UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA; ET AL *ex rel*. ALEX BOOKER and EDMUND HEBRON,	)	
Plaintiffs,	)	CIVIL ACTION NO. 10-11166-DPW
v.	)	
PFIZER, INC.,	)	
Defendant.	)	

MEMORANDUM AND ORDER
March 26, 2014

I. BACKGROUND

Relators Alex Booker and Edmund Hebron bring this *qui tam* action against Pfizer, Inc., on behalf of the United States, 25 individual states, and the District of Columbia. They allege violations of the federal False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, as well as violations of the False Claims Acts of the District of Columbia and all of the captioned states except Georgia. Pfizer has moved to dismiss.

A. Overview of the Allegations

Booker worked as a sales representative for Pfizer from June 1991 until he was terminated in January 2010. Fifth Am. Compl. ¶¶ 9-10. At the times relevant to this action, he was part of Pfizer's Neuroscience Division, based in St. Louis, Missouri, in Pfizer's South Region. *Id.* ¶ 10. Booker promoted a variety of

pharmaceutical drugs, including Geodon (zipraisidone) and Pristiq (devsvenlafaxine), to hospitals and physchiatrists. *Id.* ¶ 10.

Hebron worked as a sales representative for Pfizer from January 1997 until he was terminated in June 2006. *Id.* ¶¶ 13, 19. At the times relevant to this action, Hebron also worked in the Neuroscience Division in St. Louis and promoted Geodon to hospitals and psychiatrists. *Id.* ¶ 18.

The bulk of the Relators' allegations involve Pfizer's allegedly fraudulent promotion of Geodon and Pristiq for uses not approved by the Food and Drug Administration ("off-label" uses) and not included in certain federally-recognized drug compendia ("non-compendium" uses). Relators allege that as part of the fraudulent scheme, Pfizer made misrepresentations about the side effects of its drugs to physicians, *e.g.*, Fifth Am. Compl. ¶ 71, deliberately mischaracterized clinical studies to physicians, *e.g.*, *id.* ¶¶ 132-36, concealed negative information about its drugs from both its sales force and physicians, *e.g.*, *id.* ¶ 68, and paid kickbacks to induce physicians to prescribe Geodon and Pristiq, *id.* ¶ 114.

Relators allege that Pfizer promoted Geodon for the following unapproved uses: improvement of cognition, Fifth Am. Compl. ¶ 57; reduction of agitation and aggression, *id.* ¶ 58; improvement of functionality, *id.* ¶ 59; long-term treatment for bipolar disorder, *id.* ¶ 60; treatment of bipolar depression, *id.*

¶ 61; facilitating weight loss for mentally ill patients, *id.* ¶ 62; lowering cholesterol and lipids in the mentally ill, *id.* ¶ 63; aid in sleeping, *id.* ¶ 64; treatment of children and adolescents, *id.* ¶ 66; and use at an excessive dose, *id.* ¶ 70. Relators allege that Pfizer promoted Pristiq for the following unapproved uses: pain management, Fifth Am. Compl. ¶ 73; prescribing a 100mg dose, *id.* ¶ 85; and treatment of vasomotor symptoms associated with menopause, *id.* ¶ 108.

These uses, Relators argue, are not reimbursable under various federal health care programs, including Medicaid, CHAMPUS/TRICARE, CHAMPVA, the Federal Employees Health Benefit Program, and Part D of the Medicare program. Fifth Am. Compl. ¶¶ 23-34. Claims for reimbursement of prescriptions for those uses, they assert, are thereby false.

Relators also allege that Pfizer made false claims by avoiding its obligations under a 2009 Corporate Integrity Agreement with the government, which was the product of an August 2009 settlement resolving false claims liability stemming from a scheme of off-label Geodon promotion similar to that alleged here. Fifth Am. Compl. ¶¶ 116-127.

Count I thus seeks to hold Pfizer liable under the federal FCA based on its fraudulent conduct which caused or was material to false claims made to federal health care programs, and based

on its avoidance of obligations to pay the government under the terms of its Corporate Integrity Agreement.

Counts II through XXVI, respectively seek to hold Pfizer liable under the FCAs of the 25 named states and the District of Columbia (collectively, the "state FCAs") based on its fraudulent conduct which caused or was material to false claims made to each respective state Medicaid program.

Finally, in Count XXVII, Relator Booker alleges that his termination in January 2010 constituted illegal retaliation for his efforts to investigate and stop Pfizer's FCA violations. *See* Fifth Am. Compl. ¶¶ 128-44, 274-76.

B. Procedural History

Relators filed this action on July 13, 2010. The complaint was kept under seal while the United States considered whether to intervene, *see* 31 U.S.C. § 3730(b)(2). In the meantime, Relators filed several amendments to their complaint. When the government declined to intervene on June 21, 2012, the case was unsealed, and Relators' Fourth Amended Complaint was made public on August 15, 2012. Relators filed the operative Fifth Amended Complaint now before me on October 4, 2012. Pfizer filed a motion to dismiss, arguing that the Fifth Amended Complaint fails to state a claim and, where applicable, fails to plead fraud with the particularity required by Fed. R. Civ. P. 9(b). Relators opposed the motion, but also preemptively moved for leave to amend their

complaint as necessary to correct any pleading deficiencies identified by my resolution of the motion to dismiss.[1]

II. STANDARD OF REVIEW

In order to survive a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft* v. *Iqbal*, 129 S. Ct. 1937, 1949, (2009) (citation and internal quotation marks omitted). Dismissal for failure to state a claim is appropriate when the pleadings fail to set forth "factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory." *Berner* v. *Delahanty*, 129 F.3d 20, 25 (1st Cir. 1997) (quoting *Gooley* v. *Mobil Oil Corp.*, 851 F.2d 513, 515 (1st Cir. 1988)) (internal quotation marks omitted). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged--but it has not 'show[n]'--'that the pleader is entitled to relief.'" *Maldonado* v. *Fontanes*, 568 F.3d 263, 269 (1st Cir. 2009) (quoting *Iqbal*, 129 S. Ct. at 1949).

I "must accept all well-pleaded facts alleged in the

[1] I have already denied Relators' motion for leave to file a Sixth Amended Complaint, and will test Pfizer's motion to dismiss against the allegations as they are presented in the Fifth Amended Complaint. *See* Dkt. # 65.

Complaint as true and draw all reasonable inferences in favor of the plaintiff." *Watterson* v. *Page*, 987 F.2d 1, 3 (1st Cir. 1993). While I am "generally limited to considering facts and documents that are part of or incorporated into the complaint," I "may also consider documents incorporated by reference in the [complaint], matters of public record, and other matters susceptible to judicial notice." *Giragosian* v. *Ryan*, 547 F.3d 59, 65 (1st Cir. 2008) (citation and internal quotation marks omitted) (alteration in original).

III. THRESHOLD ISSUES

As a threshold matter, Pfizer argues that Relators' Geodon-related claims are precluded by the "first-to-file" and "public disclosure" provisions of the FCA. I address each argument in turn.

A. First-to-File Bar re Geodon Claims

The False Claims Act provides that "[w]hen a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action."[2] 31 U.S.C. § 3730(b)(5).

[2]Pfizer's motion to dismiss under this provision, which is technically "jurisdictional," is brought under Fed. R. Civ. P. 12(b)(1). Review under Rule 12(b)(1) is "similar to that accorded a dismissal for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6)," and any distinctions make no difference here. *Murphy* v. *United States*, 45 F.3d 520, 522 (1st Cir. 1995). Relators bear the burden of establishing jurisdiction. *Id.*

This so-called "first-to-file" rule bars "a later allegation if it states all the *essential facts* of a previously-filed claim or the same *elements* of a fraud described in an earlier suit." *U.S. ex rel. Duxbury* v. *Ortho Biotech Products, L.P.*, 579 F.3d 13, 32 (1st Cir. 2009) (emphasis in original; internal quotation and modification omitted). Pfizer argues that two complaints in prior actions covered largely the same ground as does Relators' Fifth Amended Complaint regarding allegations of off-label promotion of Geodon. *See United States ex rel. Kruszewski* v. *Pfizer, Inc.*, No. 07-4106-JCJ, First Amended Complaint (E.D. Pa. filed Aug. 21, 2009); *United States ex rel. Westlock* v. *Pfizer*, Inc., No. 08-11318-DPW, First Amended Complaint (D. Mass. filed Aug. 21, 2008).

Relators avoid wading into a comparison of the allegations, which are indeed quite similar, and instead contend that § 3730(b)(5) by its terms bars related actions only when the prior action remains "pending." The instant action was filed in July 2010, well after both *Kruszewski* and *Westlock* were dismissed on December 22, 2009, *Kruszewski*, No. 07-4106-JCJ, Order (E.D. Pa. Dec. 22, 2009); *Westlock*, No. 08-11318-DPW, Order (D. Mass. Dec. 22, 2009), pursuant to an August 2009 settlement agreement between Pfizer and the government. Accordingly, relators argue, *Kruszewski* and *Westlock* were not "pending actions" that could preclude the filing of this related action.

Court almost uniformly agree that "once a case is no longer pending the first-to-file bar does not stop a relator from filing a related case." *U.S. ex rel. Carter v. Halliburton Co.*, 710 F.3d 171, 183 (4th Cir. 2013); *accord U.S. ex rel. Chovanec* v. *Apria Healthcare Grp. Inc.*, 606 F.3d 361, 365 (7th Cir. 2010); *In re Natural Gas Royalties Qui Tam Litig. (CO2 Appeals)*, 566 F.3d 956, 964 (10th Cir. 2009); *cf. also U.S. ex rel. Lujan* v. *Hughes Aircraft Co.*, 243 F.3d 1181, 1188 (9th Cir. 2001) (first-to-file bar requires "pending action" at the time a related action is filed; irrelevant whether then-pending action is subsequently dismissed). Pfizer cites to one case from the Northern District of Georgia in which the court interpreted "pending" as merely a proxy for "first-filed," largely due to concerns that "relator[s] would be able to file, dismiss, and re-file identical qui tam actions." *U.S. ex rel. Powell* v. *Am. InterContinental Univ., Inc.*, No. 08-2277-RWS, 2012 WL 2885356, at *5 (N.D. Ga. July 12, 2012). I do not find such concerns sufficient justification to deviate from the plain meaning of the word "pending" and the weight of Circuit authority contrary to *Powell*.

Moreover, I note that even where an earlier relator has voluntarily dismissed his claims – generally, although not exclusively, in cases where the United States has declined to intervene, *see* 31 U.S.C. § 3730(b)(2), (b)(4), (c) - the relator in the subsequent action still must overcome the FCA's public

disclosure bar, 31 U.S.C. § 3730(e)(4)(A); relators thus still have significant incentive to be the first to the courthouse. Where a prior *qui tam* action has been resolved on the merits, meanwhile, doctrines of claim and issue preclusion serve their usual function of preventing unwarranted successive litigation on the facts underlying a prior FCA complaint. *See Chovanec*, 606 F.3d at 365. Here, of course, Pfizer's earlier settlement agreement with the government covered Pfizer's alleged illegal promotion of Geodon only between January 1, 2001, and December 31, 2007, and any resulting false claims to federal and state health care programs. Pfizer apparently hopes to use the first-to-file bar as a substitute for what would have been a futile argument of res judicata as to the later-occurring off-label promotion (and resulting false claims) alleged here. But because 31 U.S.C. § 3730(b)(5) plainly applies only where an FCA action is premised on the same essential facts as a "pending action," and because the related *Kruszewski* and *Westlock* matters were dismissed well before the current action was filed, the first-to-file rule does not operate to bar relators' Geodon claims.

Finally, Pfizer argues that this case is determined by the First Circuit's approach to the first-to-file bar in *Duxbury*, 579 F.3d 13. In *Duxbury*, the First Circuit found the relators' First Amended Complaint barred by the first-to-file rule because its allegations covered the same "essential facts" alleged in a prior

complaint in a separate action. *Id.* at 33. And, indeed, the First Circuit did so despite the fact that the prior complaint had been dismissed voluntarily before the *Duxbury* relators filed their First Amended Complaint. *Id.* at 19. Nevertheless, *Duxbury* does not reflect a binding decision from the First Circuit as to whether, under § 3730(b)(5), a prior FCA action must be "pending" in order to bar a related FCA action. The district court opinion in *Duxbury* indicates the parties failed to raise the issue below, *U.S. ex rel. Duxbury* v. *Ortho Biotech Products, L.P.*, 551 F. Supp. 2d 100, 111 n.13 (D. Mass. 2008); that failure waived the issue for purposes of appellate review as well. *See Warren Freedenfeld Associates, Inc.* v. *McTigue*, 531 F.3d 38, 48 (1st Cir. 2008) ("If any principle is settled in this circuit, it is that, absent the most extraordinary circumstances, legal theories not raised squarely in the lower court cannot be broached for the first time on appeal."). Thus, whether the first-to-file rule applied, even though the separate action was not "pending" when the *Duxbury* relator's First Amended Complaint was filed, was not before the court. Had the issue been properly presented, I believe the First Circuit would have joined its sister circuits in adhering to the plain meaning of 31 U.S.C. § 3730(b)(5).

B. Public Disclosure Bar re Geodon Claims

Pfizer also contends that Relators' Geodon claims are subject to the FCA's so-called "public disclosure bar," which

provides:

> The court shall dismiss an action or claim . . . if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed . . . in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party . . . .

31 U.S.C. § 3730(e)(4)(A)(i).

The public disclosure provision does not bar actions, however, when "the person bringing the action is an original source of the information." *Id.* § 3730(e)(4). The FCA defines an "original source" as:

> an individual who either (i) prior to a public disclosure under subsection (e)(4)(A), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) [sic] who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

Id. § 3730(e)(4)(B).[3]

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[3] I apply the provisions of § 3730(e)(4) as amended by the Patient Protection and Affordable Care Act ("PPACA"), Pub. L. 111-148, Title X, § 10104(j)(2), which became effective on March 23, 2010. Pfizer cites *Graham Cnty. Soil & Water Conservation Dist.* v. *U.S. ex rel. Wilson*, 559 U.S. 280 n.1 (2010), to support the proposition that the prior version of § 3730(e)(4) should apply to *conduct* occurring before March 23, 2010, which would capture most of the time during which relators were assembling information about the alleged fraud. But *Wilson* merely concluded that this provision of the PPACA was not retroactive, and thus refused to apply the amended statute to an action pending as of March 23, 2010. Relators' current action was not filed until July 13, 2010, and Relators' eligibility for the original source exception must be evaluated under the governing law as of that date.

That said, several of the state false claims statutes retain a definition of an "original source" analogous to the FCA's pre-amendment version, which defined original source as "an

Pfizer argues that the *Kruszewski* and *Westlock* complaints publicly disclosed the same allegations regarding Pfizer's promotion of Geodon as those alleged in Relators' Fifth Amended Complaints here, and that relators Booker and Hebron do not qualify as original sources.

There is no dispute that the *Kruszewski* and *Westlock* complaints were means of disclosure by which the public disclosure bar could apply. 31 U.S.C. § 3730(e)(4)(A)(i). Relators also do not contest that they allege Pfizer engaged in off-label promotion of Geodon in largely the same manner as alleged in the *Kruszewski* and *Westlock* complaints. However, they argue that the prior complaints disclosed off-label Geodon promotion only in the years prior to 2008. The "central allegation" of this action, by contrast, is that Pfizer *continued*

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individual who has direct and independent knowledge of the information on which the allegations are based," 31 U.S.C. § 3730(e)(4)(B) (1994). *See, e.g.*, Col. Rev. Stat. Ann. §25.5-4-306(5)(c)(II); Del. Code Ann. tit. 6, § 1206(c); Ind. Code Ann. § 5-11-5.5-7(f). Other states have amended their statutes to match the FCA's amended provision, but those provisions were not yet in effect when this action was filed. *Compre* Fla. Stat. Ann. § 68.087(3) (2003), *with* 2013 Fla. Sess. Law Serv. Ch. 2013-104 (C.S.C.S.H.B. 935) (eff. July 1, 2013). *See also, e.g.*, Conn. Gen. Stat. Ann. § 17b-301i(c)(eff. June 13, 2011); D.C. Code Ann. § 2-381.01(10) (eff. Mar. 19, 2013); Haw. Rev. Stat. Ann. § 661-31(c)(2) (eff. July 9, 2012); Ill. Comp. Stat. Ann. ch. 740, § 175/4(e)(4)(B) (eff. July 27, 2010); Mass. Gen. Laws ch. 12, § 5A (eff. July 1, 2012). I note what appears to be the only relevant difference in applying these provisions, one with respect to Relator Hebron, in footnote 6, *infra*.

to engaged in off-label Geodon promotion even after its August 2009 settlement with the government.

I conclude that the difference in time frame does not necessarily change the fact that the *Kruszewski* and *Westlock* complaints disclosed "substantially the same allegations," 31 U.S.C. § 3730(e)(4)(A)(i), with respect to off-label Geodon promotion (and resulting false claims) as those in the Fifth Amended Complaint. However, by disclosing fraud during an entirely different time frame, the Fifth Amended Complaint does reflect knowledge of the Relators that is "independent of and materially adds" to the prior public disclosures of off-label Geodon promotions. 31 U.S.C. § 3730(e)(4)(B)(2).

1. Framework for Application of Public Disclosure Rule

Few courts have addressed the proper application of the FCA's public disclosure provision to allegations of similar fraud perpetrated at different times. To be sure, a complaint that covers only "somewhat different time periods" than a prior complaint adds little value, *U.S. ex rel. Poteet* v. *Medtronic, Inc.*, 552 F.3d 503, 517 (6th Cir. 2009), particularly where a prior complaint "allege[d] a broad scheme encompassing the time and location of the later filed," *U.S. ex rel. Ortega* v. *Columbia Healthcare, Inc.*, 240 F. Supp. 2d 8, 13 (D.D.C. 2003). In such circumstances, the prior disclosure "reveal[s] the same kind of fraudulent activity against the government" as the later-filed

complaint and is "sufficient to put the government on notice of the likelihood of related fraudulent activity," and the public disclosure provision properly applies to bar the complaint. *Poteet*, 552 F.3d at 511-12; *accord U.S. ex rel. Fine* v. *Sandia Corp.*, 70 F.3d 568, 571 (10th Cir. 1995) (§ 3730(e)(4)(A) applies to bar suits where prior public disclosure "set the government squarely on the trail of the alleged fraud").

However, *Poteet*, on which Pfizer relies heavily, involved "related" fraud in the sense of additional – previously undisclosed – *individuals* whose false claims were allegedly the result of the same scheme to defraud, involving both the means and general time-frame as had been undertaken by previously disclosed individuals. *Poteet*, 552 F.3d at 514. Identification of those additional individuals could not "materially add" to the prior disclosures. The government's awareness of the scheme allowed it to investigate the full reaches of that scheme, as alleged. *Cf. U.S. ex rel. Poteet* v. *Bahler Med., Inc.*, 619 F.3d 104, 111 (1st Cir. 2010) (where "the materials necessary to ground an inference of fraud are generally available to the public . . . there is nothing to prevent the government from detecting it").

The government's awareness of fraud that occurred entirely in the past, by contrast, may not alert the government to future fraud, and thus that awareness "does not bar other potential *qui*

tam litigants from bringing additional instances of fraud to light." *U.S. ex rel. Hoggett* v. *Univ. of Phoenix*, No. 10-02478-MCE, 2012 WL 2681817, at *5 (E.D. Cal. July 6, 2012). Here, the *Kruszewski* and *Westlock* complaints publicly disclosed allegations of fraud by Pfizer prior to 2008. The government's investigation of those allegations culminated in August 2009 through its settlement agreement with Pfizer. Relators Booker and Hebron have now alleged fraud post-dating the operative dates for the prior litigation. Those allegations are plainly "additional" to the prior disclosure in some sense; the question is whether those allegations are "additional" in a sense meaningful to the public disclosure provision.

When relators allege additional fraud by substantially the same means as previously alleged, subjecting their allegations to the public disclosure bar in all cases would produce untenable results. Engaging in a scheme to defraud cannot immunize a fraudulent action from *qui tam* suits regarding related forms of fraud in perpetuity; what was once a hot trail of fraud must cool at some point. If, in the distant future, a fraudulent action reached back to revive an old fraudulent scheme, there would be little doubt that the whistleblower who came forward with allegations of the revived fraud would present helpful new information to the government, and the claims surely would not be precluded by the public disclosure bar.

Pfizer's argument is arguably palatable here because it seeks to apply the public disclosure bar to Relators' allegations that fraud continued only shortly after the same allegedly fraudulent scheme was publicly disclosed by the *Westlock* and *Kruszewski* complaints. Moreover, the alleged fraud was happening right under the government's nose, while it finalized its prior settlement with Pfizer, and while its concerns about recidivism were memorialized in a Corporate Integrity Agreement, the provisions of which I discuss in greater detail in Part IV.A, *infra*. Pfizer thus effectively advocates a system in which the government is solely responsible for investigating and enforcing new FCA violations for some period of time after public disclosure of past fraud, on the theory that the fraud is easy enough to detect and thus additional whistleblowing is unnecessary once the past fraudulent scheme has been exposed.

The issue does not appear to arise very often--likely because most persons engaged in fraudulent action, once caught, are not brazen enough to continue their particular form of fraudulent activity, or are creative enough to develop new means of fraud. Pfizer's proposed system of government-exclusive investigation and enforcement is one conceivable response to the rare case of the unimaginative recidivist. But allowing *qui tam* suits in the case of old-scheme recidivists who revive their fraudulent activity at least places an additional burden on those

contemplating renewed fraudulent activity, rather than sending the message that they can avoid relator-based FCA consequences by "perpetrating a related fraud" and hoping that the government, with its limited investigatory resources, will fail to notice the repeat offense. *Hoggett,* 2012 WL 2681817, at *4. I conclude that the public disclosure provision is not meant to deprive whistleblowers of their role as "private attorneys-general," *Poteet*, 552 F.3d at 507, when they come forward with evidence of new fraudulent activity--even new fraud that is perpetrated by old *modus operandi*.[4]

The only real question, then, is whether in these circumstances the public disclosure provision is inapplicable on its face, or whether the value added by relators' allegations brings this action under the "original source" exception. The plain language of the statute favors the latter approach: while the allegations of the Fifth Amended Complaint are "substantially the same" as those previously disclosed, they are nevertheless "independent of and materially add to" the prior disclosures.

I am also guided by the principle that the FCA's *qui tam* provisions seek the "golden mean between adequate incentives for whistle-blowing insiders with genuinely valuable information and

[4]Although the temporal proximity of the "new" fraud alleged and the previously-disclosed fraud does not necessarily bar Relators' claims, it may eventually create difficultly for Relators in demonstrating that any false claims were in fact the fruits of the "new" alleged fraud.

discouragement of opportunistic plaintiffs who have no significant information to contribute of their own." *U.S. ex rel. Springfield Terminal Ry. Co.* v. *Quinn*, 14 F.3d 645, 649 (D.C. Cir. 1994). Identifying recidivists may be somewhat less valuable than uncovering fraud in the first instance, but it is not mere opportunism and is distinguishable from repetitive disclosures of past fraud. Accordingly, it is reasonable that the public disclosure provision would not bar all *qui tam* suits against those reviving their old fraud schemes, but would recognize their lesser utility by requiring additional substantive and procedural hurdles before allowing relators to bring such suits. Thus, while finding the public disclosure provision potentially applicable here, I also conclude that the current "original source" exception is the appropriate framework for analyzing whether Relators' claims nevertheless remain viable.

2. Application

Turning first to the main procedural hurdle, Relators can only maintain this suit if they "voluntarily provided the information to the Government before filing an action." 31 U.S.C. § 3730(e)(4)(B). The initial complaint in this action contained relators' primary "independent" and "material" addition to prior disclosures--namely, that Pfizer continued its off-label promotion of Geodon after the August 2009 settlement. Moreover,

the initial complaint alleged that "[a]s required by the False Claims Act, 31 U.S.C. § 3730(b)(2), Relators have provided *previously* to [relevant government officials] a statement of all material evidence and information related to the Complaint." Compl. ¶ 5 (emphasis added). Relators thus plausibly alleged that, prior to filing the action, they provided the government with the information in their possession on which their allegations are based, including their knowledge that was independent of and materially added to the prior public disclosures.[5]

As to "knowledge that is independent of and materially adds to" prior public disclosures, the Fifth Amended Complaint alleges that relator Booker, in his capacity as a sales representative with Pfizer through January 6, 2010, obtained knowledge that Pfizer had continued or resumed its off-label promotion of Geodon even after the company's August 2009 settlement with the government. As discussed above, this information is sufficient to qualify for the "original source" exception.

Relator Hebron, by contrast, has not been employed with Pfizer since June 2006. The only allegations regarding his

[5]The Fifth Amended Complaint indicates that advance disclosure to the government may have ceased after the Third Amended Complaint. Fifth Am. Compl. ¶ 5. Although it is not clear that Relators had a continuing duty of advance disclosure after the action was "filed," Pfizer has not in any event made specific argument as to additional allegations in the Fourth and Fifth Amended complaints it seeks to have excluded.

involvement with or investigation of Geodon promotion are limited to the time of his employment, and in particular the period from 2002 to 2005. Fifth Am. Compl. ¶ 69. Nevertheless, this does not seem to pose any bar to Hebron acting as a relator in the Geodon claims. While the pre-amendment version of the public disclosure provision required that an "original source" have "direct and independent knowledge of the information on which" his allegations were based, *see* 31 U.S.C. § 3730(e)(4)(B) (1994), the amended statute requires only that a relator have "knowledge" that is "independent of and materially adds to" prior public disclosures. *Id.* § 3730(e)(4)(B) (2010). Thus Hebron can act as a relator if he, like Booker, has knowledge of Pfizer's post-settlement Geodon promotion practices. His participation in this action, and the allegation that he previously provided relevant information to the government, Compl. ¶ 5, indicate that he does. That Hebron obtained his knowledge indirectly--indeed, presumably through relator Booker--poses no obstacle to the applicability of the "original source" exception. Although in most cases a relator with the bulk (if not the entirety) of the relevant knowledge may be less willing to share his potential bounty, 31 U.S.C. § 3730(d)(1), the statute does not preclude such generosity.[6]

[6]That said, for the reasons indicated, the Fifth Amended Complaint fails to allege that Hebron had "direct and independent knowledge" of Pfizer's practices with respect to Geodon promotion

3. Summary

Relators' complaint is subject to the public disclosure provision because it includes "substantially the same allegations" as those contained in the *Westlock* and *Kruszewski* complaints. However, Relators plausibly allege that they have "knowledge that is independent of and materially adds to the publicly disclosed allegations" of those prior complaints--specifically, knowledge regarding Pfizer's continued fraudulent promotion of Geodon for unapproved uses after its August 2009 settlement with the government, which caused or was material to false claims. 31 U.S.C. § 3730(e)(4)(B). They also indicated at the outset of this litigation that, prior to filing this action, they voluntarily provided the government with the information on which their allegations are based. *Id.* Relators thus plausibly allege that they qualify for the "original source" exception, and the public disclosure provision does not provide grounds to dismiss the action.

Having addressed the preliminary hurdles posed by the FCA's first-to-file and public disclosure provisions and concluding

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after his termination in June 2006. Hebron thus cannot serve as a relator with respect to Geodon-related claims under the state FCAs that had not adopted the federal FCA's amended definition of "original source" before this action was filed. This is of little consequence, however, due to my conclusion in Part IV.B.1.b that Relators' state FCA claims premised on off-label Geodon promotion fail on other grounds.

Relators plausibly allege they can surmount them, I turn to Relators' substantive allegations.

IV. FALSE CLAIMS ALLEGATIONS

The FCA imposes liability on any person who "knowingly presents, or causes to be presented, 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," *id.* § 3729(a)(1)(B). The FCA also prohibits "reverse" false claims, imposing liability on any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." *Id.* § 3729(a)(1)(G). Conspiracy to commit violations of the foregoing provisions constitutes a separate FCA violation. *Id.* § 3729(a)(1)(C).[7]

[7]I apply the amended provisions of § 3729, which generally "apply to conduct on or after" May 20, 2009. Fraud Enforcement and Recovery Act ("FERA"), Pub. L. 111-21, § 4(f), 123 Stat. 1617, 1621 (2009). Because the Relators have limited their allegations to conduct post-dating Pfizer's August 2009 settlement with the government (by necessity of the public disclosure bar), all relevant conduct in this matter post-dates May 20, 2009.

Once again, however, many states have apparently not amended their false claims statutes to conform to the FCA amendments, or at least had not done so before this action was filed. *Compare* Conn. Gen. Stat. Ann. § 17b-301b(a)(1)-(3), (7) (eff. Oct. 5, 2009) (conforming to May 2009 FCA amendments), *and* Col. Rev.

I begin by addressing Relators' allegations that Pfizer is liable under the "reverse" false claims provision, § 3729(a)(1)(G), because those allegations present a largely discrete set of issues. I then turn to whether Relators have

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Stat. Ann. § 25.5-4-305(1)(a)-(b), (f)-(g) (eff. May 26, 2010) (same), *with* Del. Code Ann. tit. 6, § 1201(a)((1)-(3), (7) (reflecting pre-amendment language), *and* Mass. Gen. Laws ch. 12, § 5B(a)(1)-(3), (9) (eff. July 1, 2012) (adopting amended FCA language, but effective after filing of this action).

I note that, unlike most other provisions of § 3729, § 3729(a)(1)(B) reflects substantive changes from its prior incarnation as § 3729(a)(2). *Compare* 31 U.S.C. § 3729(a)(1)(B) (2009) (imposing liability on any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim"), *with id.* § 3729(a)(2) (1994) (imposing liability on any person who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government"); *see generally U.S. ex rel. Nowak* v. *Medtronic, Inc.*, 806 F. Supp. 2d 310, 343 n.20 (D. Mass. 2011). The Supreme Court, in *Allison Engine Co., Inc.* v. *U.S. ex rel. Sanders*, 553 U.S. 662, 669-72 (2008), interpreted § 3729(a)(2) to require proof of intent to cause the government to pay a false claim, if not proof of an eventual claim.

The relevant provisions of the FERA were specifically designed to overrule the Supreme Court's interpretation of § 3729(a)(2) in *Allison Engine*, eliminating any intent requirement and affirming the requirement of false claims. Congress also made § 3729(a)(1)(B) retroactive to June 7, 2008, just prior to the date on which *Allison Engine* was handed down, to prevent any gap in coverage. FERA § 4(f)(1), 123 Stat. at 1625. Given the tendency of states to conform their FCAs to the federal Act and the ability of even the prior language to bear the same meaning as that clarified by Congress in § 3729(a)(1)(B), I will construe the state statutes invoked by Relators consistently with the provisions of § 3729 as amended. *Cf. New York* v. *Amgen Inc.*, 652 F.3d 103, 109 (1st Cir. 2011).

I also note that, in contrast to their dispute about the applicable version of the "original source" provision of the FCA, the parties have not argued that the choice of applying the pre- or post-FERA language of § 3729 would affect the disposition of Pfizer's motion to dismiss.

stated a claim under §§ 3729(a)(1)(A) and (B). In that regard, Pfizer has challenged only whether Relators have alleged that any claim for reimbursement of Geodon or Pristiq was "false or fraudulent." Relators have not opposed Pfizer's argument that they have failed to plead the existence of a conspiracy to violate the FCA, 31 U.S.C. § 3729(a)(1)(C), and so I consider those claims abandoned.

As to the theories on which I have found Relators have stated a claim, I go on to determine whether Relators have alleged fraud with sufficient particularity to satisfy Fed. R. Civ. P. 9(b).

A. "Reverse" False Claims

Relators allege that Pfizer made "reverse" false claims in violation of 31 U.S.C. § 3729(a)(1)(G), by failing to comply with a Corporate Integrity Agreement (CIA) it had with the Office of Inspector General (OIG) of the Department of Health and Human Services (DHHS).

The CIA requires Pfizer, after reasonable opportunity for review, to report to OIG certain qualifying "reportable events," including violations of law applicable to federal health care programs or violation of FDA requirements relating to the promotion of government-reimbursed products. Booker alleges that a January 5, 2010 email he sent to Pfizer Corporate Compliance objecting to off-label Geodon promotions constituted a reportable

event. Fifth Am. Compl. ¶¶ 120-121. Relators allege that Pfizer's behavior constituted avoidance of its obligation to pay the CIA's "Stipulated Penalties" of $2,500 per day for failure to report a qualifying event.

The agreement, however, also provides that Pfizer's failure to comply "may lead to the imposition" of the Stipulated Penalties if the OIG "determin[es] that Stipulated Penalties are appropriate." The mere fact that Pfizer's failure to report "*might* result in a fine or penalty is insufficient" to establish an "obligation" to pay the government under § 3729(a)(1)(G). *U.S. ex rel. Bahrani* v. *Conagra, Inc.*, 465 F.3d 1189, 1195 (10th Cir. 2006). When "potential fines depend on intervening discretionary governmental acts, they are not sufficient to create 'obligations to pay.'" *U.S. ex rel. Marcy* v. *Rowan Companies, Inc.*, 520 F.3d 384, 391 (5th Cir. 2008). Without an obligation, Pfizer had nothing to avoid, and relators' claim under § 3729(a)(1)(G) must fail.

Bahrani, 465 F.3d 1189, is not to the contrary. In *Bahrani*, meat exporters sought to avoid their obligation in certain circumstances to obtain replacement "export certificates," for which the defendants would have had to pay a fee. Although the government of course retained discretion whether to impose the fee, it was the point at which the conditions obtained necessitating a new certificate that the exporters' obligation to

pay the associated fee arose, which the exporters then sought to avoid. *Bahrani*, 465 F.3d at 1204. Here, by contrast, any obligation to pay did not arise merely upon occurrence of reportable events. Rather, upon the occurrence of a qualifying event, the CIA merely imposed on Pfizer an obligation to *report*--an activity not inherently linked to the payment of any money to the government. The obligation to pay would only arise upon OIG's decision to assess the stipulated penalties. The discretion retained by the OIG here is thus the discretion whether to *impose* a penalty and thereby *create* an obligation to pay, rather than the discretion whether to *enforce* an *existing* obligation to pay the government.

Other cases cited by relators are largely inapposite because they involved clear obligations to pay money or transmit property to the government that defendants sought to avoid. *U.S. ex rel. Matheny* v. *Medco Health Solutions, Inc.*, 671 F.3d 1217 (11th Cir. 2012), for example, involved a pharmaceutical company's failure to report government overpayments, which defendant was contractually obligated to return, 671 F.3d at 1223-24; the pharmaceutical company thus had a contractual obligation to transmit money to the government, which it avoided by failing to return the overpayments. *United States* v. *Pemco Aeroplex, Inc.*, 195 F.3d 1234, 1237 (11th Cir. 1999), similarly involved a government contractor's fraud in reporting the value of excess

government property it held, which the contractor was contractually obligated to return or purchase, 195 F.3d at 1237; the contractor thus made false statements material to its obligation to transmit property or pay money to the government.

Because the CIA did not impose on Pfizer an "obligation" to pay the government, relators fail to state a claim for "reverse" false claims in violation of § 3729(a)(1)(G).

B. False Claims

Turning to Relators' claims under §§ 3729(a)(1)(A) and (B), Pfizer argues that Relators' claims fail to allege "false or fraudulent" claims for which Pfizer can be held liable. "[A]n actual false claim is the *sine qua non* of a False Claims Act violation." *U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 225 (1st Cir. 2004) (internal citation omitted). Although liability under each subsection would require Pfizer to have played a slightly different role in eventual false claims, Relators have failed to state a claim if they have not adequately alleged the falsity of any claims for reimbursement of Geodon or Pristiq prescriptions.

I discuss below the four ways in which Relators seek to allege the falsity of claims for reimbursement of off-label Geodon and Pristiq prescriptions. I then discuss issues unique to alleging the falsity of claims for reimbursement of Pristiq prescriptions.

1. Falsity Based Solely on Claims for Reimbursement of Off-Label Non-Compendium Uses

Relators first seek to establish the falsity of any claims for reimbursement of prescriptions for off-label non-compendium Geodon or Pristiq uses made to government health care programs because, they say, federal law limits reimbursement to "medically accepted indications," 42 U.S.C. § 1396r-8(k)(6), which for purposes of Medicaid coverage includes FDA-approved uses of prescription drugs ("on-label" uses), as well as off-label uses that are recognized in certain statutorily-identified drug compendia, *id.* § 1396r-8(g)(1)(B)(i); *see also id.* §§ 1395w-102(e)(1), (e)(4)(A)(ii) (incorporating definition of "medically accepted indication" into Medicare Part D coverage). Accordingly, Relators argue, federal law prohibits reimbursement for off-label non-compendium uses, and claims for reimbursement of such uses are "false or fraudulent." *United States* v. *R&F Properties of Lake Cnty., Inc.*, 433 F.3d 1349, 1356 (11th Cir. 2005) (claiming reimbursement for services or costs that are not reimbursable is a false claim). Pfizer argues the case is not so simple due to discretion that federal law permits in the administration of federally-funded health care programs.

Pfizer argues Medicaid programs (as administered by the States) and Medicare Part D Prescription Drug plans (as administered by private contractors) retain discretion to reimburse for off-label non-compendium uses of a pharmaceutical

drug. *Cf. U.S. ex rel. Franklin* v. *Parke-Davis, Div. of Warner-Lambert Co.*, No. 96-11651-PBS, 2003 WL 22048255, at *2-3 (D. Mass. Aug. 22, 2003) (noting statutory ambiguity regarding authority of state Medicaid to reimburse for off-label non-compendium uses); *Layzer* v. *Leavitt*, 770 F. Supp. 2d 579, 587 (S.D.N.Y. 2011) (concluding that Medicare Part D does not preclude reimbursement for off-label, non-compendium uses); *but see Kilmer* v. *Leavitt*, 609 F. Supp. 2d 750, 757 (S.D. Ohio 2009) (concluding Medicare Part D does not allow reimbursement for off-label, non-compendium uses). As a result, merely filing claims with state programs for reimbursement of prescriptions for off-label non-compendium uses does not in and of itself constitute a false claim, and the allegation of claims for such reimbursement is not alone sufficient to allege falsity. I address separately how this argument affects whether Relators have stated a claim under the federal FCA and the state FCAs.

a. Federal FCA

Perhaps counter-intuitively, Pfizer's argument as to federal reimbursement policy does not affect whether Relators have stated a claim under the federal FCA (Count I). Relators' task of alleging a false claim is surely easier if I find that federal law prohibits reimbursement for off-label non-compendium uses in all instances. In that circumstance, a claim for such reimbursement is false for purposes of federal law regardless of

the state practice. Any "ambiguity in a condition of payment," created by federal or state law does not mean the claim is not false, but would be "relevant only to the claimant's knowledge of falsity." *U.S. ex rel. Fox Rx, Inc.* v. *Omnicare*, Inc., No. 11-00962-WSD, 2012 WL 8020674, *9 (N.D. Ga. Aug. 29, 2012).

Relators have argued, however, and Pfizer does not dispute, that at least *some* states refuse reimbursement for off-label non-compendium uses. *Cf. U.S. ex rel. Franklin* v. *Parke-Davis, Div. of Warner-Lambert Co.*, No. 96-11651-PBS, 2003 WL 22048255, at *3-4 (D. Mass. Aug. 22, 2003). Needless to say, claims for reimbursement of such uses in states with restrictive reimbursement policies are false. Moreover, fraud on any of these federally-funded state health programs constitutes fraud on the federal government. *See* 31 U.S.C. § 3729(b)(2)(A)(ii). In combination with the allegations of promotion of off-label non-compendium uses of Geodon and Pristiq designed to induce doctors nationwide to prescribe such uses to their federally insured patients, Relators plausibly allege that Pfizer caused the filing of at least some false claims under the federal FCA. *Cf. Duxbury*, 579 F.3d at 29; *Nowak*, 806 F. Supp. 2d at 347. For purposes of federal fraud, the treatment of specific claims in states with more flexible reimbursement schemes can be reserved for later stages of the litigation, and is more appropriately viewed as a question of damages. *See Parke-Davis*, 2003 WL

22048255 at *3. But, of course, whether Relators have pled fraud with the particularity required by Fed. R. Civ. P. 9(b) is another matter, which I address separately below.

b. State FCAs

The analysis is somewhat different for purposes of alleging false claims under the state FCAs (Counts II through XXVI). While a claim for reimbursement may be false for purposes of federal law regardless of state practice, at the state level I recognize the full force of Pfizer's argument that "if a state Medicaid program chooses to reimburse a claim for a drug prescribed for off-label [non-compendium] use, then that claim is not 'false or fraudulent,' and liability cannot therefore attach for reimbursement." *U.S. ex rel. Banigan* v. *Organon USA Inc.*, 883 F. Supp. 2d 277, 294 (D. Mass. 2012). In that circumstance, even if there had been fraud against the federal government (and potential noncompliance with conditions on Medicaid funding), there cannot have been fraud against the state program.

Accordingly, plausibly alleging the falsity of claims under state FCAs will turn in part on whether the *state* programs permit off-label non-compendium reimbursements, regardless of federal reimbursement policy. Adequate allegations of false claims based solely on the filing of off-label non-compendium claims is thus a state-by-state affair. In the Fifth Amended Complaint, however, Relators have merely relied on the alleged federal reimbursement

practice, *see* Fifth Am. Compl. ¶¶ 28-34, without acknowledging the effect that state reimbursement practices might have under *state* FCA claims. Thus, in Counts II through XXVI, Relators cannot adequately plead the falsity of claims solely by alleging off-label non-compendium reimbursement claims and only the alleged *federal* policy of refusing reimbursement for those claims.

2. Falsity Based on Kickbacks

Relators also seek to establish the falsity of claims where those claims flowed from alleged kickbacks Pfizer paid to physicians as inducement to prescribe Geodon and Pristiq. Claims induced by kickbacks may be false when they "misrepresent[] 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); *see also* 42 U.S.C. § 1320a-7b(g) ("[A] claim that includes items or services resulting from a violation of [the federal anti-kickback statute] constitutes a false or fraudulent claim [for purposes of the FCA]."). Pfizer has not attacked the Relators' ability to demonstrate the falsity of kickback-derived claims.

Instead, Pfizer argues that Relators have not stated a claim for violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, that could form the basis for falseness of eventual claims. According to Pfizer, Relators needed to allege that its

payments to any physician speakers exceeded their fair market value in order to establish that those payments constituted an illegal kickback, which Relators undoubtedly did not do.

But while Pfizer's payment for services at more-than-market value might be helpful evidence of a kickback scheme, I am not convinced it is necessary to establishing a kickback in all cases. 42 U.S.C. § 1320a-7a(i)(6)(G) and (H), for example, *exclude* certain non-market value offers from the category of illegal kickbacks under particular circumstances, but neither provision *requires* an exchange at non-market value to constitute an illegal kickback. Even without such an allegation here, Relators have plausibly alleged that Pfizer was knowingly paying physicians to induce them to prescribe Geodon and Pristiq. I reserve for Part IV.D.2, *infra*, discussion of whether relators have pled the kickback scheme and resulting claims with adequate particularity for purposes of Rule 9(b).

3. Falsity Based on Fraud in Promotion

Relators next rely on allegations of fraudulent conduct by Pfizer in promoting its drugs to establish the falsity of claims. For example, Relators allege that Pfizer managers encouraged sales representatives to exclude from their promotional activities negative material about its drugs, Fifth Am. Compl. ¶ 57(d), and to conceal unfavorable FDA decisions regarding those drugs, *id.* ¶ 66(f). Relators also allege that sales managers

were trained to provide information regarding drug side effects that had no clinical support. *Id.* ¶ 71(b). Relators argue that claims induced by such fraudulent activity are themselves inherently "false or fraudulent."

While underlying fraudulent conduct, however, may constitute "false statement[s]" for purposes of § 3729(a)(1)(B), such conduct does not in and of itself establish the "false or fraudulent claim" required for liability under both §§ 3729(a)(1)(A) and (B). Consistent with the principle that the FCA "does not create a cause of action against all fraudulent conduct affecting the government" *U.S. ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 727 (1st Cir. 2007); *accord U.S. ex rel. Provuncher* v. *Angioscore, Inc.*, No. 09-12176-RGS, 2012 WL 1514844, at *4 (D. Mass. May 1, 2012) (FCA not "intended to serve as a general purpose anti-fraud statute"), courts have routinely rejected litigants' attempts to use fraudulent *conduct* to avoid the need to show false *claims*. The First Circuit, for example, squarely rejected Relators' argument in *Amgen*, reasoning that underlying fraudulent practices do not determine the falseness of third-party claims induced by those fraudulent practices. *New York* v. *Amgen Inc.*, 652 F.3d 103, 111 (1st Cir. 2011). *Amgen* was consistent with lower court decisions finding that an "alleged FCA violation arises — not from unlawful [and fraudulent] off-label marketing activity itself - but from the submission of

. . . claims for uncovered off-label uses induced by Defendant's fraudulent conduct." *Parke-Davis*, 2003 WL 22048255, at *2.

These precedents do not necessarily rule out the possibility of underlying fraudulent conduct so extreme as to allow the inference that resulting claims are also false. *E.g.*, *U.S. ex rel. Ruhe* v. *Masimo Corp.*, No. 10-08169-CJC-JCGX, 2012 WL 7681937 (C.D. Cal. July 9, 2012) (contrary to promotion, medical device was so "wildly inaccurate" any claim for its use likely was not "reasonable and necessary" as required for Medicare reimbursement). But such an allegation adds to the underlying fraudulent conduct an additional element - impossibility of reasonable and necessary use - to establish the falsity of the resulting claim. In other words, a *separate* falsehood from the fraudulent conduct itself is alleged. By contrast, Relators here attempt to establish the falseness of claims derived from fraud as a categorical matter. That avenue is foreclosed by this Circuit's precedents.

4. Falsity Based on Misbranding Alone

Relators' last effort to establish the falseness of claims is to argue that, just as claims induced by kickbacks may be false, so too may claims induced by misbranding alone--i.e., misbranding without the additional element of fraud, discussed in the preceding section. It is clear that "FCA liability does not attach to violations of federal law or regulations, such as

marketing of drugs in violation of the FDCA, that are independent of any false claim." *Rost*, 507 F.3d at 727; *see also Nowak*, 806 F. Supp. 2d at 345 ("Proof of unlawful off-label promotion alone cannot sustain a successful FCA action."). Relators, however, say that these cases do not answer whether misbranding, when it has been shown to induce claims for reimbursement by third-parties, may render those claims "false or fraudulent" because the claimant has "misrepresented compliance with a material precondition of payment." *Amgen*, 652 F.3d at 110-11. *Cf. Wilkins* v. *United Health Group, Inc.*, 659 F.3d 295, 308-10 (3d Cir. 2011) (compliance with Medicare marketing regulations not precondition to payment; noncompliance thus was not basis for FCA claim).

This theory of falsity, however, is one that Relators have failed to plead. Nothing in their complaint even remotely alleges that any of the federal or state programs at issue make compliance with marketing regulations or criminal misbranding laws a precondition to payment. Even in their response to Pfizer's motion to dismiss, Relators' response to the possibility of reimbursement for claims induced by fraud is, effectively, "it simply cannot be." As the First Circuit made clear in *Amgen*, however, the inquiry into misrepresentations of preconditions to payment is "fact-intensive and context-specific." 652 F.3d at 111.

Relators say they have adequately "alleged that the federal Medicaid statute prohibits state Medicaid programs from reimbursing for off-label uses of Geodon and Pristiq promoted by Pfizer." True enough. But this was the argument for falsity discussed in Part IV.B.1 above--namely, that claims for reimbursement of all off-label uses are false because the federal statute precludes reimbursement for those uses. Relators cannot transform such an allegation into the separate allegation that the claims induced by Pfizer are false because the relevant federal and state programs make compliance with misbranding laws or marketing regulations a precondition to payment.

5. Falsity of Pristiq Claims

Pfizer points out that the Pristiq FDA-approved label indicates it is available in "50 and 100mg tablets" and permits use of a 100mg dose for certain purposes. The federally-recognized DRUGDEX compendium, *see* 42 U.S.C. § 1396r-8(g)(1)(B)(iii), also indicates Pristiq at 100mg for treating menopausal hot flushes. Accordingly, allegations regarding Pfizer's promotion of a 100mg dose or menopause-related uses alone cannot support the falsity of resulting claims for those uses.

In Part IV.D.1, *infra*, I conclude in any event that Relators have failed to plead their Pristiq allegations with sufficient particularity. For present purposes, I observe that allegations

of claims for reimbursement of Pristiq at a 100mg dose or for menopause-related reasons are in themselves insufficient to allege the falseness of those claims.

6. Summary

Under the federal FCA (Count I), Relators have plausibly alleged that Pfizer induced claims which were false solely by seeking reimbursement for off-label non-compendium uses. Those allegations alone are insufficient, however, to allege the falseness of claims for purposes of the *state* FCAs (Counts II through XXVI).

Relators have also alleged a plausible kickback scheme that may be the basis of falseness for claims for reimbursement of Geodon and Pristiq prescriptions induced by those kickbacks. I am prepared, subject to a Rule 9(b) analysis, *see* Section IV(D) *infra*, to allow Relators to proceed on this theory as to Counts I through XXVI, although I have indicated that, upon a properly-raised challenge, the lack of state-specific pleading may jeopardize those allegations.

By contrast, Relators have not plausibly alleged that any claims for reimbursement of Geodon or Pristiq prescriptions were false solely by virtue of underlying fraudulent conduct by Pfizer. Relators have also failed to allege that any state or federal program at issue makes compliance with misbranding laws or other marketing regulations a precondition to payment, and

thus have not plausibly alleged that any claims induced by misbranding were false as a result.

D. Pleading Fraud with Particularity

As to Relators' remaining viable theories of liability, I turn to whether they have alleged fraud with sufficient particularity.

FCA allegations and their state counterparts are subject to the heightened pleading standards of Fed. R. Civ. P. 9(b). *Duxbury*, 579 F.3d at 29. Rule 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." According to this standard, "a complaint must specify the time, place, and content of an alleged false representation." *Rost*, 507 F.3d at 731 (citation and internal quotation marks omitted). Conclusory allegations are insufficient, but Rule 9(b) may be satisfied "when some questions remain unanswered, provided the complaint as a whole is sufficiently particular to pass muster." *U.S. ex rel. Gagne* v. *City of Worcester*, 565 F.3d 40, 45 (1st Cir. 2009).

The First Circuit has also recognized a "distinction between a *qui tam* action alleging that the defendant made false claims to the government, and a *qui tam* action in which the defendant induced *third parties* to file false claims with the government." *Duxbury*, 579 F.3d at 29. In the latter circumstances, a relator may 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.* (internal quotation omitted).

1. False Claims for Reimbursement of Off-Label Non-Compendium Uses

I begin with the most particular allegations, which relate to Geodon. The Fifth Amended complaint effectively has one paragraph that specifically pleads the filing of claims for reimbursement of prescriptions for off-label non-compendium Geodon uses. *See* Fifth Am. Compl. ¶ 69. Each claim alleged therein was submitted to Illinois Medicaid for reimbursement of off-label Geodon prescriptions to children and at allegedly off-label doses. *Id.* Several of the claims were made in 2011--post-dating the August 2009 settlement--and the prescribing doctors had been the objects of Pfizer's Geodon promotion dating back to 2002. *Id.*

Elsewhere, Relators rely on doctors' scripting habits and their large populations of patients covered by Medicaid or Medicare to plead false claims. For example, from 2006 until his termination in 2010, Booker promoted Geodon as a "monotherapy agent for bipolar maintenance" to doctors he knew were prescribing Geodon off-label, and who had patient populations that were 50% children and as much as 80% covered by Medicare/Medicaid. Fifth Am. Compl. ¶ 60(g). From late 2009 until his termination, Booker promoted Geodon to other child

psychiatrists in Missouri, with "large" Medicaid patient populations, and who prescribed Geodon for bipolar maintenance in children. Fifth Am. Compl. ¶ 66(i). In particular, in August 2009, Booker promoted Geodon use for bipolar maintenance to a Missouri child psychiatrist with "substantial" Medicare/Medicaid practice who was known to prescribe Geodon as a "large part of her practice." Fifth Am. Compl. ¶ 60(e). More generally, Relators also allege that, at unspecified times, Pfizer promoted Geodon use for children to a variety of child psychiatrists who "had been noted by Pfizer as high writers of Geodon scripts for children and adolescents who were Medicaid recipients." Fifth Am. Compl. ¶ 66(j).

From there, the allegations as to Geodon promotion and resulting claims (or even prescriptions) fall off in particularity. Particular allegations as to off-label promotion of Geodon for cognition, for example, are limited to promotion to doctors with Medicare/Medicaid populations that were "large," which Relators later characterize in the context of another doctor as "40%." Fifth Am. Compl. ¶¶ 57(c)-(d). The same is true as to allegations regarding promotion of Geodon for anger management, except the doctor allegedly targeted in the particular instance alleged had only a "25%" Medicare/Medicaid practice, which Relators nevertheless also characterized as "large." Fifth Am. Compl. ¶ 58(d).

Meanwhile, the only particular allegation regarding promotion of Geodon for improving sleep is actually an instance in which a doctor asked Booker about use of Geodon for improving sleep, and Booker told the doctor Geodon is not indicated for that purpose. Fifth Am. Compl. ¶ 129. There are no allegations as to prescriptions let alone claims for reimbursement of these off-label uses. And there are essentially no particularized allegations in the Fifth Amended Complaint with respect to the remaining alleged off-label Geodon uses alleged.

The allegations as to Pristiq are similarly thin. The strongest allegation is that Booker promoted the 100mg dose of Pristiq to psychiatrists in Missouri known to prescribe Pristiq off-label and who had "large" Medicaid patient populations. Fifth Am. Compl. ¶ 101. Relators allege Pfizer's promotion of the 100mg Pristiq dose to Illinois doctors with "nearly a total Medicare patient population," but include no allegation as to their prescribing habits. Fifth Am. Compl. ¶ 94. Relators allege promotion of the 100mg dose to another Illinois doctor who was "pumping it out," but allege only that he "has Medicare patients." *Id.* Relators also allege that they obtained through investigation information about Pfizer promoting Pristiq for pain management to doctors in Missouri, Indiana, Kentucky, Ohio, and Tennessee. Fifth Am. Compl. ¶ 75. They allege that Pfizer had information about the prescription history and Medicare/Medicaid

billing of those doctors, but this says next to nothing about their habits of prescribing off-label uses to federally-insured patients or claiming reimbursement from government programs for off-label Pristiq uses.

The complaint is also somewhat self-denying. For example, the complaint alleges that, in November 2009, one doctor who was the subject of off-label Pristiq promotion told Booker she was so appalled by Pfizer's off-label promotion following the 2009 Geodon settlement that she requested that no more Pfizer speakers come to her office. Fifth Am. Compl ¶ 67. This certainly does not assist the inference that doctors who were the subject of off-label promotion were rushing to prescribe off-label and to submit false claims for reimbursement.

The complaint in many ways tests the limits of the "more flexible standard" applied to allegations that a defendant induced third parties to file false claims. *Duxbury*, 579 F.3d at 30. At this point, I conclude that Relators have pled with sufficient particularity that Pfizer caused the filing of Geodon reimbursement claims for off-label prescriptions to children and adolescents, for bipolar maintenance, and at excessive dosage. They have done so through the combination of particular alleged claims for reimbursement and allegations of off-label prescriptions by physicians with substantial (as much as 80%)

Medicare/Medicaid patient populations.[8] The question is the extent to which these allegations can compensate for other deficiencies in the complaint.

To be sure, in some circumstances relators will not need particularized allegations of false claims resulting from *every*

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[8] Following oral argument on its motion to dismiss, Pfizer brought to my attention a recent decision of the First Circuit in *United States ex rel. Ge* v. *Takeda Pharmaceutical Co.*, 737 F.3d 116 (1st Cir. 2013), which it contends supports its argument that Relators have not pled their off-label reimbursement claims with sufficient particularity. As Pfizer asserts, the First Circuit in *Ge* indicated that the allegations that it allowed to proceed in *Duxbury* represent the outer limits of what can be considered sufficiently particular under Rule 9(b). *See Ge*, 737 F. 3d at 124 (citing *Duxbury*, 579 F.3d at 29-30) (characterizing the particularity of the pleadings in *Duxbury* as "barely adequate" and "just enough"). The relator in *Ge* claimed that the defendant drug maker's alleged intentional under-reporting of "adverse events" to the FDA, in violation of its duty under 21 C.F.R. §§ 314.80, 314.81, "resulted in the submission of false claims or false statements material to false claims for government payment," in the form of claims for reimbursement for prescriptions of affected drugs. *Id.* Putting aside whether compliance with the FDA's adverse-event reporting requirements was a "material precondition" to the payment of the claims at issue – the district court concluded that it was not, but the First Circuit declined to reach the issue, *see id.* at 119, 122 – the First Circuit observed that the complaint "alleged next to no facts in support of the proposition that Takeda's alleged misconduct resulted in the submission of false claims or false statements material to false claims for government payment." *Id.* at 124. Because the relator in *Ge* made "no effort to identify specific entities who submitted claims or government program payers, much less times, amounts, and circumstances," the First Circuit characterized her allegations as "far less particular than those [in *Duxbury*] whose sufficiency was deemed a 'close call.'" *Id.* Here, the specific allegations pertaining to the claims submitted as a result of off-label promotion of Geodon are at least as particular as the allegations held to pass muster in *Duxbury*, and are a far cry from the virtually non-existent specific allegations in *Ge*. For that reason, I am not persuaded that *Ge* affects the outcome of this case.

promoted off-label use alleged in their complaint; rather, "representative examples for multiple alleged off-label uses" may be sufficient. *See U.S. ex rel. King v. Solvay S.A.*, 823 F. Supp. 2d 472, 494 (S.D. Tex. 2011). But the ability of certain particularized allegations to compensate for the lack of particularity in other allegations will depend in good measure on the strength of the primary allegations and how little is alleged about the others.

Here, even the particularized allegations do not "allege[] the submission of false claims across a large cross-section of providers." *Duxbury*, 579 F.3d at 30. The particularized allegations of claims for reimbursement are few, limited to a discrete group of doctors in Illinois, and are limited to off-label dosage and use in children and adolescents. Given Pfizer's long alleged history with these physicians, the allegations are also haunted by the specter that the claims may have been induced by promotion that occurred before Pfizer's 2009 settlement with the government. As discussed in Part III.B, *supra*, such claims are not the proper subject of this suit. Claims regarding off-label use for bipolar maintenance are also tenuous, based on the inference from alleged prescriptions by physicians with substantial Medicare/Medicaid patient populations. I consider the inference fair enough here, but I find it inappropriate to stretch the inference further to reach other off-label uses as to

which Relators could not even allege the simple fact that physicians were actually writing prescriptions for those uses.

The allegations as to Pristiq are also wholly inadequate and also cannot benefit from the limited particularized allegations of claims for reimbursement of prescriptions for off-label Geodon use. It may be impractical and impose too great a burden to require particularized allegations regarding claims for reimbursement for every single off label use of a particular drug where there have been sufficiently strong allegations as to claims for reimbursement of some subset of off-label uses. But allegations regarding an entirely different drug implicate a largely different cohort of doctors, weighing a new set of considerations for prescription and reimbursement. To conclude that the woefully inadequate allegations as to Pristiq here are somehow saved by limited particularized allegations as to Geodon would not constitute a "more flexible" approach to Rule 9(b), but rather would deprive that approach of any real meaning.

As to the Geodon allegations that do survive, however, Relators have adequately pled that those claims extend over a wide geographic scope. Almost all of the allegations described above implicate a Pfizer district or regional sales manager in the promotional activity alleged to have induced false claims. Moreover, one notable strength of the complaint is in its allegations that Pfizer's drug-promotion strategy was coordinated

at a national level. *See, e.g.*, Fifth Am. Compl. ¶¶ 57(b), 58(b), 59(b)-(d), 60(b)-(d), 61(b)-(d), 69(c), (f), 70(b).

2. Kickback Scheme

As discussed in Part IV.B.2, *supra*, Relators have alleged a plausible kickback scheme by which to establish the falseness of claims induced by that scheme. The question now is whether they have alleged that scheme and resulting claims with sufficient particularity. I conclude that they have.

The Fifth Amended Complaint contains a fair amount of detail regarding Pfizer's promotional speaker program. The name is self-explanatory: Pfizer paid physicians to speak at events promotion Pfizer products. Relators allege the rapid expansion of Pfizer's promotional speaker program after 2009. Fifth Am. Compl. ¶ 114(a). They provide a fairly specific range of amounts that speakers were paid: between $1000 and $1750 at an annual cap of $50,000. Fifth Am. Compl. ¶ 114(e). They note that physicians might have made $1000 for as little as 45 minutes at a promotional event. Fifth Am. Compl. ¶ 114(i). Importantly, Relators also allege that Pfizer District Manager Stephanie Bartels, along with other District Managers, encouraged sales representatives "to select those physicians who had the highest potential to write Geodon and Pristiq scripts to be trained to become Pfizer speakers." Fifth Am. Compl. ¶ 114(b). Finally, relators link Pfizer's payments to speakers to reimbursement

claims through, for example, Dr. Lucya Puszkarski, who had a "substantial Medicare/Medicaid practice[]" and whose "script writing to kids for Geodon increased after he received his $1000 payment from Pfizer and conducted [his] lunch presentation." Fifth Am. Compl. ¶ 114(i).

Relators have thus alleged with particularity sufficient to satisfy Rule 9(b) that Pfizer was knowingly paying physicians to induce them to prescribe Geodon and Pristiq, that physicians did so prescribe, and that the resulting claims were false.

3. Knowingly Caused

Pfizer also argues that Relators have failed to plead with particularity that it "knowingly caused" the filing of any false claims.[9] It notes that the reimbursement claims potentially at issue were likely submitted by pharmacies, not even the physicians that were the object of Pfizer's promotional activities. Pfizer thus contrasts this case to others in which Relators have alleged that a defendant pharmaceutical company

[9]This argument, of course, goes only to Relators' claim under § 3729(a)(1)(A). Under § 3729(a)(1)(B), Pfizer need only have made "fraudulent statement[s] material to a false or fraudulent claim." I discussed Relators' allegations of various fraudulent conduct by Pfizer in Part IV.B.3, *supra*. There, I concluded that those allegations of fraudulent conduct could not usurp the "double falsehood" requirement of § 3729(a)(1)(B); Relators still need to allege and prove "false claims" to which those statements were material. But, Relators' allegations of fraudulent conduct are sufficiently particular allegations of "fraudulent statements" to satisfy the "first falsehood" of § 3729(a)(1)(B).

took efforts "to coach doctors on how to conceal the off-label nature of the prescription." *U.S. ex rel. Franklin* v. *Parke-Davis, Div. of Warner- Lambert Co.*, 147 F. Supp. 2d 39, 46 (D. Mass. 2001). The First Circuit has explicitly held, however, that while pleading "a connecting causal link" of this sort "strengthens the inference," the fact that there were "allegedly intervening persons who actually submitted the claims does not itself necessarily break the causal connection when the claims are foreseeable." *Rost*, 507 F.3d at 733. If the foreseeability of claims filed with state or federal programs is a question here, it is not one for the pleading stage.

4. Summary

Relators have thus pled with adequate particularity their allegations of false claims stemming from fraudulent promotion of Geodon for children and adolescents, for bipolar maintenance, and at excessive dosage, and their allegations of false claims induced by kickbacks.

V. RETALIATION

Booker's retaliation claim under 31 U.S.C. § 3730(h) (Count XXVII) presents a largely independent set of issues. To state a claim, Booker must plead that his conduct was protected under the FCA, that Pfizer knew he was engaged in such conduct, and that Pfizer discharged or discriminated against him because of his protected conduct. *Karvelas*, 360 F.3d at 235, *abrogated on other*

grounds by Gagne, 565 F.3d at 42. The allegations need not meet the heightened pleading standards of Rule 9(b). *Karvelas*, 360 F.3d at 236 n.23.

A. Relevant Allegations

Booker worked as a sales representative at Pfizer from 1991 until he was terminated on January 6, 2010. He was a consistently high-performing sales representatives. He won awards for "district sales rep of the year" five times, and Pfizer's highest sales award three times, in 2000, 2001, and 2005. Fifth Am. Compl. ¶ 11. In the fourth quarter of 2009, just before he was terminated, he had the highest sales in his district and ranked in the top five percent of sales in his region. Fifth Am. Compl. ¶ 12.

Over the course of 2009, Booker objected to a wide variety of Pfizer's off-label promotional activities and distortions of clinical research, primarily to his district manager John Tidwell. Fifth Am. Compl. ¶¶ 128-139, 141-42. On October 2009, he called the Pfizer Compliance Hotline to report that his district manager was "using false representations to sell Geodon off-label." Fifth Am. Compl. ¶ 140. On January 5, 2010, Booker sent an email to Pfizer Corporate Compliance "object[ing] to the off-label Geodon sales practices" promoted by district manager Tidwell. Fifth Am. Compl. ¶ 143.

B. Analysis

The First Circuit construes the concept of protected activity under the FCA broadly to include "investigating matters which are calculated, or reasonably could lead, to a viable FCA action." *Karvelas*, 360 F.3d 220; *accord U.S. ex rel. Provuncher* v. *Angioscore, Inc.*, CIV.A. 09-12176-RGS, 2012 WL 1514844 (D. Mass. May 1, 2012). That said, investigation of "regulatory failures" that do not involve "investigation or reporting of false or fraudulent claims" is not protected. *Karvelas*, 360 F.3d 237.

As has been discussed at length above, off-label promotion in and of itself is not the subject of FCA liability. In this respect, Booker's conduct thus might be viewed as more akin to mere reporting of regulatory failures, divorced from any false claims.

However, this case is "in a different category than in *Karvelas*," *U.S. ex rel. Rost* v. *Pfizer, Inc.*, 507 F.3d 720, 732 (1st Cir. 2007), as one involving the inducement of claims by third parties. One who causes or is material to false claims is subject of FCA liability no less than one who directly makes a false claim. Here, Booker did not report just mere regulatory failures, but also fraudulent conduct directed at physicians to encourage off-label Geodon use. Such fraudulent conduct is exactly the sort that "reasonably could lead" to false claims by

the objects of that conduct, and is thus protected conduct for purposes of the FCA. *Cf. U.S. ex rel. Gobble* v. *Forest Laboratories, Inc.*, 729 F. Supp. 2d 446, 450 (D. Mass. 2010) (finding reports of off-label promotion and kickbacks protected FCA activity).

Once Booker's protected activity is established, there is little question that he has stated a plausible claim. Pfizer's awareness of his activity is more than plausible based on the allegation that Booker reported his concerns to Pfizer Corporate Compliance. And the proximity between his protected activity and abrupt termination after years of excellent job performance are sufficient at this stage to allege that he was discharged because of his protected conduct. *Cf. U.S. ex rel. Bierman* v. *Orthofix Int'l, N.V.*, 748 F. Supp. 2d 117, 122 (D. Mass. 2010).

VI. CONCLUSION

For the reasons set forth more fully above, defendant's motion to dismiss, Dkt. No. 44, is GRANTED IN PART and DENIED IN PART. Relators may continue to pursue Count I insofar as FCA liability is premised on off-label promotion of Geodon for children and adolescents, for bipolar maintenance and at excessive dosage, or premised on claims induced by kickbacks. Relators may continue to pursue Counts II through XXVI insofar as

liability is premised on claims induced by kickbacks. Relator Booker may continue to pursue Count XXVII.

/s/ Douglas P. Woodlock
DOUGLAS P. WOODLOCK
UNITED STATES DISTRICT