UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA ex rel. LAZARO SUAREZ, and on behalf of the STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, WASHINGTON, WISCONSIN, and the DISTRICT OF COLUMBIA,	)	
Plaintiff-Relator,	)	
v.	)	**Case No. 15 C 8928**
ABBVIE, INC.,	)	**Judge Rebecca R. Pallmeyer**
Defendant.	)	

MEMORANDUM OPINION AND ORDER

In this *qui tam* action, Plaintiff-Relator Lazaro Suarez ("Relator") alleges that Defendant AbbVie Inc., a pharmaceutical company, paid kickbacks to doctors in the form of product support services for its prescription drug Humira. AbbVie provided these support services through its "Ambassador Program," in which Relator was employed through a sub-contractor. Relator alleges that the kickbacks require the conclusion that all resulting claims for government reimbursement of Humira prescriptions constitute false claims under the under the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq*. Relator asserts claims for violations of the FCA, *id.* §§ 3729(a)(1)(A), (B), and for violations of analogous laws in 29 states and the District of Columbia. On September 30, 2019, the court granted AbbVie's motion to dismiss Relator's Amended Complaint. *See United States ex rel. Suarez v. AbbVie Inc.*, No. 15 C 8928, 2019 WL 4749967 (N.D. Ill. Sept. 30, 2019) ("*Suarez I*"). Among other things, the court determined that Relator's pleadings did not adequately explain how the Humira-related services provided

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substantial independent value—as opposed to permissible product support—to physicians. *Id.* at *8. For that reason and others, the court concluded that Relator failed to plead illegal remuneration under the Anti-Kickback Statute. *See id.* at *10. In addition, the court determined that Relator did not allege sufficient detail to link the alleged kickbacks to any false claim actually submitted to the government. *See id.* The court granted Relator leave to amend all but two claims.[1]

Relator filed the SAC on November 26, 2019. AbbVie now moves to dismiss all claims with prejudice. As discussed here, AbbVie's motion to dismiss is granted in part and denied in part. The court agrees with AbbVie that Relator has not pleaded nationwide fraud, but denies AbbVie's motion to dismiss Relator's FCA claims to the extent they are based on conduct in Florida. Relator's state-law claims are dismissed without prejudice, except for claims asserted under Florida law. Finally, to the extent Relator asserts an FCA claim based on alleged violations of federal marketing laws, that claim is dismissed with prejudice.

FACTUAL BACKGROUND

The court recounts the following allegations from the SAC, accepting them as true for present purposes. *See, e.g.*, *United States ex rel. Berkowitz v. Automation Aids, Inc.*, 896 F.3d 834, 839 (7th Cir. 2018).

Relator's FCA claims concern AbbVie's Ambassador Program, through which AbbVie offers product support services in connection with its prescription drug Humira. (*See, e.g.*, SAC ¶¶ 1-3.) Relator is a registered nurse. (*Id.* ¶ 20.) From March 2013 to October 2014, he worked in South Florida as a "nurse educator" and "patient ambassador" for the Ambassador

[1] The court dismissed with prejudice Relator's claim under 31 U.S.C. § 3729(a)(1)(G) (the "reverse FCA claim") and his claim under New Hampshire law. *Id.* at *16 & n.10. The court dismissed without prejudice Relator's claim that AbbVie conspired to violate the FCA, *id.* at *15-16, but Relator has not renewed that claim in his Second Amended Complaint ("SAC") [78].

Program. (*Id.* ¶ 16.) He was employed through an AbbVie sub-contractor but "reported to and worked with" AbbVie personnel. (*Id.* ¶ 17.) According to Relator, he "worked exclusively in connection with" Humira. (*Id.*)

A. The Ambassador Program

Humira is an injectable drug that treats a "range of autoimmune conditions." (*Id.* ¶¶ 51, 53.) The Food and Drug Administration approved it in 2002. (*Id.* ¶ 52.) Relator alleges that AbbVie launched the Ambassador Program in 2012, when "the sales curve for Humira showed signs of flattening out." (*Id.* ¶ 2.) According to Relator, the program was intended "to increase prescriptions for Humira," ensure that patients continued to refill their prescriptions, and thereby increase AbbVie's profits. (*Id.*)

The "Ambassadors" in AbbVie's program are registered nurses. (*Id.* ¶ 3.) Relator alleges that "[t]hrough the Ambassador Program, AbbVie provides free professional services to health care providers . . . in exchange for their using Humira over another course of treatment." (*Id.* ¶ 3.) According to Relator, "[i]f, *and only if*, a doctor chooses to prescribe Humira, AbbVie makes an [Ambassador] available to perform time-consuming tasks that are otherwise fulfilled by the physician and their own professional staff." (*Id.*) AbbVie's Ambassadors, for example, provide the following services "at no cost" to physicians' offices: "patient care (including regular in-person visits and communications with patients in response to questions about their treatment and disease states), pharmacy and insurance authorization assistance, open enrollment resources, paperwork help, advice on insurance products, and other services and support." (*Id.* ¶ 68.)

According to Relator, AbbVie assigns Ambassadors to new clients (patients), and Ambassadors initiate contact through a telephone call. (*See id.* ¶ 117.) During the initial telephone calls, Ambassadors "assist in fulfilling the Humira prescription and answering patient questions about it." (*Id.* ¶ 118.) "After the initial contact, the Ambassador . . . sets up an in-person meeting, typically in the patient's home." (*Id.* ¶ 119.) Relator alleges that Ambassadors often spend hours with patients during home visits "and address[ ] myriad patient questions and

concerns that would otherwise be directed to the physician's office . . . ." (*Id.* ¶ 69.) For example, they "advise patients on their diagnoses and treatment plans," such as by counseling them to take Benadryl before injecting Humira to "limit adverse events at injection sites." (*Id.* ¶ 121; *see also id.* ¶ 69 (alleging that although AbbVie instructs Ambassadors to "direct medical treatment back to the physician," Ambassadors "would often draw on their past clinical work to assuage patient questions and concerns, thereby preventing yet another call to the doctor").) Relator avers that in his experience, Ambassadors sometimes answered patient questions that "ha[d] nothing to do with Humira or the diagnosis." (*Id.* ¶ 69.) For example, Relator alleges that patients "frequently used" home visits as an "opportunity to raise questions and concerns about their medical histories and other health issues." (*Id.*; *see also id.* ¶ 122 (alleging that Ambassadors talked to patients about the "comorbidities and co-mortalities to the diagnosis resulting in a Humira prescription").) In fact, Relator alleges, "a review of non-Humira related medical history was part of the Ambassadors' jobs." (*Id.*) Relator also recounts that he "frequently worked with patients to address their computer and other technology issues in fulfilling their prescriptions or dealing with their doctors' offices and insurance companies." (*Id.* ¶ 69.)

Relator further avers that during home visits, Ambassadors help ensure that patients have "access to reimbursement" for Humira. (*Id.* ¶ 119.) AbbVie has allegedly "instructed Ambassadors that while they may not call insurers directly, they can (and should) be on the phone when patients call, and can (and should) encourage patients to initiate calls to learn about coverage. This includes government insurers like Medicare and Medicaid." (*Id.* ¶ 140.) Moreover, for patients enrolled in Medicare, AbbVie allegedly 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, when the payment is relatively manageable, and at what point the patient's coverage stops during the gap period before coverage resumes (the so-called "Donut Hole")." (*Id.* ¶ 142.) According to Relator, "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.* ¶ 148.) In addition, Relator alleges that Ambassadors help patients understand how Humira works but do not provide fair and balanced safety information or ensure that patients properly report adverse events. (*See id.* ¶¶ 123-31.)

Relator alleges that "[a] typical Ambassador conducts about 20 patient visits a week." (*Id.* ¶ 73.) Ambassadors also "visit[ ] doctor's offices apart from patient visits." (*Id.* ¶ 74.) During office visits, Ambassadors allegedly give "physician[s] and their office staff" "information and training about the resources available through the Ambassador Program." (*Id.*) Relator recalls talking to physicians and their staff about how many patients he had visited, what services he had provided, and what questions the patients had asked. (*See id.*)[2]

B. Relator's Kickback Theory

Relator alleges that "[d]octors make money by seeing patients and billing for those visits." (*Id.* ¶ 5; *see also id.* ¶ 57.) By contrast, doctors "do not bill (or get paid) for administrative work that results." (*Id.* ¶ 5; *see also id.* ¶ 57.) The administrative work, Relator alleges, is a time-consuming burden. (*See id.* ¶ 55.) For example, doctors and their staff communicate with health plans and insurers about prior authorization requirements,[3] billing, claim submission, and claim

[2] According to Relator, AbbVie also provides "free materials to patients and [physician] office staff." (*Id.* ¶ 108.) The materials include "talking training pens," which are used to teach patients how to self-inject Humira, and Humira "travel kits," which are coolers that help patients store Humira at an appropriate temperature. (*Id.*) AbbVie also gives doctors' offices pre-printed insurance forms for Humira and "dedicated Humira terminals" that "print benefit verification forms and other insurance-related documents." (*Id.* ¶¶ 109-10.) Finally, as recounted in more detail in *Suarez I*, "AbbVie has given away tens of thousands of free dosages of Humira" through its "Patient Assistance Foundation." (*Id.* ¶ 144; *see Suarez I*, 2019 WL 4749967, at *2.) In opposing AbbVie's second motion to dismiss, Relator does not develop his argument that these Humira-related goods constitute kickbacks. Therefore, the alleged free materials are irrelevant for present purposes, and the court does not address them in this opinion.

[3] 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 Nov. 29, 2020). This process is sometimes called "prior authorization."

adjudication for patients. (*Id.* ¶ 58.) They also receive telephone calls and e-mails from patients inquiring about these and other topics. (*See id.* ¶ 56.) To illustrate this point, Relator cites a study conducted in 2010 by a five-doctor general medical practice. (*See id.*) The doctors in the practice reported receiving 23.7 telephone calls and 16.8 e-mails per day from patients asking about "acute medical issues, administrative questions (e.g. prior authorization for insurance)," test results, and clinical follow-up. (*Id.*) Relator alleges that after the study, the medical practice "hired additional front-desk staff and medical assistants" to conduct administrative work associated with chronic disease management, and "thereby free[d] up more physician time to see patients." (*Id.* (internal quotation marks omitted).) Similarly, Relator alleges that a study of a ten-doctor medical practice conducted in 2010 "estimated that excessive administrative complexity cost the practice more than $250,000 per year." (*Id.* ¶ 62.) And Relator points to a "survey of physicians and practice administrators" conducted in 2009 that allegedly highlights the annual costs to physicians of "dealing directly with insurance companies" and/or having their staff do so. (*Id.* ¶ 63.) According to the survey, the cost is $68,859 "per physician per year," and "[f]or medical specialist practices, the amount increases to $78,913 per physician per year." (*Id.* ¶ 64.)

Relator's allegations about doctors' administrative burdens—including answering patients' out-of-office inquiries about medical and insurance issues—are central to his kickback theory. According to Relator, AbbVie "pitches Ambassadors to doctors as free 'extensions of your office' available to take on administrative and patient work so the doctor doesn't have to." (*Id.* ¶ 4.) Relator further alleges that the Ambassador Program operates as advertised: it "save[s] physicians and their staff time and resources they would otherwise have to spend on necessary patient care," "administrative billing," and "insurance services." (*Id.* ¶¶ 4, 6.) With these burdens eased, physicians have time to "see[ ] more patients, bill[ ] for more patients, and boost[ ] the bottom line." (*Id.* ¶ 5; *see also id.* ¶ 95 (alleging that "to doctors, time is money").) By offering these time-saving benefits, Relator alleges, AbbVie "confers independent value to health care providers, and does so for sales and marketing purposes." (*Id.* ¶ 6; *see also id.* ¶ 68 (similar).)

According to Relator, the benefits "constitute kickbacks, making physicians more likely to prescribe Humira than another treatment that does not come with free professional staffing support." (*Id.* ¶ 7; *see also id.* ¶ 72 ("If given the choice between two medications, one which comes with free nurses and administrative staff and another that requires the provider to pay professional salaries, the provider cannot but help factor the substantial nursing kickback into their prescribing calculus.").)

Relator notes that "Humira is particularly challenging for doctors as it is an expensive drug that requires a great deal of non-billable support from the doctor and their staff." (*Id.* ¶ 59; *see also id.* ¶ 6 (alleging that "Humira (and Humira patients) typically require significant non-billable support due to chronic disease states, concerns about side effects, and the need to learn and manage self-injections, among other things"); *id.* ¶ 60 (alleging that "[a]s to Humira," doctors' "professional office staff counsel patients on" how to self-inject Humira, "help them with insurance coverage and insurance forms . . . navigate specialty pharmacy and prior authorization requirements, answer patient questions, and conduct follow-ups to ensure patient adherence to prescribed medication regimes").) Indeed, because Humira is expensive and requires so much non-billable support, Relator asserts, "many physicians were historically disinclined to prescribe it." (*Id.* ¶ 59; *see also id.* ¶ 67 (alleging that the Ambassador Program "was designed to overcome resistance to prescribing Humira and reward physicians for doing so").) Physicians' disinclination to prescribe Humira changed, Relator alleges, "when AbbVie took these considerations off the table by eliminating the need for the doctor's [sic] and their staff to do this work, instead providing a Registered Nurse [Ambassador] to do it for them." (*Id.* ¶ 59.) Relator alleges that the Ambassador Program has been successful. "At AbbVie's annual meetings in 2013 and 2014, for example, a VP-level company executive boasted to the Ambassadors that they had resurrected the otherwise-plateauing sales of Humira," using "before-and-after graphs" to drive the point home. (*Id.* ¶ 10.) "As of May 2014," Relator alleges, "10,000 patients were supported by an Ambassador." (*Id.* ¶ 67.)

C. Patients and Doctors Who Allegedly Have Used the Ambassador Program

In his Amended Complaint, which was the subject of *Suarez I*, Relator provided information about several physicians who have allegedly benefitted from the Ambassador Program. *See Suarez I,* 2019 WL 4749967, at *4. The court concluded that the information was not sufficiently detailed to satisfy the pleading requirements of Federal Rule of Civil Procedure 9(b). *See, e.g.*, *id.* at *9. Relator reasserts the allegations here (*see* SAC ¶¶ 75-76, 97, 99, 111), but adds other examples.

For instance, Relator alleges that in summer 2013, he visited the home of an elderly woman in Miami to provide injection training and teach her about the Ambassador Program. (*Id.* ¶ 153.) During the visit, Relator "learned she was having difficulty obtaining Medicare coverage for her prescription. Relator and the patient called Medicare that day and were able to arrange for coverage." (*Id.*) Relator states that on another occasion in 2013, he visited Dr. Tory Sullivan, a high prescriber of Humira, to "reinforc[e] the Nurse Ambassador role." (*Id.* ¶¶ 76, 154.) After the visit, Dr. Sullivan "activated" Relator's Ambassador services for "a Medicare patient living in the Little Haiti area of Miami." (*Id.* ¶ 154.) Relator alleges that after meeting with Dr. Sullivan, he visited the patient in Little Haiti and successfully "assisted in presenting an appeal to obtain assistance from [AbbVie's] Patient Assistance Foundation during the Medicare coverage gap . . . ." (*Id.* ¶ 155.) Thereafter, according to Relator, Dr. Sullivan "continued to write Humira prescriptions, and took to assigning his more 'difficult' or 'challenging' patients" to Relator. (*Id.* ¶ 156; *see id.* ¶ 154 (alleging that Dr. Sullivan's "tough" cases "would otherwise require him and his staff significant extra work").)

In April 2013, Relator alleges, he was assigned to a patient whose doctor "had been previously reluctant to use the Ambassador Program" and wanted to "test" it, particularly for the insurance challenges the patient was experiencing. (*Id.* ¶ 157.) According to Relator, he worked with the patient to appeal Medicare's denial of coverage for Humira. (*Id.*) Medicare "ultimately approved" the prescription. (*Id.*) Relator alleges that the patient's physician "communicated that

[she] will be encouraging each patient to enroll in the Ambassador Program due to the high level of support provided." (*Id.* ¶ 158.) In addition, Relator alleges that in fall 2013 or spring 2014, he helped a female patient in the Miami area secure Medicare coverage for Humira. (*Id.* ¶ 160.) Finally, Relator alleges that in October 2013, he communicated with colleagues about an 83-year-old Medicare patient who lived in Arizona and obtained a Humira prescription from a dermatologist in Seattle, Washington. (*Id.* ¶ 159.) According to Relator, an Ambassador visited the patient's home and taught him how to self-inject Humira. (*Id.*)

Relator contends that the alleged fraud occurred on a national scale. In support, Relator alleges that he and colleagues "from throughout the United States" attended Ambassador training meetings in September 2013 and 2014. (*Id.* ¶¶ 164, 167.) At a "national sales meeting in March 2014," Relator alleges, "he trained Ambassadors from throughout the Southeast region, including from Georgia and North Carolina." (*Id.* ¶ 166.) According to Relator, he helped other Ambassadors by providing Spanish-English translation over the phone for their patients in Massachusetts and North Carolina. (*Id.* ¶ 168.) Relator also alleges that he was a "national trainer" and therefore "observed the work of other Ambassadors throughout the country." (*Id.* ¶ 169.) Finally, as discussed in *Suarez I*, Relator alleges that AbbVie uses a so-called "low touch" program in which "established [Humira] patients communicate with [AbbVie-paid] nurses" over the phone. (*Id.* ¶ 170; *Suarez I*, 2019 WL 4749967, at *2.) According to Relator, this program was "designed to offer a sweeping geographic reach." (SAC ¶ 170.) Additionally, Relator alleges that in fall 2014, AbbVie "piloted" a program called "Operation Dakota," "in which prospective Humira patients living in sparsely-populated areas have contact with Ambassadors by telephone or video." (*Id.*; *Suarez I*, 2019 WL 4749967, at *2.)

D. Alleged Cover-Up Efforts

As discussed in *Suarez I*, Relator alleges that AbbVie "intentionally designed" the Ambassador Program as a "marketing program" but actively concealed its sales-driven purpose. (*Id.* ¶ 8; *see also id.* ¶¶ 65-66, 77; *Suarez I*, 2019 WL 4749967 at *4.) AbbVie allegedly created

a "cover story" that characterized the program as one offering "patient education and support." (SAC ¶ 8.) Behind the scenes, Relator alleges, AbbVie "instructed [Ambassadors] not to create a record of important aspects of their work, including . . . time spent 'dropping-by' doctor's offices to market the program" and "collaboration with members [of] the Sales team to market the Program to doctors . . . ." (*Id.* ¶ 9; *see also id.* ¶¶ 101-07.) AbbVie allegedly "tells Ambassadors not to *publicly* refer to themselves as healthcare providers" or to their patients as "patients," presumably to preserve Ambassadors' perceived role as educators. (*Id.* ¶ 114.) And Relator alleges that "Ambassadors are specifically and repeatedly told that if they have a question about what they permissibly can do in the course of their patient interactions, they should not write it down and [should] call their supervisor instead." (*Id.* ¶ 135.)

Ambassadors' compensation allegedly "depends on . . . prescription-related metrics" and is therefore "not related to education." (*Id.* ¶¶ 9, 82; *see also id.* ¶ 18 (alleging that Relator received financial rewards that were "related . . . to volume of Humira prescriptions").) Relator alleges that AbbVie keeps track of the numbers of increased prescriptions generated by the Program. (*Id.* ¶ 81; *see also id.* ¶ 83 (alleging that "[m]anagers have stressed to Ambassadors that the prescription-based metrics demonstrate the value of the Ambassador Program to senior level AbbVie personnel").) Finally, Relator alleges that Ambassadors "work with, and report to, Sales team personnel" and "play a crucial role in interfacing with physicians and marketing their free and valuable professional services," despite that Ambassadors technically are not permitted to function as sales representatives. (*Id.* ¶¶ 86-88.)

E. Humira Websites and Blogs

AbbVie contends that relevant features of the Ambassador program were disclosed in Humira websites, excerpts of which are filed in support of AbbVie's second motion to dismiss. AbbVie also filed excerpts of blogs in which patients discussed Humira.[4] There is no dispute that

[4] AbbVie filed the same excerpts in support of its first motion to dismiss.

these materials were publicly available before Relator filed this lawsuit. The court takes judicial notice of these materials, which are "matters of public record." *Cause of Action v. Chi. Transit Auth.*, 815 F.3d 267, 277 n.13 (7th Cir. 2016). One of AbbVie's Humira websites tells patients that they can obtain free "in-person injection training" at their homes or in clinics from registered nurses (*i.e.*, Ambassadors). (Humira.com, Ex. A to AbbVie Mot. ("Humira Injection Assistance Website") [87-1].) It also tells patients that "even when your doctor's office is closed, myHUMIRA nurses are on call to answer questions you might have." (*Id.*) Another Humira website tells patients that they can get insurance co-pay savings and on-call nurse support "at no additional cost." (Humira.com, Ex. B. to AbbVie Mot. ("Humira Savings & Resources Website") [87-2].) A third Humira website informs medical providers that these same services—as well as "insurance help"—are "available to your patients at no additional cost." (HumiraPro.com, Ex. C to AbbVie Mot. ("Humira Healthcare Professionals Website") [87-3].)

In one of the blogs provided by AbbVie, a patient reported calling an Ambassador "every other day when I'm not feeling well because she communicates with my doctor." (Reddit Crohn's Disease Forum, Ex. D to AbbVie Mot. [87-4] at 3).) In another, a patient reported receiving "ongoing support from [an Ambassador] anytime I have questions." (TalkPsoriasis Forum, Ex. E to AbbVie Mot. [87-5] at 2).) In a third blog, which the court discusses more fully below, a doctor named David Healy opined that Ambassadors' services are "huge gifts to the doctor in the form of 'in-kind' goods and services." (Healy Blog, Ex. G to AbbVie Mot. [87-7] at 3.)

PROCEDURAL HISTORY

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 § 1871.7.[5] On March 13, 2018, the United States declined to intervene in the action. (*See*

[5] That claim is proceeding in a separate state-court action in which the State of California has intervened. (*See* Relator Opp. to AbbVie Second Mot. to Dismiss ("Relator Opp.") [91], at 7 (citing *State of Calif. v. AbbVie Inc.*, Case No. RG 18893169 (Cal. Sup. Ct., Alameda Cnty.)).)

Notice [26].) All states and the District of Columbia declined to intervene as well. (*See* Order [28].) The court then ordered Relator's complaint unsealed. (*See id.*) Thereafter, the court granted AbbVie's first motion to dismiss and allowed Relator leave to amend all but two claims. *See Suarez I*, 2019 WL 4749967 *16 & n.10. Relator filed a Second Amended Complaint, and AbbVie's motion to dismiss that complaint is now before the court.

DISCUSSION

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) challenges the sufficiency of a complaint. *See, e.g.*, *Firestone Fin. Corp. v. Meyer*, 796 F.3d 822, 825 (7th Cir. 2015). 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).

As relevant here, the False Claims Act 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), and knowingly making, using, or causing to be made or used, a false record or statement that is material to a false or fraudulent claim paid by the government, *id.* § 3729(a)(1)(B). The Anti-Kickback Statute ("AKS") makes it illegal to "knowingly and willfully offer[ ] or pay[ ] any remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person . . . to purchase, . . . order, . . . or recommend purchasing . . . or ordering any good . . . or item for which payment may be made in whole or in part under a Federal health care program," such as Medicare. 42 U.S.C. § 1320a-7b(b)(2). Some courts in this district have stated that "the AKS defines 'remuneration' broadly to include 'anything of value.'" *United States ex rel. Derrick Roche Diagnostics Corp.*, 318 F. Supp. 3d 1106, 1113 (N.D. Ill. 2018) (quoting *United States ex*

rel. Nehls v. Omnicare, Inc., No. 07 C 05777, 2013 WL 3819671, at *15-17 (N.D. Ill. July 23, 2013)). 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. 42 U.S.C. § 1320a-7b(g). The AKS aims to protect 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).

Because Relator's claims arise under an anti-fraud statute (the FCA), 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).

A. Sufficiency of Kickback Allegations

1. Remuneration

Relator's FCA claims are based on alleged violations of the AKS. To state a claim for a violation of the AKS, Relator must allege, with the specificity required by Rule 9(b), that AbbVie (1) knowingly and willfully (2) offered or paid (3) remuneration (4) in return for purchasing or ordering any item for which payment may be made under a federal healthcare program. *See* 42 U.S.C. § 1320a-7b(b)(2); *see also, e.g.*, *United States ex rel. Grenadyor v. Ukrainian Vill.*

Pharmacy, Inc., 772 F.3d 1102, 1106-07 (7th Cir. 2014); *Roche Diagnostics Corp.*, 318 F. Supp. 3d at 1112.

Relator alleges that AbbVie offers and pays remuneration to physicians by providing, through the Ambassadors, free medical care and insurance support for Humira patients. According to Relator, these services save physicians time and resources, enabling physicians to see more patients and increase their profits. The Ambassador Program allegedly induces physicians to prescribe Humira instead of other treatments that do not come with the same free support.

a. The court's decision in *Suarez I*

In the briefing on AbbVie's first motion to dismiss, neither side cited authority from any federal court of appeals that addresses whether product support services like those alleged here constitute remuneration under the AKS. The court was also unable to locate such authority. On the other hand, both sides relied on guidance from the U.S. Department of Health and Human Services Office of Inspector General ("OIG") concerning the distinction between permissible product support services and those that violate the AKS. AbbVie, for example, emphasized the OIG's statement in 2013 that for purposes of the Anti-Kickback Statute, 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." *Suarez I*, 2019 WL 4749967, at *7 (quoting OIG, Medicare & State Health Care Programs: Fraud & Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, Final Rule, 78 Fed. Reg. 79202-01, 2013 WL 6814651, at *79210 (Dec. 27, 2013) ("OIG Dec. 2013 Final Rule")); *see also* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, Notice, 68 Fed. Reg. 23731-01, 2003 WL 2010428, at *23735 (May 5, 2003) ("OIG May 2003 Notice") ("Standing alone, services that have no substantial independent value to the purchaser may not implicate the anti-kickback statute.").

Relator, for his part, emphasized that the OIG has cautioned drug manufacturers against "reliev[ing] physicians of financial obligations they would otherwise incur." *Suarez I*, 2019 WL

4749967, at *6 n.5 (quoting OIG, OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858-01, 2005 WL 192293, at *4866 (Jan. 31, 2005)). This court interpreted the cited OIG guidance as warning that a manufacturer might "raise kickback concerns" by (1) offering services "integrally related" to Humira "in tandem with another service or program that confers a benefit on a referring provider" or (2) offering "goods or services" that "eliminate an expense that the physician would have otherwise incurred (*i.e*., have independent value to the physician)." *Suarez I*, 2019 WL 4749967, at *6-7 (quoting OIG Dec. 2013 Final Rule, 2013 WL 6814651, at *79210; OIG May 2003 Notice, 2003 WL 2010428, at *23735, *23737).

The court recognized that administrative guidance is not binding law but interpreted the parties' reliance on OIG guidance as a concession that it was authoritative for purposes of AbbVie's motion. *Suarez I*, 2019 WL 4749967, at *6. As discussed more fully in *Suarez I*, the court concluded that the alleged Ambassador services were "integrally related" to Humira and that Relator had not pleaded that AbbVie provided other goods or services that conferred a benefit on physicians. *Id.* at *7. Next, the court determined that Relator had not sufficiently pleaded that the alleged Ambassador services provided substantial independent value to physicians by eliminating an expense they otherwise would have incurred. *Id.* at *8. The court explained that although Relator had alleged that Ambassadors perform time-consuming, non-billable patient support associated with Humira prescriptions, he had not pleaded that physicians and their staff must otherwise perform those services when they do not prescribe Humira. *See id.* As written, the court concluded, the Amended Complaint did not sufficiently explain how Ambassadors' services "provided substantial independent value—as opposed to 'permissible product support'—for physicians." *Id.* (quoting *United States ex rel. Forney v. Medtronic, Inc.*, No. 15-CV-6264, 2017 WL 2653568, at *4 (E.D. Pa. June 19, 2017) (reaching same conclusion regarding theory that a manufacturer allegedly induced physicians to purchase a medical device by providing free

technical and billing support services directly related to the device)).[6]

Next, the court addressed Relator's theory that "offering free product support or reimbursement support services could violate the AKS merely because it saves physicians money." *Suarez I*, 2019 WL 4749967, at *9. The court observed that the theory "appear[ed] inconsistent with the OIG guidance" discussed above. *Id.* It went on to conclude that even if the theory was viable, Relator had not pleaded with particularity that the Ambassador Program saves physicians money. As an example, the court stated that Relator had not pleaded that any physicians "reduced their expenses or downsized their own staff as a result of Ambassadors' support services." *Id.* (citing *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), *report and recommendation adopted*, 2018 WL 3630042 (E.D. Tex. July 31, 2018) (allegations concerning free, product-specific nurse and reimbursement support services failed under Rule 9(b), including because the relators did not allege that the services allowed any single doctor to eliminate administrative staff positions or "increase patient visits", nor did the relators identify any single doctor who "actually received 'substantial value'" as a result of the services).

b. Relator's Second Amended Complaint

In moving to dismiss the SAC, AbbVie argues that Relator "again identifies only patient support services that were integrally related to helping patients use Humira and that offered no substantial independent value." (AbbVie Mem. in Supp. of Second Mot. to Dismiss ("AbbVie Br.") [87] at 10.) AbbVie points to allegations that Ambassadors help patients fill Humira prescriptions, answer their questions about Humira, ensure they have access to reimbursement or free drugs,

[6] The court distinguished Relator's cited cases on the ground that they concerned different kinds of goods, services, or fraud. *See Suarez I*, 2019 WL 4749967, at *9 (discussing *United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772 (S.D.N.Y. 2017), *rev'd and remanded on other grounds*, 889 F.3d 163 (2d Cir. 2018); *United States ex rel. Witkin v. Medtronic*, 189 F. Supp. 3d 259 (D. Mass. 2016); *United States ex rel. Boise v. Cephalon, Inc.*, No. 08-CV-287, 2015 WL 1724572 (E.D. Pa. Apr. 15, 2015)).) The court finds those cases inapposite for the same reasons discussed in *Suarez I*.

help them avoid adverse events at injection sites, and talk to them about "their backgrounds and related diagnoses." (*See id.* at 10-11 (quoting SAC ¶ 122).) AbbVie also highlights Relator's allegations that he "worked exclusively in connection with" Humira and that physicians have access to the Ambassador Program "[i]f, *and only if*," they prescribe Humira. (AbbVie Br. at 9 (quoting SAC ¶¶ 3, 17).) Finally, AbbVie emphasizes that the representative examples alleged in the SAC "solely concern Humira-related work." (AbbVie Br. at 11.)

The court agrees with AbbVie that Relator's allegations do not permit an inference that Ambassadors provide non-Humira-related services. Although Relator alleges in the SAC that Ambassadors answer patient questions having "nothing to do with" Humira (SAC ¶ 69), he does not respond to AbbVie's argument that speaking with patients about their medical histories is closely related to advising them on how to use Humira and how it works—as is helping patients avoid adverse reactions at injection sites. Likewise, Relator offers no response to AbbVie's contention that his representative examples concern only Humira-related services. And although Relator alleges in the SAC that Ambassadors help patients with technology issues that arise while they fill prescriptions or interact with doctors' offices and insurance companies, he does not argue in his briefing that these services are unrelated to Humira. (*See* Relator's Opp. at 8-14.)

Whether Relator has alleged that the Ambassador Program provides independent value to physicians is a much closer call, but the court concludes that the pleadings on this score are adequate. First, Relator persuasively argues that the allegations in the SAC, taken as true, show that the Ambassador Program "extend[s] well beyond basic product support." (Relator Opp. at 4; *see also id.* at 12-13.) As both sides observe, the OIG has provided examples of what it considers to be basic, permissible product support services. (*See, e.g.*, *id.* at 13; AbbVie Br. at 9-10.) Among other things, the OIG references providing "billing assistance tailored to the purchased products, reimbursement consultation, and other programs specifically tied to the purchased

product";[7] acting as a "clearinghouse for information" on insurance and reimbursement;[8] and providing free drugs for patients who cannot afford them.[9] In a case AbbVie cites (*see* AbbVie Br. at 10), the government defined basic product support for medication as "including educational resources such as a toll-free assistance phone line and instructions about how to administer or store the medicine." *United States ex rel. NHCA-TEV, LLC v. Teva Pharm. Prods. Ltd.*, No. 17 CV 2040, 2019 WL 6327207, at *3 (E.D. Pa. Nov. 26, 2019).

In addition to providing these permissible product services, however, Relator alleges in the SAC that in their interactions with Ambassadors, patients also "regularly raised additional questions and concerns about symptoms and health concerns that may or may not have been related to Humira or their underlying diagnosis treated by Humira." (SAC ¶ 122; *see also id.* ¶ 69 (similar); Relator Opp. at 12 n.5 (citing similar allegations).) He also alleges that Ambassadors "would often draw on their past clinical work to assuage patient questions and concerns, thereby preventing yet another call to the doctor." (SAC ¶ 69; Relator Opp. at 10 (discussing same).) And he alleges that Ambassadors instruct patients on how to avoid adverse reactions from Humira injections, such as taking Benadryl in advance. (SAC ¶ 121; Relator Opp. at 10 (discussing same).) As Relator argues, these allegations show that physicians rely on Ambassadors' "experience as medical professionals to give advice [they] would otherwise have to give." (Relator Opp. at 10.) Although these additional services may not be wholly unrelated to Humira, they can reasonably be characterized as exceeding basic product support services.

In the SAC, Relator also alleges with more specificity how Ambassadors' services can

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[7] AbbVie Br. at 9 (quoting OIG May 2003 Notice, 2003 WL 2010428, at *23735).

[8] AbbVie Br. at 9 (quoting OIG, Advisory Op. No. 00-10, 2000 WL 35747420, at *4 (Dec. 15, 2000)).

[9] AbbVie Br. at 9-10 (citing OIG, 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)).

confer independent value on physicians by reducing their administrative work. Relator does not name a physician who was able to reduce her staff or see more patients because of the Ambassador program, but he now alleges that he lacks access to such information absent discovery. (*See* SAC ¶ 161.) He also alleges that Humira patients suffer from chronic diseases and anchors his remuneration theory in a study of a medical practice whose patients also suffer from chronic diseases. (*See id.* ¶¶ 6, 56, 60.) Citing this study and others, Relator alleges that administrative work—such as answering patients' medical and insurance questions over the telephone—is especially burdensome for health care providers who treat chronic disease patients, costs medical practices thousands of dollars per year, and reduces the (billable) time physicians can spend seeing patients in person. (*See id.* ¶¶ 5, 55-58, 62-64 *cf. id.* ¶ 60 ("Humira prescribers work in Rheumatology, Gastroenterology, and Dermatology practices. These practices typically employ nurses and professional staff to provide general advice and counseling to patients and assistance with insurance and billing for prescriptions.").) These allegations raise a plausible inference that if physicians did not prescribe Humana and benefit from the services Ambassadors provide, they would otherwise have to perform, or pay staff to perform, such tasks.

AbbVie renews its contention that according to OIG guidance, a drug manufacturer does not provide illegal remuneration simply by offering product support services that save physicians money. It then argues that even if Relator's remuneration theory is viable, Relator undermines it by acknowledging that "Humira is particularly challenging for doctors" because it is expensive and "typically require[s] significant non-billable support." (AbbVie Br. at 11-12 (quoting SAC ¶¶ 59).) According to AbbVie, these allegations confirm that "the tasks Ambassadors perform are unique to Humira and thus not something physicians would need to do if they did not prescribe it." (AbbVie Br. at 12.) Relator does not respond directly to this argument, but he does allege that Humira patients suffer from chronic diseases, and that chronic disease patients typically require substantial non-billable support from physicians and their staff. (*See* SAC ¶¶ 6, 56, 60.) Discovery might prove that Humira creates extra work that physicians would not have to do if they

prescribed another drug—and therefore that the Ambassador Services do not provide value independent of Humira. But the court concludes at this stage that Relator has adequately alleged that physicians who do not prescribe Humira would need to provide services to their patients that the Ambassadors provide, without additional charge, for Humira-prescribing doctors. He has also adequately alleged that the work otherwise would cost medical practices thousands of dollars per year. Accordingly, the pleadings permit an inference that Ambassadors' services confer substantial independent value on physicians.

Arguing otherwise, AbbVie emphasizes that by moving to dismiss several other *qui tam* actions, the government has signaled its view that basic product support services do not violate the AKS and, relatedly, has confirmed that there is a strong interest in ensuring patients have access to such services. (*See* AbbVie Br. at 10.)[10] Relator effectively distinguishes these cases by noting that he has alleged that Ambassadors provide more than basic product support services. (*See* Relator Opp. at 13.) After this motion to dismiss was fully briefed, the Seventh Circuit weighed in on one of AbbVie's cited cases. *See United States ex rel. CIMZNHCA v. UCB, Inc.*, 970 F.3d 835 (7th Cir. 2020). But that case can be distinguished for the same reason: by all appearances, it concerned basic product support services. The relator in *CIMZNHCA* alleged that the defendant violated the AKS and the FCA by paying physicians kickbacks in exchange for prescribing or recommending its drug. *See id.* at 839. The alleged kickbacks "took the form of free education services provided by nurses to physicians and their patients and free reimbursement support services, that is, assistance with insurance paperwork." *Id.* at 840. The

[10] AbbVie cites the following cases: *NCHA-TEV, LLC*, 2019 WL 6327207, at *3, *6 (granting government's motion under deferential standard applicable to government motions to dismiss *qui tam* actions under 31 U.S.C. § 3730(c)(2)(A)); *United States ex rel. Harris v. EMD Serono, Inc.*, 370 F. Supp. 3d 483, 489-91 (E.D. Pa. 2019) (same); *United States ex rel. SCEF, LLC v. AstraZeneca, Inc.*, No. 2:17-CV-1328-RSL, 2019 WL 5725182, at *4 (W.D. Wash. Nov. 5, 2019) (same). *See also Suarez I*, 2019 WL 4749967, at *8 (noting that in support of its motion to dismiss in *United States ex rel. Health Choice Group, LLC v. Bayer Corp.*, No. 5:17-CV-126-RWS-CMC (E.D. Tex.), the government similarly argued that basic product support services are beneficial for patients).

government declined to intervene and moved to dismiss the lawsuit under 31 U.S.C. § 3730(c)(2)(A). *CIMZNHCA*, 970 F.3d at 838. The government represented that it sought dismissal because, after investigating the relator's claims, it found them "to lack sufficient merit to justify the cost of investigation and prosecution and otherwise to be contrary to the public interest." *Id.* at 840. In the government's view, the lawsuit "would undermine . . . practices the federal government has determined are . . . appropriate and beneficial to federal healthcare programs and their beneficiaries." *Id.* at 852 (internal quotation marks omitted).

There is a circuit split concerning the standard of review applicable to motions to dismiss under § 3730(c)(2)(A), which does not itself supply a standard. *CIMZNHCA*, 970 F.3d at 840. The district court had denied the motion to dismiss, purporting to adopt a burden-shifting framework that examines whether there is a rational relationship between dismissal and accomplishing a valid government purpose. *Id.*[11] In the Seventh Circuit's view, the district court had in fact "applied something closer to administrative law's 'arbitrary and capricious' standard" in refusing to dismiss this case. *Id.* at 838-39. The Seventh Circuit concluded that standard is too stringent and reversed with directions to dismiss. *See id.* at 853-54. In *dicta*, it noted that even if a rationality standard applied, the government's decision to dismiss the *qui tam* action would satisfy that standard:

> The government proposed to terminate this suit in part because, across nine cited agency guidances, advisory opinions, and final rulemakings, *it has consistently held that the conduct complained of is probably lawful. Not only lawful, but beneficial to patients and the public*. . . . This is not government irrationality. It oppresses no one and shocks no one's conscience.

Id. at 852 (emphasis added).

AbbVie argues that the italicized language supports its position that Ambassadors' product

[11] The district court adopted the standard from *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139 (9th Cir. 1998). In *Swift v. United States*, 318 F.3d 250, 253 (D.C. Cir. 2003), by contrast, the court determined that the government has "unfettered" discretion to dismiss under Section 3730(c)(2)(A).

support services are lawful. (*See* AbbVie Mot. for Leave to File Supp. Auth. (*CIMZNHCA*) [111] at 2.) But in *CIMZNHCA*, the Seventh Circuit described the product support services as free education and assistance with insurance paperwork; it gave no indication that the education and insurance assistance exceeded basic product support services. *See CIMZNHCA*, 970 F.3d at 940. Furthermore, the Seventh Circuit did not closely analyze whether the support services constituted remuneration because that question was not before it. *CIMZNHCA*, therefore, is not outcome-determinative here.

The court concludes that Relator has adequately alleged that Ambassadors' services constitute illegal kickbacks under the AKS.

2. Submission of false claims

Rule 9(b) requires Relator to "link specific allegations of fraud or deceit—in this case, kickbacks—to claims for government payment." *Suarez I*, 2019 WL 4749967, at *10 (citing *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")); *see also Grenadyor*, 772 F.3d at 1107 ("Violating a regulation is not synonymous with filing a false claim."). To satisfy this requirement, Relator must "allege . . . specific facts demonstrating what occurred at the individualized transactional level." *Berkowitz*, 896 F.3d at 841. In this case, that means alleging "a connection between a kickback, a patient, and a submitted claim." *Suarez I*, 2019 WL 4749967, at *11 (citing, *inter alia*, *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 . . . ."). Rule 9(b)'s requirements may be relaxed when a relator is not "in a position to obtain information concerning specific claims submitted to the government." *Suarez I*, 2019 WL 4749967, at *12 (citing *Berkowitz*, 896 F.3d at 841; *Lusby*, 570 F.3d at 853-54). But even under the relaxed standard, the alleged facts must, at a minimum, "describe the predicate acts with some specificity to inject 'precision and some measure of

substantiation' into [the] allegations of fraud." *Berkowitz*, 896 F.3d at 841 (quoting *Presser*, 836 F.3d at 776); *see also Presser*, 836 F.3d at 778 (observing that in cases where plaintiffs have satisfied the relaxed standard, "the alleged facts necessarily led one to the conclusion that the defendant had presented claims to the Government").

In *Suarez I*, the court determined that Relator had not pleaded representative examples that alleged a link between a kickback, a patient, and a submitted claim. 2019 WL 4749967, at *11. He did not "name a specific patient for whom a doctor prescribed Humira in exchange for a kickback," "allege that a claim was submitted to a government health care program for any such patient," or "suggest that he is aware of claims submitted for specific patients." *Id.* The court also determined that Relator had not shown he was entitled to a relaxed application of Rule 9(b), and could not prevail even under such a relaxed standard. *Id.* at *12.

AbbVie argues that the same defects doom the SAC. AbbVie is correct that most of the representative examples do not link a kickback with a patient and a submitted claim. For example, Relator identifies specific Medicare patients that worked with Ambassadors but does not allege that their doctors prescribed them Humira because of the Ambassador Program. (*See* SAC ¶ 153 (Relator helped a patient obtain Medicare coverage for Humira); *id.* ¶ 159 (Ambassador provided injection training for a Medicare patient in Arizona); *id.* ¶¶ 157-58 (physician was initially reluctant to use the Ambassador Program, but after seeing it in action, indicated that she would encourage her Humira patients to use the Program "due to the high level of support provided").) Relator, however, does provide one representative example of alleged fraud at the "individualized transactional level." *Berkowitz*, 896 F.3d at 841. Specifically, he alleges that he helped Dr. Sullivan's patient in Little Haiti "obtain assistance from [AbbVie's] Patient Assistance Foundation during the Medicare coverage gap . . . ." (*Id.* ¶¶ 154-55.) Dr. Sullivan then "continued to write Humira prescriptions" and assigned "difficult" cases to Relator, meaning cases that "would otherwise require him and his staff [to perform] significant extra work." (*Id.* ¶¶ 154, 156.) These allegations fill gaps the court previously identified: they connect a specific Humira prescriber with

a specific Medicare patient, suggest that Relator's work with that patient influenced the doctor's decision to keep prescribing Humira, and suggest that a claim was submitted to Medicare for the patient.

AbbVie counters that this example falls short because it alleges that the patient obtained assistance from AbbVie's Patient Assistance Foundation—not Medicare. (*See* AbbVie Br. at 14.) Relator's failure to respond to this argument is disappointing. But the court notes that according to the SAC, Medicare reimburses prescriptions for several months before the coverage gap and resumes coverage sometime later. (*See* SAC ¶ 142.) The SAC also alleges that Dr. Sullivan continued prescribing Humira after Relator's visit with the patient. (*See id.* ¶ 156.) Viewed in the light most favorable to Relator, these allegations create a plausible inference that Humira claims for the Little Haiti patient were submitted to Medicare either before or after the coverage gap (or both).

In a similar vein, AbbVie contends that the representative example does not show that the Little Haiti patient received his prescription as a result of a kickback because, according to Relator, Dr. Sullivan first prescribed Humira to the patient *before* he was enrolled in the Ambassador Program. (*See* AbbVie Br. at 14.) Again, Relator unfortunately does not respond to this argument. But in the SAC, Relator alleges that the availability of Ambassador services for time-consuming patients influenced Dr. Sullivan's decision to *continue* prescribing Humira. (*See* SAC ¶¶ 154-56.) In *United States ex rel. Dolan v. Long Grove Manor, Inc.*, No. 10 C 368, 2014 WL 3583980, at *5 (N.D. Ill. July 18, 2014), cited by AbbVie, the relator's representative example did not specify who fraudulently referred the patient to the defendant and provided no basis for the conclusion that the referral was fraudulent. By contrast, Relator's representative example ties the allegedly illegal Ambassador services to a doctor's prescribing behavior, including for a patient that submitted claims to Medicare. Relator, therefore, has adequately pleaded that a false claim was submitted to Medicare as a result of AbbVie's alleged fraud, and the court need not consider whether Relator is entitled to a relaxed application of Rule 9(b).

3. Nationwide scope of the alleged fraud

Relator seeks to hold AbbVie liable for the alleged fraud in 29 states and the District of Columbia. In *Suarez I*, the court determined that Relator had not pleaded the nationwide scope of the alleged fraud with the particularity that Rule 9(b) requires. The court recognized that Relator "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." *Suarez I*, 2019 WL 4749967, at *13. But it concluded that Relator's allegations improperly "ask[ed] the court to infer that the fraud occurred nationwide based on allegations concerning only South Florida." *Id.* (internal quotation marks omitted). Relator's allegation that AbbVie expanded the Ambassador Program to "sparsely-populated" areas in 2014 was too vague to support this inference, the court concluded, as was his allegation that AbbVie executives commented at national meetings on the Ambassador Program's success in boosting Humira sales. *Id.*

AbbVie maintains that the SAC fares no better. The court agrees. Relator has added information about a handful of states other than Florida, but no allegations that a doctor in another state prescribed Humira because of the Ambassador Program. Further, only one of Relator's new examples identifies a patient as enrolled in a federal healthcare program. (*See* SAC ¶ 159 (alleging that an Ambassador visited a Medicare patient in his Arizona home to provide Humira injection training; that the patient was originally from Alaska; and that the patient obtained his Humira prescription from a doctor in Washington); *id.* ¶ 168 (alleging that Relator provided Spanish-English translation over the telephone for unspecified patients in Massachusetts and North Carolina).) These vague allegations do not support an inference that fraud occurred in the referenced states, let alone nationwide. *See, e.g.*, *Grenadyor*, 772 F.3d at 1108 (faulting the relator for pleading specifics about the alleged unlawful practice in only two of the seven states where kickbacks allegedly occurred). In light of Relator's allegation that he "observed the work of other Ambassadors throughout the country" in his role as an Ambassador trainer (SAC ¶ 169), the court would expect him to provide more specifics about alleged fraudulent activity in states

other than Florida.

Relator's allegations that Ambassadors from across the United States converged at national meetings for training do not alter the court's conclusion. (*Id.* ¶¶ 162-64, 167.) Regarding training, Relator alleges only that Ambassadors learned about "patient interview techniques, including deflecting questions about Humira's serious side effects." (*Id.* ¶ 164.) Deflecting such questions might endanger patients, but Relator has not explained how doing so violates the FCA. At best, Relator's new allegations about the geographic scope of the Ambassador Program permit an inference that the Program operates in all states. They do not plausibly suggest, nor plead with specificity, that the Ambassador Program operates *fraudulently* in all states.

Relator offers no persuasive counterargument or case law. He cites only *United States ex rel. Turner v. Michaelis Jackson & Assocs.*, No. 03-CV-4219-JPG, 2007 WL 496384, at *4 (S.D. Ill. Feb. 13, 2007), in which the court stated that "[w]hen a complaint alleges numerous instances of fraud over a multi-year period, . . . it would be both impractical and inefficient to require detailed allegations of the who, what, when, where and how of every single submission of a false claim." To be sure, Relator need not allege the "where" of "every single submission of a false claim" to sufficiently allege nationwide fraud. *Id.* But he must provide more than a single representative example of alleged fraud in one state. Nothing in *Turner* requires a different conclusion. Indeed, there is no indication that the relator in *Turner* alleged fraud on a broad geographic scale. *See generally id.* This court concludes that, because Relator has alleged fraud with particularity in just one state, his FCA claims are limited to conduct that occurred in Florida. The court also dismisses, without prejudice, all state-law claims except those asserted under Florida law.[12]

[12] The State of California has filed a statement of interest in Relator's case. (*See* Cal. Stmt. of Int. [90].) California opposes dismissal of Relator's claims under the California False Claims Act ("CFCA"), CAL. GOV. CODE § 12652(c)(1), and in the alternative asks that the dismissal of any CFCA claims be without prejudice. (Cal Stmt. of Int. at 2.) The court notes that that, even after the court granted Relator leave to amend, the SAC does not contain any allegation

B. Scienter

To defeat AbbVie's motion to dismiss, Relator must adequately plead that AbbVie acted with scienter under the FCA and the AKS. As explained here, Relator has done both.

1. FCA

The FCA provides for civil liability if a person "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). A person acts "knowingly" under the FCA if he or she acts with "actual knowledge," "deliberate ignorance" or "reckless disregard" of the truth. 31 U.S.C. § 3729(b)(1)(A); *see Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016) (same); *Berkowitz*, 896 F.3d at 840 (same). Proof of specific intent to defraud is not required. 31 U.S.C. § 3729(b)(1)(B). As a threshold matter, the parties dispute whether the Supreme Court's decision in *Safeco Insurance Co. of America v. Burr*, 551 U.S. 47 (2007), which addresses the scienter requirement under the Fair Credit Reporting Act ("FCRA"), controls the scienter inquiry under the FCA. Relatedly, they dispute whether under *Safeco*, a defendant's objectively reasonable interpretation of an ambiguous statute precludes FCA liability regardless of the defendant's subjective intent at the time of the violation.

In *Safeco*, the Court held that a willful failure to comply with the FCRA's notice obligation includes a violation committed in reckless disregard of the Act. 551 U.S. at 57-58. The Court observed that for purposes of civil liability, the common law has generally defined recklessness as conduct that violates an "objective standard." *Id.* at 68. The Court then determined that an insurance provider (Safeco) might have violated the FCRA's notice obligation but did not do so in a way that was objectively reckless, and therefore was not liable. *Id.* at 69. The Court explained that the statutory text was ambiguous; Safeco's interpretation of the statute was "not objectively

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concerning any activity in California. Nevertheless, the court will dismiss the CFCA claims without prejudice.

unreasonable"; and there was no "authoritative guidance" from a court of appeals or the Federal Trade Commission that "might have warned [Safeco] away from the view it took." *Id.* at 69-70. The Court rejected the notion that "evidence of subjective bad faith must be taken into account in determining whether a company acted knowingly or recklessly" under the FCRA. *Id.* at 70 n.20. It explained that "[w]here . . . the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a knowing or reckless violator." *Id.* The Court continued, "Congress could not have intended such a result for those who followed an interpretation that could reasonably have found support in the courts, whatever their subjective intent may have been." *Id.*

The Seventh Circuit has not addressed whether *Safeco* governs scienter under the FCA. AbbVie argues that *Safeco* applies and maintains that "every court of appeals to consider the issue" agrees. (*See* AbbVie Br. at 19 & n.7.) For example, in *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281 (D.C. Cir. 2015), the court stated that in *Safeco*, the Supreme Court "clarified that subjective intent—including bad faith—is irrelevant when a defendant seeks to defeat a finding of knowledge based on its reasonable interpretation of a regulatory term." *Id.* at 290 (citing *Safeco*, 551 U.S. at 70 n.20). Accordingly, the *Purcell* court stated, an analysis of the "FCA's knowledge element" focuses "on the objective reasonableness of the defendant's interpretation of an ambiguous term and whether there is any evidence that the agency warned the defendant away from that interpretation." *Id.* at 290 (citing *Safeco*, 551 U.S. at 70 & nn.19-20); *see also United States ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC*, 833 F.3d 874, 879-80 (8th Cir. 2016) (applying same framework to evaluate FCA scienter); *United States ex rel. Streck v. Allergan, Inc.*, 746 F. App'x 101, 106 (3d Cir. 2018) (same); *United States ex rel. McGrath v. Microsemi Corp.*, 690 F. App'x 551, 552 (9th Cir. 2017) (applying *Safeco* standard without discussion of warning-away); *United States ex rel. Proctor v. Safeway Inc.*, 466 F. Supp. 3d 912, 928-40 (C.D. Ill. 2020) (applying *Safeco* framework to evaluate FCA scienter); *see* AbbVie Mot.

for Leave to File Supplemental Authority [101] (notifying the court of the decision in *Proctor*). Invoking *Safeco*, AbbVie argues that OIG guidance suggests that Ambassadors' product support services are lawful and is "[a]t worst . . . subject to more than one reasonable interpretation." (AbbVie Br. at 20.) AbbVie also contends that Relator's allegations do not "identify any authoritative agency guidance or court of appeals opinion that could have warned AbbVie away from" its position. (*Id.*) "That defeats scienter under the FCA as a matter of law," AbbVie argues. (*Id.*)

Relator responds that the FCA requires an analysis of a defendant's knowledge at the time of the violation, and that an FCA defendant cannot avoid liability by later identifying a reasonable statutory interpretation that it did not actually rely on. (*See* Relator Opp. at 22.) The United States—which has filed a statement of interest in this case concerning the appropriate standard for evaluating FCA scienter—advances the same argument. (*See* U.S. Stmt. of Int. [88], at 1 (AbbVie "erroneously argue[s] that the existence of an 'objectively reasonable' reading of the [AKS] defeats a finding of scienter under the FCA as a matter of law, even if the defendant did not rely on that reading at the time of the alleged misconduct").) Relatedly, the United States argues that *Safeco* does not supply the standard for evaluating scienter under the FCA in any event. (*Id.* at 5.)

The court is reluctant to construe *Safeco* as permitting a defendant to avoid liability by identifying an objectively reasonable interpretation of the relevant statute, regardless of the defendant's subjective intent at the time of the alleged violation. The court need not decide this issue, however—nor whether *Safeco* governs the scienter inquiry under the FCA—because Relator can prevail even under the standard AbbVie advocates. First, as Relator points out, AbbVie "presupposes [that] the legal landscape is ambiguous, which ignores" that the AKS prohibits drug manufacturers from offering remuneration in exchange for prescriptions. (Relator Opp. at 23.) Relator has alleged that Ambassadors' services exceed basic product support services and confer independent value on physicians; neither the AKS nor OIG guidance are

ambiguous on the question of whether such services are lawful.

Further, even if the legal landscape were ambiguous and AbbVie's interpretation objectively reasonable, AbbVie concedes that under *Safeco*, Relator can survive the motion to dismiss if his allegations identify authoritative guidance that might have warned AbbVie away from its interpretation. (*See* AbbVie Mot. at 19 ("If the defendant's understanding of the law was objectively reasonable, then the Court must dismiss *unless the relator adequately alleges the defendant '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*.'" (emphasis added) (quoting *Safeco*, 551 U.S. at 70 & n.20)).) Whether a defendant was warned away from a reasonable interpretation is not a "purely legal' question. *Purcell*, 807 F.3d at 288; *see also id.* at 289 ("[T]he factual question remains whether there was sufficient evidence that [the defendant] was warned away from its interpretation.").

AbbVie argues that Relator's allegations do not "identify any authoritative agency guidance or court of appeals opinion that could have warned AbbVie away from its view that [Ambassadors'] services were permissible." (AbbVie Br. at 20; *see also* AbbVie Reply in Supp. of Mot. to Dismiss ("AbbVie Reply") [100] at 21.) To the contrary, AbbVie maintains that the OIG guidelines "expressly permit the support services AbbVie provides for Humira." (AbbVie Br. at 20; *see also* AbbVie Reply at 22 ("OIG guidance provides that support services a pharmaceutical manufacturer offers in connection with the sale of its own products . . . do not, on their own, implicate the anti-kickback statute" (quoting *Suarez I*, 2019 WL 4749967, at *8 (internal quotation marks and citations omitted))).) But unlike in the Amended Complaint at issue in *Suarez I*, the SAC alleges that Ambassadors' services exceed basic product support services, and that Ambassadors perform work that physicians otherwise would need to if they did not prescribe Humira. Although a more complete record might show otherwise, it is reasonable to infer that the AKS itself—which prohibits offering or paying "any remuneration" in exchange for prescribing a drug for which a Federal health care program will make payment 42 U.S.C. § 1320a-7b(b)(2)—

might have warned AbbVie against its interpretation. (*See* Relator Opp. at 20 (arguing same).)

AbbVie's cited cases do not counsel otherwise. In *Purcell*, the court determined that the defendant lacked scienter as a matter of law only after a jury trial, with the benefit of a full record. *See* 807 F.3d at 289-91. In *Proctor*, where the court granted summary judgment in favor of the defendant under *Safeco*, the court determined that the only authoritative guidance concerning the disputed practice was a decision that the Seventh Circuit issued after the defendant had discontinued the disputed practice. *See* 466 F. Supp. 3d at 914, 940; *see also* Relator Resp. to AbbVie Supp. Auth. [105], at 1 (noting same).

The cases in which courts dismissed at the pleading stage do not assist AbbVie, either. In *Streck*, the court determined that the defendants were not warned away from their objectively reasonable interpretation in part because the relevant agency itself recognized there was "confusion" about disputed statute. 746 F. App'x at 109-10. AbbVie has not identified similar evidence. In *United States ex rel. Hixson v. Health Management Sys., Inc.*, 613 F.3d 1186, 1190-91 (8th Cir. 2010), the court noted that the "defendant's interpretation of the applicable law" was "perhaps . . . the most reasonable one" and explained why the relators' cited sources did not undermine that interpretation. By contrast, Relator here has sufficiently pleaded that the AKS itself could cast doubt AbbVie's interpretation of the lawfulness of the Ambassador Program. The *Hixson* court also held that to survive a motion to dismiss, a relator "must show that there is no reasonable interpretation of the law that would make the allegedly false statement true." *Id.* at 1191. As noted, this court is uncomfortable with the notion that an FCA defendant can escape liability by identifying any reasonable interpretation of the statute at issue, regardless of whether the defendant followed that interpretation or believed it to be correct. (*See* Relator Opp. at 22-23 (advancing similar argument).) The rule articulated in *Hixon* appears broad enough to supply such an escape hatch. Finally, *McGrath* did not discuss whether the defendant was warned away from its objectively reasonable interpretation. *See* 690 F. App'x at 552.

2. Anti-Kickback Statute

Liability under the AKS requires a "knowing[ ] and willful[ ]" violation. 42 U.S.C. § 1320a-7b(b)(2). 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 plaintiff to allege that the defendant "intended to engage in conduct that [it] knew was unlawful"—though the law does not require proof that the defendant "was aware of the specific statutory provisions that [it] is alleged to have violated." *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 Suarez I*, 2019 WL 4749967, at *13 ("Relator's burden is to allege facts supporting an inference that AbbVie thought the Ambassador Program was *impermissible.*").

In *Suarez I*, the court determined that Relator had not adequately pleaded scienter for purposes of the AKS. 2019 WL 4749967, at *13-14. Relator had alleged (as he does here) that a pharmaceutical company can violate the AKS by providing "extensive valuable products or services" to influence prescribing behavior. *Id.* at *13. The court stated that because "OIG guidance recognizes that a pharmaceutical company can provide product and reimbursement support services without violating the law," this general allegation (and others like it) did not raise an inference that AbbVie knew the Ambassador Program was illegal. *Id.* The court also considered Relator's allegations that AbbVie tried to conceal the sales-driven purpose of the Ambassador Program by, for example, warning Ambassadors "not to document all time they spent with doctors" and instructing them to avoid leaving a paper trail of questions about the proper scope of patient interactions. *Id.* at *14. The court determined that these allegations did not raise an inference that AbbVie knew it was engaging in illegal behavior because it was "unclear whether the alleged cover-up efforts ha[d] any relation to the services alleged to constitute illegal remunerations in this case." *Id.* The fact that AbbVie's Humira website openly advertised Ambassador Services—such as free injection training at home, free on-call nurses even when physicians' offices are closed, and a toll-free number for billing and reimbursement assistance—also "dispel[led] any inference that AbbVie was trying to conceal the services that Relator

contends violate the AKS," the court observed. *Id.*

Like the allegations concerning remuneration in the SAC, the allegations concerning AKS scienter present a very close call. The court concludes that the allegations now push across the line and permit an inference that AbbVie knew its conduct was impermissible. In the SAC, Relator now plausibly alleges that Ambassadors' services exceed the basic product support services contemplated in the OIG guidance. Relator also alleges with specificity that if physicians did not prescribe Humana, they would nevertheless be required to provide the services that Ambassadors are furnishing to Humana-prescribing physicians. These allegations together with those concerning AbbVie's cover-up efforts are sufficient to create an inference that AbbVie "required Ambassadors to hide the true nature of their work" (Relator Opp. at 20) because it knew that Ambassadors provide extensive medical counseling in addition to basic product support services.

The OIG's statements that basic product support services are permissible do not dispel these inferences, at least at this stage of the proceedings, because the OIG also cautions against providing substantial independent value to physicians. Relator emphasizes that in *United States ex rel. Bilotta v. Novartis Pharmaceuticals Corp.*, 50 F. Supp. 3d 497, 520 (S.D.N.Y. 2014), the court determined that "[t]he conduct alleged in the pleadings" violated "pharmaceutical industry standards" that were known to the defendant, and therefore "support[ed] an inference that [the defendant] acted" knowingly under the AKS. The same is true here, despite that the relator in *Bilotta*, as AbbVie notes, alleged a different kind of illegal remuneration. (*See* AbbVie Reply at 13).

AbbVie maintains that the Humira websites, as before, undermine an inference that it knew its behavior was unlawful. (*See* AbbVie Br. at 17.) Relator does not respond to this argument as it relates to scienter. But in addressing AbbVie's arguments that the public disclosure bar requires dismissal, Relator argues that the websites "do not reveal the medical counseling provided to patients for matters well beyond learning to use Humira." (Pl's Opp. at 27.) The

websites reference free, in-person injection training from nurses, on-call nurse support, and insurance co-pay savings. Because they provide few details about these services and do not mention that they eliminate expenses physicians otherwise would incur, Relator's characterization is reasonable. The Humira websites therefore do not defeat a finding of intent. Similar logic disposes of AbbVie's argument that an inference of scienter "cannot be squared" with Relator's allegations that it "openly operated a vast, nationwide network of Ambassadors" in a "highly regulated industry." (AbbVie Br. at 17.) Openly operating the Ambassador Program would not necessarily alert regulators to the unlawful conduct Relator alleges.

AbbVie's cited cases also fail to persuade the court that Relator has not adequately pleaded scienter for purposes of the AKS. As Relator notes, the plaintiffs in *Forney*, 2017 WL 2653568, at *5, and *United States ex rel. Young v. Suburban Home Physicians*, No. 14-CV-02793, 2017 WL 6625940, at *3 (N.D. Ill. Dec. 28, 2017), did not allege that the defendants acted with the intent to induce prescriptions. Relator, by contrast, does. (*See* Relator Opp. at 21.) He also supports the allegation with details about how AbbVie allegedly treated the Ambassador Program internally. (*See id.*) For example, Relator alleges that AbbVie offered prescription-based incentive programs for Ambassadors and tried to hide the extent to which Ambassadors worked with AbbVie sales personnel. (*Id.*). Relator has adequately pleaded scienter under the AKS.

C. Public Disclosure Bar

Last, AbbVie argues that the court must dismiss Relator's claims 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). "Determining whether to apply the public-disclosure bar requires the court to complete a three-step inquiry."

Bellevue v. Univ. Health Servs. of Hartgrove, Inc., 867 F.3d 712, 718 (7th Cir. 2017). First, the court "examine[s] whether the relator's allegations have been 'publicly disclosed.'" *Id.* (quoting *Cause of Action*, 815 F.3d at 274). "If so," the court "next ask[s] whether the lawsuit is 'based upon,' *i.e.*, 'substantially similar to' the publicly disclosed allegations." *Bellevue*, 867 F.3d at 718 (quoting *Cause of Action*, 815 F.3d at 274). "If it is, the public-disclosure bar precludes the action unless 'the relator is an original source of the information upon which the lawsuit is based.'" *Bellevue*, 867 F.3d at 718 (quoting *Cause of Action*, 815 F.3d at 274) (internal quotation marks omitted). The burden of proof is on the relator at every step of the analysis. *Bellevue*, 867 F.3d at 718. As discussed here, the court concludes that the public disclosure bar does not apply.

1. Public Disclosure

"[T]he allegations in a complaint are publicly disclosed when the critical elements exposing the transaction as fraudulent are placed in the public domain." *Bellevue*, 867 F.3d at 718 (quoting *Cause of Action*, 815 F.3d at 274). "This definition presents two distinct issues: whether the relevant information was placed in the public domain, and, if so, whether it contained the critical elements exposing the transaction as fraudulent." *Bellevue*, 867 F.3d at 718 (quoting *Cause of Action*, 815 F.3d at 274).

a. Public domain

"[M]aterial is in the public domain when the information is open or manifest to the public at large." *Cause of Action*, 815 F.3d at 274. AbbVie correctly states that a public disclosure can occur through "news media," 31 U.S.C. § 3730(e)(4)(A)(iii), and that courts have construed that term to include publicly available websites. (*See* AbbVie Br. at 22 (citing, *inter alia*, *Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401, 408 (2011) (stating that certain enumerated sources of public disclosure in the FCA, "especially news media, suggest that the public disclosure bar provides a broa[d] sweep" (internal quotation marks omitted)); *United States ex rel. Beauchamp v. Academi Training Ctr., LLC*, 816 F.3d 37, 43 n.6 (4th Cir. 2016) ("Courts have unanimously construed the term 'public disclosure' to include websites and online articles.").)

See also Cause of Action, 815 F.3d at 274 ("[M]aterial is in the public domain when the information is open or manifest to the public at large.").

According to AbbVie, Relator's core allegation is that the Ambassador Program induces doctors to prescribe Humira by deploying registered nurses to assist patients with injections and insurance claims at no cost. (*See* AbbVie Br. at 22; *see also id.* at 23 (arguing that according to Relator, Ambassadors' duties are to "fulfill[ ] the Humira prescription and answer[ ] patient questions about it," "mak[e] sure the patient has access to reimbursement or, as needed, free drugs," and "advis[e] patients on ways in which to limit adverse events at injection sites" (quoting SAC ¶¶ 118-22)).) As AbbVie points out, the Humira websites disclose these very features of the Ambassador Program: they reference free injection assistance, on-call nurse support, co-pay savings, and help with insurance. (*See, e.g.*, Humira Savings & Resources Website at 1; Humira Healthcare Professionals Website at 2).) These aspects of the Ambassador Program are in the public domain.

The allegation that Ambassadors' services exceed basic support services are not in the public domain, however. As discussed, Relator persuasively argues that the websites do not disclose that Ambassadors give patients medical counseling "well beyond learning to use Humira." (Relator Opp. at 27.) True, the websites reference on-call nurse support, but that phrase is too vague to indicate that Ambassadors assume the role of physicians and advise patients about their disease states. The online blogs and discussion forums that AbbVie cites present a closer call. AbbVie emphasizes that one blogger reported making telephone calls to her Ambassador "every other day" when he or she did not feel well and noted that the Ambassador communicated with his or her doctor. (AbbVie Br. at 24 (quoting Reddit Crohn's Disease Forum at 3).) Another blogger reported receiving "ongoing support" from an Ambassador "any time [he or she] ha[d] questions." (AbbVie Br. at 24 (quoting TalkPsoriasis Forum at 2).) Relator offers no response to the contents of these blogs and instead maintains that the court should not treat AbbVie's cited blogs as vehicles for public disclosures because the court cannot assess the

bloggers' credibility or determine where the blogs are circulated. (*See* Relator Opp. at 27 n.15.) The court finds this argument unpersuasive. Although AbbVie has not cited cases providing that public disclosures can occur through blogs, Relator has not cited cases providing that they cannot. Moreover, there is no dispute that the blogs at issue are "open or manifest to the public at large." *Cause of Action*, 815 F.3d at 274. The court, therefore, considers the contents of AbbVie's cited blogs but concludes that they do not disclose the extent of Ambassadors' support services. Although the bloggers reported that they called Ambassadors frequently with questions, and although one blogger reported that the Ambassador interfaced with the doctor, these statements could easily suggest that the bloggers were asking questions about the basic services advertised on the Humira websites and that the Ambassadors were discussing the same with doctors.

b. Critical elements of transaction

Because some of Relator's allegations are in the public domain—namely, that Ambassadors provide the services outlined on the Humira websites—the court examines whether they contained "the critical elements exposing the transaction as fraudulent." *Bellevue*, 867 F.3d at 718 (quoting *Cause of Action*, 815 F.3d at 274). Even if an explicit allegation of fraud is absent from the public domain, the public disclosure bar "may still apply so long as . . . facts establishing the essential elements of fraud—and, consequently, providing a basis for the inference that fraud has been committed—are in . . . the public domain." *United States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*, 764 F.3d 699, 708 (7th Cir. 2014) (internal quotation marks omitted).

Relator's theory of fraud is that the Ambassador Program induces physicians to prescribe Humira by significantly reducing the administrative work they must otherwise perform (including out-of-office clinical follow-up), thereby providing substantial independent value. AbbVie argues that the "critical elements necessary to draw [Relator's] mistaken conclusion" were publicly disclosed. (AbbVie Br. at 24 (internal quotation marks omitted).) In support, AbbVie contends that Dr. Healy, the blogger, drew the same conclusion in August 2013. (*Id.* at 24-25.) Healy wrote that AbbVie's Humira support services are "huge gifts to the doctor in the form of 'in-kind' goods

and services. The doctors and their nurses or [physician assistants] no longer have to do patient teaching. Their office staff no longer have to spend hours filling out insurance forms and arguing with adjusters . . . ." (Healy Blog at 3.) These insurance-related services, Healy continued, are "a BIG personnel expense for most U.S. medical practices." (*Id.*) He concluded, "[f]or a busy rheumatology or dermatology practice, *this is like AbbVie providing two or three extra staff members free of charge.* It's hard to overestimate the incentive this provides for the practice to use Humira." (*Id.* at 4 (emphasis supplied).)

Relator contends that Healy's comments do not "disclose a scheme to induce prescriptions and false claims for coverage." (Pl. Opp. at 27.) This argument is difficult to take seriously. Although Dr. Healy does not discuss FCA violations, he certainly discusses a scheme to induce Humira prescriptions by offering physicians what amounts to free support staff. The court concludes that the basic theory of fraud in this case was publicly disclosed. The court therefore turns to the second step of the analysis and asks whether Relator's lawsuit is "substantially similar to the publicly disclosed allegations." *Bellevue*, 867 F.3d at 718 (internal quotation marks omitted). On this issue, as explained below, Relator is on firmer ground.

2. Substantial similarity

The Seventh Circuit has "cautioned against viewing FCA claims at the highest level of generality . . . in order to wipe out *qui tam* suits." *Cause of Action*, 815 F.3d at 281 (internal quotation marks omitted). Still, "to avoid the public-disclosure bar, it is essential that a relator present 'genuinely new and material information' beyond what has been publicly disclosed." *Id.* (quoting *United States ex rel. Goldberg v. Rush Univ. Med. Ctr.*, 680 F.3d 933, 935-36 (7th Cir. 2012)). A FCA complaint that is "even partly based upon publicly disclosed allegations or transactions . . . is nonetheless based upon such allegations or transactions." *Cause of Action*, 815 F.3d at 282 (internal quotation marks and citation omitted). Thus, a relator cannot avoid the public disclosure bar simply by providing "extra details" about or "additional instances" of "the allegations already detailed" in the public domain. *United States ex rel. Heath v. Wis. Bell, Inc.*,

760 F.3d 688, 691 (7th Cir. 2014).

Several factors are relevant to determining whether a realtor's lawsuit is substantially similar to publicly disclosed allegations: "whether relators present genuinely new and material information beyond what has been publicly disclosed"; whether the relator "allege[s] 'a different kind of deceit'"; whether the relator's "allegations require 'independent investigation and analysis to reveal any fraudulent behavior'"; whether the relator's "allegations involve an entirely different time period than the publicly disclosed allegations"; and whether the relator "supplied vital facts not in the public domain." *Bellevue*, 867 F.3d at 719 (quoting *Cause of Action*, 815 F.3d at 281). AbbVie maintains that "[n]one of these factors is present here." (AbbVie Br. at 25.)

The court does not read the allegations so narrowly, however. Contrary to AbbVie's assertions, Relator's complaint does not concern only the publicly disclosed practices. As explained above, the allegation that Ambassadors' services exceed basic product support services is not in the public domain and cannot be inferred from the publicly available information AbbVie has identified. Accordingly, the allegation "present[s] genuinely new and material information" and alleges "a different kind of deceit." *Bellevue*, 867 F.3d at 719 (quoting *Cause of Action*, 815 F.3d at 281). Relator also emphasizes that he offers new, non-public information that supports his theory of fraud. (*See* Relator Opp. at 27-28.) For example, he alleges that AbbVie instructs Ambassadors to avoid documenting all time they spend at physicians' offices; ties Ambassadors' compensation to prescription-based metrics; and touts the Ambassador Program's success in increasing Humira prescriptions. (*See, e.g.*, SAC ¶¶ 10, 18, 105; Relator Opp. at 27-28.) Likewise, he alleges that a specific doctor (Dr. Sullivan) who treats Medicare patients continued prescribing Humira after seeing the Ambassador Program in action. (*See* SAC ¶¶ 154-56; *see also id.* (alleging that the doctor assigned Relator his more "difficult" patients, meaning patients "that would otherwise require him and his staff significant extra work").)

AbbVie is correct that one of the factors articulated in *Bellevue* weighs against Relator: the allegations in the SAC appear to concern the same time period as the conduct that Dr. Healy

discussed in his blog. *See Bellevue*, 867 F.3d at 719. But the court is not persuaded that this factor standing alone demonstrates substantial similarity between Relator's allegations and those in the public domain. On the other side of the scale, Relator alleges new, material non-public information and a different kind of deception. These allegations are critical to his lawsuit and undermine AbbVie's argument that "anyone with an internet connection would have had all the information necessary to draw the same flawed inferences and make the same flawed claims [Relator] makes here." (AbbVie Br. at 26.) For the same reasons, Relator's case is distinguishable from those on which AbbVie relies. *See United States ex rel. Solomon v. Lockheed Martin Corp.*, 878 F.3d 139, 145 (5th Cir. 2017) (holding that a complaint is "based on public disclosures" where publicly available facts "could have been synthesized to form the same inference" alleged in the complaint); *United States ex rel. Feingold v. AdminaStar Fed., Inc.*, 324 F.3d 492, 497 (7th Cir. 2003) (holding that the relator "based th[e] action on publicly disclosed documents" where he "point[ed] to no evidence upon which [the] suit depend[ed] that [was] not publicly disclosed").

Relator's allegations are not substantially similar to publicly disclosed information and allegations. Accordingly, the public disclosure bar does not apply, and it is unnecessary to determine whether Relator was an original source of the allegations in the SAC.

D. Marketing-Based Claims

AbbVie argues that Relator does not state a claim for an FCA violation based on allegations that it violated federal marketing laws. The court agrees. First, in his briefing, Relator does not identify what marketing laws AbbVie allegedly violated. Second, "[v]iolating a regulation is not synonymous with filing a false claim," *Grenadyor*, 772 F.3d at 1107, and Relator does not link any alleged marketing misconduct to the submission of a false claim. In opposing AbbVie's motion to dismiss, Relator addresses the marketing-related allegations only in a two-sentence footnote. (*See* Relator Opp. at 30 n.18 (arguing that Ambassadors' interactions with patients are veiled sales visits that violate unspecified marketing laws and make the alleged kickbacks

especially "pernicious").) Relator's footnote does not clarify whether Relator is, in fact, asserting an FCA claim based on violations of federal marketing laws. Nor does it address the pleading flaws just identified. Any FCA claim based on alleged marketing misconduct is dismissed.

CONCLUSION

Defendant's Motion to Dismiss Relator's Second Amended Complaint [86] is granted in part and denied in part. The court agrees with AbbVie that Relator has not pleaded nationwide fraud, but denies AbbVie's motion to dismiss Relator's FCA claims to the extent they are based on conduct in Florida. Relator's state-law claims are dismissed without prejudice, except for claims asserted under Florida law, which may proceed. If Relator purports to assert an FCA claim based on alleged violations of federal marketing laws, that claim is dismissed with prejudice.

ENTER:

Dated: November 30, 2020

REBECCA R. PALLMEYER
United States District Judge