UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *et al.*, *ex rel.* MICHAEL BAWDUNIAK,	*	
Plaintiffs-Relators,	*	
	*	Civil Action No. 12-cv-10601-IT
v.	*	
BIOGEN IDEC, INC.,	*	
Defendant.	*	

MEMORANDUM & ORDER

April 27, 2018

TALWANI, D.J.

Plaintiff-Relators Michael Bawduniak and Fernando Villegas's Third Amended Complaint ("Complaint") [#132] charged Defendant Biogen Idec, Inc. ("Biogen") with causing health care providers to file fraudulent Medicare and Medicaid reimbursement claims in violation of the False Claims Act, 31 U.S.C. § 3729, *et seq*., and various state laws, by paying kickbacks to influence them to prescribe of Biogen's multiple sclerosis ("MS") products (the *qui tam* claims), and with retaliating against Villegas in violation of 31 U.S.C. § 3730(h). The court allowed in part Defendant's Motion to Dismiss [#137] for lack of subject matter jurisdiction, dismissing Villegas's (but not Bawduniak's) claim under 31 U.S.C. § 3730(b). Mem. & Order [#166].[1] Now before the court is Biogen's Motion to Dismiss Relators' Third Amended Complaint Pursuant to Rules 8, 9(b), and 12(b)(6) [#139]. For the reasons set forth below, the

[1] That Memorandum and Order recounts the procedural history of this case. Id. at 1-2.

motion is ALLOWED as to Villegas's retaliation claim and as to certain state *qui tam* claims, but is otherwise DENIED.

I. Overview of the Allegations

The court's recitation of the facts is limited to a brief overview of Relators' substantive allegations, with further details provided as relevant below.

Relators allege that Biogen paid illegal kickbacks to healthcare providers by retaining providers in sham consulting and speaking programs, in order to increase prescriptions of Biogen's MS drugs Avonex, Tysabri, and Tecfidera. With regard to the sham consulting programs, Biogen held dozens of consulting meetings with hundreds of physicians, "liberally paying consulting fees to the physicians who attended." Compl. ¶ 9. The physicians were selected based on their prescribing volume and ability to influence peers rather than expertise on the topic of the consulting meeting. Id. ¶¶ 9-10. Relators allege that Biogen "retained far more consultants than it required, and never did anything with the expensive 'consulting product' that it received." Id. ¶ 10.

With regard to the alleged sham speaking programs, Biogen trained physicians to speak to other physicians about Biogen's products. Id. ¶ 11. Biogen paid physicians both when they obtained training and again when they gave presentations. Id. Biogen "constantly" trained speakers, though most would present only twice, or less, a year, and many presented only to a single person. Id. Relators allege that like the consultants, speakers were selected based on prescribing ability, not speaking ability. According to the Complaint, "[g]iven that there was no demand for additional presentations . . . and that there were many experienced speakers who

could handle what little demand existed, the expansion of the speaking program was a complete sham operated solely to pay physicians to remain loyal to Biogen." Id.

In 2009 and 2010, Biogen paid $18 million to 1,500 physicians and nurses, who collectively wrote prescriptions totaling approximately 60% of the MS market. Id. ¶ 2. Relators allege that though Biogen's internal Compliance Department routinely expressed concerns that there were too many meetings, too many consultants, and too many payments, these concerns were disregarded by Biogen's marketing executives. Id. ¶ 13.

II. Standard

In reviewing a motion to dismiss, the court "accept[s] as true all well-pleaded facts, analyzing those facts in the light most hospitable to the plaintiff's theory, and drawing all reasonable inferences for the plaintiff." U.S. ex. rel. Kelly v. Novartis Pharm. Corp., 827 F.3d 5, 11 (1st Cir. 2016) (quoting U.S. ex rel. Hutcheson v. Blackstone Med. Inc., 647 F.3d 377, 383 (1st Cir. 2011)).

Federal Rule of Civil Procedure 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake," while "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Relators are "required to set forth with particularity the who, what, when, where, and how of the alleged fraud." U.S. ex rel. Ge v. Takeda Pharm. Co., Ltd., 737 F.3d 116, 123 (1st Cir. 2013) (internal citation and quotation marks omitted); see also Lawton ex rel. U.S. v. Takeda Pharm. Co., Ltd., 842 F.3d 125, 130 (1st Cir. 2016).

There is, however, "a difference between qui tam actions alleging that the defendant made false claims to the government and those alleging that the defendant induced third-parties to file false claims with the government." U.S. ex rel. Nargol v. DePuy Orthopaedics, Inc., 865

F.3d 29, 39 (1st Cir. 2017) (quoting Lawton, 842 F.3d at 130). In the latter, indirect type of action, the court must "apply a more flexible standard." Id. "[W]here the defendant allegedly induced third parties to file false claims with the government a relator could satisfy Rule 9(b) by providing factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each false claim." Id. (quoting U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 29 (1st Cir. 2009)) (internal quotation marks and omission omitted).

III. Pleading Anti-Kickback Statute Violations with Particularity

Defendant contends that the purported underlying violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, on which Relator's fraudulent claims reimbursement allegations are based, have not been pled with the specificity required by Rule 9(b).

The Anti-Kickback Statute prohibits the knowing and willful offer or payment of "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" 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) (emphasis added). These provisions were "intended to strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the [M]edicare and [M]edicaid programs, . . . because fraud and abuse among practitioners . . . is relatively difficult to prove and correct.'" U.S. ex rel. Greenfield v. Medco Health Solutions, Inc., 880 F.3d 89, 96 (3d Cir. 2018) (quoting H.R. Rep. No. 95-393, at 1, 27 (1977)) (quotation marks omitted).

Relator alleges throughout the Complaint that Biogen identified and paid top prescribers to keep prescriptions at profitable levels, and did so by retaining the prescribers as consultants and

hiring them as speakers. See, e.g., Compl. ¶ 1 ("The goal of [Biogen's] kickback scheme was . . . to preserve the eroding market share of Biogen's . . . product Avonex; increase the market share of its . . . product Tysabri, and to ensure that its new oral MS drug, Tecfidera, once approved, would be prescribed at a high rate. Biogen knowingly identified the top prescribers and paid them millions of dollars to keep their prescriptions at profitable levels."); id. ¶ 8 ("Biogen expanded [its mechanisms for retaining physicians as consultants and hiring them as speakers] so that its . . . consulting and speaking schemes were . . . conduits for the channeling of illegal payments to . . . high prescribers."); id. ¶ 10 ("Biogen did not pay doctors to consult unless they were high prescribers[] . . . .[Biogen] retained far more consultants than it required, and never did anything with the expensive 'consulting product' that it received."); id. ¶ 11 ("Speakers are paid when they obtain training and paid again when they present, even if no one attends the scheduled meeting. Biogen constantly trained speakers . . . even though most speakers would only present twice (or less) a year and many presented only to a single person . . . . Biogen selected all speakers based on their prescribing ability, not their speaking ability."); id. ¶ 53 ("Just 300 neurologists . . . write 30% of all [MS treatment] prescriptions. 1,200 prescribers write 60% of [MS treatment] prescriptions. Biogen devised a way to identify and target the doctors who wrote 60% of prescriptions for MS . . . and thus would provide the 'most bang for the buck.'"); id. ¶ 73 ("None of the feedback from any of the [consulting] meetings was ever used by Biogen. After an Executive Summary was prepared, no one expressed any interest in the opinions of Biogen's expensive consultants.").

Biogen responds that its payments to physicians were exactly the kind of personal services contracts protected by the statutory safe harbor adopted by Congress and that the Complaint fails

to plead with specificity Defendant's failure to comply with the safe harbor requirements. Def.'s Mem. in Support of Mot. to Dismiss ("Def. Mem.") 5-7 [#139].

The safe harbor provisions exempt the payment of remuneration from liability where "[t]he aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the service," 42 C.F.R. § 1001.952(d)(7), and "[t]he aggregate compensation paid to the agent over the term of the agreement . . . is consistent with fair market value in arms-length transactions" and does not "take[] into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs," id. § 1001.952(d)(5). The Complaint pleads numerous specific allegations that, if true, are sufficient to support the conclusion that the consulting and speaking programs that Defendant contracted for did exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the service. See, e.g., Compl. ¶ 66 [#132] (alleging that "the market research generated by [the consulting] programs had no effect on Biogen's marketing" because "the marketing plans for the foreseeable future had already been drafted and were not affected by the results of the consulting meeting," and that "[o]nly once or twice did anyone ever acknowledge that they had received reports from the consulting meetings, much less use them"); id. ¶¶ 74-75 (alleging that Biogen's internal compliance department "regularly expressed reservations regarding Biogen's physician consultant meeting programs" and on at least one instance warned that a request for consulting meetings was "for a *very high* # of . . . consultants (up to 280) + meetings (28)," and "[s]trongly recommend[ed] that approver consider whether this need can be met w/ fewer consultants + mtgs" (emphasis in original)).

Defendant also argues that the Complaint fails to allege a violation of the Anti-Kickback Statute with sufficient specificity because it fails to plead that any specific payment to an individual physician was a quid pro quo in exchange for prescriptions, or that any physician actually changed prescribing habits after receiving a consulting or speaker payment from Biogen. Def. Mem. 7-8 [#140]. However, as discussed in greater detail below, a claim is false if it seeks reimbursement for a prescription that was not provided in compliance with the Anti-Kickback Statute, regardless of whether the claim was the result of a quid-pro-quo exchange or would have been submitted even absent the kickback. See Greenfield, 880 F.3d at 96. Relators need not show that a quid pro quo exchange occurred, or that the physicians would not have prescribed Defendant's medication but for the kickbacks. It is sufficient to show that Defendant paid kickbacks to a physician for the purpose of inducing the physician to prescribe specific drugs, and that the physician then prescribed those drugs, *even if* the physician would have prescribed those drugs absent the kickback.

Accordingly, the Complaint sufficiently alleges that Biogen violated the Anti-Kickback Statute.

IV. Pleading False Claims With Particularity

Biogen argues further that the Complaint fails to plead claims rendered false by the alleged Anti-Kickback Statute violation. The argument is raised and addressed separately as to allegations concerning claims submitted prior to changes to the Anti-Kickback Statute enacted in March 2010 and those concerning later claims.[2]

[2] The 2010 amendments do not apply retroactively to claims submitted prior to March 2010. See U.S. ex rel. Rost v. Pfizer, Inc., 736 F. Supp. 2d 367, 377-78 (D. Mass. 2010)..

A. Pre-March 2010 Claims

Defendant contends that to the extent the Complaint is based on claims submitted prior to the March 2010, it must be dismissed because "Relators fail to plead any specific representations in any of these claims that were rendered false by alleged non-compliance with the [Anti-Kickback Statute]" and because "Relators likewise fail to plead that Biogen in any way caused a physician to certify compliance with the antikickback statute in spite of an actual [Anti-Kickback Statute] violation." Def. Mem. 16 [#140] (citation omitted).

Under the implied false certification theory, however, FCA liability can arise where "the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement." Universal Health Servs., Inc. v. U.S. ex rel. Escobar, 136 S. Ct. 1989, 2001 (2016). This follows the rule that "half-truths – representations that state the truth only so far as it goes, while omitting critical qualifying information – can be actionable misrepresentations." Id. at 2000. Even prior to this decision, the First Circuit has concluded that a claim was false where the defendant medical device manufacturer had allegedly paid kickbacks to induce physicians to use the device in surgery, and physicians had subsequently submitted claims that certified compliance with the Anti-Kickback Statute. U.S. ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 392–93 (1st Cir. 2011). In that case, the First Circuit found sufficient the complaint's allegations that the "underlying transaction" violated the Anti-Kickback statute and that "resulting claims" were ineligible for payment. Id.

Defendant argues further that the Complaint fails to allege that the Medicaid programs to which the nine relevant claims were submitted prior to March 2010 would have considered compliance with the Anti-Kickback Statute to be material. Def. Mem. 16 n.6 [#140]. As the First

Circuit summarized on remand in Escobar: "[t]he materiality standard is demanding, as the False Claims Act is not an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations." U.S. ex rel. Escobar v. Universal Health Servs., 842 F.3d 103, 110 (1st Cir. 2016) (quoting Escobar, 136 S. Ct. at 2003) (internal quotation marks omitted). "Materiality 'cannot be found where noncompliance is minor or insubstantial.'" Id. (quoting Escobar, 136 S. Ct. at 2003). "'Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance.'" Id. (quoting Escobar, 136 S. Ct. at 2003). The First Circuit has thus concluded that "in assessing materiality in connection with a different section of the False Claims Act, the fundamental inquiry is 'whether a piece of information is sufficiently important to influence the behavior of the recipient.'" Id. (quoting U.S. ex rel. Winkelman et al. v. CVS Caremark Corp., 827 F.3d 201, 211 (1st Cir. 2016)).

Even applying this demanding standard, the Complaint suffices to state a claim at the pleading stage. It alleges that the United States cannot pay a claim induced through the payment of a kickback and that, if the program administrators knew the claims at issue were the result of the payment of kickbacks, the claims would have been denied. Compl. ¶ 230 [#132]. In the specific context of the Anti-Kickback Statute, these allegations survive a motion to dismiss.

B. Post-March 2010 Claims

Under the March 2010 amendment, "a claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for the purposes of [the False Claims Act]." Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 § 6402(f)(1) (2010); see also U.S. ex rel. Rost v. Pfizer, Inc., 736 F. Supp. 2d 367, 377 (D. Mass. 2010).

Defendant contends that the amended statutory language requires Relator to plead that claims "resulted from" an Anti-Kickback Statute violation, and that the Third Amended Complaint fails to do so. Def. Mem. 13-14[#140]. Specifically, Defendant argues that "Relators 'simply [have] not established the necessary links between a fraudulent scheme and a false claim.'" Def. Mem. 12 [#140] (quoting Mason v. Medline Indus., Inc., No. 07-cv-5615, 2009 WL 1438096, at *4 (N.D. Ill. May 22, 2009)) (alteration in original). In Defendant's view, the "resulting from" language added by Congress in 2010 "must mean something more," and the Complaint must "allege facts demonstrating that the claims they identify were . . . caused by, influenced by, or connected to the payments they identify." Reply 8 [#150].

Defendant's argument would require the court to find that the 2010 amendment to the statute narrowed the claims that may be subject to FCA liability. The court finds no support for that notion. The legislative history, as recounted by various courts, leads to the opposite conclusion. See, e.g., Greenfield, 880 F.3d at 96; U.S. ex rel. Kester v. Novartis Pharm. Corp., 41 F. Supp. 3d 323, 332 (S.D.N.Y. 2014); U.S. ex rel. Westmoreland v. Amgen, Inc., 812 F. Supp. 2d 39, 52–53 (D. Mass. 2011).

As these courts have explained, "[t]here is no indication in either the law itself or the legislative history that Congress intended to narrow the scope of 'falsity' under the FCA when it amended the AKS to add Section 1320a–7b(g)." Kester, 41 F. Supp. 3d at 332. As the Third Circuit noted, the 2010 amendment was "part of an overall effort . . . 'to strengthen[] whistleblower actions based on medical care kickbacks" and "to ensure that all claims resulting from illegal kickbacks are considered false claims. " Greenfield, 880 F.3d at 96.

The court in Kester explained the reason for the amendment in detail:

> In enacting the [amendment], Congress legislated against the backdrop of . . . literally hundreds of cases around the country that interpreted the word "false" in

> the FCA to include claims submitted under false pretenses of any kind—including "false certifications" of compliance with statutes that are preconditions to payment. Congress gave absolutely no indication that it intended to amend the definition of the word "false" in the FCA, or to limit the FCA's reach where kickbacks were concerned.
>
> The legislative history of the 2010 AKS amendment (Section 1320a–7b(g)) demonstrates that the new provision was intended to do anything but narrow existing law. Rather, Congress corrected a single district court decision that the sponsors of the predecessor bill feared construed the . . . "false certification" theory of FCA liability too narrowly in the AKS context.

Kester, 41 F. Supp. 3d at 332; see also Greenfield, 880 F.3d at 96 ("[T]he Congressional Record indicates [the amendment] was enacted to avert 'legal challenges that sometimes defeat legitimate enforcement efforts.'" (quoting 155 Cong. Rec. S10852 (2009))).

As the Third Circuit concluded, "the Anti-Kickback Statute and the False Claims Act were not drafted to cabin healthcare providers' liability for certain types of false claims or for certain types of illegal kickbacks. Instead, Congress intended both statutes to reach a broad swath of 'fraud and abuse' in the federal healthcare system." Greenfield, 880 F.3d at 96. In light of that context, Greenfield held that "if a medical service provider pays kickbacks to a doctor to induce referrals and then submits claims to Medicare for services it provided to patients who were referred by that doctor, the claims are false" because the care was not provided in compliance with the Anti-Kickback Statute. Id. (citation omitted). Moreover, "[t]his outcome is the same regardless of whether the doctor would have referred the patients absent the kickbacks . . . and regardless of whether the patients would have chosen the service provider absent the referral." Id. (omission in original) (citation omitted).

Here, Relators have alleged that Defendant paid kickbacks to physicians identified in the Complaint to induce those physicians to prescribe particular medications, and that the physicians then prescribed those medications, causing claims to be submitted to Medicare and Medicaid.

Applying Greenfield's reasoning, the Complaint sufficiently alleges that the claims therefore "resulted from" the kickbacks.

V. Pleading Knowledge

The FCA imposes liability only where a defendant "knowingly . . . causes to be presented a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). To establish scienter, a complaint must allege that the defendant either "ha[d] actual knowledge" of the claim's falsity, or acted with "deliberate ignorance" or "reckless disregard" to the falsity of the claim. Id. § 3729(b)(1). Defendant contends that "[t]he only specific allegation of scienter in the [Complaint] is that 'Biogen knew its kickback scheme would cause Medicare and Medicaid to pay for unnecessary, excessive, abusive, and tainted claims for Avonex, Tysabri and Tecfidera,'" and argues that "Relators plead no facts to support this wholly conclusory assertion." Def. Mem. 17 [#140].

As already noted, the Complaint alleges that Defendant's Compliance Department repeatedly expressed concern over Defendant's speaking and consulting programs, and that those concerns were communicated but ignored. See Compl. ¶¶ 74-79 [#132]. Those allegations are sufficient at this stage to establish that Defendant had either actual knowledge, deliberate ignorance, or reckless disregard that they were violating the Anti-Kickback Statute and thereby causing physicians to present false claims.

VI. State False Claims Acts

Defendant contends that the Complaint's allegations of violations of state false claims acts are subject to dismissal for the same reasons as Relators' federal claims. Def. Mem. 18 [#140]. Because the federal claims are not subject to dismissal at this stage of the proceedings for the reasons described above, this argument similarly fails.

Defendant also raises the alternative argument that, though the Complaint includes state Medicaid and/or Medicare claims for eleven states,[3] the Complaint "fails to allege any facts connecting Biogen's purported conduct to [the other] 17 of the States on whose behalf Relators seek to assert claims, and thus fails to plausibly allege violations of those States' false claims acts." Def. Mem. 18 and n.8 [#140]. Relators respond that the Complaint "includes representative Medicaid claims data for five states"—California, Georgia, Massachusetts, North Carolina, and Texas—and that the Complaint "provides many examples of speaker programs and consultant meetings that were held in various states." Opp'n 20 [#144]. Relators, however, cite no authority stating that holding a speaker program or consulting meeting in a state may establish a violation of that state's false claims act, even where no Medicare or Medicaid claims were filed in that state. Accordingly, the motion to dismiss is ALLOWED as to the following state counts for which no claims have been specifically pled: Count 2 (Washington, D.C.), Count 4 (Colorado), Count 6 (Delaware), Count 7 (Florida), Count 9 (Hawaii), Count 11 (Indiana), Count 12 (Iowa), Count 13 (Louisiana), Count 14 (Maryland), Count 16 (Michigan), Count 17 (Minnesota), Count 18 (Montana), Count 19 (Nevada), Count 21 (New Mexico), Count 24 (Oklahoma), Count 25 (Rhode Island), Count 28 (Virginia), and Count 29 (Washington).[4]

[3] Specifically, New York, Tennessee, Connecticut, Illinois, Wisconsin, New Jersey, California, Georgia, Massachusetts, North Carolina, and Texas. See Compl. ¶¶ 178-200.

[4] In addition, Defendant contends the Maryland and New Mexico state claims, which are brought in Counts 14 and 21 of the Complaint, fail for the further reason that the states have not satisfied certain statutory conditions. Def. Mem. 18 [#140] (citing Md. Health-Gen. Code § 2-604(a)(1), (7) (requiring dismissal of relator's action "[i]f the State does not elect to intervene and proceed with the action . . . before unsealing the complaint"); N.M. Stat. § 27-14-7E(2) (prohibiting relator from pursuing *qui tam* action without state intervention or written determination by the state of substantial evidence of a violation)). Relators do not contest this argument in their

VII. Villegas's Retaliation Claim

Count 31 of the Complaint contains a claim by Fernando Villegas for retaliation in violation of 31 U.S.C. § 3730(h). 31 U.S.C. § 3730(h) protects an employee who "is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee" in furtherance of an action under the False Claims Act. 31 U.S.C. § 3730(h)(1). Defendant contends that the Complaint fails to plead facts alleging the elements of a retaliatory discrimination claim. Def. Mem. 19 [#140]. In response, Relators state that "Villegas is not pursuing his claim under 31 U.S.C. § 3730(h)." Opp'n 1 n.1. Accordingly, Count 31 is DISMISSED.

VIII. Conclusion

For the reasons set forth above, Defendant's Motion to Dismiss Relators Bawduniak and Villegas's Third Amended Complaint Pursuant to Rules 8, 9(B), and 12(B)(6) [#139] is ALLOWED as to Counts 2, 4, 6-7, 9, 11-14, 16-19, 21, 24-25, 28-29, and 31, and DENIED as to the remainder of the Complaint.

IT IS SO ORDERED.

Date: April 27, 2018

/s/ Indira Talwani
United States District Judge

Opposition [#144], and conceded at the motion hearing that the Maryland and New Mexico claims are subject to dismissal.