UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA *ex rel*. LAZARO SUAREZ, and on behalf of the STATE OF CALIFORNIA, *et al.*,	)	
Plaintiff-Relator,	)	
v.	)	**Case No. 15 C 8928**
ABBVIE INC. and ABBOTT LABORATORIES,	)	**Judge Rebecca R. Pallmeyer**
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Plaintiff-Relator Lazaro Suarez ("Relator"), a registered nurse, commenced this *qui tam* action under the False Claims Act (FCA), 31 U.S.C. §§ 3729-33, which establishes penalties for the submission of false claims for payment to federal health care programs. Under the FCA's *qui tam* provisions, relators—meaning private citizens acting as whistleblowers—are authorized to sue on behalf of the United States to recover damages for the submission of materially false claims. *See* 31 U.S.C. § 3730; *Thulin v. Shopko Stores Operating Co.*, 771 F.3d 994, 998 (7th Cir. 2014). In this action, Relator alleges that Defendant AbbVie Inc., a pharmaceutical company with its principal place of business in Illinois, and its predecessor, Abbott Laboratories (collectively, "AbbVie"), paid kickbacks to doctors in the form of product support services for AbbVie's prescription drug Humira. AbbVie provided these support services through its "Ambassador Program", in which Relator was employed through a subcontractor. Relator alleges that the kickbacks require the conclusion that all resulting claims for government reimbursement of Humira prescriptions constitute false claims under the FCA. Relator asserts claims for violations of the FCA, § 3729(a)(1)(A), (B), (G), and conspiracy to violate the FCA, § 3729(a)(1)(C). In addition, he asserts claims for violations of analogous laws in 30 states and the

District of Columbia.[1]

Relator filed this lawsuit on October 8, 2015. He amended his complaint on February 12, 2018, to remove a claim arising under the California Insurance Frauds Prevention Act, CAL. INS. CODE § 1871 *et seq*. On March 13, 2018, the United States declined to intervene in the action. (*See* Notice [26].) So, too, did all thirty states and the District of Columbia. (*See* Order [28].) Thereafter, the court ordered Relator's complaint unsealed. (*See id.*) AbbVie has moved to dismiss Relator's amended complaint. For the following reasons, the motion is granted, but the court will allow Plaintiff leave to amend.

BACKGROUND

The following summary is taken from Relator's amended complaint, whose factual allegations the court accepts as true for present purposes. *See United States ex rel. Berkowitz v. Automation Aids, Inc.*, 896 F.3d 834, 839 (7th Cir. 2018).

Relator's FCA claims concern product support services that AbbVie offers in connection with its prescription drug Humira. Humira is an "injectable drug that treats various autoimmune diseases." (Am. Compl. [20] ¶ 2.) It was "the highest-grossing drug in the world in 2014." (*Id.* ¶ 3.)

Relator holds a bachelor's degree in nursing and has been a registered nurse since 1996. (*Id.* ¶ 16.) From March 2013 to October 2014, he worked in South Florida as a "nurse educator" and "patient ambassador" for AbbVie's Ambassador Program: an "education and support program" for Humira patients. (*Id.* ¶¶ 8, 14-15, 19.) Although Relator was hired by an AbbVie sub-contractor—Quintiles Transactional Holdings, Inc.—he "reported to and worked with personnel at AbbVie, maintained an AbbVie email address, and worked exclusively in connection with . . . Humira." (*Id.* ¶¶ 14-15.)

[1] Relator asserts two claims under Illinois law: one for violations of the Illinois False Claims Act, 740 ILL. COMP. STAT. § 175/1 *et seq*., and one for violations of the Illinois Insurance Frauds Prevention Act, 740 ILL. COMP. STAT. § 92/1 *et seq*.

A. The Ambassador Program

AbbVie's Ambassador Program is limited to patients for whom physicians have prescribed Humira, and whose prescriptions are for purposes that have been approved by the Food and Drug Administration. (*Id.* ¶¶ 40, 56.) "Ambassadors" are registered nurses who serve as representatives for AbbVie. (*See id.* ¶ 53.) They "are primarily tasked with going into patients' homes to discuss the patients' disease states and their treatment with Humira," and "to work with patients directly to enable payment for the drug." (*Id.*) More specifically, Ambassadors train patients on obtaining insurance payment for the drug, self-injecting the drug, and disposing of injection equipment. (*See id.* ¶ 65.) The "initial patient visit" usually takes "an average of one hour" but can take "as many as two-and-a-half" hours. (*Id.* ¶ 92.) Following the initial patient visit, "Ambassadors typically make two additional in-person visits" and thereafter contact patients by telephone. (*Id.* ¶¶ 101-02.)

Relator alleges that Ambassadors spend approximately one third of an initial patient visit "making sure the patient has access to reimbursement or, as needed, free drugs." (*Id.* ¶ 92.) AbbVie, for example, instructs Ambassadors that "they can (and should) be on the phone when patients call [their insurers]" and that they "can (and should) encourage patients to initiate calls to learn about coverage." (*Id.* ¶ 104.) For "Government Payor patients," AbbVie requires Ambassadors "to contact Medicare to determine the patients' payment status: namely, how much the patient must pay in the first couple of months of treatment . . . and at what point the patient's coverage stops during the gap period before coverage resumes." (*Id.* ¶ 105.)[2] After obtaining this information, Ambassadors refer government payor patients to AbbVie's "Patient Assistance Foundation," which "has ample free supply to give patients during their . . . payment gap period." (*Id.* ¶ 107.) Relator alleges that he recalls hearing at an AbbVie national meeting that AbbVie

[2] This gap period occurs under Medicare Part D, a federal program that covers "pharmacy-dispensed outpatient drugs including Humira" in certain circumstances. (*Id.* ¶¶ 7, 35.) The coverage gap period is commonly called the "Donut Hole." (*Id.* ¶¶ 7, 105.)

provided 94,000 free doses to government payor patients in 2013. (*Id.* ¶ 110.) Relator further alleges that "AbbVie management provides information about open enrollment periods for Medicare plans and requires Ambassadors to try to push their patients into plans that maximize reimbursement for Humira." (*Id.* ¶ 111.)

Ambassadors also "visit, or communicate with, doctors' offices to respond to specific questions about specific patients, including if the patient has routed an administrative question to the doctor's office rather than to the Ambassador." (*Id.* ¶ 75.) And Ambassadors encourage "patients to enroll on the website 'MyHumira.'" (*Id.* ¶ 98.) According to Relator, AbbVie uses patient data collected on the website to "target the marketing of Humira" and "focus resources to have maximal return." (*Id.* ¶¶ 98-100.) Similarly, AbbVie identifies "high prescribers of injectable biologics" that "might benefit from receiving visits from Ambassadors" and sends Ambassadors to "tout[] [the program's] benefits to doctors and their staff." (*Id.* ¶ 71-72.) Relator alleges that he himself made "at least four such calls in August 2014 alone." (*Id.* ¶ 72.)

According to Relator, AbbVie "launched [the Ambassador Program] around the time the sales curve for Humira appeared to be flattening." (*Id.* ¶ 52.) The program's true goal, Relator avers, is not patient education and support, but rather "ensur[ing] that patients *start on* and *continue to take* Humira." (*Id.* ¶ 8.) Initially, Ambassadors "focus[ed] on newer patients who may be wavering on whether to take the medicine, and/or for whom payment has not been set up." (*Id.* ¶ 61; *see also id.* ¶ 89 (alleging that "in a material percentage of the time, the patient has *not yet decided whether to fill the prescription*, and thus Ambassadors highly influence the decision to take Humira in the first place"); *id.* ¶ 90 ("Patients frequently told Relator that they likely would not have started on Humira if he had not contacted them."); *id.* ¶¶ 58-60 (alleging that AbbVie "evaluates Ambassadors' performance on prescription-based metrics").) More recently, "AbbVie launched [a] 'low touch' program for patients who already have been taking Humira for longer periods." (*Id.* ¶ 61.) Presumably to ensure that the patients continue to do so, Ambassadors communicated with them by telephone. (*Id.*) Additionally, in or around fall 2014, AbbVie "piloted

'Operation Dakota'": a "program in which prospective Humira patients living in sparsely-populated areas have contact with Ambassadors by telephone or video." (*Id.*) By virtue of Operation Dakota, "no market is beyond the reach of the Ambassador Program." (*Id.*)

The Ambassador Program "has been enormously successful." (*Id.* ¶ 9.) At annual meetings in 2013 and 2014, high-level AbbVie employees told Ambassadors "that until the [program] was initiated, sales of Humira had begun to plateau after its ninth year on the market." (*Id.* ¶ 133.) A graph displayed at one such meeting "compar[ed] where sales were *before* the program and where the sales had gone *as a direct result*" of the program, and "[t]he difference amounted to billions of dollars in sales." (*Id.* ¶ 134-35.) "As of May 2014," approximately 10,000 Humira patients "were supported by an Ambassador." (*Id.* ¶ 131.)

B. The Anti-Kickback Statute

The Anti-Kickback Statute (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)(1), (2); *see* Am. Compl. ¶ 28. A claim that includes items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the False Claims Act. 42 U.S.C. § 1320a-7b(g); *see* Am. Compl. ¶ 33. In other words, when a claim is submitted to government health care programs such as Medicare and Medicaid, and "a kickback [was] involved in the underlying transaction," that claim is "false within the meaning of the federal False Claims Act and State analogs." (Am. Compl. ¶ 142.) To illustrate, when a health care provider submits a claim to Medicare, he or she must certify that the claim complies with all Medicare regulations, including the AKS. (*Health Insurance Claim Form, Form CMS-1500*, CENTERS FOR MEDICARE AND MEDICAID SERVICES (rev. Feb. 1, 2012) (https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/ CMS1500. pdf) (last visited Sept. 30, 2019).) Accordingly, receiving or providing kickbacks to influence referrals for Medicare patients would necessarily require a false statement in the certification form, resulting in an FCA violation. The AKS is aimed at protecting federal health care programs from

"increased costs and abusive practices resulting from provider decisions that are based on self-interest rather than cost, quality of care or necessity of services." *United States v. Patel*, 778 F.3d 607, 612 (7th Cir. 2015) (internal quotation marks omitted).

C. Alleged kickbacks

Relator alleges that the Ambassador Program "consists of kickbacks to doctors in the form of free services and products." (*Id.* ¶ 137.) The kickbacks, Relator alleges, "caused the submission of false claims to federal and state health care programs." (*Id.* at IX; *see id.* ¶¶ 138-154.)

According to Relator, Humira "requires a great deal of non-billable [patient] support from the doctor and/or his or her office." (*Id.* ¶ 65.) Patients need training on obtaining insurance payments for Humira, self-injecting the drug, and discarding injection equipment. (*Id.*) Relator alleges that Ambassadors "take over these functions." (*Id.*) Similarly, doctors' offices receive administrative questions from patients concerning Humira. (*See id.* ¶ 75.) Ambassadors step in and answer these questions. (*See id.*) By serving in these capacities, Relator alleges, Ambassadors "off-load[] the work of [doctors'] office[s], thus providing free and valuable services." (*Id.* ¶ 64.) Stated differently, AbbVie "offer[s] up their Ambassadors to perform general and time-consuming tasks that otherwise must be performed by doctors and their staff . . . ." (*Id.* ¶ 5.) "These extensive free services," Relator alleges, "are kickbacks." (*Id.*; *see also id.* ¶ 53 ("Ambassadors assume several functions of the physicians and administrative functions of their office staff associated with Humira treatment, which offers tremendous value and time saving to physicians and incentivizes them to prescribe Humira").) Indeed, AbbVie's sales representatives "pitch Ambassadors to doctors as free 'extensions of your office.'" (*Id.* ¶¶ 5, 69; *see also id.* ¶ 68 (alleging Humira sales representatives tell doctors that Ambassadors will "take that [patient] call," "take that [patient's] insurance question," "take your concerns about [calls to the office, dealing with billing, disposal] *off the table*").) Relator alleges that "the collective value" of Ambassadors' "nursing visits" and other services "is enormous." (*Id.* ¶ 132.) And he alleges that the

Ambassadors' services influence doctors' decisions to prescribe Humira, including by "reliev[ing] the initial barrier to the sale." (*Id.* ¶¶ 64-65; *see also id.* ¶ 65 (alleging that "[b]efore the Ambassador Program, many physicians were disinclined to prescribe Humira" because it is "very expensive" and "requires a great deal of non-billable support from the doctor and/or his or her office," including the types of training the Ambassadors have stepped in to provide); *id.* ¶ 53 (alleging that Ambassadors' valuable and "time-saving" services "incentivize[] [doctors] to prescribe Humira).)

Separately, Relator alleges that the free drugs provided by AbbVie's Patient Assistance Foundation constitute kickbacks. (*See id.* ¶ 7.) Relator also alleges that Ambassadors provide free materials to doctors' offices—including "Humira travel kits", "Talking Training Pens"[3], pre-printed insurance benefit forms (such as prior authorization forms),[4] and "dedicated Humira terminals" that "print benefit verification forms and other insurance-related documents"—and that these materials, too, constitute kickbacks. (*Id.* ¶¶ 73-74.)

Relator provides information concerning several physicians who have allegedly reaped the benefits of the Ambassador Program. Relator, for example, attended a meeting at Dr. Robert Sarro's office, where Dr. Sarro and his assistant were "persuaded that the Ambassador Program would 'make their lives easier.'" (*Id.* ¶ 76.) Dr. Avelino A. Guiribitey "responded positively to the" pitch that Ambassadors would serve as "extension[s] of [his] office" and "opted to prescribe Humira as a result of the Ambassador Program." (*See id.* ¶¶ 69-70.) Furthermore, "some doctors,

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[3] Neither party defines a "talking training pen." According to AbbVie's Humira website, MyHumira.com, doctors can prescribe a Humira "pen" or syringe. (*See* Excerpt of MyHumira.com, Ex. A to AbbVie Mem. in Supp. of Mot. to Dismiss [58-1], 1.) A "talking training pen" appears to be a device that gives automated instructions to patients on how to inject Humira.

[4] Sometimes, a health insurer or health plan requires a patient to obtain a decision that a prescription drug is medically necessary before the insurer or plan will reimburse for the prescription. *See* HealthCare.gov Glossary, *Preauthorization*, https://www.healthcare.gov/glossary/preauthorization/ (last visited Sept. 30, 2019). This process is sometimes called "prior authorization." Relator's amended complaint implies that some health insurers and plans require prior authorization for Humira.

especially in the competitive South Florida dermatology market for wealthy older patients," have "brag[ged] about the program and impl[ied] it was a service the doctor[s] had arranged for [their] own patients." (*Id.* ¶ 81.) Hollywood Dermatology falls into this category and "[o]ne high-prescribing doctor in that practice was Dr. Eduardo Weiss." (*Id.*) "Other examples of high-prescribing dermatologists who actively have touted the Ambassador Program, and [have] worked especially closely with Ambassadors," include Dr. Francisco Kerdel—an "affiliate of among the highest prescribing" dermatology offices in South Florida—Dr. Tory Sullivan, Dr. Weiss, and Dr. Alejandro Pedrozo. (*Id.* ¶ 82; *see also id.* ¶ 70 (identifying Dr. Pedrozo as a doctor to whom sales representatives pitched the Ambassador Program and alleging that he "dramatically increased" his Humira prescriptions after the pitch); *id.* ¶ 78 (alleging that Ambassadors "influenced [the] prescribing behavior" of Dr. Jerome R. Obed and Dr. Varee N. Poochareon by pitching the program to them at "speaker dinners").)

Finally, Relator alleges that AbbVie has taken active measures to conceal the true nature of the Ambassador Program, and that such conduct "demonstrates AbbVie's reckless or knowing misconduct." (*Id.* ¶ 125.) Specifically, AbbVie "warn[s] Ambassadors not to formally record all the time they spend with doctors" (*id.* ¶ 77); trains Ambassadors to avoid referring to themselves as healthcare providers and to their patients as patients (*id.* ¶ 86-87); instructs Ambassadors "not to refer specifically to Humira in writing up patient visits, despite the fact that Humira is the only reason for their presence in the patient's home" (*id.* ¶ 119); and tells Ambassadors that "if they have a question about what they can permissibly do in the course of their patient interactions," they should call a supervisor rather than put the question in writing (*Id.* ¶ 120). AbbVie has also changed the way it describes Ambassadors; it emphasizes the educational services that Ambassadors provide while downplaying Ambassadors' role in giving medical advice, doing clinical work, and building the Humira brand. (*See id.* ¶¶ 54-55.)

D. Relator's claims

Relator asserts claims against AbbVie and Abbott for knowingly presenting and causing

to be presented to the federal government false or fraudulent claims for payment in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A) (Count I); knowingly making, using, or causing to be made or used, false or fraudulent records or statements material to the payment of false or fraudulent claims, thereby causing false or fraudulent claims for payment to be paid or approved, in violation of § 3729(a)(1)(B) (Count II); knowingly conspiring with each other; Relator's employer, Quintiles; doctors; and other medical professionals to utilize the Ambassador Program in violation of § 3729(a)(1)(A) and (B), which itself violates § 3729(a)(1)(C) (Count III); and violating analogous laws in 30 states and the District of Columbia (Counts V through XXXVI). Relator also asserts a "reverse False Claims Act" claim against AbbVie (but not Abbott)—that is, a claim for knowingly concealing, avoiding, or decreasing an obligation to pay money to the government, in violation of § 3729(a)(1)(G) (Count IV).

LEGAL STANDARD

A motion to dismiss under Rule 12(b)(6) challenges the sufficiency of the complaint. FED. R. CIV. P. 12(b)(6); *see Camasta v. Jos. A. Bank Clothiers, Inc.*, 761 F.3d 732, 736 (7th Cir. 2014). In construing the complaint, the court accepts all well-pleaded facts as true and draws all reasonable inferences in Relator's favor. *Berkowitz*, 896 F.3d at 839. To survive a motion to dismiss, the 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 has facial plausibility 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.*)

Relator's claims arise under the FCA, an anti-fraud statute. Accordingly, the heightened pleading requirements of Federal Rule of Civil Procedure 9(b) apply. *See Berkowitz*, 896 F.3d at 839. Under Rule 9(b), complaints alleging fraud must be pleaded with particularity. This means that a "plaintiff must describe the 'who, what, when, where, and how' of the fraud—'the first

paragraph of any newspaper story.'" *Id.* (quoting *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 853 (7th Cir. 2009)). "What constitutes 'particularity' . . . may depend on the facts of a given case." *Berkowitz*, 896 F.3d at 839. But a plaintiff must "use some . . . means of injecting precision and some measure of substantiation into their allegations of fraud." *Id.* at 840 (quoting *United States ex rel. Presser v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770, 776 (7th Cir. 2016)). "The heightened pleading requirement in fraud cases forces the plaintiff to conduct a careful pretrial investigation to minimize the risk of damage associated with a baseless claim." *Berkowitz*, 896 F.3d at 840 (internal quotation marks omitted).

DISCUSSION

AbbVie moves to dismiss all claims. It argues that Relator has not sufficiently pleaded kickbacks or the submission of any false claim. In addition, it contends that Relator has not sufficiently pleaded scienter under either the Anti-Kickback Statute or the False Claims Act. Even absent these deficiencies, AbbVie maintains, the public disclosure bar precludes Relator's claims. Finally, AbbVie argues that Relator's FCA conspiracy, reverse FCA, and state-law claims fail for the same reasons (and independent ones).

A. Sufficiency of kickback allegations

1. Remuneration

Relator's FCA claims are based on alleged violations of the Anti-Kickback Statute. Although "the AKS itself does not provide for a private right of action, courts within this jurisdiction have recognized FCA claims based on violations of the AKS." *United States ex rel. Kalec v. NuWave Monitoring, LLC*, 84 F. Supp. 3d 793, 806 (N.D. Ill. 2015). As noted, the AKS prohibits soliciting, receiving, offering, or paying "remuneration" in exchange for referring a patient for services that are reimbursed by a federal health care program. 42 U.S.C. § 1320a-7b(b)(1), (2). To state a claim for a violation of the AKS, Relator must allege, with the specificity required by Rule 9(b), that defendants (1) knowingly and willfully; (2) offered, paid, solicited, or received; (3) remuneration; (4) in return for purchasing or ordering any item or service for which payment may

be made under a federal healthcare program. *See Patel*, 778 F.3d at 609; *United States ex rel. Grenadyor v. Ukranian Vill. Pharmacy, Inc.*, 772 F.3d 1102, 1106-07 (7th Cir. 2014); *United States ex rel. Young v. Suburban Homes Physicians*, No. 14-CV-02793, 2017 WL 6625940, at *2 (N.D. Ill. Dec. 28, 2017).

Relator alleges that AbbVie offered or paid "remuneration" in form of goods—namely, free drugs for patients and Humira travel kits, training pens, dedicated terminals, and pre-printed insurance benefit forms (such as Prior Authorization forms) for physicians. (Am. Compl. ¶¶ 7, 73-74.) AbbVie counters that under relevant regulations and guidance from the U.S. Office of the Inspector General (OIG), it was "expressly *allowed*" to provide these goods, meaning that they do not constitute remuneration. (AbbVie Mem. in Supp. of Mot. to Dismiss ("AbbVie Mot.") [58], 11 (emphasis in original) (citing, *inter alia*, OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., MEDICARE & STATE HEALTH CARE PROGRAMS: FRAUD & ABUSE; ELECTRONIC HEALTH RECORDS SAFE HARBOR UNDER THE ANTI-KICKBACK STATUTE, 78 Fed. Reg. 79202-01, 2013 WL 6814651, at *79210 (Dec. 27, 2013) (to be codified at 42 C.F.R. pt. 1001) ("OIG Dec. 2013 Final Rule") (laboratory would not violate the AKS by providing free computer to physician if the computer "could be used only, for example, to print out test results produced by the laboratory company" and therefore provided no "independent value" to physician); OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., PUBLICATION OF OIG SPECIAL ADVISORY BULLETIN ON PATIENT ASSISTANCE PROGRAMS FOR MEDICARE PART D ENROLLEES, 70 Fed. Reg. 70623-03, 2005 WL 3107149 (Nov. 22, 2005) (pharmaceutical manufacturers can lawfully provide free drugs to patients under some circumstances); OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., OIG ADVISORY OPINION NO. 12-10, at 2 (Aug. 23, 2012), *available at https://oig.hhs.gov /fraud/docs/advisoryopinions/2012/AdvOpn12-10.pdf* (last visited Sept. 30, 2019) (providing free services in connection with obtaining insurers' pre-authorization for medical procedures—including completion of prior authorization paperwork—would not violate the AKS so long as, for example, provider of such services has "no ancillary agreements with referring

physicians that would reward referrals to" provider).) AbbVie's cited OIG regulations and guidelines do not expressly discuss the implications under the AKS of providing travel kits and training pens to patients, but AbbVie contends that the cited language is broad enough to cover such goods. (*See* AbbVie Mot. 12.) Relator does not respond to AbbVie's arguments and therefore concedes the point.

As discussed above, Relator also alleges that AbbVie offered or paid "remuneration" by having Ambassadors provide Humira-related services to patients and physicians—including training on self-injections, assistance with insurance coverage, and answering administrative questions that patients originally relayed to doctors' offices. (Am. Comp. ¶¶ 5, 53, 64-65, 68-69, 75, 132, 137.) AbbVie argues that Relator has not sufficiently pleaded, nor could he, that these services constitute remuneration under the AKS. As explained below, the court agrees that Relator's complaint fails to allege with particularity how the Ambassadors' free services amount to illegal remuneration.

Both parties cite OIG guidance concerning services that pharmaceutical manufacturers offer in connection with their products. The court interprets the parties' reliance on the guidance as a concession that it is authoritative for purposes of this motion, even though administrative guidance is not binding law. In 2003, OIG discussed "billing assistance tailored to the purchased products, reimbursement consultation, and other programs specifically tied to support of the purchased product." OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., OIG COMPLIANCE PROGRAM GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS, 68 Fed. Reg. 23731-01, 2003 WL 2010428, at *23735 (May 5, 2003) ("OIG May 2003 Notice"). OIG stated that "[s]tanding alone, services that have no substantial independent value to the purchaser may not implicate the anti-kickback statute." *Id.* But there are caveats. For example:

> [I]f a manufacturer provides a service having no independent value (such as limited reimbursement support services in connection with its own products) in tandem with another service or program that confers a benefit on a referring provider (such as a reimbursement guarantee that eliminates normal financial risks), the arrangement would raise kickback concerns.

Id. Additionally, OIG stated that if a pharmaceutical manufacturer offers "anything of value to a physician who might prescribe [its] product, the manufacturer should examine whether it is providing a valuable tangible benefit . . . with the intent to induce or reward referrals." *Id.* at *23737.[5] The OIG further illustrated this concept:

> [I]f goods or services provided by the manufacturer eliminate an expense that the physician would have otherwise incurred (i.e., have independent value to the physician), or if items or services are sold to a physician at less than their fair market value, the arrangement may be problematic if the arrangement is tied directly or indirectly to the generation of federal health care program business for the manufacturer.

Id. at *23737. And in 2013, the OIG reiterated that it "ha[s] long distinguished between free items and services that are integrally related to the offering provider's or supplier's services and those that are not." OIG Dec. 2013 Final Rule, 78 Fed. Reg. 79202-01, 2013 WL 6814651, at *79210.

Neither party has cited decisions from the Seventh Circuit (or any other federal court of appeals) that interpret this guidance, and the court has found none. Thus, the court will hew closely to the guidance in determining whether Relator has alleged illegal remunerations with particularity. Specifically, the court will assess whether Relator has alleged that Ambassadors offered services "integrally related" to Humira "*in tandem with* another service or program that confers a benefit on a referring provider." *Id.*; OIG May 2003 Notice, 68 Fed. Reg. 23731-01, 2003 WL 2010428, at *23735 (emphasis added). The court will also assess whether Relator alleges with particularity that Humira-related "goods or services provided by [AbbVie] eliminate an expense that the physician would have otherwise incurred (i.e., have independent value to the physician)." OIG May 2003 Notice, 68 Fed. Reg. 23731-01, 2003 WL 2010428, at *23737; *see*

[5] Relator cites a similar OIG notice, but it concerns "compensation arrangements" between hospitals and physicians and therefore has less relevance here. (*See* Relator Opp. 8 (citing OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., OIG SUPPLEMENTAL COMPLIANCE PROGRAM GUIDANCE FOR HOSPITALS, 70 Fed. Reg. 4858-01, 2005 WL 192293, at *4866 (Jan. 31, 2005) (stating that in some circumstances, arrangements that "relieve physicians of financial obligations they would otherwise incur" may give rise to an inference "that the remuneration may be in exchange for generating business").)

also United States ex rel. Forney v. Medtronic, Inc., Civil Action No. 15-6264, 2017 WL 2653568, at *4 (E.D. Pa. June 19, 2017) ("[P]roduct support services are permissible" under the AKS "unless they are not tied to the product purchased, or if they provide some substantial independent value to the purchaser.").

Applying this framework, the court has little trouble concluding that Relator has alleged only the provision of Humira-related services. In other words, the pleadings are devoid of allegations that AbbVie provided non-Humira-related goods or services "in tandem with" Humira-related services, 68 Fed. Reg. 23731-01, 2003 WL 2010428, at *23735, such as free meals or travel. *See United States ex rel. Witkin v. Medronic*, 189 F. Supp. 3d 259, 269, 271 (D. Mass. 2016) (allegations that defendant provided "collateral benefits" with its product support services, such as free sample devices, meals, travel, and accommodations for conferences, sufficiently pleaded illegal remunerations). By Relator's own account, Ambassadors served patients by training them on how to inject Humira, showing them how to dispose of injection equipment, helping them obtain insurance coverage for Humira, and helping them obtain free Humira during insurance coverage gaps. Ambassadors served doctors by providing these services to patients, giving doctors' offices pre-completed insurance authorization forms for Humira, and answering Humira patients' administrative questions. In his briefing, Relator contends that these services were "not limited solely to the use of Humira," (Relator Opp. to AbbVie Mot. ("Relator Opp.") [60], 13), but the only allegations in his complaint that he cites are paragraphs that undisputedly concern Humira. (*See id.* (citing Am. Compl. ¶ 5, which refers to "patient management, billing communications, and other functions such as waste disposal" but does not explain how these "functions" could possibly relate to anything other than Humira); *id.* (citing Am. Compl. ¶ 65, which refers specifically to Humira-related training).) In adjudicating AbbVie's motion to dismiss, the court can consider only the pleadings; it cannot "consider allegations raised for the first time in [Relator]'s opposition brief." *Kalec*, 84 F. Supp. 3d at 803 (citing *Gen. Elec. Capital Corp. v. Lease Resolution Corp.*, 128 F.3d 1074, 1080 (7th Cir. 1997)).

Nor has Relator sufficiently pleaded that Humira-related "goods or services provided by [AbbVie] eliminate an expense that the physician would have otherwise incurred (i.e., have independent value to the physician)." 68 Fed. Reg. 23731-01, 2003 WL 2010428, at *23737. Relator alleges that when physicians prescribe Humira, they must provide "a great deal of non-billable [patient] support" for the drug. (Am. Compl. ¶ 65; *see also* Relator Opp. 2.) According to Relator, Ambassadors "take over" that support role—in other words, "perform general and time-consuming tasks that otherwise must be performed by doctors and their staff"—by providing the aforementioned services to patients and doctors' offices. (Am. Compl. ¶¶ 5, 65, 75; *see also id.* ¶¶ 64, 68-69 (alleging that Ambassadors "off-load[] the work of [doctors'] office[s]", serve as "extensions" of doctors' offices, and take patients' insurance, billing, and drug disposal concerns "off the table").) In so doing, Relator alleges, Ambassadors confer "tremendous value" on physicians. (*Id.* ¶ 53; *see also* Relator Opp. 1, 4.)

These allegations do not satisfy Rule 9(b). First, Relator pleads no factual content to support the conclusory allegation that physicians and their staff must "otherwise . . . perform[]" the services just discussed. (Am. Compl. ¶ 5.) In opposing AbbVie's motion to dismiss, Relator argues that "physicians and their staff are responsible for [the services] when those physicians do not prescribe Humira." (Relator Opp. 10.) But these allegations appear nowhere in Relator's complaint, which is the focus of the court's analysis. *See Kalec*, 84 F. Supp. 3d at 803. More critically, OIG guidance provides that "support services" a pharmaceutical manufacturer offers "in connection with the sale of its own products"—including "billing assistance tailored to the purchased products" and "reimbursement consultation"—do not, on their own, "implicate the anti-kickback statute." OIG May 2003 Notice, 68 Fed. Reg. 23731-01, 2003 WL 2010428, at *23735; *see also Forney*, 2017 WL 2653568, at *4 (providing technical support with a pharmaceutical product "might induce physicians to purchase [defendant's] products, but only because they are better-supported products than competing products"). Relator alleges that AbbVie provided these exact types of support services—and no others.

Relator argues that *Forney* is distinguishable because there, "relator failed to explain *how* a free support service" amounted to an illegal remuneration (Relator Opp. 12-13). According to Relator, he has provided "significant detail" concerning how Ambassadors' services constitute remunerations. (*Id.* at 13.) The court disagrees. Although Relator has offered details concerning the type of services Ambassadors provide, he has not sufficiently explained how the services provided substantial independent value—as opposed to "permissible product support"—for physicians. *Forney,* 2017 WL 2653568, at *4. The United States has expressed concerns similar to this court's in a pending motion to dismiss a *qui tam* action concerning free nurse services and reimbursement support services. *See* United States Mot. to Dismiss Relator's Second Am. Compl., *United States ex rel. Health Choice Grp., LLC v. Bayer Corp.*, No. 5:17-CV-126-RWS-CMC, Dkt. No. 116 (E.D. Tex. Dec. 17, 2018) (*Bayer*). Specifically, in its motion to dismiss, the government stated that "federal healthcare programs have a strong interest in ensuring that . . . patients have access to basic product support relating to" appropriately prescribed medication, such as free "instructions on how to properly inject or store their medication"). *Id.* at 16. After an "extensive investigation" of relators' allegations, the government "concluded that [they] conflict with [these] important policy and enforcement prerogatives . . . ." *Id.* at 14, 16.

The government's position in *Bayer* has no application here, Relator argues, because a "professional relator" brought that case—along with ten others—and "us[ed] the same complaint template" for each. (Relator Sur-Reply [70-1], 1.) Whatever significance those circumstances might have in the abstract, they are less weighty in light of the similarity of the *Bayer* allegations to this case, and the fact that the government investigated the substance of those allegations. *See* United States Mot. to Dismiss Relator's Second Am. Compl. at 3 (stating that the free nurse services at issue included "visiting patients at home to provide instruction on how to properly administer their newly-prescribed medications," and that the free reimbursement support services at issue included "helping physicians complete insurance documents, such as benefit verifications and prior authorization forms"). Tellingly, before the United States moved to dismiss *Bayer*,

Relator argued that the alleged "nurse educator services" in *Bayer* are "similar to those at issue here." (Relator Opp. 11 (arguing that *Bayer* is "on point").) Relator's efforts to argue otherwise now are not credible.

No more persuasive are the cases Relator highlights as contrary authority. In one such case, relator alleged that defendant's provision of free products conferred independent value on physicians because the products effectively subsidized surgical and prescribing costs that physicians would otherwise have had to incur. *See United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 807-09 (S.D.N.Y. 2017) (*Wood*) (determining, in relevant part, that relator's allegations raised a question of fact "not suitable for resolution at the motion to dismiss stage" concerning the provision of illegal remunerations under the AKS), *rev'd and remanded on other grounds*, 889 F.3d 163 (2d Cir. 2018). The relator in *Wood* also alleged that defendant provided the free products to physicians "who agreed to prescribe or already prescribed significant quantities of" defendant's drugs. *Id.* at 807. Here, Relator's allegations do not concern free products, but rather product-related support services that OIG guidance characterizes as permissible. And unlike in *Wood*, Relator does not allege a quid pro quo agreement between AbbVie and doctors.. Finally, Relator alleges only in a conclusory manner that the Ambassadors' services eliminated costs that doctors would otherwise have had to cover. *Compare Wood*, 246 F. Supp. at 807 (alleging that defendant "subsidized surgical costs" that physicians "would otherwise have had to" pay by providing free drugs that Medicare does not reimburse, but that are necessary for a common surgery Medicare does reimburse).

In *Witkin*, 189 F. Supp. 3d at 269-70, and *United States ex rel. Boise v. Cephalon, Inc.*, Civil Action No. 08-287, 2015 WL 1724572, at *11-12 (E.D. Pa. Apr. 15, 2015), also cited by Relator, the courts determined that allegations concerning reimbursement support services (as opposed to provision of free collateral goods) plausibly pleaded illegal remunerations. *Witkin* and *Cephalon* do not influence the outcome here. In *Witkin*, relator alleged that defendant taught doctors how to bill Medicare for product support services that defendant provided to the doctors

for free. *Witkin*, 189 F. Supp. at 269-70. Similarly, in *Cephalon*, relator alleged that defendant "suppli[ed] physicians with 'front office' personnel in the form of Cephalon sales representatives who were instructed to provide free services to ensure that the physicians obtained reimbursement from Medicare and Medicaid without having to pay their own staff to perform the work." *Cephalon*, 2015 WL 1724572, at *11. Here, Relator does not allege that by virtue of the Ambassador Program, doctors could obtain payouts from government health care programs for services that they did not provide.

Even assuming that offering free product support or reimbursement support services could violate the AKS merely because it saves physicians money[6]—a premise that appears inconsistent with the OIG guidance discussed above—Relator does not plead with the particularity required by Rule 9(b) that AbbVie did so here. Though he names doctors that benefitted from the Ambassador Program generally, Relator does not allege that any doctors (let alone any specific doctors) reduced their expenses or downsized their own staff as a result of Ambassadors' support services. Notably, even before the United States moved to dismiss *Bayer*, the court determined based on this very deficiency that relators had not sufficiently pleaded illegal remunerations under Rule 9(b). *See Health Choice Grp., LLC v. Bayer Corp.*, No. 5:17-CV-126-RWS-CMC, 2018 WL 3637381, at *40 (E.D. Tex. June 29, 2018) (Craven, M.J.) (*Bayer*), *report and recommendation adopted*, No. 5:17-CV-126-RWS-CMC, 2018 WL 3630042 (E.D. Tex. July 31, 2018 (although allegations concerning free, product-specific nurse and reimbursement support services were sufficient under Rule 12(b)(6), they failed under Rule 9(b), including because relators did not allege that the services allowed any single doctor to eliminate administrative staff positions or "increase patient visits", nor did relators identify any single doctor who "actually received

[6] *See Witkin*, 189 F. Supp. at 270 ("[E]ven a physician *legitimately* billing Medicare for properly-supervised iPro clinic services has received remuneration when he otherwise would have had to expend additional money or time to administer the services himself or pay staff to do so."); *see also* Relator Opp. 1, 4 (alleging that Ambassadors "saved time and money for health care professionals that prescribed Humira").

'substantial value'" as a result of the services).

Because Relator has not pleaded illegal remuneration under the AKS, and his FCA claims are premised on alleged AKS violations, Relator's FCA claims necessarily fail. For the sake of completeness, however, the court explains why Relator's complaint is deficient in other respects.

2. Submission of false claims

i. Linking kickbacks to an actual false claim

AbbVie argues that Relator does not allege sufficient detail to link the alleged kickbacks to any false claim actually submitted to the government. The FCA prohibits knowingly presenting, or causing to be presented to the government, a false or fraudulent claim for payment, 31 U.S.C. § 3729(a)(1)(A); knowingly making or using a false record or statement that is material to a false or fraudulent claim paid by the government, § 3729(a)(1)(B); or conspiring to do either, § 3729(a)(1)(C). In alleging a violation of the FCA, a plaintiff must link specific allegations of fraud or deceit—in this case, kickbacks—to claims for government payment. *See United States ex rel. Garst v. Lockheed-Martin Corp.*, 328 F.3d 374, 378 (7th Cir. 2003) (dismissing complaint that "fail[ed] to link [specific allegations of deceit] to any claim for payment"). A plaintiff cannot allege this link by merely describing fraudulent or unlawful activity. Rather, he or she must allege the submission of a fraudulent claim. *See Berkowitz*, 896 F.3d at 841 (affirming dismissal of FCA claims where "the complaint fail[ed] to allege . . . any specific facts demonstrating what occurred at the individualized transactional level for each defendant"); *Grenadyor*, 772 F.3d at 1107 ("Violating a regulation is not synonymous with filing a false claim."); *Garst*, 328 F.3d at 378; *Singer v. Progressive Care,* SC, 202 F. Supp. 3d 815, 825 (N.D. Ill. 2016) ("In the FCA context, the particularity requirement means that a relator must plead at least some actual examples of false claims."); *United States ex rel. Soulias v. Nw. Univ.*, No. 10 C 7233, 2013 WL 3275839, at *3 (N.D. Ill. June 27, 2013) (similar) (collecting cases).

Where a relator's FCA claim depends on violations of the Anti-Kickback statute, the relator must identify a link between the alleged kickback and a claim for government payment. *See*

Grenadyor, 772 F.3d at 1107; *Kalec*, 84 F. Supp. 3d at 806 (complaint failed to state an FCA claim premised on an AKS violation where it did not provide any "representative examples" of "fraudulent transaction[s]"). "[S]uch an allegation necessarily requires a relator to name 'a specific patient referred in exchange for a kickback, and allege that a claim was submitted to Medicare for that patient.'" *United States ex rel. Stop Ill. Mktg. Fraud, LLC v. Addus HomeCare Corp.*, No. 13 C 9059, 2018 WL 1411124, at *4 (N.D. Ill. Mar. 21, 2018) ("*Addus II*") (quoting *United States ex rel. Stop Ill. Mktg. Fraud, LLC v. Addus HomeCare Corp.*, No. 13 CV 9059, 2017 WL 467673, at *10 (N.D. Ill. Feb. 3, 2017) ("*Addus I*")); *see Grenadyor*, 772 F.3d at 1107 ("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 . . . ."); *Kalec*, 84 F. Supp. 3d at 806-07 (where relators "fail[ed] to identify a single patient that was referred by" a physician in exchange for alleged kickbacks, they "fail[ed] to specifically link the alleged kickback scheme to an actual claim that was submitted to Medicare" (citing *Grenadyor*, 772 F.3d at 1107)).

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. Accordingly, Relator does not "specifically link the alleged kickback scheme to an actual claim that was submitted to" a government health care payor. *Kalec*, 84 F. Supp. 3d at 806-07; *see Grenadyor*, 772 F.3d at 1107. Therefore, he does not satisfy the pleading requirements of Rule 9(b).

Relator insists that the law does not require him to identify a specific patient referred in exchange for a kickback, nor to allege that a claim was submitted to the government for that patient (Relator Opp. 14), but the court is not persuaded. Relator, for example, contends that the court in *Grenadyor* imposed these requirements only because the alleged fraud was aimed at patients rather than doctors, meaning that without the name of a patient who received a kickback, defendant would not be "on notice of the claims against it . . . ." (*Id.* at 17.) Patient-specific

information is not necessary here, Relator contends, because AbbVie's scheme was aimed at doctors. (*See id.*) *Grenadyor* did not limit its conclusion to circumstances in which the alleged fraud targets patients, however. 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 "[v]iolat[ion] [of] a regulation." *Grenadyor*, 772 F.3d at 1107; *see also id.* (citing, *inter alia*, *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 504 (6th Cir. 2007) (holding that "pleading an actual false claim with particularity is an indispensable element of a complaint that alleges a FCA violation in compliance with Rule 9(b)")). In fact, Relator himself admits that a plaintiff asserting an FCA claim must allege "representative examples" of fraudulent transactions. (Relator Opp. 14.)

Other courts, following *Grenadyor*, have required that relators allege a connection between a kickback, a patient, and a submitted claim even where defendants aimed their alleged fraud at doctors. *See, e.g.*, *Kalec*, 84 F. Supp. 3d at 806-07; *Addus II*, 2018 WL 1411124, at *4. Relator argues that these cases were wrongly decided, but his cited authority for that proposition does not support it. (*See* Relator Opp. 18 (citing *Goldberg v. Rush Univ. Med. Ctr.*, 929 F. Supp. 2d 807 (N.D. Ill. 2013) and *United States ex rel. Gear v. Emergency Med. Assocs. of Ill.*, No. 00 C 1046, 2004 WL 1433601 (N.D. Ill. June 25, 2004)).) In *Goldberg*, the complaint named doctors and entities that allegedly submitted false statements but omitted "specific patient names to protect confidentiality." 929 F. Supp. 2d at 819-20. Here, Relator does not even suggest that he is aware of claims submitted for specific patients. In *Gear*, the FCA claims were not based on violations of the AKS. *See generally* 2004 WL 1433601. The alleged fraud had nothing to do with referring patients for services or prescribing drugs to patients in exchange for kickbacks. Rather, it 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. *See id.* at *6. *Goldberg* and *Gear*, moreover, both predate *Grenadyor*.

Relator also suggests that the court in *Kalec* dismissed the relevant claim not because relators failed to identify a specific patient, but rather because they failed to offer *any* "reliable indicia that a claim was submitted as a result of the scheme." (Relator Opp. 18 n.11.) Relator may be correct that the *Kalec* complaint was deficient in other ways, as well, but the court's language was clear: it dismissed the claim because relators "fail[ed] to identify a single patient that was referred" by the doctor who allegedly received kickbacks, and "[a]s a result, [relators] fail[ed] to specifically link the alleged kickback scheme to an actual claim that was submitted to Medicare." *Kalec*, 84 F. Supp. 3d at 807.

In arguing that he need not identify a specific patient associated with a kickback and a submitted claim, Relator also contends that courts in this district apply Rule 9(b) flexibly—meaning that they allow relators to rely on reasonable inferences that a false claim was submitted to the government, and thus excuse relators from producing invoices, bills, or accompanying details at the pleading stage. (Relator Opp. at 14-15.) Indeed, the Seventh Circuit has recognized that a relator may not always be in a position to obtain information concerning specific claims submitted to the government, and Rule 9(b)'s requirements may be relaxed in this circumstance. *See, e.g.*, *Lusby*, 570 F.3d at 853-54; *see also Berkowitz*, 896 F.3d at 841. Under this relaxed standard, relators are entitled to rely on reasonable inferences that false claims were, in fact, submitted, and need not "present, or even include allegations about, a specific document or bill." *Presser*, 836 F.3d at 777-78; *see also Berkowitz*, 896 F.3d at 841; *Lusby*, 570 F.3d at 853-54; *Goldberg*, 929 F. Supp. 2d at 818. But as the Seventh Circuit has acknowledged, pleadings lacking such detail have satisfied Rule 9(b) only where "the alleged facts *necessarily* led one to the conclusion that the defendant had presented claims to the Government." *Presser*, 836 F.3d at 778 (emphasis added); *United States ex rel. Derrick v. Roche Diagnostics Corp.*, 318 F. Supp. 3d 1106, 1112-13 (N.D. Ill. 2018) (citing *Presser* for same); *see also Berkowitz*, 896 F.3d at 841 (even when the Seventh Circuit applies the "relaxed" Rule 9(b) standard, "the relator must still describe the predicate acts with some specificity to inject 'precision and some measure of substantiation' into

his allegations of fraud" (quoting *Presser*, 836 F.3d at 776)).

Lusby—which Relator cites in arguing that this court should apply Rule 9(b) with flexibility (*see* Relator Opp. 14-15)—was a case in which the allegations "necessarily" led to the conclusion that defendants submitted a false claim to the government. *See Presser*, 836 F.3d at 777-78 (noting that in *Lusby*, the plaintiff described "parts that were shipped to the Government, noted that a contract *required* his employer to certify the parts in order to receive payment, and stated that payment was received," and lacked only "an invoice showing a specific request for payment"). Whether the same can be said about Relator's allegations in this case is addressed below.

ii. Whether the allegations "necessarily" create the inference that a false claim was submitted

Because Relator here has not alleged that he lacked access to claim information, he is not entitled to a relaxed application of Rule 9(b). *See, e.g.*, *Berkowitz*, 896 F.3d at 841. Moreover, his complaint would not pass muster even under a relaxed application because his allegations do not "necessarily" create the inference that a false claim was submitted to the government. *Presser*, 836 F.3d at 778. Indeed, the allegations do not even provide "reliable indicia" that false claims were submitted—the standard that Relator advocates. (*See, e.g.*, Relator Opp. 18 n.11.) For example, although Relator names specific, high-prescribing doctors who used and touted the Ambassador Program—and alleges that some of them prescribed more Humira as a result of the Program—Relator does not allege that any of the doctors ever prescribed Humira to Medicare, Medicaid, or other government payor patients. Relator's allegations concerning specific doctors, therefore, do not suggest that those doctors, independently or through AbbVie, necessarily submitted false claims to the government. Relator's allegations that Ambassadors helped government payor patients obtain insurance coverage for Humira do not "reliably" or "necessarily" suggest that false claims were submitted for Humira, either. Specifically, they provide no plausible basis for the necessary antecedent conclusion: that doctors prescribed Humira to government payor patients in exchange for the alleged kickbacks. Put another way, the allegations just as

easily allow for an inference that doctors prescribed Humira to government payor patients because they thought the drug was medically necessary. The same is true of Relator's allegations that AbbVie focused resources on government payor Humira patients; provided information concerning Medicare open enrollment periods; and provided 94,000 free Humira doses to government payor patients in 2013.

In addition to highlighting the allegations just discussed, Relator argues that its complaint creates an inference that false claims were necessarily submitted by explaining in general the process through which reimbursement claims are submitted to government payors. (*See* Relator Opp. 16 (citing Am. Compl. ¶¶ 41, 44-48, 143).) Explaining how any person or entity could hypothetically submit false claims does not suggest that AbbVie necessarily did so as a result of the alleged kickback scheme, however. Finally, Relator contends that AbbVie sought to "ensure" the submission of false claims by providing reimbursement support services, and that the "design" of AbbVie's kickback scheme therefore creates a "strong inference" that false claims were necessarily submitted. (Relator Opp. 16.) This argument is unconvincing for each of the reasons just discussed. In the case that Relator cites for this proposition, moreover, the kickback scheme included paying specific doctors to "facilitate falsified prior authorization requests in order to obtain reimbursement" for prescriptions that payors were hesitant to cover, and helping doctors submit the falsified reimbursement requests. *Cephalon*, 2015 WL 1724572, at *4, *11. Relator here does not allege such a direct connection between the alleged kickbacks and the false claims. Overall, the facts Relator alleges do not "necessarily," or even reliably, "le[ad] one to the conclusion that [AbbVie] presented claims to the Government." *Presser*, 836 F.3d at 778.

iii. Sufficiency of allegations concerning nationwide fraud

Relator's complaint also fails to satisfy Rule 9(b) to the extent it alleges nationwide fraud. Relator is correct that he need not allege the exact time or specific location that a fraudulent claim was transmitted, nor specific details concerning every false claim allegedly submitted over multiple years. (Relator Opp. 19 (citing, *inter alia*, *United States ex rel. Oughatiyan v. IPC The*

Hospitalist Co., No. 09 C 5418, 2015 WL 718345, at *5 (N.D. Ill. Feb. 17, 2015)).) Relator cannot "ask[] the court to infer" that the fraud occurred nationwide based on allegations concerning only South Florida, however. *Addus II*, 2018 WL 1411124, at *6; *see also Grenadyor*, 772 F.3d at 1108 (dismissing complaint where, among other things, relator failed to allege how he "obtained . . . information about a large number of pharmacies scattered over a number of states" when he "work[ed] for just one of the defendant pharmacies"). Relator does allege that AbbVie expanded the Ambassador Program to "sparsely-populated areas" in 2014 through the"Operation Dakota" initiative. (Am. Compl. ¶ 61.) And he alleges that at national sales meetings, AbbVie executives announced that the Ambassador Program boosted Humira's overall sales. But the court cannot infer from these allegations that the alleged fraud took place in 30 states and the District of Columbia. If Relator amends his complaint, he must provide more detail to support this inference.

3. Scienter

To state an FCA claim based on an AKS violation, a plaintiff must allege that the defendant acted with the requisite scienter under the AKS: a "knowing[] and willful[]" violation. 42 U.S.C. § 1320a-7b(b)(1), (2); *Young*, 2017 WL 6625940, at *2. Courts in the Seventh Circuit have interpreted "knowingly and willfully" in this context to mean that defendant "intended to engage in conduct that he knew was wrongful." *United States v. Patel*, 17 F. Supp. 3d 814, 824 (N.D. Ill. 2014), *aff'd*, 778 F.3d 607 (7th Cir. 2015); *see also, e.g.*, *United States v. Williams*, 218 F. Supp. 3d 730, 736 (N.D. Ill. 2016) (same). Defendant need not have been "aware of the specific statutory provisions that he is alleged to have violated," however. *Patel*, 17 F. Supp. 3d at 824; 42 U.S.C. § 1320a-7b(h). And although the circumstances constituting fraud must be pleaded with particularity, a defendant's "[m]alice, intent, knowledge, and other conditions of . . . mind may be alleged generally." FED. R. CIV. P. 9(b); *see Presser*, 836 F.3d at 781 n.29. The law nonetheless requires a relator to allege facts supporting an inference that defendant intended to act in a way it knew was wrongful. *See Patel*, 17 F. Supp. 3d at 824. AbbVie contends that

Relator has not done so here.

Relator provides no response to this argument[7] and the court agrees that Relator has not sufficiently pleaded scienter for purposes of the AKS. For example, in responding to AbbVie's arguments concerning FCA scienter, Relator states that his complaint "does not contain a single allegation that AbbVie thought its program was permissible." (Relator Opp. 21.) As AbbVie points out, Relator's burden is to allege facts supporting an inference that AbbVie thought the Ambassador Program was *impermissible*. (AbbVie Reply [69], 10.) Relator also alleges that a pharmaceutical company can violate the AKS by "provid[ing] extensive valuable products or services to procure use of their drugs," or paying remuneration "purposefully to induce or reward referrals or items or services payable by a Federal healthcare program." (Am. Comp. ¶¶ 29-31.) Relator also alleges that AbbVie signed a Corporate Integrity Agreement (CIA) with the U.S. Office of the Solicitor General in 2012, and that the agreement required AbbVie to comply with the AKS. (*See id.* ¶¶ 122-30.) But as discussed above, OIG guidance recognizes that a pharmaceutical company can provide product and reimbursement support services without violating the law. Relator, moreover, offers no basis for an assumption that the CIA addressed remunerations specifically. Thus, the court cannot reasonably infer from the allegations in paragraphs 29-31 or 122-30 of Relator's complaint that AbbVie (1) knew the Ambassador Program was unlawful and (2) implemented the program despite that knowledge. *See Patel*, 17 F. Supp. 3d at 824.

Nor can the court draw this inference based on Relator's allegations that AbbVie took pains to paper over the true nature of the Ambassador Program. This is because it is unclear whether the alleged cover-up efforts have any relation to the services alleged to constitute illegal remunerations in this case. (*See* Am. Compl. ¶¶ 54-55, 77, 86-87, 119, 120, 125 (alleging that AbbVie sought to downplay Ambassadors' role as healthcare providers and ensure they were not

[7] He responds only to the argument that he has not sufficiently pleaded scienter under the FCA.

perceived as sales representatives; warned Ambassadors not to document all time they spent with doctors; instructed Ambassadors not to mention Humira in write-ups concerning patient visits; and instructed Ambassadors to call supervisors about questions concerning "what they [could] permissibly do in the course of their patient interactions," rather than put those questions in writing).) Even viewing these allegations in the light most favorable to Relator, AbbVie's Humira website dispels any inference that AbbVie was trying to conceal the services that Relator contends violate the AKS; the website openly advertises these services. (*See, e.g.*, Excerpt of MyHumira.com (advertising free, at-home injection assistance from myHumira nurses; free Humira pen and syringe disposal service; free, on-call nurses "even when your doctor's office is closed"; and a toll-free number for assistance "if you cannot afford your medication").) In these circumstances, the court cannot infer from Relator's allegations that AbbVie acted "knowingly and willfully." 42 U.S.C. § 1320a-7b(b)(1), (2).

B. FCA scienter

AbbVie argues that, independent of the AKS, Relator has not pleaded—and cannot plead—that AbbVie acted with the requisite scienter under the FCA. (AbbVie Mot. 14.) To violate the FCA, a person must act "knowingly." *See, e.g.* 31 U.S.C. § 3729(a)(1)(A) (imposing liability where a person "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval"). The FCA's "scienter requirement defines 'knowing' and 'knowingly' to mean that a person has 'actual knowledge of the information,' 'acts in deliberate ignorance of the truth or falsity of the information,' or 'acts in reckless disregard of the truth or falsity of the information.'" *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016) (quoting 31 U.S.C. § 3729(b)(1)(A)); *see also Berkowitz*, 896 F.3d at 840 (same). Because Relator's FCA claims depend entirely on the assertion that AbbVie violated the AKS—and because Relator has failed to state a claim for an AKS violation—the court need not address

whether Relator's complaint sufficiently pleads scienter under the FCA.[8] The court notes that Relator's complaint likely fails in this regard, however. As already discussed, Relator's allegations do not support an inference that AbbVie acted with actual knowledge of wrongdoing. And Relator makes no effort to argue how the same allegations would support an inference that AbbVie acted with deliberate indifference or reckless disregard.

C. Public disclosure bar

AbbVie argues that Relator's claims must be dismissed under the FCA's public disclosure bar, which requires a court to "dismiss an [FCA] action . . . if substantially the same allegations or transactions as alleged in the action . . . were publicly disclosed . . . unless . . . the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4)(A). Congress enacted the public disclosure bar "to strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits . . . ." *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 294-95 (2010). The court has already determined for independent reasons that Relator's FCA claims must be dismissed, and if Relator files an amended complaint, it will likely contain new facts that could affect the court's analysis of the public disclosure bar. Accordingly, the court declines to address at this time whether the public

[8] Accordingly, at this time, the court declines to address whether the Supreme Court's decision in *Safeco Ins. Co. of America v. Burr*, 551 U.S. 47 (2007), which concerned the Fair Credit Reporting Act's scienter requirement, applies equally to the FCA's scienter requirement. (*See* AbbVie Mot. 16-17 (arguing that under *Safeco*, if the court determines that AbbVie acted according to an "objectively reasonable" interpretation of the AKS, the court "must dismiss unless [Relator] adequately alleges that [AbbVie] 'had the benefit of guidance from the courts of appeals or the [relevant agency] that might have warned it away from the view it took'" (quoting *Safeco*, 551 U.S. at 70 & n.20)); United States States Stat. of Interest in Resp. to AbbVie Mot. to Dismiss [61], 7 (maintaining that *Safeco* does not apply, and that the court should "reject [AbbVie's] attempt to foreclose a finding of scienter whenever a defendant can point to an 'objectively reasonable' interpretation that played no role in the defendant's actual conduct, and instead reaffirm the principle that knowledge turns on the defendant's mindset at the time of the challenged conduct" (citing *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1933 (2016) (holding that "[t]he subjective willfulness of a patent infringer, intentional or knowing, may warrant enhanced damages, without regard to whether his infringement was objectively reckless," and noting that "culpability is generally measured against the knowledge of the actor at the time of the challenged conduct")).)

disclosure bar requires dismissal.[9]

D. FCA conspiracy claim

AbbVie argues that Relator has failed to state a claim for conspiracy to violate the FCA. The court agrees. To adequately plead an FCA conspiracy claim, a plaintiff must allege (1) that the defendants "had an agreement . . . to defraud the government by getting a false or fraudulent claim allowed or paid; and (2) that the [d]efendants did so for the purpose of obtaining or aiding to obtain payment from the government or approval of a claim against the government[.]" *Addus I*, 2017 WL 467673, at *16 (quoting *United States ex rel. McGee v. IBM Corp.*, 81 F. Supp. 3d 643, 666 (N.D. Ill. 2015)). A plaintiff must also "plead the underlying fraud with particularity." *Addus I*, 2017 WL 467673, at *16; *see also McGee*, 81 F. Supp. 3d at 666. Because the court has already determined that Relator has not pleaded the underlying fraud with particularity, his conspiracy claim fails. *See, e.g.*, *Singer*, 202 F. Supp. 3d at 828 (plaintiff's failure to sufficiently "plead[] . . . the underlying FCA claims" was "enough to doom his conspiracy claim").

Relator also fails to state a claim for conspiracy because he does not allege with particularity the existence of an agreement between the defendants. *See, e.g.*, *Kalec*, 84 F. Supp. 3d at 805 (dismissing FCA conspiracy claim where relator's complaint was "devoid of any of the

[9] The court notes that the public disclosure bar is likely not jurisdictional. Before 2010, the statute provided that "[n]o court shall have jurisdiction over an action" if the public disclosure bar applies. 31 U.S.C. § 3730(e)(4)(A) (2006). In 2010, Congress amended the statute and removed this language. The relevant provision now states, "The court shall dismiss an action or claim under this section, unless opposed by the government . . . ." 31 U.S.C. § 3730(e)(4)(A) (2012). Several courts of appeals have determined that the "amended bar is not jurisdictional." *United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 300 (3d Cir. 2016); *see also United States ex rel. Osheroff v. Humana, Inc.*, 776 F.3d 805, 810 (11th Cir. 2015); *United States ex rel. May v. Purdue Pharma L.P.*, 737 F.3d 908, 916 (4th Cir. 2013). The Seventh Circuit has stated that it "is unclear whether the language of the 2010 amendment is jurisdictional," but has declined to decide the issue. *See Bellevue v. Univ. Health Servs. of Hartgrove, Inc.*, 867 F.3d 712, 717-18 (7th Cir. 2017). It has acknowledged that other circuits have determined that the language is *not* jurisdictional, however. *See id.*; *Cause of Action v. Chi. Transit Auth.*, 815 F.3d 267, 271 n.5 (7th Cir. 2016). The conduct at issue in this case occurred well after 2010, and the court declines to assume that the Seventh Circuit would take a position contrary to that of the Third, Fourth, and Eleventh Circuits if pressed to decide.

particulars of the alleged agreement," including "whom from [each allegedly conspiring entity] engaged in the agreement"); *see also Singer*, 202 F. Supp. 3d at 828 (plaintiff must "allege the who, what, when, where, and how of the conspiracy to defraud the government" (internal quotation marks omitted)). Relator alleges that AbbVie and Abbott conspired with each other and Quintiles, the subcontractor that employed Relator, to submit false claims. But as in *Kalec*, Relator does not identify any employees that "engaged in the agreement," or when. *Kalec*, 84 F. Supp. 3d at 805. Likewise, allegations that Quintiles staffed the Ambassador Program and used AbbVie's "sanitized" job descriptions—which allegedly concealed the Ambassador Program's focus on profit—are not sufficient to support an inference that Quintiles conspired with AbbVie to submit false claims to the government. (Relator Opp. 29-30.) The court dismisses Relator's FCA conspiracy claim.

E. Other claims

Relator asserts a "reverse FCA claim" (Count IV) but provides no response to AbbVie's arguments that it should be dismissed. Accordingly, that claim is forfeited. The court dismisses it with prejudice.

Separately, Relator concedes that his claims for violations of state-law equivalents to the FCA rise and fall with his FCA claims. (*See* Relator Opp. 27 ("Because Relator has sufficiently stated a claim for violations of the FCA, his claims invoking state law analogs are similarly well-pled.").) Having determined that Relator has not sufficiently pleaded any violation of the FCA, the court dismisses Relator's state-law claims without prejudice as well.[10]

[10] Relator has withdrawn his claim under New Hampshire law, so that claim is dismissed with prejudice. (*See* Relator Opp. 28 n.15 (referencing Count XXIV).) Separately, in his complaint, Relator appears to support his FCA claims with allegations concerning violations of federal marketing rules. (*See, e.g.*, Am. Compl. ¶ 137 (alleging that the Ambassador Program "consists of . . . unlawful imbalanced marketing to patients"); *id.* ¶ 4 (alleging that AbbVie has "turned Ambassadors . . . into covert sales representatives"). AbbVie contends that such allegations do not support Relator's FCA claims because they "are not linked to any claims for payment." (AbbVie Mot. 7.) Relator does not respond to that argument. (*See generally* Relator Opp.) Accordingly, even assuming such allegations could support Relator's FCA claims, Relator has forfeited his ability to rely on them.

CONCLUSION

For the foregoing reasons, the court grants AbbVie's motion to dismiss plaintiff's amended complaint [56]. The court grants Relator leave to amend, except for Counts IV and XXIV, which are dismissed with prejudice. Relator must file an amended complaint, if any, by October 31, 2019.

ENTER:

Dated: September 30, 2019

REBECCA R. PALLMEYER
United States District Judge