligation to pay the

<sup>&</sup>lt;sup>30</sup> The Court is skeptical about this hypothetical for the same reasons the court gave in United State ex rel. Meyers v. America's Disabled Homebound, Inc.:

A number of district courts have held ... that when a claim brought pursuant to subsection (G) ... is based on the same submissions of false statements and records underlying claims brought pursuant to subsections (A) and (B) ..., the subsection (G) reverse false claim should be dismissed as redundant of the subsection (A) and (B) claims. Myers argues that this reasoning is not sound because subsection (G) requires repayment of any obligation, whether or not derived from false statements or records, and "obligation" is defined as the "retention of any overpayment." 31 U.S.C. § 3729(b)(3). But the definition of "obligation" also requires the existence of an "established duty," and here the only alleged "established duty" is founded on Defendants' alleged false statements and records. The Court agrees with the reasoning of the decisions cited above that the statute should not be interpreted to permit such a redundancy.

<sup>2018</sup> WL 1427171, at \*3 (N.D. Ill. Mar. 22, 2018) (citations omitted).

government. As Relators will be granted leave to amend, they may try to flesh out their factual allegations or identify another legal obligation to pay. At that time, the Court will consider whether there is any chance the claim might not be redundant and address Relators' prematurity argument.

#### B. State Law Claims

In Counts V through XXXVI, Relators bring claims under state law FCA analogues; Counts XXXVII and XXXVIII assert that Allergan violated California and Illinois insurance anti-fraud statutes. [See Dkt. 65.] Allergan argues that these claims must be dismissed because Relators' FCA claims fail and they allege no alternative factual basis for their state law claims. [Dkt. 133 at 21–22.] Allergan also argues that the state FCA analogue claims fail because the Operative Complaint "contains no allegations about speaker physicians in most States where Relators raise state FCA claims, no claims data, and no examples of specific claims submitted to *any* state government payors (*i.e.*, Medicaid)." [*Id.* at 22.] Likewise, Allergan argues that the insurance claims fail because Relators do not plead the existence of insurance claims submitted to private insurance companies with particularity. [*Id.*]

Relators agree that their state law claims generally rise and fall with their FCA claims. [*See* Dkt. 137 at 19 ("The discussion above of Relators' claims allegations and data should remove any doubt about the sufficiency of Relators' state FCA claim allegations.").] Because the Court has ruled that Relators' primary FCA claims are insufficient as currently pleaded, the state law claims must be dismissed too.

Regarding Allergan's arguments about pleading state-specific information, the Court views the pleading standard the same as under the FCA: naming a specific patient or claim is unnecessary, but Relators' allegations must be particularized and make it plausible that Allergan has violated these statutes. The Operative Complaint currently has no allegations about Medicaid akin to the Medicare claim submission data. [See Dkt. 65 (mentioning "Medicaid" only in background sections and in listing state law claims).] If such data is available, it may be possible to make similar allegations relevant to the state law claims. If no such data is available, then Relators may be able to allege facts showing that the Court can rely on inference. *Cf. Presser*, 836 F.3d at 778. But even if the state law claims are similar to the federal claims, Relators still must satisfy Rule 8 and Rule 9(b) with respect to each claim; their state law claims may not automatically follow the federal claims.<sup>31</sup>

# C. FCA Retaliation

Finally, Allergan moves to dismiss Jackson's claim that he was retaliated against in violation of the FCA. [Dkt. 133 at 22–24.] The Court agrees with Allergan that, as presently alleged, Jackson fails to state an FCA retaliation claim.

The FCA protects an employee who "is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done in furtherance of an action under the FCA or 'other efforts to stop' a violation of the statute." *Sibley*, 44 F.4th at

<sup>&</sup>lt;sup>31</sup> Relators suggest that some states' FCA analogues are more permissive than the federal statute. [*See* Dkt. 137 at 19 n.5.] If that is the case, they are free to allege facts and make legal arguments to support those claims in an opposition to a motion to dismiss, if one is filed. The Court notes, however, that Relators' invocation of Texas's more lenient standard would be irrelevant to the Operative Complaint, which contains no Texas-specific allegations that would allow the Court to consider whether they stated a claim under that statute even if their federal claims fell short.

661 (internal alteration omitted) (quoting 31 U.S.C. § 3730(h)(1)). Acts done "in furtherance of an" FCA action "include[e] investigation for, initiation of, testimony for, or assistance in an action filed or to be filed." United States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc., 764 F.3d 699, 715 (7th Cir. 2014) (quotation omitted). The employee must allege that he "engaged in protected conduct and was fired because of that conduct," requiring the Court to "ask 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." Sibley, 44 F.4th at 661 (cleaned up). Rule 9(b)'s heightened pleading standard does not apply to FCA retaliation claims because they are not fraud based. Id. at 661–62. Thus, Jackson need only state facts making it plausible that he is entitled to relief. See Twombly, 550 U.S. at 570.

The bulk of Jackson's allegations do not support an FCA retaliation claim. He primarily alleges that he refused to follow Allergan's Viberzi marketing strategy based on "concerns about patient safety and privacy, *not* the submission of false claims"; his "retaliation allegations largely ignore the FCA altogether." [Dkt. 133 at 23 (footnote omitted).] The relevant section of the Operative Complaint leads off with Jackson being "concerned that Allergan was illegally promoting Viberzi and other drugs, including through the illegal solicitation of confidential patient information in violation of HIPAA. He worried that Allergan's sales and marketing strategy was not only unlawful but was resulting in harm to patients." [Dkt. 65 ¶ 192.] He alleges that his direct supervisor, Foust, instructed him "not to raise the contraindications and

potential dangers associated with Viberzi and to minimize the potential risks of the drug to particular patients." [*Id.* ¶ 194.] In his reports to managers and HR, Jackson again discussed concerns about patient safety. [*E.g.*, *id.* ¶¶ 200–02.] The FCA does not protect against retaliation for raising concerns about patient safety. *See Absher*, 764 F.3d at 715 ("Mitchell's complaints demonstrate her concern about the standard of care provided ..., but there is nothing to suggest that she was trying to investigate or report suspected fraud on [the defendant's] part.").

In addition to these off-topic allegations, Jackson pleads some facts about offlabel marketing that could be relevant to an FCA retaliation claim. Prescribing FDAapproved drugs for off-label purposes is legal, but promotion of off-label uses may violate the FCA. See United States v. King-Vassel, 728 F.3d 707, 709 (7th Cir. 2013); see also Sidney Hillman Health Ctr. of Rochester v. Abbott Lab'ys, 873 F.3d 574, 575 (7th Cir. 2017). Jackson alleges that he reported to HR and to Foust's supervisor, regional manager Martin, that Viberzi was being promoted for off-label uses in Jackson's territory. [Dkt. 65 ¶¶ 201–02.] In the conversation with Martin, Jackson alleges that he also informed Martin that "Foust was retaliating against him for refusing to downplay the dangerous contraindications and other warnings and precautions associated with Viberzi and for refusing to promote Viberzi for off-label purposes in violation of the FCA." [Id. ¶ 202.] After these conversations, Jackson alleges that Foust again reprimanded him "for not describing Viberzi in a deceptive manner to prescribers." [Dkt. 65 ¶ 204.] Foust allegedly said, "we are going to make some decisions tonight and will let you know something in the morning"; the next day, Foust and a different HR employee informed Jackson that he had been fired for not meeting expectations. [*Id.*] Jackson alleges that he met and exceeded performance benchmarks and that he was actually fired in retaliation for his reports of possible FCA violations. [*Id.* ¶¶ 204–06.]

These allegations, taken as true and construed in Jackson's favor, come close to stating a plausible FCA retaliation claim, but don't quite make it over the line between conceivable and plausible. See Alarm Detection Sys., 930 F.3d at 821. To be sure, Jackson plausibly alleges that he knew and that a reasonable employee in his shoes would have known that off-label promotion *can lead to* FCA liability. [See Dkt. 65 ¶ 193.] Foust and Martin allegedly knew likewise. [Id. ¶ 199 ("Mr. Foust is well aware that off-label marketing, the practice of promoting drugs for uses other than what the [FDA] has approved can result in a *qui tam* lawsuit and FCA liability."), ¶ 203 (same for Martin).] But knowing that certain conduct that may be occurring can lead to FCA liability does not mean that Jackson acted in furtherance of an FCA action. He does not allege that he told Foust, Martin, or any HR employee that FCA violations had occurred, that he was investigating violations, or that he had filed or was preparing an FCA action. Cf. Absher, 764 F.3d at 715. Nor does he allege facts "show[ing] that an FCA action [was] a distinct possibility at th[at] time." Fanslow v. *Chi. Mfg. Ctr., Inc.*, 384 F.3d 469, 479 (7th Cir. 2004) (cleaned up).

Jackson's best allegation appears in paragraph 202:

Relator Jackson told Mr. Martin that Mr. Foust was consistently encouraging sales representatives to promote Viberzi for off-label purposes and for patients who do not exhibit IBS-D symptoms. Promoting Viberzi to such patients is potentially dangerous because of the contra-indications of Viberzi, its addictive opioid properties, and because it can result in the physician failing to properly identify the root cause of patient's symptoms if they are not suffering from IBS-D. In this conversation, Relator Jackson also informed Mr. Martin that Mr. Foust was retaliating against him for refusing to downplay the dangerous contraindications and other warnings and precautions associated with Viberzi and for refusing to promote Viberzi for off-label purposes in violation of the FCA. Despite receiving detailed information about the allegations of potential FCA violations in his territory, Mr. Martin ignored Relator Jackson's concerns.

[Dkt. 65 ¶ 202.] But even in this paragraph, Jackson does not allege that physicians were in fact prescribing Viberzi for dangerous off-label uses; he alleges that Foust was pushing sales representatives to promote such uses. [See Dkt. 137 at 20 (describing Jackson's allegations as "object[ing] to Allergan's off-label marketing").]

Merely objecting to conduct that might violate the FCA is insufficient. See Brandon v. Anesthesia & Pain Mgmt. Assocs., Ltd., 277 F.3d 936, 944–45 (7th Cir. 2002) (rejecting an FCA retaliation claim where the plaintiff "used terms like 'illegal,' 'improper,' and 'fraudulent'' but "never explicitly told the shareholders that he believed they were violating the FCA and had never threatened to bring a *qui tam* action'' or "report their conduct to the government"; "simply trying to convince the shareholders to comply with the Medicare billing regulations'' was not protected by the FCA (citations omitted)); United States ex rel. Kennedy v. Aventis Pharms., Inc., 512 F. Supp. 2d 1158, 1168–69 (N.D. Ill. 2007) ("Though Kennedy may have complained about off-label marketing, there is no indication in her complaint that she informed her employers that she suspected that Aventis was defrauding the government or that she was pursuing or assisting in making an FCA claim."). Even read in Jackson's favor, the Operative Complaint does not support a reasonable inference that Jackson was reporting FCA violations, investigating potential violations, or threatening to file an FCA claim. *Cf. Absher*, 764 F.3d at 715. In other words, Jackson's allegations do not make it plausible that he was not "simply trying to convince" Allergan not to market Viberzi for dangerous off-label uses. *Cf. Brandon*, 277 F.3d at 944–45.<sup>32</sup>

#### VI. Leave to Amend

Allergan requests that the Court dismiss Relators' claims with prejudice because they already have had three opportunities to amend but have been unable to plausibly allege claims against Allergan. [Dkt. 133 at 6 & n.2.] Relators, naturally, ask for leave to amend, but in support of this request they cite only Rule 15(a)(2), which directs courts to "freely give leave when justice so requires." [Dkt. 137 at 20.] Allergan notes that Relators did not engage with its reasons for a dismissal with prejudice [Dkt. 141 at 2 n.1], and the Court agrees that a more complete response by Relators would have been appropriate. Even so, the Court agrees with Relators that the dismissal should be without prejudice.

<sup>&</sup>lt;sup>32</sup> Allergan also argues that "Jackson does not allege that anyone to whom he allegedly expressed his concerns about 'off-label' marketing played any role in his termination." [Dkt. 133 at 23.] This line of argument is unconvincing. Construed in Jackson's favor, the Operative Complaint sufficiently alleges causation. He alleges that he refused to market Viberzi as Foust told him to, for which Foust reprimanded him repeatedly. [Dkt. 65 ¶¶ 194–98.] Jackson raised his substantive concerns and Foust's alleged retaliation with Martin and HR. [*Id.* ¶¶ 200–02.] Yet Foust continued to reprimand Jackson and told him that "we are going to make some decisions," suggesting that Foust was involved in decision to terminate Jackson. [*Id.* ¶ 204.] Although the Court has rejected Jackson's arguments that his current allegations give rise to an inference that he engaged in activity that the FCA protects, if he can remedy these deficiencies in an amended pleading, the current allegations about the causal connection between his complaints and his firing are sufficient at the pleading stage.

Seventh Circuit precedent is clear that a plaintiff typically should receive at least one opportunity to amend his complaint; "a court should deny leave to amend only if it is certain that amendment would be futile or otherwise unwarranted." *Zimmerman v. Bornick*, 25 F.4th 491, 494 (7th Cir. 2022) (citations omitted). Leave to amend is unwarranted when, for example: (1) "a proposed amendment is untimely," (2) "the plaintiff has already had multiple chances to cure deficiencies," or (3) "amendment would cause substantial delay and prejudice." *Id.* (citations omitted). None of these conditions applies here. The first is inapplicable because the Court set no deadline for amend. As to the third, amendment would cause no delay because discovery has not yet begun, and the Court sees no reason why Allergan would be prejudiced by an amendment, except insofar as dismissal with prejudice would close the case entirely.

The second reason is a closer call. True, Relators have amended their pleading three times, and Allergan's argument that three amendments are enough has some force behind it. But the Court's normal practice is to give one chance to amend after a motion to dismiss is briefed, even if a plaintiff has amended his complaint previously. *See, e.g., Garza v. Nestle USA, Inc.,* —F. Supp. 3d—, 2023 WL 6141371, at \*5 (N.D. Ill. Sept. 20, 2023) (dismissing on jurisdictional grounds without addressing the merits but warning the plaintiff that she would receive only one chance to amend). This practice is consistent with *Zimmerman*'s phrasing: "multiple chances to cure deficiencies," not "multiple chances to amend." 25 F.4th at 494. Here, all of Relators' amendments came before Allergan's motion to dismiss was even filed. Relators filed their First and Second Amended Complaints in 2018, while this case was still under seal. [Dkt. 14, 19, 17-cv-427 (E.D. Wash.).] Relators filed a letter indicating their preparation of the Third Amended Complaint in August 2021, mere days after the case was unsealed and before Allergan filed an appearance. [Dkt. 54, 21-cv-306 (M.D. Ga.).] The pleading itself came two months later, and only afterward did Allergan move to dismiss. This is the first time Relators' allegations have been subject to adversarial testing, so the Court concludes that it is appropriate to give them one chance to fix the deficiencies the Court has identified. To be clear, this will be Relators' last opportunity to amend at this stage of the proceedings.

# VII. Next Steps

Ordinarily, the Court would impose an amendment deadline, but given the complexity of this case and the review of data that may be necessary before Relators file an amended pleading, the Court will first solicit the parties' view on appropriate next steps. To be clear, this is not the time for Relators to begin a new line of in-depth investigation; the Court is providing time for Relators to marshal information or data they have already have access to. By April 12, 2024, the parties shall file a joint status report that proposes next steps, including an amendment deadline. If that deadline is later than May 3, 2024, the status report must explain, in detail, why Relators need so much time to prepare an amended pleading and whether Allergan opposes Relators' preferred deadline. By no means does the Court wish to rush what may be a time-intensive amendment process, but it expects that Relators will work diligently

to move the case along now that the Court has ruled on dismissal. Though the fault is not theirs, this case is much older than its docket number suggests.

Separately, the Court observes that Jackson's retaliation claim appears almost entirely distinct from Relators' other claims. Although it involves alleged violations of the FCA, those violations are different than the ones Relators' other claims raise off-label marketing instead of kickbacks. The witnesses and evidence seem unlikely to substantially overlap, and the retaliation claim is a relatively straightforward employment law claim, whereas the others are sprawling fraud claims. Accordingly, the status report should state the parties' positions as to whether this claim should be severed and, if so, whether it should be transferred to a different district to serve the convenience of parties and witnesses. *See* 28 U.S.C. § 1404(a). Any severance or transfer would occur only if this Court denies a motion to dismiss this claim as alleged in an amended pleading, if such a motion is filed.

### VIII. Conclusion

For the foregoing reasons, Allergan's motion to dismiss [Dkt. 132] is granted. The Operative Complaint [Dkt. 65] is dismissed without prejudice.

Enter: 22-cv-3013 Date: March 22, 2024

Lindsay C. Jenkins United States District Judge