

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES *ex rel.* KURT KROENING,

Plaintiffs / Relator,

v.

Case No. 12-CV-366

FOREST PHARMACEUTICALS, INC., et al.,

Defendants.

DECISION AND ORDER

I. Procedural History

On April 18, 2012, relator Kurt Kroening filed the present action on behalf of the United States, 30 states, and the District of Columbia under the False Claims Act and similar state statutes. After a lengthy period for investigation, the United States filed notice on January 31, 2014, that it was not intervening. (ECF No. 23.) The case was unsealed (ECF No. 24), and on June 13, 2014, Kroening filed an amended complaint on behalf of the United States, the District of Columbia, and twenty-eight states (ECF No. 34). After the court approved several stipulations to extend the deadline for defendants Forest Pharmaceuticals, Inc. and Forest Laboratories, Inc. (herein collectively "Forest") to respond to the amended complaint (ECF Nos. 39, 40, 43, 44, 45, 47), on March 16,

2015, Forest filed a motion to dismiss (ECF No. 50). Briefing on the motion was completed on May 11, 2015. All parties have consented to have this court enter final judgment in this matter. (ECF Nos. 38, 41, 42.)

II. Allegations in the Amended Complaint

In June of 2007, Kroening began working for Forest Pharmaceuticals, Inc. as a pharmaceutical sales representative. (ECF No. 34, ¶¶ 3, 19.) For several years prior to Kroening's employment and continuing until at least the filing of the amended complaint (ECF No. 34, ¶ 19), Forest maintained a "Speakers Bureau" program whereby it would pay prescribers of Forest drugs for speaking at presentations. Speakers received not only direct compensation of between \$1,000 and \$1,750 per presentation (ECF No. 34, ¶ 48) but also lavish meals, drinks (ECF No. 34, ¶¶ 43, 49), and travel expenses (ECF No. 34, ¶¶ 29, 58). The purpose of the Speakers Bureau was not education but to incentivize prescribers to write prescriptions for Forest drugs. (ECF No. 34, ¶ 30.) Educational content and even actual attendance were not relevant to Forest. (ECF No. 34, ¶¶ 38, 46, 50.) Sometimes prescribers were paid a speaker's fee even though they did not present a speech or make a presentation. (ECF No. 34, ¶¶ 53, 59.) When a presentation did occur, it was generally only about 5 to 10 minutes in length and not necessarily related to any Forest drug. (ECF No. 34, ¶ 59.) After Forest changed its policies in 2010 to require two providers at a presentation, attendance

records were often falsified in an effort to provide evidence that the attendance requirement was met. (ECF No. 34, ¶¶ 28, 50, 54, 55, 56, 58.)

Physicians were chosen to give presentations “based on their actual and potential prescription writing volume.” (ECF No. 34, ¶ 31.) Also relevant was whether the physician had a high number of Medicare and/or Medicaid patients. (ECF No. 34, ¶ 41.) Sales representatives actively tracked the prescriptions of speakers to ensure an adequate “return on investment.” (ECF No. 34, ¶¶ 32, 34, 60.) If a provider in the Speakers Bureau did not increase or maintain his prescription volume for Forest drugs, he was dropped from the program. (ECF No. 34, ¶¶ 28, 35, 45.)

Kroening contends that the speaking fees and related compensation constituted unlawful kickbacks. As a result of the “kickbacks, misrepresentations and submissions of non-reimbursable claims” described in the amended complaint (ECF No. 34, ¶¶ 64, 69, 74), Forest “knowingly presented or caused to be presented false or fraudulent claims for the improper payment or approval of prescriptions of Forest drugs” (ECF No. 34, ¶ 64 (citing 31 U.S.C. § 3729(a)(1)(A))), “knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim for the improper payment or approval of prescriptions of Forest drugs” (ECF No. 34, ¶ 69 (citing 31 U.S.C. § 3729(a)(1)(B))), and “knowingly conspired to commit violations of the False Claims Act for the improper payment or approval of prescriptions of all of its

drugs for which it included providers in its Speakers Bureau” (ECF No. 34, ¶ 74 (citing 31 U.S.C. § 3729(a)(1)(C))).

III. Motion to Dismiss Standard

“To survive a motion to dismiss under Rule 12(b)(6), a complaint must provide enough factual information to ‘state a claim to relief that is plausible on its face’ and ‘raise a right to relief above the speculative level.’” *Thulin v. Shopko Stores Operating Co., LLC*, 771 F.3d 994, 997 (7th Cir. 2014) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007)). The court not only considers the context of the case but also may draw upon its own judicial experience and common sense when assessing whether a complaint states a claim upon which relief may be granted. *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679, (2009)). Well-pleaded facts are accepted as true and construed in the light most favorable to the plaintiff. *Id.* (citing *Camasta v. Jos. A. Bank Clothiers, Inc.*, 761 F.3d 732, 736 (7th Cir. 2014)). Because this action arises under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, the amended complaint must satisfy the heightened pleading requirements of Fed. R. Civ. P. 9(b). *Id.* at 998 (citing *United States ex rel. Gross v. AIDS Research Alliance-Chicago*, 415 F.3d 601, 604 (7th Cir. 2005)).

IV. Analysis

The False Claims Act (FCA) is “the primary vehicle by the Government for recouping losses suffered through fraud.” 31 U.S.C. § 3729 *et seq.* The Attorney General may bring actions under the FCA directly in the name of the United States. 31 U.S.C.

§ 3730(a). Alternatively, a private person known as a “relator” may bring a *qui tam* action “in the name of the Government.” 31 U.S.C. § 3730(b). If the *qui tam* action results in the recovery of money for the government, the relator shares in the award. *See* 31 U.S.C. § 3730(d).

The FCA imposes civil liability on any person who “knowingly presents, or causes to be presented” to the United States or its representatives “a false or fraudulent claim for payment or approval,” 31 U.S.C. § 3729(a)(1)(A), or “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim,” 31 U.S.C. § 3729(a)(1)(B). To establish liability under the FCA, the defendant must have acted with “actual knowledge” or with “deliberate ignorance” or “reckless disregard” to the possibility that the submitted claim was false. 31 U.S.C. § 3729(b)(1)(A). The FCA does not require proof of specific intent to defraud. 31 U.S.C. § 3729(b)(1)(B).

The Anti-Kickback Statute, in relevant part, makes it unlawful to

knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

... (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a-7b(b)(2). Congress amended the Anti-Kickback Statute in 2010 to explicitly state that “a claim that includes items or services resulting from a violation of

this section constitutes a false or fraudulent claim for purposes of” the FCA. 42 U.S.C. § 1320a-7b(g).

A. Allegation of any Fraudulent Claim

Kroening’s amended complaint does not allege that Forest made any false claim to any plaintiff. Rather, Kroening alleges that Forest violated 31 U.S.C. § 3729(a)(1)(A) and (B) when it *caused* false claims to be submitted to the plaintiffs by being the first step in a four-step causal chain. This causal chain began with the defendants, who provided physicians with lavish meals and other perks as well as money for sham presentations. In return, the physicians prescribed the defendants’ drugs to their patients. The patients then filled the prescriptions at pharmacies. Lastly, the pharmacies sought payment from the patients’ insurers, some of which are funded by the plaintiffs. Kroening contends that the prescription claims submitted through the speaker physicians were false because they were tainted by the illegal kickbacks in violation of the Anti-Kickback Statute.

The defendants’ motion to dismiss presents two questions. First, does the scheme alleged by Kroening plausibly state a claim under the FCA? Second, if the legal theory is sufficient to state a claim under the FCA, has Kroening provided sufficient particularity as required by Rule 9(b)?

1. Alleged Scheme as a Violation of the FCA

“The Supreme Court has long held that a person may be liable under the FCA for causing an innocent third party to submit a false claim to the government without knowing it is false.” *United States ex rel. Rost v. Pfizer, Inc.*, 736 F. Supp. 2d 367, 376 (D. Mass. 2010) (citing, in part, *United States v. Bornstein*, 423 U.S. 303, 313 (1976)); *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 539-43 (1943)); see also *Mason v. Medline Indus.*, 731 F. Supp. 2d 730, 738 (N.D. Ill. 2010) (“The wealth of case law supports the proposition that the FCA reaches claims that are rendered false by one party, but submitted to the government by another.”). Thus, the fact that the claim was submitted by a pharmacy without knowledge of the alleged kickbacks to the speaker physicians does not bar Kroening’s action.

Kroening argues that the claims the pharmacies submitted were false because they were “not legally reimbursable” (ECF No. 56 at 23) (all citations to ECF documents herein utilize the ECF pagination) due to the illegal kickbacks. In effect, Kroening argues that, if the plaintiffs knew of Forest’s scheme as alleged in the complaint, they would not have paid the claims. See *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 32 (D.D.C. 2003) (“The cases stating that kickback claims state a cause of action under the FCA rely on precedent stating that FCA liability arises where information is concealed in the submission of a claim that, if known to the government, would affect the government’s decision to pay on that claim.”).

Any claim resulting from the scheme alleged in the first amended complaint that was submitted after the March 23, 2010 effective date of the amendment to the Anti-Kickback Statute is plainly within the scope of the FCA. However, while the parties agree that the amendment was not retroactive (ECF Nos. 51 at 16; 56 at 21), they disagree as to what that means. Kroening says that the non-retroactivity of the amendment is immaterial because the amendment merely made explicit what had long been understood to be the law—namely, that a violation of the Anti-Kickback Statute constitutes a false claim for purposes of the FCA. Forest contends that before the amendment a violation of the Anti-Kickback Statute constituted a false claim under the FCA only if (1) the defendant falsely certified its compliance with the Anti-Kickback Statute and (2) compliance was a precondition for payment of the claim. (ECF No. 51 at 16-20.) Kroening argues that a specific false certification is not required. (ECF No. 56 at 22.)

According to Forest, Kroening’s theory is one that courts have taken to calling the “implied-certification theory of false claims.” *U.S. ex rel. Grenadyor v. Ukrainian Vill. Pharmacy, Inc.*, 772 F.3d 1102, 1106 (7th Cir. 2014). “The theory treats a bill submitted to the government as an implicit assurance that the bill is a lawful claim for payment, an assurance that’s false if the firm submitting the bill knows that it’s not entitled to payment.” *Id.* Many courts around the country, including district courts within the Seventh Circuit, have accepted this implied certification theory for FCA actions. *See, e.g.,*

United States v. Rogan, 459 F. Supp. 2d 692, 717-18 (N.D. Ill. 2006) (citing *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244 (3d Cir. 2004)).

However, while Forest's motion to dismiss was pending before this court, the Court of Appeals for the Seventh Circuit explicitly declined to adopt the implied certification doctrine in an FCA case. *United States v. Sanford-Brown, Ltd.*, 788 F.3d 696, 711-12 (7th Cir. 2015). That decision triggered a variety of filings from the parties: Forest sought leave to file supplemental authority alerting the court to the case (ECF No. 60); Kroening responded with his own take on *Sanford-Brown* (ECF No. 61); Forest replied (ECF No. 62); the United States sought leave to file a statement with its view on *Sanford-Brown* (ECF No. 63, 64); and Forest responded (ECF No. 65). The relevant motions regarding the *Sanford-Brown* case (ECF Nos. 60, 63) will be granted.

Forest argues that *Sanford-Brown* is controlling and conclusively holds that Kroening's implied certification theory is not viable. (ECF Nos. 60-1 at 1-3; 62 at 1-2; 65 at 1-6.) Kroening and the United States argue that *Sanford-Brown* is distinguishable and that the present case is instead governed by a prior court of appeals decision, *United States v. Rogan*, 517 F.3d 449 (7th Cir. 2008). (ECF No. 61 at 2-3; 64 at 1-7.)

Rogan never used the term "implied certification" nor referred to any sort of certification. Instead, according to the United States, the court discussed "the issue in terms of 'materiality.'" (ECF No. 64 at 5.) However, the core of the defendant's materiality argument on appeal in *Rogan* was one of the sufficiency of the evidence—

specifically, that judgment could not be sustained because no federal employee testified that it would have denied the claims had the defendant's violations of the Stark Amendment and the Anti-Kickback Statute been disclosed. *Rogan*, 517 F.3d at 452. As such, the court finds it an untenable stretch to conclude that the decision in *Rogan* answers the question presently before the court.

In *Sanford-Brown* the relator alleged that a for-profit college's failure to comply with federal regulations related to recruiting and retaining students rendered false the college's claims for subsidies from the Department of Education. 788 F.3d at 700. The court of appeals rejected the relator's FCA action notwithstanding the fact that, as a condition of participating in the federal program, the college explicitly agreed to comply with all applicable federal regulations. *Id.* at 708-09. The court noted that there was no evidence that the college entered into the agreement in bad faith. *Id.* at 709. The court regarded compliance with the agreement merely as a condition of the college's participation in the program, not as a condition of payment, and therefore not actionable under the FCA. *Id.* at 709-12. Amidst this discussion the court stated, "Although a number of other circuits have adopted this so-called doctrine of implied false certification, we decline to join them and instead join the Fifth Circuit." *Id.* at 711-12 (citing *U.S. ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*, 764 F.3d 699, 711 n.13 (7th Cir. 2014); *U.S. ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 270 (5th Cir.2010)).

Perhaps when the court said it was declining to join the courts that had adopted the implied certification theory it meant that it was declining to do so *at this time* and was instead leaving the issue unsettled as the court had repeatedly done in the past. *See Grenadyor*, 772 F.3d at 1106 (noting that the implied certification theory is “treated as unsettled by our court” but finding that, even if accepted, the relator’s claim nonetheless fails) (citing *Absher*, 764 F.3d at 711 and n.13). This reading of the court’s statement is bolstered by reviewing the case from the Fifth Circuit that the court states it is joining. The court in *Steury* did not reject the implied certification theory but instead said only what the Court of Appeals for the Seventh Circuit had repeatedly said prior to *Sanford-Brown*: the implied certification theory had not yet been recognized in the circuit and the court declines to resolve the question now. *Id.* at 268. But if the court intended to say again only what it had repeatedly said in the past, it would be odd to phrase this as joining the Fifth Circuit. And, in any event, the parties do not advocate such a nuanced reading of the court’s statement in *Sanford-Brown*.

Therefore, the court turns to the question of whether *Sanford-Brown* is distinguishable. It is clear that the court’s conclusion in *Sanford-Brown* was motivated in part by a concern that a contrary decision would explode the scope of the FCA, turning every hyper-technical violation of a myriad of laws and regulations into a potential action under the FCA. *Sanford-Brown*, 788 F.3d at 711-12 and n.6. It was amidst its discussion of this concern that the court stated it declined to adopt the implied

certification theory. The court in *Sanford-Brown* also relied heavily upon the fact that the defendant's agreement to comply with federal laws was a condition of *participation* in the program rather than a condition of *payment*. *Sanford-Brown*, 788 F.3d at 712. Based upon this distinction, it concluded that, rather than an action under the FCA, the remedy was for the Department of Education to pursue administrative remedies to bring the defendant into compliance. *Sanford-Brown*, 788 F.3d at 712.

Compliance with the Anti-Kickback Statute, however, is a condition of payment under the government programs at issue here. *United States v. Omnicare, Inc.*, 2011 WL 1059148, 3 (N.D. Ill. Mar. 21, 2011) (citing *United States v. Rogan*, 459 F. Supp. 2d 692, 724 (N.D. Ill. 2006); *United States ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 616 (N.D. Ill. 2003)). And unlike the various laws and regulations allegedly violated to render false the claims at issue in *Sanford-Brown*, the Anti-Kickback Statute, like the FCA, is a fraud prevention statute aimed directly at safeguarding the public fisc, *see United States v. Rogan*, 517 F.3d at 452. Thus, a violation of the Anti-Kickback Statute is not a hyper-technical violation but rather a fundamental prerequisite to reimbursement.

The nature of the present case also sets it apart from *Sanford-Brown*. Unlike *Sanford-Brown*, Forest is alleged to have caused innocent third-parties (pharmacies) to submit claims without the knowledge that the claims were the result of impermissible kickbacks. Because Forest never directly sought reimbursement from a plaintiff, there was no equivalent occasion for it to certify its compliance with the Anti-Kickback

Statute. If a violation of the Anti-Kickback Statute was actionable under the FCA only if the defendant explicitly certified that it would comply with the Anti-Kickback Statute, a malefactor could effectively insulate itself from liability by ensuring that any claim resulting from a violation of the Anti-Kickback Statute is laundered through an innocent third-party. *Cf. U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp. 3d 323, 333-35 (S.D.N.Y. 2014) (quoting statements of Sen. Kaufman in support of amendment to the Anti-Kickback Statute, 155 Cong. Rec. S10852-01, and criticizing *United States ex rel. Thomas v. Bailey*, No. 06 Civ. 465, 2008 WL 4853630 (E.D. Ark. Nov. 6, 2008)); *see also U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 393 (1st Cir. 2011). In short, an FCA claim that a person “caused” another to submit a false claim would be unlikely to ever apply to FCA actions grounded in violations of the Anti-Kickback Statute.

A factually similar case, *U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377 (1st Cir. 2011), involved a manufacturer of products used in certain spinal surgeries who, in an effort to induce physicians to use its products, allegedly paid kickbacks to the physicians in the form of sham consulting agreements, entertainment expenses, travel and accommodations, and speaker fees, among others. *Id.* at 380. The physicians then used the manufacturer’s products in surgeries, which led to hospitals, lacking knowledge of the alleged kickbacks, to seek reimbursement from government healthcare programs. *Id.* at 378-79. The court rejected the manufacturer’s argument that

the FCA did not cover its alleged conduct. *Id.* at 388-92. The court finds *Hutcheson* persuasive.

That is not to say that every violation of a statute or regulation somewhere along the causal chain that led to a claim renders that claim false for purposes of the FCA. *See Sanford-Brown*, 788 F.3d at 711-12; *U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999) (holding that defendant's failure to comply with Federal Transit Act regulations are not fraud); *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997) (“[C]laims for services rendered in violation of a statute do not necessarily constitute false or fraudulent claims under the FCA.”); *see also United States v. McNinch*, 356 U.S. 595, 599 (1958) ([T]he False Claims Act was not designed to reach every kind of fraud practiced on the Government.”); *U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 225 (1st Cir. 2004) (“Not all fraudulent conduct gives rise to liability under the FCA.”). Nor is “a violation of the federal antikickback provision ... a per se violation of the FCA.” *Rost*, 736 F. Supp. 2d at 376 (quoting *United States ex rel. Franklin v. Parke-Davis*, 147 F.Supp.2d 39, 54 (D. Mass. 2001)).

However, in light of the mutual purpose of the Anti-Kickback Statute and the FCA in preventing fraud against the government and the necessity of complying with the Anti-Kickback Statute for payment under the relevant government programs, it logically follows that, when a violation of the Anti-Kickback Statute leads to a claim submitted to the government that it would not have paid had it known of the violation

of the Anti-Kickback Statute, such a claim is false and actionable under the FCA. The court finds it unnecessary to opine as to whether that conclusion can be characterized as accepting the implied certification theory under the circumstances presented in this case; such an emphasis on labels and court-developed doctrines arguably obfuscates rather than clarifies. After all, the FCA makes no mention of certifications as a prerequisite to a false claim. *Hutcheson*, 647 F. 3d at 389.

The court's focus and conclusion are narrow. If a pharmaceutical company knowingly and willfully pays or offers to pay any remuneration to a physician in exchange for the physician prescribing a particular product, it violates the Anti-Kickback Statute. 42 U.S.C. § 1320a-7b(b)(2). If the pharmaceutical company knows that the violation of the Anti-Kickback Statute will lead to a claim for payment submitted to the government, including a claim by a third-party without knowledge of the Anti-Kickback Statute violation, the pharmaceutical company violates the FCA, provided the government would not have paid the claim had it known of the violation. *See Hutcheson*, 647 F.3d at 389 ("When the defendant in an FCA action is a non-submitting entity, the question is whether that entity knowingly caused the submission of either a false or fraudulent claim or false records or statements to get such a claim paid."). This view, the court finds, is most consistent with Congress's intent that the FCA be read broadly "to reach all types of fraud, without qualification, that might result in financial loss to the Government." *Mason*, 731 F. Supp. 2d at 737 (quoting *Cook County, Ill. v. United*

States ex rel. Chandler, 538 U.S. 119, 129 (2003)); *see also Hutcherson*, 647 F.3d at 392 (same).

In short, the court finds that the 2010 amendment of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(g), although not retroactive, accurately re-states the law as it existed prior to the amendment.

2. Sufficiency of Counts One and Two of the Amended Complaint

Having set forth the law with respect to how a violation of the Anti-Kickback Statute may lead to a claim under the FCA, the court must turn to the details alleged in the first amended complaint to determine whether Kroening has met this standard with the particularity required under Rule 9 of the Federal Rules of Civil Procedure.

“The *sine qua non* of a False Claims Act violation is the submission of a fraudulent claim.” *Mason v. Medline Indus., Inc.*, 2009 U.S. Dist. LEXIS 43500 (N.D. Ill. May 22, 2009) (citing *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002)). After all, it is “not the underlying fraudulent activity or ... the government’s wrongful payment, but ... the ‘claim for payment’” that is unlawful under the FCA. *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999) (quoting *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995)). It is at this crucial final step that the amended complaint is devoid of detail; there is no allegation of any specific claim being made to a plaintiff.

Forest contends that every count of the amended complaint is deficient because it fails to point to any claim that was allegedly submitted to any government health

program. (ECF No. 51 at 14-15.) Kroening responds that requiring this level of particularity “in a case like this would be absurd and would give defendants such as Forest a free pass at avoiding civil liability for providing illegal remuneration in exchange for increased sales.” (ECF No. 56 at 17.) Kroening points to *United States ex rel. Kennedy v. Aventis Pharms., Inc.*, 512 F. Supp. 2d 1158, 1167 (N.D. Ill. 2007), wherein the court stated, “It is well established, however, that the requirements of Rule 9(b) are relaxed when the plaintiff lacks access to all facts necessary to detail his claim.” *Id.* (citing *Corley v. Rosewood Care Ctr., Inc.*, 142 F.3d 1041, 1051 (7th Cir. 1998); *Emery v. Am. Gen. Fin., Inc.*, 134 F.3d 1321, 1323 (7th Cir. 1988) (Rule 9(b) is relaxed when plaintiff shows that “further particulars of the alleged fraud could not have been obtained without discovery.”).) Other courts have concluded that relaxing the pleading standard under Rule 9(b) must be limited to “rare circumstances” because “relaxing the Rule 9(b) pleading standard would undermine the purposes of fraud pleading generally and the FCA specifically.” *United States v. Ortho-McNeil Pharm., Inc.*, 2007 U.S. Dist. LEXIS 52666, 13-14 (N.D. Ill. July 20, 2007) (citing *Karvelas*, 360 F.3d at 230-31 (refusing to relax Rule 9(b) pleading standard where evidence of FCA claim was allegedly unavailable to plaintiff)).

Kroening admits that the amended complaint contains no detail of any specific claim that was submitted to the government as a result of a violation of the Anti-Kickback Statute. Although it alleges that the “[d]efendants target providers with a high

number of Medicare and/or Medicaid patients for its speaker reward events” (ECF No. 34, ¶ 41), it requires an inference that some prescriptions written by physicians who received kickbacks from Forest must have been paid by the plaintiffs “[g]iven the significant proportion of medical care in this country that is financed by Medicare and Medicaid.” *Kennedy*, 512 F. Supp. 2d at 1167. However, the amended complaint does not contain any specific allegation as to Medicare’s and Medicaid’s role in healthcare generally or regarding Forest’s product’s specifically. Kroening contends that he cannot be any more specific because he does not have that information, despite the fact that the amended complaint alleges that Forest provided its sales representatives such as Kroening with reports that list the percentage of each physician’s patients who are beneficiaries of Medicare and Medicaid. (ECF No. 34, ¶ 41.) Under such circumstances, he argues, he need only “alleg[e] particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.” (ECF No. 56 at 19 (citing *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)).

Rule 9(b)’s particularity requirement ought not be relaxed automatically simply because the relator lacks access to certain details. Read too broadly, such a holding could undermine the rule’s core purposes of: “(1) protecting a defendant’s reputation from harm; (2) minimizing ‘strike suits’ and ‘fishing expeditions’; and (3) providing notice of the claim to the adverse party.” *Vicom, Inc. v. Harbridge Merchant Servs.*, 20 F.3d

771, 777 (7th Cir. 1994). Conversely, Rule 9(b) ought not stand as a needless technical obstacle when the other details of the amended complaint persuasively demonstrate that the absent detail is likely to be uncovered if the case is permitted to proceed. However, “Rule 9(b) ... does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government.” *Clausen*, 290 F.3d at 1311.

The core of Kroening’s amended complaint is that Forest engaged in a nationwide scheme to provide lavish benefits to prescribers of its drugs through sham speaker fees. Setting aside the requirement that a claim for payment be submitted to a plaintiff, Kroening must allege that (1) a prescriber received an impermissible kickback from Forest, and (2) the prescriber wrote a prescription for a Forest product. When alleging an expansive scheme to defraud the government, the amended complaint need not contain details of every instance of fraud; rather, it need provide only “representative examples of the fraud.” *United States ex rel. Cieszyski v. LifeWatch Seros.*, 2015 U.S. Dist. LEXIS 141721, 33 (N.D. Ill. Oct. 19, 2015) (quoting *U.S. ex rel. Bragg v. SCR Medical Transp., Inc.*, 2011 U.S. Dist. LEXIS 38786, 6-7 (N.D. Ill. April 8, 2011)). Although the amended complaint contains details of how the scheme worked, those details do not cohere into representative examples of fraud.

The amended complaint identifies five prescribers who allegedly received some sort of kickback from Forest. Dr. Juan Albino, MD of Neenah, Wisconsin was paid \$1,000.00 or \$1,250.00 for speaking to Dr. Stephen Shopbell, MD at Dr. Shopbell's office on November 10, 2011. (ECF No. 34, ¶ 56.) Dr. Alvin Wells was paid \$2,500.00 to give two speeches in 2010. (ECF No. 34, ¶¶ 53, 58.) He gave only one presentation but was still paid the full amount. (ECF No. 34, ¶¶ 53, 58.) Another physician, Dr. Jeffrey Junig, attended a "speaker reward event" on January 19, 2011 and impliedly received a "free lunch"; there is no allegation of any further compensation paid to Dr. Junig. (ECF No. 34, ¶ 55.) Dr. Tim Turbett reportedly said on February 28, 2012, at a presentation he conducted, "I love Bystolic, but I really love my paycheck from Forest." (ECF No. 34, ¶ 57.) Finally, the amended complaint implies that one other physician, Dr. Cheryl Tapp, received compensation for speeches at some point. (ECF No. 34, ¶ 35 (stating that Forest's manager told relator, "We are paying [Dr. Tapp] to speak on Viibryd and she has only written three prescriptions. If she is not prescribing the medication, how can we pay her to speak on it?").) She was subsequently a speaker at an event on July 16, 2012, but there are no details as to what, if any, compensation she received for that speech. (ECF No. 34, ¶ 35.)

The amended complaint also references the following individuals. Dr. Ekaterina Soforo was a speaker on March 10, 2010, but there is no allegation she was compensated. (ECF No. 34, ¶ 54.) Dr. Kurtida Ringwalla and Nurse Practitioner Brooke

Vanevehaven allegedly falsely signed a sheet indicating their attendance at Dr. Junig's event on January 19, 2011 (ECF No. 34, ¶ 55), and Dr. Suzanne Grimm was terminated from the "speaker reward program" at some point (ECF No. 34, ¶ 45), but there are no details of any benefits any of them received.

As for prescriptions written by individuals who received impermissible benefits from Forest, the amended complaint provides scant details. It is generally silent with respect to the physicians referenced above, providing only the barest of details with respect to two of them. With respect to Dr. Wells, Kroening states, "Upon information and belief, Dr. Alvin Wells is the number one prescriber of Savella in Wisconsin." (ECF No. 34, ¶ 53.) The only other specific allegation regarding prescriptions written by a speaker is that Dr. Tapp "has only written three prescriptions" for Viibryd over an undefined period. (ECF No. 34, ¶ 34.)

Thus, in only the barest sense does the amended complaint connect specific kickbacks to specific prescriptions. Yet the amended complaint indicates that Kroening should have knowledge of such information. Specifically, it alleges that Forest sales representatives reviewed the prescription rates for each of the providers in their territories for Forest drugs and competing products. (ECF No. 34, ¶ 39.) The sales representatives then used that information to decide which providers to give the so-called kickbacks to in order to maximize the "return on investment." (ECF No. 34, ¶¶ 29, 34.) Thus, it would seem that, if Forest executed the scheme as Kroening alleges,

Kroening would be able to identify specific physicians who received kickbacks and who, in turn, wrote a lot of prescriptions for Forest drugs. But he did not include those allegations in the amended complaint. As such, the court finds that it falls short of the particularity required under Rule 9(b).

While Rule 9(b) requires particularity, not proof, and does not mean that the court is foreclosed from drawing reasonable inferences to bridge gaps in a plaintiff's allegations, the allegations contained in Count One of the amended complaint fall short of the particularity required by Rule 9(b). Moreover, although the amended complaint alleges violations of both 31 U.S.C. § 3729(a)(1)(A), regarding "a false or fraudulent claim for payment or approval," and 31 U.S.C. § 3729(a)(1)(B), regarding "a false record or statement material to a false or fraudulent claim," it is unclear what Kroening alleges to be the material "false record or statement." This distinction is not developed in the parties' briefs. To the extent that Count Two depends upon the same facts as Count One, it is likewise insufficient. Alternatively, Count Two is insufficient for failure to identify any particular "false record or statement material to a false or fraudulent claim."

B. Sufficiency of Count Three of the Amended Complaint

Kroening alleges in Count Three of the amended complaint:

By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly conspired to commit violations of the False Claims Act for the improper payment or approval of prescriptions of all of its drugs for which it included providers

in its Speakers Bureau by virtue of its corporate-wide conduct throughout the United States.

(ECF No. 34, ¶ 74.)

“The FCA provides for conspiracy claims, *see* 31 U.S.C. § 3729(a)(3), and general civil conspiracy principles apply.” *United States ex rel. Durcholz v. FKW Inc.*, 189 F.3d 542, 546 n. 3 (7th Cir. 1999) (citing *United States v. Murphy*, 937 F.2d 1032, 1039 (6th Cir. 1991)). Because Kroening alleges that the conspiracy was one to commit fraud, the heightened pleading requirements of Rule 9(b) also apply to this claim. *See United States ex rel. Rockey v. Ear Inst. of Chi., LLC*, 92 F. Supp. 3d 804, 813 (N.D. Ill. 2015) (citing *Cincinnati Life Ins. Co. v. Beyrer*, 722 F.3d 939, 948 (7th Cir. 2013)). “A civil conspiracy is a combination of two or more persons acting in concert to commit an unlawful act, or to commit a lawful act by unlawful means, the principal element of which is an agreement between the parties to inflict a wrong against or injury upon another, and an overt act that results in damage.” *Id.* 92 F. Supp. 3d at 825 (quoting *Lenard v. Argento*, 699 F.2d 874, 882 (7th Cir. 1983)); *see also Richardson v. Indianapolis*, 658 F.2d 494, 500 (7th Cir. 1981) (quoting *Hampton v. Hanrahan*, 600 F.2d 600 (7th Cir. 1979)).

As an initial matter, Kroening’s conspiracy claim is insufficient for the same reasons Counts One and Two of the amended complaint are insufficient: he has failed to allege sufficient details to create a strong inference that the alleged scheme led to false claims being submitted to the plaintiffs. “[A]n actionable FCA conspiracy exists only where at least one of the alleged co-conspirators actually committed an FCA violation.”

Rockey, 92 F. Supp. 3d at 826 (citing *United States ex rel. Farmer v. City of Houston*, 523 F.3d 333, 343 (5th Cir. 2008)).

Count Three is also deficient because it is merely a bare allegation of conspiracy. See *United States ex rel. Watkins v. KBR, Inc.*, 2015 U.S. Dist. LEXIS 66948 (C.D. Ill. May 22, 2015) (quoting *Cooney v. Rossiter*, 583 F.3d 967, 970 (7th Cir. 2009)). While the naturally secretive character of an unlawful conspiracy will often mean that direct evidence of an agreement among conspirators does not exist, see *Durcholz*, 189 F.3d at 545, a conspiracy claim must contain sufficient facts to suggest the existence of an agreement. *United States ex rel. Watkins v. KBR, Inc.*, 2015 U.S. Dist. LEXIS 66948, 56 (C.D. Ill. May 22, 2015). Moreover, the complaint must identify with whom the defendant is alleged to have conspired. *United States ex rel. McGinnis v. OSF Healthcare Sys.*, 2014 U.S. Dist. LEXIS 12600, 22 (C.D. Ill. Jan. 31, 2014).

Kroening does not identify with whom Forest was alleged to have conspired. He seems to imply that the doctors who participated in Forest's speaker program were co-conspirators in the alleged fraud (see ECF No. 56 at 27-28), but such allegations, much less specific supportive allegations tied to representative co-conspirators, are absent from the amended complaint. From the face of the amended complaint, it is unknowable whether, perhaps, Kroening was attempting to impermissibly allege that the conspiracy existed amongst the various Forest employees who participated in the

fraud. *Cf. Rockey*, 92 F. Supp. 3d at 826 (noting that a conspiracy does not exist merely because employees of a corporate defendant allegedly conspired with each other).

C. Sufficiency of Counts Four through Thirty-two of the Amended Complaint

Forest does not individually address the 29 remaining counts of the amended complaint, each of which alleges a claim under a state version of the FCA. Rather, it argues that each state law is construed consistent with the FCA and thus each claim fails for the same reason Kroening's FCA claims fail. (ECF No. 51 at 22-23 and fn.7 (citing *U.S. ex rel. Thayer v. Planned Parenthood of the Heartland*, 765 F.3d 914, 916 n.1 (8th Cir. 2014) (Iowa FCA); *United States v. Caremark, Inc.*, 634 F.3d 808, 820-22 (5th Cir. 2011) (finding "reverse" false claims actionable under Arkansas statute even absent specifically designated provision); *Mendondo v. Centinela Hosp. Med. Ctr.*, 521 F.3d 1097, 1102 n.3 (9th Cir. 2008) (California FCA); *U.S. ex rel. Grenadyor v. Ukrainian Vill. Pharmacy, Inc.*, No. 09-C-7891, 2013 WL 6009261, at *6 (N.D. Ill. Nov. 7, 2013), *aff'd in part and rev'd in part*, 772 F.3d 1002 (7th Cir. 2014) (Georgia False Medicaid Claims Act, Massachusetts FCA, Illinois FCA); *United States v. Minn. Transitions Charter Sch.*, No. 12-1359 (JRT/JSM), 2014 WL 4829081, at *5 n.2 (D. Minn. Sept. 29, 2014) (Minnesota FCA); *City of Providence v. Buck Consultants, LLC*, No. 13-131S, 2013 WL 4047133, at *3 n.5 (D.R.I. Aug. 9, 2013) (Rhode Island FCA); *U.S. ex rel. Keltner v. Lakeshore Med. Clinic, Ltd.*, No. 11-CV-00892, 2013 WL 1307013, at *2 (E.D. Wis. Mar. 28, 2013) (Wisconsin FCA); *United States v. Alpharma, Inc.*, 928 F. Supp. 2d 840, 842 n.1 and 846 n.7 (D. Md. 2013) (District of

Columbia FCA, Florida FCA, Indiana False Claims and Whistleblower Protection Act, Louisiana Medical Assistance Programs Integrity Law, Michigan Medicaid FCA, Montana FCA, New Mexico Medicaid FCA); *U.S. ex rel. Johnson v. Universal Health Serv.*, 889 F. Supp. 2d 791, 793 (W.D. Va. 2012); (Virginia Fraud Against Taxpayers Act); *U.S. ex rel. King v. Solvay S.A.*, 823 F. Supp. 2d 472, 519, 528-30, 539-40 (S.D. Tex. 2011), *order vacated in part*, 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012) (Colorado Medicaid FCA, Connecticut FCA, New Jersey FCA, North Carolina FCA, Oklahoma Medicaid FCA); *U.S. ex rel. Pervez v. Beth Israel Med. Ctr.*, 736 F. Supp. 2d 804, 816 (S.D.N.Y. 2010) (New York FCA); *U.S. ex rel. Lockyer v. Haw. Pac. Health*, 490 F. Supp. 2d 1062, 1072 (D. Haw. 2007), *aff'd*, 343 F. App'x. 279 (9th Cir. 2009) (Hawaii FCA); *U.S. ex rel. Rost v. Pfizer Inc.*, 446 F. Supp. 2d 6, 12 n.13 (D. Mass. 2006), *aff'd in part and vacated in part*, 507 F.3d 720 (1st Cir. 2007) (Delaware FCA, Tennessee Medicaid FCA, Texas Medicaid Fraud Prevention Act); *Simonian v. Univ. & Cmty. Coll. Sys. of Nev.*, 128 P.3d 1057, 1060 (Nev. 2006) (Nevada FCA)).

Kroening does not dispute Forest's argument on this point. Accordingly, for the reasons set forth above with respect to Counts One, Two, and Three, all remaining counts (Counts Four through Thirty-two) of the amended complaint will also be dismissed.

Forest offers an alternative argument for dismissing Counts Four through Thirty-one of the amended complaint (i.e., all state claims other than the claim under

Wisconsin law): because the amended complaint identifies kickbacks occurring only in Wisconsin. (ECF Nos. 51 at 23; 57 at 13-14.) Kroening responds that the amended complaint adequately alleges the existence of a nationwide scheme because he spoke with sales representatives from other states. (ECF No. 56 at 29.)

The court finds that Kroening's assertion that he spoke with other Forest sales representatives from 17 other states (the total is actually 15 based upon the court's tally from paragraphs 26 and 27 of the complaint) insufficient to satisfy the particularity required under Rule 9(b). Even Kroening implicitly concedes that he lacks any details regarding alleged false claims in Colorado (Count Six), Connecticut (Count Seven), Delaware (Count Eight), Washington D.C. (Count Nine), Hawaii (Count Twelve), Maine (Count Seventeen), Massachusetts (Count Eighteen), Montana (Count Twenty-one), Nevada (Count Twenty-two), North Carolina (Count Twenty-six), Oklahoma (Count Twenty-seven), Rhode Island (Count Twenty-eight), and Tennessee (Count Twenty-nine). The amended complaint is devoid of any details regarding false claims in those states, lacking even purported hearsay from other sales representatives.

With respect to the 15 states that were represented by the other sales representatives with whom Kroening spoke, he offers no authority to support his contention that such vague allegations suggesting a larger scheme are sufficient to state claims under individual states' false claims statutes. (*See* ECF No. 56 at 29.) Other courts have concluded that claims under companion state false claims statutes must each be

supported with details sufficient to satisfy the particularity required under Rule 9(b). See, e.g., *U.S. ex rel. Hagerty v. Cyberonics, Inc.*, 95 F. Supp. 3d 240, 270 (D. Mass. 2015); *U.S. ex rel. Acad. Health Ctr., Inc. v. Hyperion Found., Inc.*, 2014 WL 3385189, 33 (S.D. Miss. July 9, 2014); *U.S. ex rel. Woods v. SouthernCare, Inc.*, 2013 WL 1339375, 6 (S.D. Miss. Mar. 30, 2013); *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F. Supp. 2d 709, 723 (N.D. Tex. 2011). The court finds that the lack of any specific allegations directed towards fraudulent conduct occurring in any state other than Wisconsin presents an additional reason why Counts Four through Thirty-one must be dismissed.

V. Leave to Amend

The court having concluded that all counts in the amended complaint are deficient and that Forest's motion to dismiss must be granted, the question remains whether Kroening should be permitted to file an amended complaint. Kroening requests such leave. (ECF No. 56 at 8.) Forest opposes the request, noting in a footnote (never an appropriate means for presenting an argument, see *Procedures for Litigants Appearing Before Magistrate Judge William E. Duffin*, ¶ 3. B., available at http://www.wied.uscourts.gov/index.php?option=com_docman&task=doc_download&gid=227&Itemid=30; see also *Long v. Teachers' Ret. Sys. of Ill.*, 585 F.3d 344 (7th Cir. 2009)), that Kroening has already amended his complaint once and arguing that Forest would be prejudiced should the court permit further amendment.

“The well-settled rule is that a party may amend its complaint once as a matter of right, twice or more only at the district court’s discretion.” *Sanford-Brown*, 788 F.3d at 706. “Rule 15(a) states that ‘leave [to amend] shall be freely given when justice so requires.’” *United States ex rel. Fowler v. Caremark RX, L.L.C.*, 496 F.3d 730, 740 (7th Cir. 2007). “Although the rule reflects a liberal attitude towards the amendment of pleadings, courts in their sound discretion may deny a proposed amendment if the moving party has unduly delayed in filing the motion, if the opposing party would suffer undue prejudice or if the pleading is futile.” *Id.* (quoting *Campania Mgmt. Co., Inc. v. Rooks, Pitts & Poust*, 290 F.3d 843, 848-49 (7th Cir. 2002)).

The cases Forest cites in support of its request that this action be dismissed with prejudice are distinguishable. In *United States v. Acacia Mental Health Clinic, LLC*, 2014 WL 3530747, 6 (E.D. Wis. July 15, 2014), the court granted a prior motion to dismiss but granted the relator leave to file an amended complaint, explicitly stating, “no further leave to amend will be granted.” Only after the subsequent amended complaint again proved insufficient did the court dismiss the action with prejudice. *Id.* In *Thulin v. Shopko Stores Operating Co., LCC*, 2013 WL 5946503, 10 (W.D. Wis. Nov. 5, 2013), the court dismissed the complaint with prejudice only because it concluded that further amendment would be futile because the plaintiff’s theory of liability failed as a matter of law.

It is certainly conceivable that the shortcomings identified in this decision may be successfully remedied by Kroening in a second amended complaint. The court finds that any risk of prejudice to the defendants is minimal. In the interest of justice, Kroening should be permitted to amend his complaint.

IT IS THEREFORE ORDERED that the motion of Forest Laboratories, Inc. and Forest Pharmaceuticals, Inc. to dismiss the first amended complaint (ECF No. 50) is **granted**.

IT IS FURTHER ORDERED that relator Kurt Kroening may file a second amended complaint not later than **February 5, 2016**.

IT IS FURTHER ORDERED that the motion of Forest Laboratories, Inc. and Forest Pharmaceuticals, Inc. to file supplemental authority (ECF No. 60) is **granted**.

IT IS FURTHER ORDERED that the motion of the United States for leave to file a statement of interest (ECF No. 63) is **granted**.

Dated at Milwaukee, Wisconsin this 6th day of January, 2016.


WILLIAM E. DUFFIN
U.S. Magistrate Judge