UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA and WISCONSIN and the DISTRICT OF COLUMBIA ex rel. ALEX BOOKER and EDMUND HEBRON,	)	
Plaintiffs,	)	CIVIL ACTION NO. 10-11166-DPW
v.	)	
PFIZER, INC.,	)	
Defendant.	)	

MEMORANDUM AND ORDER
May 23, 2016

I. BACKGROUND

Relators Alex Booker and Edmund Hebron brought this *qui tam* action against Pfizer, Inc., on behalf of the federal government, 25 states, and the District of Columbia, alleging violations of the federal False Claims Act ("FCA") and state analogues, chiefly related to the promotion of the prescription drug Geodon. The relators filed this action on July 13, 2010, and thereafter amended their complaint a number of times. The

Fifth Amended Complaint is now the operative pleading. The United States has declined to intervene in this action.

Relators' allegations are discussed in detail in my March 26, 2014 Memorandum and Order, *U.S.* ex rel. *Booker* v. *Pfizer, Inc*., 9 F. Supp. 3d 34 (D. Mass. 2014). In this Memorandum, I assume familiarity with those allegations and with the issues raised in this litigation.

Briefly stated, Booker and Hebron were sales representatives in Pfizer's Neuroscience Division and promoted a variety of pharmaceutical drugs, including Geodon (zipraisidone). They allege that Pfizer improperly promoted Geodon in a variety of ways. Improper Geodon promotion had been the subject of previous false claims litigation against Pfizer, which had settled and resulted in a 2009 Corporate Integrity Agreement between Pfizer and the federal government. Relators asserted that Pfizer continued to promote Geodon unlawfully even after that Agreement. This action concerns only Pfizer's conduct after August 31, 2009, when the settlement was reached.

Among other things, relators allege that Pfizer promoted Geodon for uses not approved by the Food and Drug Administration ("off-label" uses), misrepresented the clinical effects of Geodon to physicians, and paid kickbacks to prescribing physicians through a sham speaker series in order to induce additional Geodon prescriptions. These allegations are said to

implicate the False Claims Act because claims for reimbursement arising from them were submitted to federal health care programs. Additionally, relator Booker alleges that he was unlawfully fired in retaliation for his whistleblowing activities.

In the March 26, 2014 Memorandum and Order, I dismissed many aspects of the action. Specifically, I dismissed allegations of "reverse" false claims involving Pfizer's failure to comply with its Corporate Integrity Agreement; claims based on Pfizer's allegedly fraudulent conduct in promoting its drugs, including the misrepresentation of clinical information; claims based on Pfizer's alleged misbranding of drugs; off-label promotion claims brought under state law; all claims relating to a second drug, Pristiq; and certain off-label promotion claims relating to Geodon. In the March 26, 2014 Memorandum and Order, I also concluded that the Relators had adequately pled their claims concerning the off-label promotion of the drug Geodon for children and adolescents, as a bipolar maintenance monotherapy drug, and at excessive dosages. In addition, I permitted relators' claims alleging false claims caused by kickbacks to proceed under both the federal False Claims Act and state equivalents. Finally, I denied Pfizer's motion to dismiss relators' retaliation claims.

The parties have conducted discovery and have moved for summary judgment: Pfizer seeks summary judgment on the entirety of the case and relators seek it only on Pfizer's knowing off-label promotion of Geodon. Relators have failed to comply with the requirements of Local Rule 56.1, which requires a "concise statement" — of the material facts as to which there is no genuine issue to be tried — to be filed along with its motion for summary judgment and a statement of the issues where a genuine issue does exist to be filed along with its opposition to summary judgment. First, they assert that their statement of facts is incorporated into their briefing in support of summary judgment; second, they provide nothing resembling a response to Pfizer's statement of uncontested facts as contemplated by Local Rule 56.1. Such disregard of the Local Rules could provide grounds sufficient for denial of relators' motion for summary judgment and is certainly grounds to deem admitted the statements set forth in Pfizer's statement of uncontested facts. *See Zimmerman* v. *Puccio*, 613 F.3d 60, 63 (1st Cir. 2010) (discussing importance of L.R. 56.1 and applying its sanctions).

For purposes of this Memorandum, where relators' briefing provides adequate references to the evidentiary record, I have treated that briefing as responsive to the requirements of Local Rule 56.1 in order to assure myself that the shortcomings in Rule 56 practice by relators' counsel do not obscure the merits

of the case; nevertheless, I also proceed by accepting the relevant Pfizer statements of fact as uncontested. *See Swallow* v. *Fetzer Vineyards*, 46 Fed. Appx. 636, 638-39 (1st Cir. 2002) (district courts have discretion over sanctions under Rule 56.1 but should still "parse the record" where factual analysis required). Given this posture, I will discuss the evidence topically in this memorandum.

II. STANDARD OF REVIEW

On a motion for summary judgment, the moving party bears the burden of showing that "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). An issue is genuine if it "may reasonably be resolved in favor of either party." *Vineberg* v. *Bissonnette*, 548 F.3d 50, 56 (1st Cir. 2008). A fact is material if it could sway the outcome of the litigation. *Id.* In determining whether genuine disputes of material fact exist, all reasonable inferences must be drawn in the non-movant's favor. *Id.*

Once the moving party has carried its burden, the burden shifts to the non-moving party, which must provide specific and supported evidence of disputed material facts. *LeBlanc* v. *Great Am. Ins. Co.*, 6 F.3d 836, 841 (1st Cir. 1993). The non-moving party "may not rest upon mere allegation or denials" and must "establish a trial-worthy issue." *Id.*

Cross-motions for summary judgment "do not alter the basic Rule 56 standard." *Adria Int'l Grp., Inc*. v. *Ferre Dev., Inc*., 241 F.3d 103, 107 (1st Cir. 2001). Rather, the court must assess each motion for summary judgment independently and "determine whether either of the parties deserves judgment as a matter of law on facts that are not disputed." *Id.*

III. OFF-LABEL PROMOTION OF GEODON

Off-label promotion can give rise to False Claims Act liability because if government health programs do not cover particular off-label uses, seeking reimbursement for those off-label uses would be a false claim; causing such claims to be submitted is within the proscriptions of the FCA as well. *Booker*, 9 F.Supp.3d at 51-52. Medicaid, the program at issue here,[1] covers both on-label uses and off-label uses recognized in specific drug compendia identified by statute. *Id*. Accordingly, relators purport to show that Pfizer promoted Geodon for three non-reimbursable indications - use in children and adolescents, use as a bipolar monotherapy maintenance drug, and use at excessive dosages not approved by the FDA – leading to false claims against Medicaid.

[1] Relators' complaint discusses claims for reimbursement from a variety of federal health care programs. However, the evidentiary materials they marshal at this stage in the litigation discuss only Medicaid.

The "sine qua non" of a False Claims Act violation is, as the name of the statute would suggest, an "actual false claim." *U.S.* ex rel. *Karvelas* v. *Melrose-Wakefield Hosp*., 360 F.3d 220, 225 (1st Cir. 2004). Without proof of a false claim, there is no liability under the False Claims Act. There is some flexibility in the specificity with which a false claim must be pled, particularly where a defendant does not itself submit claims directly to the government. *U.S*. ex rel. *Rost* v. *Pfizer, Inc*., 507 F.3d 720, 732-33 (1st Cir. 2007). However, a necessary condition for establishing liability is proving the existence of a false claim.

In this case, relators cannot meet this basic threshold requirement with respect to their off-label promotion claims. First, relators appear to rely primarily on aggregate data to show that false claims must have been submitted to the government as a result of off-label promotion. Such mathematical deductions, even if statistically sound, do not suffice to prevent summary judgment. *See U.S*. ex rel. *Quinn* v. *Omnicare Inc*., 382 F.3d 432, 440 (3d Cir. 2004) ("Without proof of an actual claim, there is no issue of material fact to be decided by a jury. [Relator]'s theory that the claims 'must have been' submitted cannot survive a motion for summary judgment."); *United States* v. *Kitsap Physicians Serv*., 314 F.3d 995, 1003 (9th Cir. 2002) (damages may be extrapolated from aggregate

information, but "submission of a single false claim" necessary); *U.S.* ex rel. *Crews* v. *NCS Healthcare of Illinois*, Inc., 460 F.3d 853, 856 (7th Cir. 2006) (adopting reasoning of Third and Ninth Circuits).

Notably, the First Circuit has deemed it a "close call" whether an FCA complaint could survive a motion to dismiss where it did not identify specific claims but had "identified, as to each of the medical providers (the who), the illegal kickbacks (the what), the rough time periods and locations (the where and when), and the filing of the false claims themselves." *U.S.* ex rel. *Duxbury* v. *Ortho Biotech Products, L.P.*, 579 F.3d 13, 30 (1st Cir. 2009). Here – on summary judgment rather than a motion to dismiss – relators have not offered even this level of specificity as to any particular false claim.

Relators point to case law allowing circumstantial evidence that false claims were submitted, *see United States* v. *Acadiana Cardiology, LLC*, 2014 WL 1323388, *3 (W.D. La., March 31, 2014) and *U.S.* ex rel. *El-Amin* v. *George Washington University*, 522 F.Supp.2d 135, 143 (D.D.C. 2007). But those cases are fully consistent with the requirement that an actual false claim be established. They dealt with whether a particular Medicare claim form must be submitted or whether a "mountain of billing records" could instead be used to demonstrate specific false claims. *El-Amin*, 522 F. Supp. 2d at 142. Here, relators have

pointed to no such specific false claim, on a claim form, in billing documents, or otherwise. Given this record, no reasonable jury could find that a false claim exists and gives rise to False Claims Act liability.

Second, relators cite to affidavits from Booker himself and from another Pfizer sales representative, Dave Furmanek, which aver that they know false claims for off-label uses to have been submitted. Booker, for example, declares that "I know that Dr. [Jordan] Balter wrote at least one Geodon prescription for a dosage exceeding the package insert maximum which was paid for by the Missouri Medicaid program in the period between September 1, 2009 and January 5, 2010." Nearly identical statements, with the doctor and off-label use changed, are repeated through the declaration. Furmanek, for his part, states that "I know that Dr. [Slawomir] Puszkarski wrote at least one Geodon prescription for a child or adolescent patient which was paid for by the Illinois Medicaid program after he became a Geodon speaker at the end of March 2010."

This evidence, however, is plainly inadmissible. Under Federal Rule of Civil Procedure 56(c)(4), "[a]n affidavit or declaration used to support or oppose a motion must be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant or declarant is competent to testify on the matters stated." The First Circuit has been

clear that declarants must do more than simply claim a fact to be true. The purpose of summary judgment "is not to replace conclusory allegations of the complaint or answer with conclusory allegations of an affidavit." *Santiago* v. *Canon U.S.A., Inc*., 138 F.3d 1, 6 (1st Cir. 1998). Thus, the First Circuit has deemed inadmissible descriptions of an affiant's meetings with certain company "representatives" where the representatives were not named, the time of the meetings was unstated, and the specific contents of the conversation were undefined. *Perez* v. *Volvo Car Corp*., 247 F.3d 303, 316 (1st Cir. 2001). Here, even less information is provided; indeed, Booker and Furmanek do not claim to have developed their information from direct participation in conversations with doctors. They provide no foundation for their claims or information at all about the source of their statements. The affidavits will, as Pfizer moves [Dkt. No. 179], be struck from the record insofar as they purport to show the existence of a false claim. *Id.* at 315 (affidavit lacking any detail should be struck selectively where inadmissible). Bare assertions that false claims were submitted are no substitute for admissible evidence of false claims, which remain entirely lacking. This alone is enough to require summary judgment on relators' off-label promotion claims.

But even if relators could point to any such claims, they face a more fundamental challenge. It has not been demonstrated that any of the states in which Pfizer allegedly promoted Geodon for off-label uses and in which Geodon was so prescribed (precisely what states those are is, again, unstated) bar reimbursement for off-label uses. Many states cover certain off-label, non-compendia uses. *Cf. U.S.* ex rel. *Polansky* v. *Pfizer, Inc*., No. 04-CV-0704 (ERK), 2009 WL 1456582, at *9 (E.D.N.Y. May 22, 2009) ("the Medicaid scheme does not contain a flat prohibition against reimbursement for off-label prescriptions. Instead, it leaves the issue to the discretion of the states"). For example, Pfizer states, and relators do not contest, that the Illinois Medicaid program covered Geodon for children over eight and allows it to be covered with prior authorization for children under eight, while Florida's Medicaid program covered Geodon for children aged six and over. In such states, a doctor who prescribes Geodon for a pediatric patient is not seeking the improper reimbursement of a non-covered drug but rather reimbursement for a drug that the state has chosen to cover. This is not a fraud on the federal government; it is the ordinary and anticipated operation of a health program, and there is no room for False Claims Act liability. *See U.S.* ex rel. *Banigan* v. *Organon USA Inc*., 883 F. Supp. 2d 277, 294 (D. Mass. 2012) ("if a state Medicaid program chooses to reimburse a

claim for a drug prescribed for off-label use, then that claim is not 'false or fraudulent,' and liability cannot therefore attach for reimbursement"); *U.S.* ex rel. *Worsfold* v. *Pfizer Inc*., No. CIV.A. 09-11522-NMG, 2013 WL 6195790, at *3-4 (D. Mass. Nov. 22, 2013) ("Whether a claim for payment is 'false' for purposes of liability under the FCA, in the off-label promotion context, turns on whether the claim is reimburseable under the relevant federal program, i.e. Medicaid or Medicare.").

This basic analysis might be viewed as complicated by a closer examination of the relevant statutory language, but in the end the outcome is the same. Relators argue that the federal Medicaid statute does not grant states the discretion to cover additional off-label, non-compendium uses. This interpretive question is of some relevance because a claim for reimbursement might be false even where states purport to cover a drug if the Medicaid statute does not permit them to do so. *See, e.g., U.S.* ex rel. *Brown* v. *Celgene Corp*., No. CV 10-3165-GHK SSX, 2014 WL 3605896, at *4 (C.D. Cal. July 10, 2014) ("courts are in broad agreement that a claim for reimbursement from Medicare or Medicaid is "false" when it is statutorily ineligible for such reimbursement").

The statutory language is somewhat ambiguous, as other courts have noted. *U.S.* ex rel. *Franklin* v. *Parke-Davis, Div.*

of Warner-Lambert Co., No. CIV.A. 96-11651PBS, 2003 WL 22048255, at *2-3 (D. Mass. Aug. 22, 2003) (inviting amicus brief on the issue); *Banigan*, 883 F. Supp. 2d at 294 ("Organon's argument assumes that state Medicaid programs have the discretion to cover reimbursement for off-label use of a drug that is not supported by a citation in a medical compendium listed in the Medicaid statute; whether the Medicaid statute authorizes such discretion is up for debate"). In abbreviated form, the ambiguity is as follows. One section of the statute provides that states "may exclude or otherwise restrict coverage of a covered outpatient drug" if the drug is off-label and non-compendium. 42 U.S.C. § 1396r–8(d)(1)(B). This implies that states retain the discretion *not* to exclude such drugs. On the other hand, "covered outpatient drug" is a defined term which on a simple reading does not include off-label, non-compendium uses. 42 U.S.C. § 1396r-8(k)(3), 1396r-8(k)(6). Thus, the provision might be read redundantly to give states only the discretion to exclude drugs that are already excluded by Medicaid in the first place. Relators also claim, unconvincingly, that CMS has adopted this interpretation and is owed deference.[2]

[2] The "interpretation" in question merely restates the statutory definition at issue. The statute already excludes from the definition of "covered outpatient drug" ("COD') any drug or biological "used for a medical indication which is not a

However, even if relators were to have the better of the interpretive debate, it is immaterial for one of two closely related reasons identified by courts in this district. First, where states have misconstrued the statute and announced their coverage of specific off-label uses, the relators would be hard pressed to establish that Pfizer had the scienter needed to prove a False Claims Act violation. *Franklin*, No. CIV.A. 96-11651PBS, 2003 WL 22048255, at *3. Notably, Medicaid is administered through the states – the entities announcing their coverage of off-label uses - with federal reimbursement occurring only indirectly. Relators do not provide the sort of

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medically accepted indication." 42 U.S.C. § 1396r-8(k)(3). The relevant rule cited by relators – which is aimed at a different set of issues altogether - states that a "covered outpatient drug" does not include "any drug product or biological used for a medical indication which is not a medically accepted indication." 42 C.F.R. § 447.502. CMS's explanation of that definition provides that "the proposed regulatory definition of a COD, which we are finalizing, excludes drugs used for a medical indication which is not a medically accepted indication." 81 Fed. Reg. 5189 (February 1, 2016). No deference is owed to such "parroting regulations," *Gonzales* v. *Oregon*, 546 U.S. 243, 257 (2006), and in any case, no act of interpretation by CMS to which to give deference occurred in this rulemaking. Certainly, relators point to no statement from CMS, formal or informal, declaring that states may not cover off-label uses, beyond this same statutory/regulatory language. Had such an interpretive initiative been undertaken, one might have expected greater emphasis and clarity given the significant expenditures at stake. *Cf. Whitman* v. *Am. Trucking Associations*, 531 U.S. 457, 468 (2001) (Congress does not "hide elephants in mouseholes").

evidence that could show scienter in this setting.[3] Second, "if a state knowingly chose to reimburse for a drug, even for an off-label use, . . . liability would not attach because extensive government knowledge would 'negate the intent requirement under the FCA as a matter of law.'" *U.S.* ex rel. *Rost* v. *Pfizer*, *Inc*., 253 F.R.D. 11, 16 (D. Mass. 2008) (citing *Shaw* v. *AAA Eng'g & Drafting, Inc*., 213 F.3d 519, 534 (10th Cir. 2000). Here, a great many states have decided, through the ordinary administration of their Medicaid programs, to cover Geodon off-label and publicized this coverage accordingly.

The False Claims Act was "enacted in 1863 with the principal goal of 'stopping the massive frauds perpetrated by large [private] contractors during the Civil War.'" *Vermont Agency of Nat. Res*. v. *U.S.* ex rel. *Stevens*, 529 U.S. 765, 781 (2000). It is not fraud, without more, for physicians and drug manufacturers to accept the government's offer to pay, even if that offer might eventually be held to be inconsistent with some other federal requirements. *Cf. U.S.* ex rel. *Loughren* v. *Unum Grp*., 613 F.3d 300, 314 (1st Cir. 2010) (suggesting no FCA liability where defendant "did merely what the [government] bid

[3] The lack of scienter does not turn on the identity of the submitting entity. *Cf. U.S. ex rel. Hutcheson* v. *Blackstone*, 647 F.3d 377, 388-92 (1st Cir. 2011). Rather, in this context, and given this record, Pfizer cannot be said to have the requisite scienter when any illegality to off-label submissions by any foreseeable entity is at the very least uncertain.

it do" or was "following the government's explicit instructions" and that to "take advantage of a disputed legal question" is insufficient for scienter under the FCA). Thus, even under relators' preferred interpretation of the Medicaid statute, False Claims Act liability would not attach for the off-label promotion of Geodon in states that cover Geodon off-label.

Relators provide no evidence that any off-label promotion occurred in any state which did not cover off-label uses. Consequently, summary judgment must be granted with regard to relators' off-label promotion claims.[4]

IV. ANTI-KICKBACK CLAIMS

A. Evidence of Kickbacks

A claim induced by a kickback can be false when it "misrepresents compliance with a material precondition of payment forbidding the alleged kickbacks." *New York* v. *Amgen Inc.*, 652 F.3d 103, 110–11 (1st Cir. 2011). Kickbacks can come cloaked as speakers' fees, as relators allege occurred here.

[4] I do not reach the question whether, were an identified false claim to exist, relators have adduced enough evidence of off-label promotion to survive summary judgment. Relators allege off-label promotion both under a theory of direct off-label promotion (a theory supported only by highly general and unspecific testimony of relator Booker himself) or under three theories of indirect off-label promotion (each of which has serious conceptual or evidentiary deficiencies in this case). Thus, even if I assumed that off-label promotion occurred in some form, the failure to show a related false claim is determinative in any event.

Booker, 9 F. Supp. 3d at 52. *See also United States* v. *TEVA Pharm. USA, Inc*., No. 13 CIV. 3702 (CM), 2016 WL 750720, at *16-17 (S.D.N.Y. Feb. 22, 2016); *U.S.* ex rel. *Bilotta* v. *Novartis Pharmaceuticals Corp*., 50 F. Supp. 3d 497 (S.D.N.Y. Sept. 30, 2014). But relators have presented insufficient admissible evidence to overcome summary judgment; the record simply cannot be found to show that Pfizer's speaker series was a sham or pretext to conceal kickbacks.

The Anti-Kickback Statute prohibits the payment, receipt, offering, or solicitation of "remuneration" to induce business that is reimbursable under a federal health care program. 42 U.S.C. § 1320a-7b. However, certain safe harbors are provided as exclusions from the definition of "remuneration," including a safe harbor for personal services contracts. 42 C.F.R. § 1001.952(d). This safe harbor requires seven standards to be met:

> (1) The agency agreement is set out in writing and signed by the parties.
> (2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.
> (3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.
> (4) The term of the agreement is for not less than one year.

> (5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes 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.
> (6) The services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law.
> (7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

Id.

The speaker series was organized under written contracts that, on their face, meet these requirements. Moreover, it is uncontested that Pfizer used external consultants to establish fair market values for its speaker series, provided trainings to comply with anti-kickback requirements, and otherwise established systems that purportedly protect against the speaker series turning into a kickback scheme. Formal policies, of course, are only as good as their implementation; the very nature of a sham is that it pretends to be compliant when it is not. *See Bilotta*, 50 F. Supp. 3d at 519 (describing sham speaker series where official policies were compliant). If relators had adduced evidence that Pfizer's speaker series was really meant to compensate doctors for prescribing Pfizer drugs, then the series would quickly fall out of the personal services safe harbor.

No such sufficient evidence exists, however. Relators rely largely on the testimony of Dave Furmanek, a Chicago-area Geodon sales representative. He testified that sales reps, including himself, picked speakers in order to induce them to write additional prescriptions, and that managers approved the speakers knowing this. He claims that Geodon prescriptions written by doctors increased after they became Geodon speakers and that he "heard from other people within Pfizer that the speaker [sic] themselves were the ones whose scripts actually increased." Relators also point out that Pfizer tracked return on investment from its speaker series, that it conducted its speaker series in one-on-two lunch programs rather than in larger groups, and that the speakers were not, according to relators' expert witness Dr. Fugh-Berman, "nationally known opinion leaders" as might be expected from an educationally-focused series. Dr. Fugh-Berman also opined, based on the evidence mentioned here, that the speaker series was a sham.

This evidence is insufficient to establish the speaker series to be a sham. That the speakers presented to small groups and might not have been at the top of their field could show that this was not the best, most cost-efficient, or most fully educational speaker series that could be mounted. That does not, however, suggest that the program necessarily had a "universal and improper purpose" of inducing the speakers to

prescribe Geodon. *TEVA Pharm*., No. 13 CIV. 3702 (CM), 2016 WL 750720, at *17). *Compare Bilotta*, 50 F. Supp. 3d at 515-17 (sham speaker series alleged where drugs not even discussed, doctors did not attend, or identical speakers presented to identical participants on same topic repeatedly). It is likewise unremarkable that Pfizer tracked its return on investment from the series; as a for-profit company, this is to be expected. It is noteworthy, however, that Pfizer did not track the prescriptions written by speakers, but rather the prescriptions written by attendees – a fact uncontestedly established by defendants and not rebutted by admissible evidence from Furmanek.[5] This fact directly refutes any accusation that the series was a sham meant to compensate prescribing speakers rather than pitch to prescribing attendees.

Furmanek's testimony is hearsay with respect to the invitation practices of other sales representatives; indeed, he was unable even to name the other representatives he claimed

[5] Furmanek's direct deposition testimony was "A: The purpose of the event was essentially to sell Geodon. Q: To whom? A: To the target audience. And also, believe it or not, I had heard from other people within Pfizer that the speaker themselves were the ones whose scripts actually increased." Later, Furmanek testified that "they had told us that based on the data that they had seen . . . the only person in the speaker program that was raising their scripts after the talk was the speaker and not the attendees." These are quintessential examples of hearsay and "[i]t is black-letter law that hearsay evidence cannot be considered on summary judgment for the truth of the matter asserted." *Kenney* v. *Floyd*, 700 F.3d 604, 609 (1st Cir. 2012).

chose speakers to induce them to prescribe Pfizer drugs. Relators are left with the say-so of one sales representative, Furmanek, about his own invitation habits, weighed against substantial evidence that Pfizer instructed its sales force on compliance issues and internally tracked results in a manner inconsistent with Furmanek's testimony. What is more, even Furmanek identifies his invitation methods as also looking to whether a doctor could be an effective speaker, who was experienced and likeable. Drawing every inference in favor of relators, no reasonable juror could find that this speaker series was a mere smokescreen for kickbacks, sufficient to take it out of the safe harbor expressly provided by regulation.

A comparison of the facts of record developed in discovery with the complaint in this case is instructive. The facts which I found important in alleging a plausible kickback scheme were apparently not developed in discovery. Relators alleged that speakers were being overpaid, for example, but the record shows that the fees were objectively calculated to provide fair market value. Relators alleged that Pfizer District Manager Stephanie Bartels, Dave Furmanek's supervisor, directly encouraged sales reps to invite, as speakers, the doctors with the highest potential for writing Geodon and Pristiq prescriptions. At most, however, the record shows that Furmanek made his invitations in this way and that Bartels did not stop him.

Finally, relators alleged that speakers' off-label prescription of Geodon increased after they were paid, but the only record evidence for this is, once again, Furmanek's generalized and unsupported observation. No documentary evidence, data, or testimony from doctors themselves supports Furmanek's personal perception – and Pfizer did not track this metric.[6] Relators appear not to have found any meaningful evidence of what they alleged and as such cannot show a genuine issue of material fact on the existence of kickbacks. Summary judgment is appropriate against these claims.[7]

B. Public Disclosure Bar and Sanctions

Pfizer also argues that Relators' kickback-related claims are defeated by the public disclosure bar of the FCA. 31 U.S.C. § 3730(e)(4)(A). Because I find that summary judgment is appropriate based on the lack of evidence, I need not reach the

[6] Furmanek claims to have seen "data compiled and transmitted by Pfizer on a monthly basis" showing the Geodon prescription rates of certain doctors and he states that the numbers of pediatric Geodon prescriptions written by two doctors, Dr. Pasic and Dr. Puszkarski, increased after they became Geodon speakers. Regardless of whether this is even admissible evidence — since it is hearsay and lacking the necessary foundation as discussed in Section III — an anecdotal report of possibly coincidental changes in prescription trends is hardly enough to show, on its own, that the speaker series was a sham and that the compensation for speakers was truly a kickback.

[7] Because the lack of evidence means that there is no genuine issue of material fact on these claims, I do not reach defendant's argument that relators' anti-kickback claims are defeated by the public disclosure bar.

substance of this issue. However, Pfizer also seeks [Dkt. No. 180] sanctions against Relators under Federal Rule of Civil Procedure 37(b)(2) for a failure to produce a relevant document on this issue in a timely manner, in violation of a court order.

The public disclosure bar of the FCA requires the dismissal of an action that makes allegations substantially similar to those already alleged in a prior federal hearing in which the government was a party. 31 U.S.C. § 3730(e)(4)(A). An exception exists, however, where the relator is an "original source of the information," having previously divulged certain relevant information to the government. *Id.* § 3730(e)(4)(B). This sanctions motion concerns the production of documents related to the original source exception.

Pfizer, seeking the protection of the public disclosure bar in this action, sought discovery of disclosure statements by relators to the government that might qualify relators as original sources under the statute. Relators' counsel asserted various privileges and Pfizer moved to compel the production of these documents. In a hearing held on June 15, 2015, after a discussion of the motion, I granted Pfizer's motion to compel. Two days later, Relators produced three documents and certified their compliance with my order.

This year, Pfizer argued that the public disclosure bar covered certain of Relators' claims, including their kickback

allegations, and that no disclosures to the government sufficed to make Relators' original sources. In response, Relators' counsel introduced an email from their office to the Department of Justice, not previously produced, which they assert qualifies as an original source. Notably, Pfizer had previously inquired whether this document was a disclosure statement and was informed by Relators' counsel that it was. Because the document was not produced promptly in response to my order on the motion to compel, Pfizer now seeks sanctions, specifically, striking the late-disclosed email from the record and the award of attorneys' fees for work required by the failure to timely disclose. Relators do not argue that their failure to produce this document was not a violation of my discovery order; rather, they argue only that sanctions are not appropriate remedially.

Rule 37 allows a court to issue "further just orders" in response to a failure to obey a discovery order, including directing certain facts to be taken as established, striking pleadings, dismissing proceedings, and finding a party in contempt of court. Fed. R. Civ. P. 37(b)(2)(A). It also requires the court to order the disobedient party or its attorney to pay the reasonable expenses, including attorney's fees, caused by the failure to comply unless such an award would be unjust. *Id.* 37(b)(2)(C). In determining the appropriate sanction, if any, a court should "consider the totality of

events and then choose from the broad universe of available sanctions in an effort to fit the punishment to the severity and circumstances of the violation." *Young* v. *Gordon*, 330 F.3d 76, 81 (1st Cir. 2003). Relevant factors include "the severity of the violation, the legitimacy of the party's excuse, repetition of violations, the deliberateness vel non of the misconduct, mitigating excuses, prejudice to the other side and to the operations of the court, and the adequacy of lesser sanctions" as well as the existence of a prior warning from the court. *Robson* v. *Hallenbeck*, 81 F.3d 1, 2-3 (1st Cir. 1996). The goal of a sanction is both to penalize wrongful conduct and to deter future similar conduct by the particular party and others "who might be tempted to such conduct in the absence of such a deterrent." *Companion Health Servs., Inc*. v. *Kurtz*, 675 F.3d 75, 84 (1st Cir. 2012).

Relators seek to avoid sanctions primarily on the grounds that their failure to comply with the discovery order was inadvertent and caused little if any prejudice to Pfizer. I find neither argument compelling. It is implausible that, after directly identifying — in an email to Pfizer's counsel — the relevant email as a "disclosure[] to the Government," relators' counsel would later deem it not to be a disclosure simply because it was not marked as a relevant disclosure in the document itself, as they claim. Moreover, while Pfizer suffered

relatively modest prejudice because of the untimely disclosure – indeed, I will grant Pfizer summary judgment on alternate grounds – Pfizer nevertheless credibly shows how earlier disclosure might have caused it to organize its briefing differently, to pose additional questions to Booker in his deposition, and have avoided an additional round of motions and briefing on this very issue of sanctions.

Relators ignored a clear order – discussed in open court – and undertook a clear violation. Some sanction is appropriate. *Cf. Young* v. *Gordon*, 330 F.3d at 82-83 (1st Cir. 2003) (bad faith not required even for the strong sanction of dismissal under Rule 37); even where no harm is found, "the court has an institutional interest in ensuring compliance with its orders").

In principle, Pfizer's requested sanctions are appropriate. First, I strike the relevant email from the summary judgment record. While this has no bearing on my decision to grant summary judgment on Relators' kickback claims, which rests on different grounds, the record should not include that belatedly disclosed email in the unlikely event the public disclosure issue should be relevant in subsequent proceedings. Second, I grant attorneys' fees associated with the preparation of the motion for sanctions and the sections of Pfizer's summary judgment briefing related to the original source exception, to the extent they can be isolated. Rule 37 uses mandatory

language for a grant of attorneys' fees when a discovery order has been violated, "unless the failure [to comply] was substantially justified or other circumstances make an award of expenses unjust." *See also Ins. Recovery Grp., Inc*. v. *Connolly*, 977 F. Supp. 2d 16, 27 (D. Mass. 2013). Seeing no substantial justification for relators' failure here, I am obligated to grant reasonable expenses and fees.

But the circumstances here justify something less than yet another round of detailed briefing and record development of expense and fee material. The misconduct of relator's counsel had the incidental benefit to Pfizer of permitting repetition of arguments in a light unfavorable to relator. Under these circumstances, I find that an award of $5,000 is sufficient to vindicate the purposes of Rule 37.

V. RETALIATION CLAIMS

Relator Booker also claims that he was fired in retaliation for his whistleblowing activities. The False Claims Act protects against retaliation. 31 U.S.C. § 3730(h). To show retaliation, a plaintiff must establish that "he engaged in conduct protected under the FCA; the employer knew that he was engaged in such conduct; and the employer discharged or discriminated against him because of his protected conduct." *Maturi* v. *McLaughlin Research Corp*., 413 F.3d 166, 172 (1st Cir. 2005). The First Circuit uses a *McDonnell Douglas* burden-

shifting approach to this test, in which a plaintiff must first set forth a prima facie case of retaliation, at which point the defendant must show a "legitimate, nonretaliatory reason for the adverse employment action," after which the plaintiff takes on the additional burden of "showing that the proffered reason is a pretext." *Harrington* v. *Aggregate Indus. Ne. Region, Inc*., 668 F.3d 25, 31 (1st Cir. 2012). Booker identifies his firing as resulting from five separate incidents, each of which I will address in turn.

First, Booker called Pfizer's Corporate Compliance telephone hotline in October, 2009. He told Compliance that Geodon sales representatives "were making inappropriate claims about cognition, about depression, about overt anger, and about the weight loss." This call was anonymous and Booker did not otherwise identify himself, his manager, or his sales district, telling Compliance only that he was in the "south region." This telephone call cannot serve as the basis for a retaliation claim because it provided Pfizer no way to connect the call with Booker. Pfizer, acting through Booker's managers, could not have fired Booker for making this telephone call because it did not know that he made it; both the knowledge and causation elements of a retaliation claim are missing.

Second, Booker alleged in his complaint that he objected to off-label marketing in a December 14, 2009 conversation with

regional manager Don Sanderson. However, Booker has not substantiated this allegation at this stage in the litigation by presenting evidence. Without any evidence, such claims cannot survive summary judgment. *See Celotex Corp.* v. *Catrett*, 477 U.S. 317 (1986).

Third, Booker emailed Corporate Compliance on January 5, 2010, alleging that he was being coached by his manager, Jon Twidwell, to make unsubstantiated claims concerning Geodon's clinical effects. This email was not anonymous and so Pfizer could have retaliated in response to it, but the record is clear that Pfizer did not do so. To be sure, Booker was told he was fired the day after he sent this email. In many circumstances, this close temporal proximity would support a finding of retaliation. *Collazo* v. *Bristol-Myers Squibb Mfg., Inc.*, 617 F.3d 39, 50 (1st Cir. 2010). But on this record, the timing forecloses any possibility of retaliation.

The path to Booker's termination indisputably began, and by admission reached a conclusion, well before January 5, 2010. After a series of negative performance reviews, on May 30, 2008 Booker was placed on an "Immediate Action Plan" to improve his performance on May 30, 2008. That plan stated that a failure to improve could result in termination. While Booker successfully completed that action plan, he continued to receive negative performance reviews and on September 14, 2009, was placed onto a

new "Written Plan for Improvement." Once again, the plan threatened termination. Booker was placed on a third plan, titled his "Final Plan" on November 13, 2009, which gave him 45 days to improve or face termination. On December 18, 2009, Regional Manager Donald Sanderson emailed Booker to tell him that he had failed to meet the requirements of the Final Plan. Booker understood this email to mean he was at significant risk of being fired. He sought assurances (which he did not receive) from his manager that he would be able to "survive" the Final Plan and requested more time (which he also did not receive). The decision to fire Booker was made, according to Twidwell, in late December of 2009. Given these uncontested facts, it is clear that the decisions that led to Booker's termination, including the choice to fire him, occurred before his email to Corporate Compliance. On this record, Pfizer could not have retaliated against him for this email.[8] *See also U.S.* ex rel. *Hamrick* v. *GlaxoSmithKline, LLC*, 814 F.3d 10, 23 (1st Cir. 2016) (where employee already "on the path to discharge," temporal proximity of a "last-minute" act of whistleblowing not enough,

[8] More precisely, it could not have retaliated against him for this email *alone*. If Booker had shown a pattern of protected activity and a pattern of increasing retaliation, this entire sequence of events might be retaliatory, with the final decision to fire Booker only actualized after his additional act of informing Compliance. But as this section makes clear, that pattern is not visible in the evidentiary record before me.

on its own, for that act to be considered factor in employee's termination).

This leaves only Booker's fourth and fifth alleged instances of whistleblowing as possible bases for retaliation. Booker asserts that on September 10, 2009, he and District Manager Jon Twidwell visited Dr. Radhika Rao together. Booker claims that Twidwell coached him to promote Geodon to improve sleep in patients, improve their cognition, and reduce their depression and overt anger. Booker allegedly got into a "big argument in the car" with Twidwell, disagreeing over the propriety of making such claims, and was ordered by Twidwell to do so. Twidwell, for his part, denies making any of these statements to Booker. Similarly, Booker claims that at a September 16, 2009 meeting in Kansas City (held days *after* Booker was placed on his second plan for improvement), he objected to Twidwell's direction that sales representatives cite various studies concerning Geodon's effect on cognition, aggression, depression, and weight loss. Whether these discussions occurred is a contested issue of fact, not appropriate for summary judgment.

But the contents of the discussions, even under Booker's account of what was said, do not show conduct protected under the False Claims Act. "Protected conduct" under the FCA is "limited to activities that 'reasonably could lead' to an FCA

action; in other words, investigations, inquiries, testimonies or other activities that concern the employer's knowing submission of false or fraudulent claims for payment to the government." *U.S. ex rel. Karvelas* v. *Melrose-Wakefield Hosp.*, 360 F.3d 220, 237 (1st Cir. 2004). Reports of "regulatory failures," without a connection to "fraudulent claims knowingly submitted to the government," do not constitute protected conduct under the FCA. *Id.*

In the March 26, 2014 Memorandum and Opinion, I stated that Booker's conduct was protected against retaliation insofar as he reported fraudulent conduct directed at physicians to encourage off-label Geodon use, as alleged in the operative complaint. *Booker*, 9 F. Supp. 3d at 60. But the September conversations did not involve promotion of Geodon off-label; they were not about the pediatric prescription of Geodon, the prescription of Geodon at excessive dosages,[9] or the prescription of Geodon for new diagnoses, for example. Rather, they were about claims concerning symptoms or side effects which might at some point be made to support the use of Geodon on-label.[10] Those activities

[9] Booker testified that he talked with a different doctor, Dr. Gunawardhana, about excessive dosages while Twidwell was with him. Booker depo. p. 82 lines 23-25, p. 83 lines 2-5. However, Booker also testified that he did not object about this to Twidwell.

[10] Booker may subjectively have believed that these studies concerned off-label indications. But the First Circuit uses an objective standard, not a subjective one, for determining what

may have been inappropriate but they are not adequately connected to the admission of false or fraudulent claims. Under First Circuit law, therefore, they are not protected conduct under the FCA and cannot give rise to a retaliation claim.

Because none of the incidents identified by Booker as the basis for a retaliation claim either individually or together suffices to make out a prima facie case, I will grant summary judgment to Defendants on Booker's retaliation claim and need not move to the next stage of addressing whether Pfizer's proffered nonretaliatory reason for firing Booker - his poor sales performance - was a pretext.

VI. CONCLUSION

For the reasons set forth above, defendant's motion to strike the declarations of Booker and Furmanek [Dkt. No. 180] is GRANTED in part; the defendant's motions for summary judgment [Dkt. Nos. 151 and 154] are GRANTED; Relators' motion for summary judgment [Dkt. No. 155] is DENIED; the pending motions to strike expert testimony [Dkt. Nos. 159, 161, 168] are TREATED

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conduct is protected by the False Claims Act. *See Karvelas*, 360 F.3d at 236 (protected conduct is that which "reasonably could lead to a viable FCA action"); *U.S.* ex rel. *Gobble* v. *Forest Labs., Inc*., 729 F. Supp. 2d 446, 450 (D. Mass. 2010) ("the definition of protected conduct in this Circuit is objective and broad and, as stated, can be read to incorporate Gobble's allegations. Cases from other circuits which do not employ the same test but rather utilize a standard that considers the subjective belief or intent of the relator or require more affirmative action on his part are inapposite.").

as MOOT; and the defendant's motion to strike and for attorney's fees is GRANTED [Dkt. No. 179] to the extent that relator's counsel shall, on or before June 23, 2016 pay defendant the sum of $5,000 in attorney's fees.

/s/ Douglas P. Woodlock_____
DOUGLAS P. WOODLOCK
UNITED STATES DISTRICT JUDGE