UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, et al., ex rel. HELEN GE, M.D.,	)	
Plaintiffs and Relator,	)	**Civil Action Nos. 10-11043-FDS**
v.	)	**11-10343-FDS**
TAKEDA PHARMACEUTICAL COMPANY LIMITED and TAKEDA PHARMACEUTICALS U.S.A., INC., f/k/a TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,	)	
Defendants.	)	

MEMORANDUM AND ORDER
ON MOTIONS TO DISMISS

SAYLOR, J.

These two *qui tam* actions were brought by relator Dr. Helen Ge, a former medical reviewer in Takeda's pharmacovigilance division. Her claims arise from the alleged failure of defendants Takeda Pharmaceutical Company Limited and Takeda Pharmaceuticals North America, Inc. (collectively, "Takeda") to report adverse events for the drugs Actos (Case No. 10-11043) and the drugs Uloric, Kapidex/Dexilant, and Prevacid (Case No. 11-10343), as required by law.

Relator brought these actions on behalf of the United States for treble damages and civil penalties, alleging violations of the False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA"). The actions were also brought under the respective *qui tam* provisions of similar state statutes on behalf of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana,

Massachusetts, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin, and the District of Columbia. The alleged violations involve false claims for payments being made to Medicare, Medicaid, Tricare and other federally funded government health-care programs as a result of defendants' alleged failure to properly report to the Food and Drug Administration ("FDA") adverse events with respect to the named drugs.

Defendants have moved to dismiss both complaints under Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted and under Fed. R. Civ. P. 9(b) for failure to satisfy the heightened pleading requirements for fraud. For the reasons set forth below, the motions will be granted.

I. Background

A. Factual Background

The facts are stated as alleged in the complaints.[1]

Dr. Helen Ge, M.D., was a contractor working for Takeda from September 2008 to January 2010. (Uloric Compl. ¶¶ 11, 13). All four subject drugs, Actos, Uloric, Kapidex/Dexilant, and Prevacid are sold by Takeda and have received FDA approval.

During the time of Dr. Ge's employ, Takeda failed to properly report to the FDA a number of post-marketing adverse events for the four subject drugs. (Uloric Compl. ¶¶ 26, 29-31, 63, 74, 76, 79, 88, 111, 118-119). Specifically, with respect to Uloric, Kapidex/Dexlant, and

[1] The Court also draws on exhibits to the complaints and other uncontested documents on which the complaints rely. *See Beddall v. State Street Bank & Trust Co.*, 137 F.3d 12, 17 (1st Cir. 1998) ("When . . . a complaint's factual allegations are expressly linked to—and admittedly dependent upon—a document (the authenticity of which is not challenged), that document effectively merges into the pleadings and the trial court can review it in deciding a motion to dismiss under Rule 12(b)(6)."). Here, there are exhibits attached to the declarations of Bijan Esfandiari that are the subject of motions to strike by defendants. To the extent that the Court relies on those documents here, the motions to strike will be denied.

Prevacid, the complaint alleges that several life-threatening adverse reactions had been known by Takeda to occur as a result of these drugs' interaction with other drugs commonly used by the same patient population; however, Takeda did not adequately change the package insert warnings to reflect this. (Uloric Compl. ¶ 3). Furthermore, Takeda avoided properly reporting to the FDA serious adverse events caused by these interactions. (Uloric Comp1.¶ 5). The complaint alleges that Takeda, through its employees, intentionally misrepresented and altered the descriptions of adverse events in reports, and intentionally misclassified adverse events as "non-serious" or as "labeled" drug-drug interactions, to avoid filing expedited 15-day adverse event reports. (*See* Uloric Comp1.¶¶ 50-66, 75-77, 84-86). With respect to Actos, Takeda intentionally did not report hundreds of non-hospitalized or non-fatal congestive heart failure cases as "serious" adverse events. (*See* Actos Compl. ¶ 9).

Had Takeda properly reported these adverse events, FDA might have required drug label amendments and/or additional information to be posted in FDA databases. (*See* Actos Compl. ¶¶ 16, 18, 91-92; Uloric Compl. ¶¶ 6, 36, 39, 126-127). These additional warnings or database entries might have prompted physicians to prescribe the subject drugs less often, resulting in a decrease in claims for reimbursement. (*See* Actos Comp. ¶¶ 16, 18, 91-92; Uloric Compl. ¶¶ 114). Had Takeda properly reported the serious adverse events, FDA might never have approved or, in the alternative, it might have withdrawn approval for the subject drugs. (*See* Actos Compl. ¶ 91; Uloric Compl. 43, 66, 114).

On June 18, 2010, Dr. Ge commenced the first action, which related to the drug Actos. (Case no. 10-11043). On March 1, 2011, Dr. Ge commenced a second action that related to the drugs Uloric, Kapidex/Dexilant, and Prevacid (Case No. 11-10343). Defendants have moved to

dismiss both actions.

B. Legal Background

The False Claims Act, 31 U.S.C. § 3729, protects the government from efforts to fraudulently collect government reimbursement.[2] To bolster enforcement, the FCA includes *qui tam* provisions allowing whistleblowers (known as relators) to bring fraud claims on behalf of the government. *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 16 (1st Cir. 2009). In successful *qui tam* actions, a relator collects a portion of the award to the government, regardless of whether the government intervenes in the action. *Id.*

The complaints allege violations of 31 U.S.C. § 3729(a)(1)(A), (B) and (C). Subsection (1)(A) of the FCA imposes liability on any person who "knowingly presents to the government, or causes to be presented, a false or fraudulent claim for payment or approval." Subsection (1)(B) imposes 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." Subsection (1)(C) imposes liability on any person who conspires to commit a violation of, among other things, subsection (1)(A) or (1)(B).

The FDA is the agency responsible for the approval of drugs for commercial marketing under the Food, Drug, and Cosmetic Act ("FDCA"). 21 U.S.C. §355(a). After a drug has been

[2] It should be noted that Subsection 3729(a) of the False Claims Act was amended by the Fraud Enforcement and Recovery Act ("FERA") on May 20, 2009. *See* Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1621 (2009). FERA provides that amendments to the FCA take effect upon enactment except for the amendment to the old § 3729(a)(2) (now § 3729(a)(1)(B)), which "shall take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act . . . that are pending on or after that date." FERA § 4(f)(1), 123 Stat. at 1625. Courts have "almost uniformly interpreted 'claims' to mean claims for reimbursement" rather than the resulting lawsuits under the FCA. *United States ex. rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 314 n.1 (quoting *United States ex rel. Carpenter v. Abbott Labs, Inc.*,723 F. Supp. 2d 395, 402 (D. Mass. 2010) (collecting cases)). Because both the plaintiff and the defendants refer to the post-FERA version of the FCA, and because the alleged violations involve actions observed during Dr. Ge's employ at Takeda (beginning in September 2008), this Court's analysis will focus on the post-FERA formulation of the FCA.

approved, the FDCA enables the FDA to continue to evaluate the safety and effectiveness of the drug and, when appropriate, withdraw the approval of the New Drug Application ("NDA") or change the labeling. 21 U.S.C. §355(k). In furtherance of this aim, FDA regulations require expedited and accurate reports of adverse drug experiences by drug manufacturers. 21 C.F.R. §§314.80 and 314.81.

FDA regulations and Guidance Documents classify four types of adverse experiences and corresponding reporting requirements. Serious and unexpected events must be reported to the FDA within 15 days of initial receipt of news of the adverse event. 21 C.F.R. §314.80(b)(1). Serious and expected adverse events must be reported to the FDA in the manufacturer's quarterly and/or annual safety reports. Non-serious and unexpected events must be reported to the FDA in the manufacturer's quarterly and/or annual safety reports. Non-serious and expected adverse events technically are to be reported to the FDA in the manufacturer's quarterly and/or annual safety reports, but the FDA encourages manufacturers to obtain waivers from having to submit individual case safety reports.

A manufacturer's failure to comply with these reporting obligations subjects the manufacturer to various potential civil and criminal penalties, including, but not limited to, withdrawal of the approval of the NDA (that is, prohibiting the continued marketing and sale of the drug), injunctive orders, monetary fines and imprisonment for individual defendants. *See* 21 U.S.C § 331(e); 21 U.S.C § 332(a); 21 U.S.C § 333(a)(1); 21 U.S.C. §355(e); and 21 C.F.R.§314.80(j).

II. Standard of Review

A. Failure to State a Claim Under Rule 12(b)(6)

On a motion to dismiss, the Court "must assume the truth of all well-plead[ed] facts and give plaintiff the benefit of all reasonable inferences therefrom." *Ruiz v. Bally Total Fitness Holding Corp.*, 496 F.3d 1, 5 (1st Cir. 2007) (citing *Rogan v. Menino*, 175 F.3d 75, 77 (1st Cir. 1999)). To survive a motion to dismiss, the plaintiff must state a claim that is plausible on its face. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). That is, "[f]actual allegations must be enough to raise a right to relief above the speculative level, . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* at 555 (citations omitted). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 556). Dismissal is appropriate if the complaint's well-pleaded facts do not "possess enough heft to show that plaintiff is entitled to relief." *Ruiz Rivera v. Pfizer Pharm., LLC*, 521 F.3d 76, 84 (1st Cir. 2008) (quotations and original alterations omitted).

B. Pleading Requirements of Rule 9(b)

Fed. R. Civ. P. 9(b) requires that "in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." These heightened pleading requirements apply to claims brought under the subsections of the FCA at issue here. *United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 45 (1st Cir. 2009); *see also United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 231 (1st Cir. 2004) (rejecting the contention that Rule 9(b)'s heightened pleading standard should be relaxed as to fraud claims

brought under the FCA). In such cases, relators are required to set forth with particularity the "who, what, when, where, and how of the alleged fraud." *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 46 (D. Mass. 2001); *see also Arruda v. Sears, Roebuck & Co.*, 310 F.3d 13, 18-19 (1st Cir. 2002).

The FCA imposes liability only for the filing of false claims, not for merely "underlying fraudulent activity or the government's wrongful payment." *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 551 F. Supp. 2d 100, 114 (D. Mass. 2008), *aff'd in part, rev'd in part*, 579 F.3d 13 (1st Cir. 2009). Therefore, evidence of a false claim is "the *sine qua non* of a False Claims Act violation." *Karvelas*, 360 F.3d at 225. In *Karvelas*, the First Circuit explained the pleadings requirements for relators in the context of alleged false Medicare and Medicaid claims:

> [A] relator must provide details that identify particular false claims for payment that were submitted to the government. In a case such as this, details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on these practices are the types of information that may help a relator to state his or her claims with particularity. These details do not constitute a checklist of mandatory requirements that must be satisfied by each allegation included in the complaint. However, . . . we believe that some of this information for at least some of the claims must be pleaded in order to satisfy Rule 9(b).

Id. at 232-233. *Karvelas* suggests that Rule 9(b) may be satisfied if "the complaint as a whole is sufficiently particular to pass muster under the FCA, although some questions remain unanswered." *Id.* at 233 n.17.

III. Analysis

A. Failure to Plead Fraud with Particularity

In the FCA context, the precise requirements imposed by Rule 9(b) depend on whether the defendants are alleged to have directly submitted false claims or to have induced third parties to submit false claims. *Duxbury*, 579 F.3d at 29. When inducement, rather than direct submission, of claims is alleged, a relator must, at a minimum, "provid[e] factual or statistical evidence to strengthen the inference of fraud beyond possibility" where details as to each false claim are not offered. *Id.* (quoting *U.S. ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007)); *see also United States ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 147 (D. Mass. 2000) (holding that relator failed to satisfy Rule 9(b) when his complaint did not cite one single false claim arising out of an alleged methodology that conceivably could have produced false claim invoices).

Here, although relator has alleged facts that would demonstrate a "fraud-on-the-FDA" with respect to intentional under-reporting of adverse events, she has failed to allege the specific details of any claims that were allegedly rendered "false" as a result. In an attempt to cure that inadequacy, relator subsequently filed a declaration of Bijan Esfandiari, which included an attachment providing the total expenditures by the federal government for Actos. Even assuming that it is permissible for the Court to consider this document for the purposes of a motion to dismiss, this aggregate expenditure data does not satisfy the particularity requirement.[3] The aggregate figure is in the billions of dollars and accompanied by no identifying information as to the payees. By contrast, in the *Duxbury* case, the relator identified eight specific medical

[3] As noted earlier, the defendants have moved to strike that declaration.

providers who allegedly submitted false claims; identified the rough time periods, locations, and amounts of the claims; and identified the specific government programs to which the claims were made. *Duxbury*, 579 F.3d at 29-30. The First Circuit found that those allegations satisfied Rule 9(b). Here, the only claim details provided are for one of the four drugs at issue, presented in aggregate form, and identify no specific claimants or government program payors. In addition, relator makes no showing of any claims paid by the *state* programs of the relevant states.

Instead of providing details of allegedly false claims, relator apparently suggests that *all* of the claims for these particular drugs in the relevant years were rendered false by Takeda's failure to properly report adverse events. Relator, however, has failed to provide the specific factual allegations necessary to support the inference that the FDA would have withdrawn approval from all four drugs immediately upon receiving the proper adverse reports. Withdrawal of drug approval is not mandatory for the type of reporting violations alleged. *See* 21 C.F.R. §§ 314.80(j), 81(d) ("FDA *may* withdraw approval") (emphasis added); *see also Cutler v. Hayes*, 818 F.2d 879, 893 (D.C. Cir. 1987) ("[t]he [FDCA] imposes no clear duty upon FDA to bring enforcement proceedings to effectuate either the safety or the efficacy requirements of the Act"). Even accepting the unsubstantiated premise that the drugs would have been taken off the market, relator has also failed to allege how the fraudulent reporting renders false claims that were filed prior to the adverse events.

In summary, relator has failed to plead her allegations with the requisite specificity under Rule 9(b).

B. Failure to State a Claim

1. Federal False Claims Act

The First Circuit has established two requirements for an FCA claim to survive a motion to dismiss:

> First, relator must show that the claims at issue in this litigation misrepresented compliance with a material precondition of Medicaid payment such that they were false or fraudulent. Second, they must show that the defendants knowingly caused the submission of the false or fraudulent claims, the submission of false records or statements to get the false or fraudulent claims paid, or otherwise conspired to defraud the state by getting the false or fraudulent claims paid.

New York v. Amgen Inc., 652 F.3d 103, 110-111 (1st Cir. 2011). Here, the complaints adequately allege that defendants knowingly caused the claims at issue to be submitted. As a consequence, the sufficiency of the complaints turns on whether the claims at issue were false or fraudulent—that is, whether the claims misrepresented compliance with a material precondition of payment.

The complaints provide no details of the actual claims from providers to show that they misrepresented compliance with anything. Relator instead relies on the argument that Takeda's compliance with adverse-event reporting requirements is an implied condition of continued FDA approval, and because Takeda intentionally did not comply with these requirements with respect to the four drugs at issue, all subsequent claims for those drugs were therefore false. Relator alleges that every claim for the drugs at issue contained an implied representation of compliance with these reporting requirements. It is true that the First Circuit has held that a claim may be found to be false on the basis of an implied representation of compliance with a precondition of payment that is not expressly stated in a statute or regulation. *United States ex rel. Hutcheson v. Blackstone Med.*, Inc., 647 F.3d 377, 387 (1st Cir. 2011). Here, however, relator relies on a blind,

unsupported assertion that the claims at issue included such an implied representation as to compliance with reporting requirements.

Assuming that the unspecified claims that are the basis of this case do include such an implied representation, relator still must demonstrate that compliance with the reporting requirements was a material precondition of payment. Unfortunately for her, that is simply not the case. As noted earlier, the FDA has discretion to take a number of different actions should a drug manufacturer violate the adverse-event reporting requirements. The harshest of those actions is the withdrawal of drug approval. *See* 21 C.F.R. §§ 314.80(j), 81(d). However, the FDA exercises discretion in its enforcement procedures for such types of violations, and does not always prosecute them, let alone enforce the harshest penalty available. *See Cutler*, 818 F.2d at 893 ("[t]he [FDCA] imposes no clear duty upon FDA to bring enforcement proceedings to effectuate either the safety or the efficacy requirements of the Act"). These enforcement procedures have for many years allowed for citizens to petition FDA to bring action against specific violators. 21 C.F.R. § 10.30. It is through that mechanism, rather than an FCA lawsuit, that relator should have brought the reporting issues illuminated in the complaints to the attention of the FDA.

Because relator has not adequately established that compliance with adverse-event reporting procedures was a material precondition to payment of the claims at issue, the complaints do not state a claim upon which relief can be granted under Rule 12(b)(6).

2. State False Claims Acts

With respect to the state FCA claims, the issue is whether claims submitted to the state Medicaid programs misrepresented compliance with a precondition of payment recognized by the

relevant programs. *Amgen*, 652 F.3d at 111. Relator, however, has not alleged with sufficient particularity how any of the state statutory regimes, many of which employ language identical to the FCA, differ from the federal government in terms of what constitutes a material precondition of payment.[4] The complaints have thus failed to state a claim under state law, and the complaints will be dismissed with respect to the states.

Finally, and in any event, even if the brief citation in the complaints to the state FCAs were sufficient to allege that a particular state considers compliance with FDA adverse-event reporting requirements a material precondition of payment, dismissal would still be appropriate because the complaints fail to plead with specificity the details of any claims for payment made to any of the states.

IV. Conclusion

For the foregoing reasons, defendants' motions to dismiss the complaints for failure to state a claim upon which relief can be granted and for failure to plead fraud with particularity are GRANTED.

So Ordered.

/s/ F. Dennis Saylor
F. Dennis Saylor IV
United States District Judge

Dated: November 1, 2012

[4] *See, e.g.*, N.J. Stat. § 2A:32C-1 (providing liability for any person who: "(1) knowingly presents, or causes to be presented, to an officer or employee, officer or agent of the State or to any contractor, grantee, or other recipient of State funds a false or fraudulent claim for payment or approval; (2) 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 State; (3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.").