United States Court of Appeals for the First Circuit

No. 13-1088

UNITED STATES, *ex rel.* Helen Ge, M.D.

Relator – Appellant

STATE OF CALIFORNIA; STATE OF DELAWARE; STATE OF FLORIDA; STATE OF GEORGIA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF LOUISIANA; STATE OF MICHIGAN; STATE OF INDIANA; STATE OF MINNESOTA; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH CAROLINA; STATE OF OKLAHOMA; STATE OF RHODE ISLAND; STATE OF TENNESSEE; STATE OF TEXAS; STATE OF WISCONSIN; COMMONWEALTH OF MASSACHUSETTS; COMMONWEALTH OF VIRGINIA; DISTRICT OF COLUMBIA

Plaintiffs

v.

TAKEDA PHARMACEUTICAL COMPANY LIMITED; TAKEDA PHARMACEUTICAL NORTH AMERICA, INC.

Defendants - Appellees

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Plaintiffs

v.

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Defendants - Appellees

OPENING BRIEF OF RELATOR-APPELLANT

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RELATOR-APPELLANT'S RULE 26.1 DISCLOSURE

Relator-appellant Helen Ge., M.D. is a natural person. As such, a corporate disclosure statement is not required. Fed. R. App. P. 26.1(a).

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REASONS WHY ORAL ARGUMENT SHOULD BE HEARD

Pursuant to Federal Rule of Appellate Procedure 34(a), Relator-appellant respectfully requests oral argument. Oral argument will assist the Court in deciding this appeal, which raises important questions regarding pleading requirements under the False Claims Act, the ability of the government to prevent pharmaceutical fraud, and the extent to which a district court is allowed to deny requests to amend a purportedly deficient complaint. Oral argument will allow the parties to address these issues fully and respond to any questions or concerns.

JURISDICTIONAL STATEMENT

This is an appeal from a final decision of the United States District Court for the District of Massachusetts dismissing this matter with prejudice, entered on November 1, 2012. Following the denial of a motion for reconsideration, entered on December 18, 2012, a Notice of Appeal was timely filed on January 14, 2013. Accordingly, this Court has jurisdiction pursuant to 28 U.S.C. § 1291.

PRELIMINARY STATEMENT

Doctors and patients, and the entities insuring them, rely on the Food and Drug Administration ("FDA") to regulate the safety of prescription drugs. The FDA, in turn, relies on the accurate reporting of safety risks from pharmaceutical companies. When pharmaceutical companies like Defendant-Appellees Takeda Pharmaceutical Company Limited and Takeda Pharmaceutical North America, Inc. (hereinafter "Takeda") abuse that trust, the system breaks down. A pharmaceutical company, using fraud, gains access to the prescription drug market, and uses the "FDA approved" label to promote its drugs as safe. Doctors and patients, in turn, are deceived into prescribing and taking a drug that is not as safe as they were led to believe. The rub, however, is that the entity paying for a substantial portion of those fraudulently induced prescriptions is the federal government. In this case, Takeda was able to mislead one hand of the government (the FDA) while getting paid handsomely for its deception by the other (federally-funded healthcare organizations). That is what this appeal is about—whether, pursuant to the False Claims Act ("FCA"), the government can recoup federal funds spent on drugs that Takeda *misbranded* and, thus, *fraudulently marketed*.

Here, the district court adopted an overly restrictive interpretation of the FCA and established a precedent that undermines the ability of the federal government to recoup money lost to pharmaceutical fraud. The

district court's decision undercuts the key rationale underlying the FCA and federal pleading principles. As such, district court should be reversed.

STATEMENT OF THE ISSUES

(I) Whether the district court erred in dismissing Relator-Appellant's complaints pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b). Specifically, whether:

(a) The complaints state a False Claims Act cause of action pursuant to Rule 12(b)(6) by alleging that a pharmaceutical company deliberately misled the government, the medical community, and patients about the risks associated with its drugs, which, in turn, caused doctors and patients to submit claims to federally-funded healthcare organizations.

(b) The complaints meet the particularity requirements of Rule 9(b) by providing statistical evidence and individual examples of how defendant's fraudulent conduct caused the submission of false claims to federally-funded healthcare organizations.

(II) In the alternative, whether the district court abused its discretion when it denied Relator-Appellant an opportunity to amend her complaint after the district court's dismissal, when there was no reason given, and there was no indication or finding of bad faith, dilatory conduct, undue delay, or futility.

STATEMENT OF THE CASE

This matter is on appeal from the United States District Court for the District of Massachusetts, following the dismissal of two whistleblower actions filed by Relator-Appellant Helen Ge, M.D. ("Dr. Ge"), pursuant to the Civil False Claims Act, 31 U.S.C. §§ 3729, *et seq*. The District Court dismissed both actions in a single order pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6). Dr. Ge, thereafter, moved the District Court to reconsider pursuant to Federal Rules of Civil Procedure 59(e) and 60(b), citing the procurement of new evidence and a manifest error of law. In addition, Dr. Ge requested leave to file an amended complaint. The District Court, however, summarily denied Dr. Ge's motion for reconsideration. This timely appeal followed.

STATEMENT OF THE FACTS

I. The Relator: Dr. Helen Ge

Relator-Appellant Helen Ge, M.D. ("Dr. Ge") received her medical degree from First Medical University of Shanghai. (Appendix 23, 136.) In the 1980s and 1990s, Dr. Ge was a Clinical Research Fellow at the University of Pittsburgh School of Medicine and Harvard Medical School, and later became an Associate Medical Director at the Harvard Medical Clinical Research Institute. (*Id.*) In 1998, Dr. Ge began consulting with various pharmaceutical companies to assist in preparing Food and Drug Administration ("FDA") mandated safety

reports. (*Id.*)

In September 2008, Dr. Ge accepted a position with Takeda as a Contract Physician of Drug Safety. (*Id.* at 24, 137.) She was contracted to perform medical reviews of adverse event reports and ascertain the seriousness of the event, determine causation, and determine if the event represented a safety signal, *i.e.*, whether the drug needed additional safety warnings. (*Id.*) Dr. Ge was responsible for medically reviewing adverse events associated with Actos, Uloric, Kapidex/Dexilant, and Prevacid. (*Id.*) Dr. Ge worked for Takeda until January 2010, when her contract was prematurely terminated. (*Id.*) Subsequently, Dr. Ge filed *United States ex rel. Helen Ge v. Takeda Pharmaceutical Co., et al*, 10-cv-11043-FDS ("Actos Complaint") and *United States ex rel. Helen Ge v. Takeda Pharmaceutical Co., et al*, 11-cv-10343-FDS ("Uloric Complaint").

II. Actos

Actos (pioglitazone) is a thiazolidinedione ("TZD"), a type of insulin sensitizer designed to decrease a patient's insulin resistance and thereby reduce blood sugar levels. (*Id.* at 20.) Actos is used primarily to treat Type II diabetes. (*Id.*) The two primary TZDs marketed in the United States are Actos (manufactured by Takeda) and Avandia (rosiglitazone), which is manufactured and distributed by GlaxoSmithKline, LLC ("GSK"). (*Id.*)

Actos was first approved by the FDA in 1999. (*Id.*) By 2008, Actos

developed into Takeda's most profitable drug with annual sales of $3.4 billion in 2009. (*Id.*) It is estimated that over half of all Actos prescriptions are paid for by various federal-funded healthcare organizations. (*Id.* at 268-71.) Takeda was able to capture a majority of the diabetes drug market by portraying Actos as safer than it actually was, including that it was safer than Avandia. (*Id.* at 45-46.) Actos, however, is not as safe as Takeda has led the FDA, doctors, and the general public to believe.

While Dr. Ge was working at Takeda, she was responsible for reviewing adverse event reports associated with Actos. (*Id.* at 8.) These adverse events involved toxicities causing serious adverse reactions observed in patients taking Actos. (*Id.*) Dr. Ge would investigate each adverse event to determine whether Actos was causally related and ascertain the severity of the event. (*Id.*) These reports were then submitted to the FDA. (*Id.* at 29-33); *see* 21 C.F.R. §§ 314.80, 314.81. The FDA relies on post-marketing adverse event reporting to monitor the safety of approved drugs. (Appendix at 29-33); *see* 21 U.S.C. § 355(k); 21 C.F.R. §§ 314.80, 314.81. Using these reports, the FDA can take a variety of actions, such as adding additional safety warnings, restricting access, or completely removing the drug from the market. (Appendix at 29-33); *see* 21 C.F.R. §§ 314.80, 314.81. More importantly, physicians and patients rely upon the accuracy of the toxicities / adverse reactions and risk reporting in the label to make prescribing

decisions.

During her time at Takeda, Dr. Ge was continually asked to falsify, misclassify, or change her medical conclusions about adverse event reports for Actos. The Actos Complaint details numerous instances wherein Dr. Ge was directed to misreport adverse events, including incidences of congestive heart failure, renal failure, pancreatic cancer, cardiomyopathy, suicidal ideation and most notably, bladder cancer. (*See* Appendix at 39-44, 47-58.) Takeda's Vice President over its Pharmacovigilance Department, Maria Paris, told her staff that adverse event reporting is one thing, but Takeda's profitability comes first. (*Id.* at 21.)

While at Takeda, Dr. Ge reviewed multiple adverse event reports involving Actos and bladder cancer. (*Id.* at 47-48.) In each case, Dr. Ge concluded that Actos was causally related to the bladder cancer. In one such case, Dr. Ge reviewed an adverse event report involving a participant in an ongoing clinical trial. (*Id.*) Dr. Ge concluded that Actos was causally related to the cancer, but Takeda management pressured Dr. Ge to change her assessment and find, contrary to her medical opinion, that Actos was "unrelated." (*Id.*) Dr. Ge resisted the pressure to alter her report and investigated the correlation between Actos and bladder cancer. (*Id.*) Dr. Ge discovered that Takeda had been systematically underreporting the incidence of bladder cancer in adverse event reports. (*Id.* at 48-54.) Dr. Ge further learned that there

were pre-clinical and clinical trials performed by Takeda indicating Actos caused bladder cancer. (*Id.*) Dr. Ge discovered that Takeda had suppressed this information by, among other things, fraudulently underreporting adverse events since 1999 and systematically resisting label changes. (*Id.*) Based on the information available to Takeda, Dr. Ge believes there was a clear safety signal that Actos substantially increased the risk of bladder cancer as early as 1999 based on the animal studies and in humans starting, at the latest, in 2005. (*Id.*) Nonetheless, between 2005 and 2011, Takeda denied a link between Actos and bladder cancer. (*Id.*)

Dr. Ge's contract with Takeda was prematurely terminated on January 15, 2010, after Dr. Ge refused "to play ball" with Takeda management. (*Id.* at 43.) Shortly thereafter, on June 18, 2010, Dr. Ge filed the Actos Complaint under seal in the district court. (*Id.* at 1.) On September 17, 2010, the FDA issued a Safety Alert indicating that it would begin a review "to evaluate the risk of bladder cancer associated with use of this drug." U.S. Food and Drug Administration, FDA reviewing preliminary safety information on Actos (pioglitazone) (Sept. 17, 2010) *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2010/ucm226244.htm. In June 2011, France and Germany pulled Actos from the market because of concerns over bladder cancer. *See* Ryan Jaslow, *Actos banned in Europe after diabetes drug tied to cancer*, CBS, June 10,

2011. A week later, the FDA issued an official warning "that use of the diabetes medication Actos (pioglitazone) for more than one year may be associated with an increased risk of bladder cancer" and mandated a label change. *See* U.S. Food and Drug Administration, Update to ongoing safety review of Actos (pioglitazone) and increased risk of bladder cancer (June 15, 2011) *available at* http://www.fda.gov/Drugs/DrugSafety/ucm259150.htm.

From the time the risks associated with Actos and bladder cancer were made available to the public, starting with the FDA's initial announcement in September 2010 and culminating with the decision to mandate a label change in June 2011, Actos sales plummeted over 60%. (Appendix at 273.) By December 2011, six months after the label change, Actos sales plummeted an additional 56.5%. (*Id.*)

On December 29, 2011, a Multidistrict Litigation proceeding was created in the United States District Court for the Western District of Louisiana to address numerous personal injury claims involving Actos and bladder cancer. *In re: Actos Products Liab. Litig.*, 840 F. Supp. 2d 1356, 1356-57 (J.P.M.L. 2011). In addition, coordinated state proceedings are ongoing in California and Illinois. To date, several thousand personal injury and wrongful death claims have been filed relating to bladder cancer caused by Actos. (Appendix at 262.) Recently, one personal injury case went to a jury trial in *Cooper v. Takeda Pharmaceuticals America Inc.*, CGC-12-518535, in California

Superior Court, Los Angeles. After a two month-long trial, the jury returned a $6.5 million dollar verdict against Takeda.[1]

III. Uloric, Kapidex/Dexilant, and Prevacid

Uloric (febuxostat) is a urate lowering prescription medication designed to treat gout by suppressing the excess production of uric acid, which was approved by the FDA in 2009. (Appendix at 133-34.) Prior to its approval, however, the gout-treatment market was dominated by allopurinol, an inexpensive generic medication that has been used to treat gout for over four decades. (*Id.*) On average, Uloric costs $5.00 a day, whereas allopurinol only costs $0.10 a day. (*Id.*) Thus, when Uloric entered the market in 2009, Takeda knew that, to be competitive with allopurinol, it needed to market Uloric as a superior drug. (*Id.*) To that end, Takeda marketed Uloric as having a superior safety profile to allopurinol because, according to Takeda, Uloric has fewer drug interactions and less incidences of the adverse effects associated with allopurinol. (*Id.*)

Kapidex/Dexilant (dexlansoprazole) and Prevacid (lansoprazole) are both proton-pump inhibitors sold by Takeda. (*Id.*) They are designed to inhibit the stomach's production of certain acids and are used to treat

[1] After the jury returned the $6.5 million verdict, the trial judge vacated the judgment because it determined, post-trial, to exclude the testimony of one of the plaintiff's experts. These issues are the subject of post-trial motions scheduled to be heard on June 20, 2013.

gastroesophageal reflux disease. Prevacid was first put to market in 1995 and its patent expired in November 2009. (*Id.*) Kapidex/Dexilant was approved by the FDA in January 2009 and is closely related to Prevacid. (*Id.*)

As with Actos, Dr. Ge was responsible for reviewing adverse event reports associated with Uloric, Kapidex/Dexilant, and Prevacid. (*Id* at 137.) Her evaluations, like with Actos, were sent to the FDA pursuant to federal regulation and were made part of the FDA's adverse event database. As detailed in the Uloric Complaint, on numerous occasions, Dr. Ge was directed by Takeda management to falsify her medical conclusions by classifying events as "non-serious" or changing her causality assessments to "unrelated" in order to avoid 15-day reports required by the regulations. (*Id.* at 150-155, 158-167, 172-174, 175-177.) Specifically, Dr. Ge observed in numerous adverse event reports that Uloric, Kapidex/Dexilant, and Prevacid had dangerous drug interactions with other medications that were likely to be taken by senior citizens. (*Id.*) These drug interactions involved serious adverse events such as internal bleeding, bone marrow failure, renal failure, fatal arrhythmia, and death. (*Id.*) However, Takeda management directed Dr. Ge to alter her analysis and to label these adverse events as non-serious and unrelated. (*Id.*)

When Dr. Ge investigated further, she learned that Takeda was systematically underreporting adverse events associated with Uloric,

Kapidex/Dexilant, and Prevacid in violation of federal law. (*Id.*) In addition, Dr. Ge determined that the drug labels for Uloric, Kapidex/Dexilant, and Prevacid were misleading because they failed to warn about serious and fatal drug interactions (*e.g.*, *id.* at 147-48, 178, 180). On March 1, 2011, Dr. Ge filed a *qui tam* action under seal exposing Takeda's misconduct associated with Uloric, Kapidex/Dexilant, and Prevacid. (*Id.* at 7.)

IV. The Dismissals

On November 1, 2012, the district court dismissed the Actos and Uloric Complaints pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b). First, the district court held that Takeda's fraudulent conduct was not *material* as a matter of law, because compliance with FDA regulations was not a precondition for payment. (Addendum at 73-74.) Second, the district court held that the Actos and Uloric Complaints failed to meet the Rule 9(b) particularity requirement because the complaints failed to identify which claims submitted to the government were rendered false by Takeda's alleged misconduct. (*Id.* at 71-72.)

Shortly after the district court entered its order, Dr. Ge filed a motion for reconsideration. (Appendix at 5, 10.) As part of the motion, Dr. Ge submitted additional evidence to support her allegations. (*Id.* at 251-701.) Specifically, Dr. Ge submitted the declaration of Joel E. Hay, Ph.D, a Professor and Founding Chair of Pharmaceutical Economics and Policy in the School of Pharmacy at the University of Southern

California. (*See id.* at 263-84.) Dr. Hay ascertained the amount of Actos claims submitted to and paid by the government that would not have occurred had Takeda not falsified safety data concerning Actos and bladder cancer. (*Id.* at 274-75.) The motion for reconsideration also contained eight declarations from patients, with accompanying pharmacy records, who submitted claims to the government for Actos prescriptions that they would not have submitted if Takeda had properly warned them about the risks of bladder cancer. (*Id.* at 358-454.) In addition, since the district court's order of dismissal did not indicate whether the dismissal was with prejudice, Dr. Ge's motion for reconsideration requested leave to file an amended complaint. (*See id.* at 5, 10.)

The District Court summarily denied Dr. Ge's Motion for Reconsideration using an electronic docket entry. (*Id.* at 6, 11.) Since the motion for reconsideration requested leave to amend the Actos and Uloric Complaints, the District Court's denial indicates that the original dismissal was with prejudice. On January 15, 2013, Dr. Ge filed a notice of appeal. (*Id.* at 702-05.)

SUMMARY OF ARGUMENT

Dr. Ge maintains that the district court erred in (I) dismissing the Actos and Uloric Complaints pursuant to Rule 12(b)(6) and 9(b) and (II)

disallowing Dr. Ge any opportunity to amend the complaints post-ruling.

With regard to Rule 12(b)(6), the district court erred by adopting an overly narrow definition of materiality and an overly restrictive interpretation of Dr. Ge's theories of liability. Dr. Ge alleges that Takeda is liable under the FCA for (1) misrepresenting the safety profile of the subject drugs which, in turn, induced the submission of claims to the government; (2) knowingly causing the submission of claims to the government that falsely certified the drug was "reasonable and necessary" for treatment when it was not, and (3) using fraud on the FDA to cause claims to be submitted to the government for ineligible and misbranded drugs.

With regard to Rule 9(b), the district court erred by using an improper Rule 9(b) standard that, inconsistent with this Court's flexible pleading standards, required Dr. Ge to plead the details of specific false claims submitted to the government. Dr. Ge's complaints, however, met Rule 9(b) requirements by exhaustively pleading Takeda's fraudulent conduct and how that conduct led to the submission of false claims. Notwithstanding, Dr. Ge met the district court's improper Rule 9(b) requirements by providing specific examples of false claims and expert statistical analysis to show, beyond "possibility," that Takeda caused the submission of false claims. The district court, however, rejected this new evidence without explanation.

Finally, although Dr. Ge believes the district court erred in dismissing her Actos and Uloric complaints, in addition, the district court erred in denying Dr. Ge an opportunity to amend the complaints without any justifying explanation. The district court summarily denied Dr. Ge's detailed request to amend the complaints, despite Dr. Ge's submission of the specific type of evidence demanded by the district court. Denying a request to amend a complaint without explanation is an abuse of discretion and mandates reversal, particularly when there has been no post-dismissal motion opportunity to amend Relator's complaints to address concerns raised by the district court.

ARGUMENT

I. The District Court Erred in Dismissing the Actos and Uloric Complaints Under Rules 12(b)(6) and 9(b)

A district court's dismissal of a case pursuant to Federal Rule of Civil Procedure 12(b)(6) or 9(b) is reviewed *de novo*. *Rodriguez-Reyes v. Molina-Rodriguez*, 711 F.3d 49, 52 (1st Cir. 2013); *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13, 20 (1st Cir. 2009). All factual allegations of the complaint should be accepted as true and all reasonable inferences should be drawn in favor of the relator. *See Rodriguez-Reyes*, 711 F.3d at 52. The Court should affirm the trial court's dismissal "only if, under the facts alleged, the plaintiff cannot

recover on any viable theory." *IOM Corp. v. Brown Forman Corp.*, 627 F.3d 440, 446 (1st Cir. 2010).

The Civil False Claims Act ("FCA"), 31 U.S.C. §§ 3729, *et seq*., is the primary tool of the United States to combat fraud on the government. *See* S. REP. NO. 99-345, at 2 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5267. At its core, the FCA is a remedial statute that "reaches beyond 'claims' which might be legally enforced, to all fraudulent attempts to cause the Government to pay out sums of money." *United States v. Neifert-White Co.,* 390 U.S. 228, 233 (1968). Its purpose is to "provide protection against those who would cheat the United States" and liability was intended "to reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud, without regard to whether that person had direct contractual relations with the government." *United States ex rel. Marcus v. Hes*s, 317 U.S. 537, 544-45 (1943); *see also United States ex rel. Loughren v. Unum Group*, 613 F.3d 300, 305-06 (1st Cir. 2010) ("The FCA covers all fraudulent attempts to cause the government to pay out sums of money[.]"). Accordingly, a defendant may be liable for causing the submission of a false claim by pursuing a fraudulent scheme that ultimately results in the submission of a false claim, even if that defendant did not participate in the submission of the claim. *See United States v. Bornstein,* 423 U.S. 303, 309 (1976) (upholding FCA liability of a subcontractor who causes a contractor to submit a false

claim); *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 390 (1st Cir. 2011) *cert. denied,* 132 S. Ct. 815 (2011) ("We have made clear that unlawful acts by non-submitting entities may give rise to a false or fraudulent claim even if the claim is submitted by an innocent party."); *United States v. Rivera*, 55 F.3d 703, 707 (1st Cir. 1995) ("[F]alse claim may be presented through an innocent third party[.]").

While defense contractors were the original target of the FCA, in the last decade, as healthcare costs have overtaken military spending, the government and *qui tam* relators[2] have successfully utilized the FCA to combat fraud perpetuated by the pharmaceutical industry. Today, the top FCA settlements are against pharmaceutical companies who have violated the Food Drug and Cosmetic Act ("FDCA"). A few include FCA civil settlements against GlaxoSmithKline ($2 billion), Pfizer ($1 billion), Merck ($650 million), Serono ($567 million), and Takeda ($559 million).[3] There is good reason for these steep fines and settlements. In the same fashion that a defense contractor who mixes sawdust with gun powder overcharges the government and places

[2] To bolster enforcement of the FCA, the statute allows private citizens, known as relators, to bring *qui tam* actions against a defendant on behalf of the federal government. *Duxbury*, 579 F.3d at 16.

[3] *See* http://www.taf.org/general-resources/top-100-fca-cases (listing FCA settlement and fines paid by the defendants).

soldiers' lives at risk,[4] so too does a pharmaceutical company that conceals a drug's safety risks and sells expensive brand name drugs to people receiving government healthcare benefits. In both scenarios, the government pays for an overpriced and dangerous product because of fraud.

The FCA specifies seven types of conduct that give rise to FCA liability. 31 U.S.C. § 3729(a). Here, Subsections 3729(a)(1)(A), (B) and (C) are relevant to Dr. Ge's claims. Subsection 3729(a)(1)(A) creates FCA liability when a defendant "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." Thus, to establish a Subsection 3729(a)(1)(A) cause of action, the government/relator must allege sufficient facts to establish that (1) the defendant acted knowingly; (2) the defendant presented or caused to be presented a claim for payment; and (3) the claim was materially[5] false or fraudulent. *See id.*; *Hutcheson*, 647 F.3d at 394; *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 225 (1st Cir. 2004). Subsection 3729(a)(1)(A) specifically contemplates situations in which

[4] The original FCA was passed in response to rampant fraud against the Union Army during the Civil War. Reports of artillery shells filled with sawdust and soldier's boots made of cardboard prompted passage of the FCA. *See* Cong. Globe, 37th Cong., 3d Sess. 955 (1863); 132 Cong. Rec. 22,339 (1986) (remarks of Rep. Berman).

[5] Although materiality is not specifically stated in Subsection 3729(a)(1)(A), courts require the false or fraudulent nature of a claim be material to the transaction. *Hutcheson*, 647 F.3d at 394.

the defendant's fraudulent conduct causes another to submit a claim. *See Duxbury*, 579 F.3d at 29 (citing *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 732 (1st Cir. 2007)). This Court explained that "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 n. 9. Thus, if a defendant engages in fraudulent conduct that causes the submission of materially false claims to the government, liability attaches.

Subsection 3729(a)(1)(B) provides for FCA liability when a defendant "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim[.]" 31 U.S.C. § 3729(a)(1)(B); *United States ex rel. Jones v. Brigham & Women's Hosp.*, 678 F.3d 72, 82 (1st Cir. 2012). To establish a Subsection 3729(a)(1)(B) cause of action, the government/relator must allege that (1) the defendant acted knowingly; (2) the defendant made, used, or caused to be made a record or statement; (3) the record or statement was false; (4) the record or statement was material to a claim; and (5) the claim was false or fraudulent. 31 U.S.C. § 3729(a)(1)(B); *see Allison Engine Co., Inc. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008).

Subsection 3729(a)(1)(C) allows for FCA liability when a defendant conspires to commit a FCA violation. Thus, to establish liability under Subsection 3729(a)(1)(C), the government/relator must allege facts

showing that "(1) the defendant conspired with one or more persons to get a false or fraudulent claim allowed or paid by the United States; and (2) one or more conspirators performed any act to effect the object of the conspiracy." *United States v. President & Fellows of Harvard Coll.*, 323 F. Supp. 2d 151, 196 (D. Mass. 2004). Moreover, "[g]eneral civil conspiracy principles apply." *Id.* (citations omitted).

Dr. Ge alleges that Takeda violated Subsections 3729(a)(1)(A), (B), and (C) of the FCA and the respective *qui tam* statutes in various states. (*See* Appendix at 12, 28 (listing states).) At the core of the Actos and Uloric Complaints is an allegation that Takeda misrepresented the safety profile of Actos, Uloric, Kapidex/Dexilant, and Prevacid by falsifying and manipulating the submission of adverse event reports to FDA and evading needed label changes. This fraud on the FDA, physicians, and patients resulted in the publication and dissemination of fraudulent drug labels and allowed Takeda to market these drugs without properly disclosing safety information and risks. Takeda, capitalizing on the fraud, marketed its drugs as possessing a superior safety profile than its competitors.[6] This, in turn, caused doctors and

[6] Takeda's business plan was tremendously successful. In 2005, Actos and Avandia sales were nearly equal. In 2007, however, the FDA released information about the increased risk of Avandia and congestive heart failure ("CHF"). Avandia sales plummeted 65%. Actos, the only remaining TZD competitor on the market, having evaded adding proper warnings to its label, gobbled up market share. (*See* Appendix at 45-46.) In fact, in 2010, the FDA specifically restricted access to Avandia but not Actos because Actos supposedly possessed a superior CHF

patients to be misled about the true safety of these drugs and submit claims to various government healthcare organizations. Thus, Takeda's fraudulent conduct, which included the publication of false statements and a conspiracy among numerous consultants and intermediaries, caused the submission of false claims to the government.

The district court, however, did not believe that Dr. Ge sufficiently alleged a cause of action under the FCA. The District Court dismissed the Actos and Uloric Complaints because (A) the complaints failed to allege how the claims submitted to the government were false or fraudulent, that is, how Takeda's misconduct was material to the submission of a false or fraudulent claim; and (B) the complaints failed to plead with sufficient particularity which claims were rendered false or fraudulent as a result of Takeda's misconduct. Both of these holdings were in error and should be reversed.

A. Dr. Ge's Section 3729(a)(1)(A), (B), and (C) Causes of Action Sufficiently Allege the Claims Were Materially False or Fraudulent

For years, courts evaluated whether a claim was "false or

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safety profile. *See* Memorandum, Janet Woodcock, U.S. Food and Drug Administration, Decision on continued marketing of rosiglitazone (Avandia, Avandamet, Avandaryl), at 2 (September 22, 2010) *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM226959.pdf. As outlined in the Actos Complaint, Actos possesses serious CHF risks that have been concealed from the FDA.

fraudulent" under the FCA within the rubric of three theories of falsity: (1) factual falsity; (2) legal falsity under an express certification theory; and (3) legal falsity under an implied certification theory. In *Hutcheson*, however, this Court abolished the rigid divisions between factual and legal falsity, and express and implied certification, noting that the text of the FCA does not make such distinctions. 647 F.3d at 387. Instead, this Court adopted a broad view of what constitutes a false or fraudulent statement to avoid "foreclos[ing] FCA liability in situations that Congress intended to fall within the Act's scope." *Id.* (quoting *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1268 (D.C. Cir. 2010)); *see Neifert–White,* 390 U.S. at 232-33 (The False Claims Act is "intended to reach all types of fraud, without qualification, that might result in financial loss to the Government ... [T]he Court has consistently refused to accept a rigid, restrictive reading[.]"). This Court held that "[s]o long as the statement in question is knowingly false when made, it matters not whether it is a certification, assertion, statement, or secret handshake; False Claims liability can attach." *Hutcheson*, 647 F.3d at 390 (*quoting United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1172 (9th Cir. 2006), *cert. denied*, 550 U.S. 903 (2007)).

A claim is false or fraudulent when it misrepresents compliance, either directly or impliedly, with a precondition for payment. *Hutcheson*, 647 F.3d at 392. What qualifies as a precondition for

payment is typically found in an underlying contract, a statute or regulation, or is implied in the transaction itself. *Id.* at 394. There are, however, exceptions. For instance, in bid rigging cases, when a defendant invoices the government for work actually performed at prices set forth in a contract, the claims submitted to the government are technically not-false as they are pursuant to the contract's terms. But, the claims are nonetheless rendered false or fraudulent because the underlying contract, upon which the claims are based, is fraudulent. *See Hutcheson*, 647 F.3d at 390 ("[W]e held that the defendant has caused the submission of false or fraudulent claims because the government contract bids it relayed to a submitting entity had been secretly inflated in response to tips about the government's willingness to pay.") (citing *Murray & Sorenson v. United States*, 207 F.2d 119, 123-24 (1st Cir. 1953); *Hess*, 317 U.S. at 542-43; *see Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 787 (4th Cir. 1999). Indeed, courts recognize that, when a defendant knowingly engages in a fraudulent course of conduct, which, in turn, causes a third party to submit claims, the claims can be rendered false or fraudulent. *See, e.g.*, *Hendow*, 461 F.3d at 1173; *United States ex rel. Main v. Oakland City Univ.*, 426 F.3d 914, 916-17 (7th Cir. 2005).

The question of *materiality*, however, is distinct from falsity. *See Hutcheson*, 647 F.3d at 392. For FCA liability to attach to a claim, in addition to being false or fraudulent, the underlying false statement or

conduct must be material to the payment of the claim. *Id.* at 384. Determination of whether a claim is materially false or fraudulent "is a fact-intensive and context-specific inquiry." *New York v. Amgen Inc.*, 652 F.3d 103, 111 (1st Cir. 2011) *cert. denied*, 132 S. Ct. 993 (2011). A false statement is material if it has "a natural tendency to influence, or is capable of influencing, the decision of the decision-making body to which it was addressed." *Loughren*, 613 F.3d at 307 (quoting *Neder v. United States*, 527 U.S. 1, 16 (1999)). Thus, in evaluating whether the claims at issue were false or fraudulent, there is a two-step inquiry: "We first address whether the claims at issue here misrepresented a precondition of payment so as to be false or fraudulent" pursuant to the broad view espoused in *Hutcheson*, and "then address whether those misrepresentations were material." 647 F.3d at 392.

The district court conceded in its order dismissing the Actos and Uloric Complaints that the "complaints adequately allege that defendants knowingly caused the claims at issue to be submitted." (Addendum at 73.) In addition, the district court acknowledged that the Actos and Uloric Complaints "alleged facts that would demonstrate 'fraud-on-the-FDA' with respect to intentional underreporting of adverse events[.]" (*Id.* at 71.) The district court, however, determined that Dr. Ge failed to sufficiently allege that the claims at issue were false or fraudulent. (*Id.* at 73.) Specifically, the district court reasoned that, for the claims to be "false" or "fraudulent," the underlying

fraudulent conduct or statement must be a material precondition for payment. (*Id.*) The district court held that "[b]ecause relator has not adequately established that compliance with adverse-event reporting procedures was a material precondition of payment of the claims at issue, the complaints do not state a claim upon which relief can be granted under Rule 12(b)(6)." (*Id.* at 74.)

Respectfully, the district court's analysis was flawed. First, the district court established a definition for materiality that is not supported by FCA case law. The district court improperly reasoned that, since the FDA had *discretion* to remove the drug from the market for violations of reporting requirements, the conduct was, as a matter of law, not *material*. Second, the district court misapprehended the theories of liability espoused in the Actos and Uloric Complaints, and in so doing, failed to see how FCA liability would attach outside of the restrictive "fraud-on-the-FDA" claim addressed by the district court. Dr. Ge alleges that Takeda systemically underreported serious adverse events for Actos, Uloric, Kapidex/Dexilant, and Prevacid to avoid changing the drugs' labels, which created an unfair marketing advantage over its competitors and rendered the drugs misbranded and fraudulently on the market. *See* 21 U.S.C. § 352(a) (a drug is misbranded if "its labeling is false or misleading in any particular."); 21 U.S.C. § 331(a). This conduct was specifically designed to induce doctors and patients to submit claims for these drugs that they

otherwise would not. By illegally marketing these misbranded prescription drugs, Takeda violated the FDCA and caused the government to pay fraudulent claims. Accordingly, the allegations in the Actos and Uloric Complaints raise three theories of liability, each of which was material to the government's willingness to pay.

(1) The district court used an improper definition of materiality

The district court used a definition for materiality that simply is not supported by FCA case law. Specifically, the district court reasoned that, since the FDA had discretion to remove the drug from the market for violations of reporting requirements, the conduct was, as a matter of law, not material. However, this reasoning is backwards. It is precisely because the FDA has discretion to enforce a regulation and remove the drug from the market that the fraudulent conduct was material. The act of using fraud to rob the government of its ability to exercise its discretion is what creates FCA liability in the first place. What is important is not what particular agency staff do when presented with evidence of fraud, *but what they are entitled to do under the governing law*. As the Seventh Circuit explains:

> [T]he laws against fraud protect the gullible and the careless -- perhaps especially the gullible and the careless -- and could not serve that function if proof of materiality depended on establishing that the recipient of the information would have protected his own interests. The United States is entitled to guard the public fisc against schemes designed to take advantage of overworked, harried, or inattentive disbursing officers; the False Claims Act does this by

> insisting that persons who send bills to the Treasury tell the truth.

United States v. Rogan, 517 F.3d 449, 452 (7th Cir. 2008) (internal citations omitted); *see also United States ex rel. Feldman v. van Gorp*, 697 F.3d 78, 95 (2d Cir. 2012) (same). As Judge Douglas P. Woodlock explains in *United States v. President & Fellows of Harvard College*, 323 F. Supp. 2d 151, 186 (D. Mass. 2004):

> Evidence of the government's actual *conduct* is less useful for FCA purposes than evidence of the government's legal *rights*. I decline to adopt rules of law that would enable the government to determine materiality by its reaction to either a violation of the [regulations], or a failure to submit properly signed financial forms. Materiality must turn on how [the government] was *authorized* to respond to such failures, or else violation of identical provisions in separate cases could have different materiality results based on the predilections of particular program or accounting staff.

What the Seventh Circuit, Second Circuit, and Judge Woodlock recognize is that the question of materiality does not require a showing that the government *would* not have paid, but that they *could* not have paid. By depriving the government of its right to exercise its judgment in determining whether the product is still subject to payment is what creates FCA liability. Thus, the district court analysis, which hinges on the fact that "the FDA exercises discretion in its enforcement procedures," is in error. (Addendum at 74.)

(2) The district court misunderstood the three theories of FCA liability espoused in the Actos and Uloric Complaints

Dr. Ge does not allege that the claims submitted to the government were false only because compliance with FDA's adverse event regulations was a precondition for payment. Such a narrow view of what constitutes a false claim is precisely the type of rigid analysis eschewed by this Court in *Hutcheson*. Rather, Dr. Ge maintains that Takeda's fraudulent conduct, which includes not only fraud on the FDA in misreporting adverse events but also publication of fraudulent drug labels, caused the submission of claims to various governmental healthcare organizations. This fraudulent conduct gives rise to three theories of liability.

(a) Takeda violated the FCA by misrepresenting the safety profile of Actos, Uloric, Kapidex/Dexilant, and Prevacid, which induced the submission of claims to the government

i. *Falsity: The claims were false or fraudulent because the drugs at issue were not as safe as Takeda purported them to be*

A defendant can be liable under the FCA for causing the submission of a claim to the government for a product that is not to the quality or standard it purports to be. *E.g.*, *Bornstein*, 423 U.S. at 307 (subcontractor liable for causing lead contractor to submit claims for electron tubes that were falsely marked as meeting a quality they did not meet); *Mann v. Heckler & Koch Def., Inc.*, 630 F.3d 338, 346 (4th Cir. 2010) (a claim may be fraudulent where the defendant "misrepresents the quality of a product in an effort to achieve an unwarranted payment for inferior goods."); *United States v. Aerodex,*

Inc., 469 F.2d 1003, 1007 (5th Cir. 1972) (attaching FCA liability to claims submitted for substandard airplane parts). In fact, the FCA was specifically designed to prevent suppliers from providing substandard products at the government's expense. *See* Cong. Globe, 37th Cong., 3d Sess. 955 (1863) (expressing concerns over reports of artillery shells filled with sawdust and soldiers' boots made of cardboard). Just as a subcontractor is liable under the FCA for delivering a subpar product to a government contractor, so too are drug companies for providing a subpar drug to the beneficiaries of federally-funded healthcare programs. If a defendant fraudulently induces the submission of a claim to the government for a product that is not to the standard it purports to be, the claim is rendered false. *See Bornstein,* 423 U.S. at 309.

In the context of prescription drugs, fraudulent representations about safety and efficacy that, in turn, cause the submission of claims to the government for that drug, render the claims false. *See United States ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.*, 147 F. Supp. 2d 39, 45 (D. Mass. 2001) (finding FCA liability for claims submitted as a result of fraudulent representations about a drug's safety and efficacy); *Strom ex rel. United States v. Scios, Inc.*, 676 F. Supp. 2d 884, 885 (N.D. Cal. 2009) (same). Here, Dr. Ge alleges that Takeda misrepresented the safety risks associated with Actos, Uloric, Kapidex/Dexilant, and Prevacid by falsifying and underreporting

adverse events and by failing to update the drugs' warning labels.[7] Doctors and patients, in reliance on this fraudulent safety profile, submitted claims to various federally-funded healthcare organizations. These claims, however, were false and fraudulent because they sought payment for a product that was not as safe as Takeda purported it to be. In other words, doctors and patients submitted claims for a substandard product because they were misled and the government paid these claims.

The case of *United States ex rel. Westrick v. Second Chance Body Armor, Inc.* 685 F. Supp. 2d 129 (D.D.C. 2010) is instructive. In *Westrick*, a relator brought a *qui tam* lawsuit involving the sale of defective bullet-proof vests made of Zylon, a material that was purportedly the "world's strongest fiber." *Id.* at 132. Although Kevlar had been used for decades, Zylon purported to be lighter, more durable, and heat resistant. *Id.* In 1996, Defendants Toyobo, Ltd. / Toyobo America, Inc. ("Toyobo") contracted with Defendant Second Chance Body Armor, Inc., ("Second Chance") to supply Zylon for bullet-proof

[7] Takeda, as a drug manufacturer, owes a duty to physicians and patients to ensure its drug labels are truthful and accurate. *Wyeth v. Levine*, 555 U.S. 555, 570-71 (2009). When a drug label is misleading, it is deemed misbranded and cannot be sold in interstate commerce. 21 U.S.C. § 352(a); 21 U.S.C. § 331(a), (b). This issue of misbranding, and how the ineligibility for sale was a precondition of payment, is discussed in Section I (C)(2)(c), pg. 40. Here, at issue is whether the fraudulent conduct, which is reflected in a misleading label, caused the submission of false claims.

vests. *Id.* Between 1998 and 2004, over 40,000 vests were sold to the United States government and local law enforcement agencies using federal grant money. *Id.* In 1998, Toyobo and Second Chance learned that Zylon's strength degraded when exposed to light, heat, and humidity, resulting in reduced protection. *Id.* Despite learning these new risks, Toyobo continued to supply Zylon to Second Chance, who in turn sold the vests to the United States and local law enforcement. *Id.* In 2003, two police officers were killed in the same month when bullets passed through their Zylon bullet-proof vests. *Id.* By 2004, in the midst of a media wildfire, the vests were recalled. *Id.*

The relator, a former employee, alleged that Toyobo and Second Chance engaged in a deliberate scheme to suppress the safety data about Zylon's deterioration. *Id.* Just as Takeda has done here, Toyobo moved to dismiss the case for failure to state a claim under Rule 12(b)(6) and Rule 9(b). *Id.* at 133. The *Westrick* court, however, rejected Toyobo's motion. *Id.* at 142. The court held that the government/relator sufficiently alleged a FCA claim by giving specifics of how Toyobo fraudulently concealed information about Zylon's safety and how that fraudulent scheme induced the government to pay. *Id.* at 136-39. The court explained that "[a]t the Rule 12(b)(6) stage, the government is required merely to allege with factual specificity that defendants duplicitously induced the government to pay for a product[.]" *Id.* at 137. The court's reasoning and holding reflect an

intuitive and deeply rooted precept in FCA jurisprudence—that the FCA is supposed "to reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud[.]" *Hess,* 317 U.S. at 544-45. Since Toyobo deliberately suppressed safety information about a product, its fraudulent scheme and conduct caused the submission of false claims. *Westrick*, 685 F. Supp. 2d at 138.

In this case, just as Toyobo marketed Zylon as superior to Kevlar, Takeda marketed Actos, Uloric, Kapidex/Dexilant, and Prevacid as being superior to generic and brand name alternatives. Moreover, just as Toyobo learned about Zylon's deterioration, Takeda learned that its drugs possessed safety risks that had not been previously disclosed. However, instead of disclosing these risks in the form of adverse event reports and label changes, Takeda falsified and concealed adverse event reports and did not amend its drug labels, just as Toyobo withheld information about Zylon's deterioration. The result was, sadly, the same—people were hurt by an inferior product paid for with government funds. Instead of bullets, however, the injuries in this case came in the form of cancer and other traumatic adverse events.

The district court fundamentally misunderstood how the allegations in the Actos and Uloric Complaints stated a claim under the FCA. The district court mistakenly concluded that the Actos and UIoric Complaints hinged on Takeda's failure to comply with adverse event reporting requirements. This limited view, however, ignores the more

basic allegation that, regardless of Takeda's fraud on the FDA,[8] Takeda defrauded the medical community and patients about the safety of Actos, Uloric, Kapidex/Dexilant, and Prevacid knowing that a substantial percentage of the prescriptions would be paid for with government funds.

ii. *Materiality: Representing the drugs as being safer than they actually were was material to the submission and payment of claims*

In addressing materiality, the district court focused only on the conduct of the FDA and whether compliance with adverse event reporting was material to the government's willingness to pay. This focus on "what the FDA might do" was in error because it misapprehends how the claims submitted to Medicare and Medicaid were false. In the context of Medicare and Medicaid, the government does not make an individual determination of whether to reimburse a claim submitted for a drug. Instead, the government relies on doctors to make a determination about whether a drug is appropriate for a particular treatment. Only then will Medicare and Medicaid (not the FDA) pay for the treatment. Thus, the question of materiality, in the prescription drug context, turns on whether the fraudulent conduct, *i.e.*,

[8] Arguably, even if Takeda sufficiently complied with FDA regulations, a fact to which Dr. Ge refutes, FCA liability still attaches since the duty to properly label a drug is not discharged by getting FDA approval. *Levine*, 555 U.S. at 570-71. Takeda's duty runs to the doctor and patient, particularly when the drug label misrepresents serious, and sometimes fatal, health concerns.

representing these drugs as being safer than they actually are, had a tendency to influence *doctors* and *patients* to submit claims to the government. *See Franklin*, 147 F. Supp. 2d at 52-53.

At the outset, Dr. Ge submits that this determination was not suitable for disposition at the pleading stage. The issue of materiality is "fact-intensive and context-specific" and this Court has been reluctant to make materiality determinations absent any discovery. *Amgen*, 652 F.3d at 111; *Hutcheson*, 647 F.3d at 394. Determining whether honest disclosures of safety risks to the FDA and medical community would have had a tendency to influence a doctor's decision to prescribe a drug cannot be resolved without an evaluation of the facts of the case—an activity circumscribed in a motion to dismiss.

Moreover, central to the Actos and Uloric Complaints is the allegation that Takeda's fraudulent conduct resulted in the publication of misleading and insufficient drug labels. The representations on a drug label are material to the decision of physicians to prescribe a drug. *See Kwikset Corp. v. Superior Court*, 51 Cal. 4th 310, 328 (Cal. 2011) ("Simply stated: labels matter."). Indeed, there is a *presumption* "that a physician would have heeded an adequate warning" in deciding whether to prescribe a drug. *Garside v. Osco Drug, Inc.,* 976 F.2d 77, 80-81 (1st Cir. 1992); *Knowlton v. Dessert Medical, Inc.*, 930 F.2d 116, 123 (1st Cir. 1991) ("The presumption is accepted in most jurisdictions, including Massachusetts, that if a warning is given, it will be

followed."). Thus, by alleging that the drug labels were false and misleading, Dr. Ge has sufficiently alleged that Takeda's fraudulent conduct had a tendency to influence the decision of prescribing physicians.

Moreover, even if one ignores Takeda's fraudulent publication of drug labels, as the district court did, Takeda's conduct in misreporting adverse events, by itself, is material. In a recent Supreme Court decision, *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1321 (2011), a plaintiff successfully pleaded a securities fraud case alleging that a pharmaceutical company's concealment of adverse events in clinical trials caused an inflation of stock prices. *Id.* at 1323. The Court held that a failure to report adverse events in clinical trials was material to whether an investor would buy a company's stock. *Id.* If failure to report a small number of adverse events is material to investors who are deciding whether to risk their money, *see id.* at 1323, it follows that a company's failure to report *hundreds* of serious adverse events is material to doctors who are deciding whether to risk their patient's life.

Furthermore, in addition to alleging how Takeda's fraudulent conduct was material, in Dr. Ge's motion for reconsideration, Dr. Ge provided the court with the expert testimony of Joel E. Hay, PhD, to

support the fact that Takeda's fraudulent marketing was material.[9] (Appendix at 263-84.) Dr. Hay evaluated whether claims were submitted as a result of Takeda's fraudulent representations to the FDA and medical community that Actos did not cause bladder cancer. (*Id.* at 267.) His testimony showed that, shortly after the risks of Actos causing bladder cancer were signaled in 2010, Actos sales plummeted approximately 65%. (*Id.* at 273-75.) This precipitous drop in sales indicates that nearly two-thirds of all Actos prescriptions were materially influenced by Takeda's false representations about Actos. Dr. Hay opines that, had the bladder cancer warnings been issued in 2005[10] when Takeda had a clear safety signal that Actos caused bladder cancer in humans, sales to patients receiving government healthcare benefits would have been reduced by approximately $6.24 billion. (*Id.* at 275.) Dr. Hay's testimony provides clear evidence, at least in the

[9] Use of aggregate statistical evidence was endorsed by this Court in ascertaining whether fraudulent promotion prompted third-party payors (here the federal government) to pay for pharmaceutical products. *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, 45-48 (1st Cir. 2013). In *Neurontin*, this Court explained that "[t]he existence of some doctors who purportedly were not influenced by Pfizer's misinformation would not defeat the inference that this misinformation had a significant influence on prescribing decisions which injured Kaiser." *Id.*

[10] While Dr. Ge worked at Takeda between 2008 and 2010, she observed not only Takeda's underreporting and misbranding violations that occurred during her tenure, but through her investigation and review of internal records, she learned that these types of violations had preceded her.

case of Actos, that Takeda's fraudulent representations about Actos' safety profile materially influenced the submission of claims to the government.

(b) Takeda violated the FCA by inducing doctors and patients to submit false claims that wrongly certified the drug was "reasonable and necessary" for treatment

i. *Falsity: The claims were false or fraudulent because they falsely implied compliance with a precondition of payment*

A claim is false or fraudulent when it is submitted to the government and fails to comply with a precondition for payment. *See Hutcheson*, 647 F.3d at 392. Under Medicare or Medicaid,[11] "no payment may be made ... for items or services ... which ... are not reasonable and necessary for the diagnosis or treatment of illness or injury[.]" 42 U.S.C. § 1395y(a)(1)(A). If a drug or procedure is not medically necessary or reasonable, then Medicare and Medicaid will not pay for the claim. *Heckler v. Ringer*, 466 U.S. 602, 605 (1984) (citing 42 U.S.C. § 1395y (a)(1)). Thus, implied in any claim submitted to Medicare or Medicaid for a prescription medication is a certification that the drug is reasonable and necessary. *See Strom*, 676 F. Supp. 2d at 891-92. Typically, the prescribing doctor determines whether a drug is reasonable and necessary. That determination is made, however, by

[11] The Medicaid regulations for the various states at issue in the Actos and Uloric Complaints also contain similar preconditions for payment under their respective Medicaid programs. *See, e.g.*, 130 Mass. Code Regs. 450.204; N.Y. Comp. Codes R. & Regs. tit. 18, § 515.2(b)(1)(i).

evaluating the risks associated with a drug and weighing those risks against potential benefits, which is dependent on an accurate description of the risks in the drug's label.

When a drug company fraudulently promotes the safety and efficacy of a drug, and doctors and patients are induced to submit claims to Medicare and Medicaid as a result, the claims are false and fraudulent because they falsely represent that the drug is suitable for payment, that is, that the drug is "reasonable and necessary." *See, e.g.*, *Strom*, 676 F. Supp. 2d at 891-92. In *Strom*, a district court recognized that fraudulent promotion to doctors about a prescription drug's safety and efficacy could give rise to FCA liability if the fraud prompted the submission of claims. *Id.* In *Strom*, the United States brought FCA claims against a pharmaceutical company for promoting the off-label use of a prescription drug. *Id.* at 885-87. The United States alleged that the defendant misrepresented the safety and efficacy of the drug to doctors, which in turn caused prescriptions to be written and claims to be submitted to Medicare. *Id.* The court held that the claims were false and fraudulent because each claim presented to Medicare falsely represented that the drugs were "reasonable and necessary" for treatment. *Id.* at 891-94. The court stated:

> Plaintiff alleges that the drug was not, in fact, effective when used for the off-label purpose. Because the statute permits reimbursement only for "reasonable and necessary" treatments, 42 U.S.C. § 1395y, a prescription of Natrecor in a context where it is not "reasonable" or "necessary" would

> be statutorily ineligible for reimbursement. This satisfies the FCA's requirement of a "false" statement.

Id. at 891. The court further explained that:

> This is not to say, as Defendants suggest, that this Court is "second-guess[ing] doctors' considered medical opinions." [docket citation omitted] Rather, this Court acknowledges that the Complaint alleges that doctors did not, in fact, make considered medical judgments. Instead, the Complaint alleges that doctors prescribed Natrecor for outpatient use *only because* they were induced to do so by Defendants' misrepresentations.

Id. at 891 n.2. Each claim submitted for off-label use was false and fraudulent because, even though off-label use of a drug is permitted, doctors were induced to prescribe the drug as a result of the defendant's fraud. *Id.* The claims submitted to Medicare could not accurately represent that the drug was "necessary and reasonable" because any determination to that effect was predicated on that fraud. *See also Franklin*, 147 F. Supp. 2d at 51 (finding FCA cause of action when drug manufacturer "caused the submission of numerous off-label prescription for Neurontin to the Medicaid program through both its fraudulent statements about the safety and efficacy of Neurontin[.]").

Here, the Actos and Uloric Complaints allege that Takeda misrepresented the safety profile of Actos, Uloric, Kapidex/Dexilant, and Prevacid by falsifying and withholding adverse event reports and publishing misleading drug labels. By concealing safety risks and using fraudulent drug labels, Takeda made it impossible for doctors to properly weigh the risks associated with these drugs. Just as in *Strom*,

this fraudulent conduct rendered all claims to Medicare and Medicaid false and fraudulent because every claim submitted to Medicare and Medicaid falsely asserted that the prescription was "reasonable and necessary" to treat the patient—a determination that was not possible without knowing the safety risks that Takeda deliberately concealed. In other words, by misleading doctors and patients about the risks of these drugs, Takeda induced the submission of claims for these drugs to Medicare and Medicaid that falsely certified that the drug was "reasonable and necessary" for treatment.

ii. *Materiality: The false claims were material because, absent the false certification, the government would not pay the claim*

The Medicare statute contains an express condition of payment – "no payment may be made" – and thus explicitly links each Medicare payment to the requirement that the particular item or service be "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A). This is a bright-line condition of payment and, thus, falsely certifying compliance with this condition is material to the government's decision to pay the claim.

(c) Takeda violated the FCA by using fraud to maintain access to and eligibility in the prescription drug market

i. *Falsity: The claims were false and fraudulent because the drugs were fraudulently on the market*

A new prescription drug cannot be distributed in interstate commerce unless the sponsor of the drug demonstrates that the drug is

safe and effective for each of its intended uses. *See* 21 U.S.C. § 355(a) & (d). Once a drug is approved for a specific indication, the FDA continues to monitor the drug to ensure that new risks are discovered, evaluated, and addressed. *See* 21 U.S.C. § 355(e) & (k). An integral component of the FDA's post-market surveillance of drug safety is the monitoring of adverse event reports. *See* 21 U.S.C. § 355(k); 21 U.S.C. § 355b; 21 C.F.R. §§ 314.80 and 314.81; *see also* 21 U.S.C. § 356b (governing the submission of the results of clinical trial data). Every drug manufacturer is required to catalogue, evaluate, and promptly report adverse events to the FDA. 21 C.F.R. § 314.80. Failure to comply with these reporting requirements can lead the FDA to "withdraw approval of the application and, thus, prohibit continued marketing of the drug[.]" 21 C.F.R. § 314.80(j).

In addition to adverse event reporting requirements, a drug manufacturer is also responsible for ensuring its drug label is truthful, accurate and up-to-date. *See Wyeth v. Levine*, 555 U.S. 555, 570-71 (2009). "[I]t has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Id.* A drug manufacturer must revise its label "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug[.]" 21 C.F.R. § 201.80(e); *see also* 21 C.F.R. §

201.56(a)(1) (discussing labeling requirements). Failure of a drug manufacturer to update a drug label to provide truthful safety information renders the drug "misbranded" under federal law. *See* 21 U.S.C. § 352 (a). Any drug that is misbranded is prohibited from being introduced into interstate commerce. 21 U.S.C. § 331(a), (b).

In the context of the FCA, when compliance with a federal law or regulation is a material condition for participation in a federal program, failure to comply with those laws and regulations serves as a basis for FCA liability. *Hendow*, 461 F.3d at 1176; *Main*, 426 F.3d at 916; *Westinghouse*, 352 F.3d at 916-17; *United States ex rel. Bierman v. Orthofix Int'l, N.V.*, 748 F. Supp. 2d 123, 128-29 (D. Mass. 2010) (failure to comply with Medicare regulation rendered claims false). The reasoning underlying this theory of FCA liability is that the "FCA is intended to reach all fraudulent attempts to cause the Government to pay out sums of money or to deliver property or services. Accordingly, a false claim may take many forms[.]" S. Rep. No. 99–345, at 9 (1986), *as reprinted* in 1986 U.S.C.C.A.N. 5266, 5274. Congress contemplated that "claims may be false even though the services are provided as claimed if, for example, *the claimant is ineligible to participate in the program*[.]" *Id.* (emphasis added). Thus, when a defendant uses fraud and deceit to gain or maintain access to a market or government benefit program, the claims submitted to the government by virtue of that

access are inherently false and fraudulent because they are predicated on a fraudulent course of conduct.

In *Hendow*, a university agreed to "abide by a panoply of statutory, regulatory, and contractual requirements" so that it could receive government funds under "Title IV and the Higher Education Act." 461 F.3d at 1169. As part of these regulations, the university agreed to follow federal laws that forbid paying incentives to recruiters. *Id.* In return, students seeking to attend the university would be eligible to apply for low-interest student loans. *Id.* at 1169-70. A relator brought a FCA case against the university alleging that the university violated federal law by paying recruiters incentives to enroll students. *Id.* The district court dismissed the case reasoning that the relator had failed to allege how compliance with the federal law was a precondition to payment. *Id.*

The Ninth Circuit reversed and held that the relator had sufficiently stated a claim under the FCA. *Hendow*, 461 F.3d at 1175-76. Specifically, the Ninth Circuit stated that, to state a claim, the relator needed to allege "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *Id.* at 1174. The panel examined the relator's claims and reasoned that, since compliance with the federal law prohibiting the use of incentives in recruiting was required to participate in the federal loan program, any

claims submitted to the government as a result of the university's fraudulent enrollment in the program were false claims. *Id.* at 1175-78.

As in *Hendow*, Takeda used fraud to maintain access to the prescription drug market to sell the drugs at issue. The Actos and Uloric Complaints allege that Takeda failed to comply with adverse event reporting regulations and published fraudulent labels concealing various safety risks associated with Actos, Uloric, Kapidex/Dexilant, and Prevacid. Accordingly, Takeda was not in compliance with federal law and the drugs, as labeled, were misbranded. Any claim submitted for these drugs was inherently false and fraudulent because the drugs were not eligible to be part of the Medicare and Medicaid programs, or *any* program for that matter. Just as compliance with the federal law prohibiting the payment of incentives to recruiters was a precondition for eligibility in the loan program in *Hendlow*, so here compliance with federal reporting and labeling laws was a precondition for putting these drugs into interstate commerce. However, because Takeda was able to conceal the safety risks associated with the drugs using false reports, it was able to maintain access to the pharmaceutical market and promote its drugs to doctors and patients, many of whom were beneficiaries of federally-funded healthcare programs. Any claims submitted to Medicare or Medicaid were, therefore, false and fraudulent since they were predicated on fraudulent conduct.

ii. *Materiality: The failure to comply with federal reporting*

and labeling laws was material because being "saleable" is a precondition for payment

Before a drug is eligible for reimbursement through any government healthcare program, the drug must be saleable, *i.e.*, must be permitted in interstate commerce. *See* 21 U.S.C. § 331. Because Takeda published misleading drug labels and concealed safety risks from the FDA and medical community, Actos, Uloric, Kapidex/Dexilant, and Prevacid were misbranded drugs and not suitable for interstate commerce. *See Franklin*, 147 F. Supp. 2d at 44. Thus, the falsity of the claims is material since being saleable is a precondition for payment.

B. The Actos and Uloric Complaints satisfy Rule 9(b) because the submission of fraudulent claims to the government was alleged beyond possibility

The Federal Rules of Civil Procedure require a civil complaint to state "a short and plain statement of the claim showing that the plaintiff is entitled to relief." Fed. R. Civ. P. 8(a). Rule 9(b), however, provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). The "particularity" requirement means that a complaint must specify "the time, place, and content of an alleged false representation." *Doyle v. Hasbro, Inc.,* 103 F.3d 186, 194 (1st Cir.1996) (quoting *McGinty v. Beranger Volkswagen, Inc.,* 633 F.2d 226, 228 (1st Cir.1980)). "Conclusory allegations and references to 'plans and schemes' are not sufficient." *Rost*, 507 F.3d at 731. The purpose of Rule 9(b) "is to 'give notice to defendants of the plaintiffs' claim, to protect

defendants whose reputation may be harmed by meritless claims of fraud, to discourage 'strike suits,' and to prevent the filing of suits that simply hope to uncover relevant information during discovery.'" *Karvelas*, 360 F.3d at 226 (quoting *Doyle,* 103 F.3d at 194).

Since the FCA is an anti-fraud statute, the pleading requirements of Rule 9(b) govern. *Id.* at 228. There is, however, "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 (citing *Rost*, 507 F.3d at 732). In cases where the relator alleges that the defendant directly submitted false or fraudulent claims, Rule 9(b) "requires relators to 'provide details that identify particular false claims for payment that were submitted to the government.'" *Rost*, 507 F.3d at 731 (quoting *Karvelas*, 360 F.3d at 232). In cases alleging that the defendant *induced* a third-party to submit an otherwise false or fraudulent claim, however, "a relator could satisfy Rule 9(b) by providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility' without necessarily providing details as to each false claim." *Duxbury*, 579 F.3d at 29 (quoting *Rost*, 507 F.3d at 733); *accord United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) ("[A] relator's complaint ... may nevertheless survive by alleging particular details of a scheme to

submit false claims paired with reliable *indicia* that lead to a strong inference that claims were actually submitted.").

Here, Dr. Ge does not allege that Takeda directly submitted false claims to the government. Rather, Dr. Ge maintains that Takeda's fraudulent conduct induced doctors and patients to submit false claims. Thus, to satisfy Rule 9(b)'s particularity requirements, Dr. Ge must provide factual or statistical evidence to strengthen the inference of fraud beyond just possibility. *Rost*, 507 F.3d at 733. Dr. Ge, however, is not required to provide information about every claim submitted to the government that was rendered false or fraudulent because of Takeda's conduct. As Chief Judge Patti Saris remarked in *Franklin*: "Where the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible. Courts facing similar claims under the FCA have not placed the bar so high as to require pleading with total insight." 147 F. Supp. 2d at 49 (collecting citations). Requiring a complaint to identify every claim would eviscerate the ability of the United States to recover money lost to unlawful marketing practices involving an FDA-approved drug, whether it be illegal kickbacks, *Duxbury*, 579 F.3d at 29, off-label promotion, *United States ex rel. Kennedy v. Aventis Pharmaceuticals, Inc.*, 512 F. Supp. 2d 1158, 1167 (N.D. Ill. 2007), or misleading marketing, *Strom*, 676 F. Supp. 2d at 888.

When, as alleged here, the fraud at issue is complex and involves hundreds of thousands of false claims, Rule 9(b) particularity requirements should be relaxed to ensure otherwise meritorious claims are not rejected because of a hyper-technical application of pleading requirements that serve no purpose other than to insulate fraudulent conduct. *See e.g., Franklin,* 147 F.Supp.2d at 47; *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc.*, 238 F. Supp. 2d 258, 269 (D. D.C. 2002); *United States ex rel. Johnson v. Shell Oil Co.*, 183 F.R.D. 204, 206-07 (E.D. Tex. 1998) (collecting cases). In *Johnson*, the court observed:

> It is only common sense that the sufficiency of pleadings under Rule 9(b) may depend 'upon the nature of the case, the complexity or simplicity of the transaction or occurrence, the relationship of the parties and the determination of how much circumstantial detail is necessary to give notice to the adverse party and enable him to prepare a responsive pleading.' ... Similarly, it has been widely held that where the fraud allegedly was complex and occurred over a period of time, the requirements of Rule 9(b) are less stringently applied ... To approach the issue otherwise would allow the more sophisticated to escape liability under a False Claims case due to the complexity of their scheme and their deviousness in escaping detection.

183 F.R.D. at 206-07. Thus, the gravamen of Rule 9(b) in the FCA context is to ensure that the alleged misconduct of the defendant is pleaded with sufficient particularity such that fraud on the government is not just possible or based on "speculation," but creates "a strong inference" that claims were actually filed. *See Duxbury*, 579 F.3d at 29.

Courts within this circuit and elsewhere have grappled with how to apply Rule 9(b) to FCA cases where a defendant's conduct caused the submission of false claims for prescription drugs. *See United States ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 353-58 (D. Mass. 2011); *United States ex rel. Carpenter v. Abbott Lab., Inc.*, 723 F. Supp. 2d 395, 409 (D. Mass. 2010); *Franklin*, 147 F. Supp. 2d at 46. Central to this inquiry are the Court's decisions in *Rost* and *Duxbery*. *Rost,* 507 F.3d at 733-35; *Duxbury,* 579 F.3d at 29-31. Both *Rost* and *Duxbury* involved allegations that "false claims were allegedly submitted by doctors who were allegedly induced and seduced by defendants into prescribing [a drug.]" *Rost,* 507 F.3d at 732; *Duxbury,* 579 F.3d at 29. In *Rost*, this Court found that the complaint "amply describe[d] illegal practices in which [the defendant] allegedly engaged" but did "not sufficiently establish that false claims were submitted for government payment in a way that satisfies the particularity requirement." 507 F.3d at 732–33.

In *Duxbury*, however, this Court distinguished *Rost* because the relator had done "more than 'suggest fraud was possible.'" 579 F.3d at 29–30 (quoting *Rost,* 507 F.3d at 733). Unlike Rost, Duxbury identified eight hospitals that submitted false claims and, although he did not list specific claims, provided "information as to the dates and amounts of the false claims filed by these providers with the Medicare program." *Id.* at 30. This Court held that Duxbury satisfied Rule 9(b)'s particularity

requirement because "he has alleged the submission of false claims across a large cross-section of providers that alleges the 'who, what, where and when of the allegedly false or fraudulent representation[.]'" *Id.* (citation omitted). The evidence of these eight providers' claims "support[ed] a strong inference that such claims were also filed nationwide." *Id.* at 31.

(1) The Actos and Uloric Complaints sufficiently allege the *who*, *what, where* and the *when*, of the fraud perpetrated on the government

As a preliminary matter, Dr. Ge maintains that her Actos and Uloric Complaints met Rule 9(b)'s pleading requirements by alleging the *who*, *what, where* and the *when*, of the fraud perpetrated by Takeda on the government. Specifically, Dr. Ge alleges, *who* was involved with Takeda's fraudulent reporting scheme: Maria Paris, Vice President of Takeda's Pharmacovigilance Department; Gregory Fusco, Director of Pharmacoepidemiology; Niela Smith, Senior Medical Director; Michelle Peralta, a project manager; Mike Zabinas, a nurse specialist; Betsy Fletcher, the Uloric Post-Marketing Manager; and Michelle Hisada, a Medical Director.

Dr. Ge also specifically alleges *what* these Takeda personnel were doing to mislead the FDA and medical community. Dr. Ge provides detailed descriptions of the dates and personnel, including managers, who directed her and others to alter adverse event reports, with specific descriptions of what was actually entered into Takeda's adverse event

database. (Appendix at 39-44, 47-58, 150-155, 158-167, 172-174, 175-177.) She provided descriptions of conversations Takeda pharmacoviglance personnel had with healthcare professionals to get them to express doubt or uncertainty regarding their assessments. (*E.g.*, *id.* at 21.) The Actos and Uloric Complaints provide instances in which Takeda management directed medical reviewers (including Dr. Ge) to alter and fraudulently reclassify adverse event reports before sending them to the FDA. (*Id.* at 39-43, 150-57.) In addition, Dr. Ge alleges that Takeda rebuffed efforts to add additional warnings to the drug labels despite there being clear safety signals. (*E.g.*, *id.* at 50.)

Dr. Ge also alleges *when* these fraudulent events occurred. For Actos, Dr. Ge alleges that Takeda was certainly aware of the human risks associated with bladder cancer by 2005 and the risks shown in pre-clinical animal studies by 1999, and continued to mislead the FDA and the medical community about this risk until 2010, when the FDA finally announced it had begun investigating Actos. For Uloric, Dr. Ge alleges that Takeda was aware of possible safety risks associated with dangerous drug interactions starting in 2005 until the present. For Prevacid, Dr. Ge alleges that Takeda concealed significant safety risks associated with the drug from August 26, 2001, when an adverse event report of serious bone marrow suppression was submitted to Takeda. For Kapidex/Dexilant, Dr. Ge alleges that Takeda concealed serious cardiac arrhythmia caused from drug interactions associated with the

drug since January 2009. Finally, Dr. Ge alleges *where* all these events occurred—Takeda's U.S. headquarters in Lake Forest, Illinois, and in some cases, offices within the headquarters where the specific conversations took place.

Dr. Ge maintains that these allegations of fraud, which provide substantial detail about how Takeda was able to defraud the FDA, the medical community, and patients about these drugs' safety, is sufficient to meet the pleading requirements of Rule 9(b). *See Strom*, 676 F. Supp. 2d at 893-94; *Kennedy*, 512 F. Supp. 2d at 1167; *Franklin*, 147 F. Supp. 2d at 49 ("[T]he complaint amply details both a general framework of the purported Medicaid fraud and provides more specific information on the individuals, locations, the precise statements alleged to be false and time-frames involved."). Although Dr. Ge does not provide specific details of each false claim, her allegations specify Takeda's fraud and put Takeda on notice of what categories of government claims are at issue. This is particularly true since this matter has not even proceeded to discovery. *See United States ex rel. Downy v. Corning, Inc.*, 118 F. Supp. 2d 1160, 1173 (D.N.M. 2000) (allowing relator to plead general scheme of fraud where information concerning individual instances of fraud could be sought during discovery).[12] As the *Strom* court explained:

[12] In light of the documents that have been produced in parallel litigation, Dr. Ge is confident that identification of the government's

> [G]iven the purposes of Rule 9(b), the specifics of all claims are unnecessary at the pleading stage. The gravamen of this action concerns fraudulent inducement of doctors, and the Complaint provides exhaustive allegations relating to this fraud. In this context, the specifics of the claims themselves are somewhat less important. Instead, the case concerns the marketing activities of Defendants and whether they acted in reckless disregard of the truth. The allegations in the Complaint put defendants on sufficient notice of the nature of the action, and given the immense number of claims at issue, requiring them to be listed one-by-one in the Complaint is ungainly and unfair.
>
> ...
>
> Plaintiff has alleged a thorough and complex series of actions which, if true, constitutes a violation of the False Claims Act. ... Plaintiff is clear as to the wrongs it believes Defendants to have committed. While there may indeed be factual disputes as to which claims, if any, were the result of Defendants' fraudulent activity, it is not Plaintiff's burden to prove such causation at the pleading stage.

S*trom*, 676 F. Supp. 2d at 894. Like the relator in *Strom*, Dr. Ge alleges, in exhausting detail, how Takeda defrauded the FDA and, in turn, the medical community and patients. To require more at this stage, in the absence of any discovery, would not serve the purposes of Rule 9(b)—Dr. Ge's allegations are not baseless nor is Takeda unaware of the allegations leveled against it, *see Karvelas*, 360 F.3d at 226. It would only serve as a technicality allowing drug manufacturers to get away with fraud.

(2) Dr. Ge provided factual and statistical evidence to meet the district court's *Duxbury* requirements for the Actos Complaint

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exact expenditures for Actos will be available should this matter proceed to discovery.

Relying on *Duxbury*, wherein the relator identified eight specific medical providers who had submitted false claims, the district court held that, because Dr. Ge failed to identify any specific claims, her claims did not satisfy Rule 9(b). This reading of *Duxbury*, however, is misguided. Simply because the *Duxbury* relator had access to eight specific claims, does not mean each relator must likewise plead sample claims to meet Rule 9(b)'s requirements. Otherwise, any claim brought against a company that artfully segregates the components of its fraud would be able to thwart whistleblower claims. Indeed, this Court in *Duxbury* took care to note that it was not drafting a "litigation manual full of scenarios." 579 F.3d at 32; *see Karvelas*, 360 F.3d at 233. By presenting specific details of Takeda's fraud and an estimate of the amount of false claims the government paid as result, Dr. Ge met the requirements of Rule 9(b). *See, e.g.*, *United States ex rel. Westmoreland v. Amgen, Inc.*, 738 F. Supp. 2d 267, 276 (D. Mass. 2010). However, to the extent *Duxbury* established a litmus test, Dr. Ge respectfully contends that the additional information produced in her motion for reconsideration satisfied the district court's requirements.

The district court noted that, in *Duxbury*, "the relator identified eight specific medical 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." (Addendum at 71-72.) Thus, to satisfy these

"requirements," Dr. Ge submitted the declarations of eight individuals addressing the submission of specific claims for Actos. The declarations and supporting pharmacy records provide:

(a) the name of the patients who initiated the submission of the Actos claim;

(b) the name of the respective pharmacies that filled the prescription;

(c) the dates the prescriptions were filled;

(d) the name of the governmental agencies to whom the claims were made and who ultimately paid the claims;

(e) the supporting pharmacy records (for a number of declarants) identifying the amount that was paid;

(f) whether the patient was eventually diagnosed with bladder cancer and the amount of money the respective governmental entity paid to treat their cancer; and

(g) an attestation that the patient would not have submitted claims to the government had they known the truth about Actos' association with increased bladder cancer risks.

(Appendix at 358-454.) These declarations and supporting pharmacy records, which Dr. Ge proposed adding to the Actos Complaint, cure the purported deficiencies identified by the district court.

Moreover, in addition, Dr. Ge provided "statistical evidence to strengthen the inference of fraud beyond possibility." *Duxbury*, 579

F.3d at 29. Specifically, Dr. Ge presented the declaration of Joel W. Hay, PhD, a Professor and Founding Chair of Pharmaceutical Economics and Policy in the School of Pharmacy at the University of Southern California. (Appendix at 263-84.) Dr. Hay constructed economic models to determine the amount of claims that would have been submitted to the government for Actos prescriptions and bladder cancer treatment if Takeda had properly disclosed Actos' bladder cancer risks. Dr. Hay's prescription model is based on an extrapolation of how Actos sales responded to the FDA issuing its initial warning of Actos and bladder cancer in 2010 and the mandated label changes in 2011. "[E]xtrapolation is a reasonable method for determining the number of false claims[.]" *United States ex rel. Loughren v. UnumProvident Corp.*, 604 F. Supp. 2d 259, 261 (D. Mass. 2009). Dr. Hay's analysis reveals a clear statistical link between the issuance of bladder cancer warnings in 2011 and the steep decline of Actos' sales. (Appendix at 272-75.) Dr. Hay estimates that, had Takeda issued bladder cancer warnings in 2005 (when it became aware of the statistically significant increased risk between Actos and bladder cancer in humans), the warnings would have caused the state and federal government to spend $6.24 billion less on Actos. (*Id.* at 275.) This statistical evidence, which Dr. Ge proposed including in an amendment of the Actos Complaint, provides

strong statistical evidence that false claims were submitted for Actos "beyond possibility."[13]

II. The District Court Abused Its Discretion in Denying, Without Explanation, Leave to File at Least One Post-Ruling Amended Complaint

Although Dr. Ge maintains that the district court erred in dismissing the Actos and Uloric Complaints, at the very least, the district court erred in disallowing Dr. Ge *any* opportunity to amend the complaints. A district court's denial of a request to amend a complaint is reviewed for an abuse of discretion. *O'Connell v. Hyatt Hotels of Puerto Rico*, 357 F.3d 152, 154 (1st Cir. 2004). In conducting this review, the Court should "defer to the district court if any adequate reason for the denial is *apparent on the record*." *Grant v. News Group Boston, Inc.,* 55 F.3d 1, 5 (1st Cir. 1995) (emphasis added). Federal Rule of Civil Procedure 15(a) provides that leave to amend a pleading "shall be freely given when justice so requires," and reflects a liberal amendment policy. *O'Connell*, 357 F.3d at 154. Grounds for denial

[13] In addition, the recent jury trial in *Cooper v. Takeda Pharmaceuticals America Inc.*, CGC-12-518535, in California Superior Court, has released a treasure trove of documents relating to Takeda's policies and conduct in concealing the risks of bladder cancer associated with Actos. *See e.g.*, Jef Feeley & Margaret C. Fisk, Takeda Worried About Actos's Cancer Link, Filing Shows, Bloomberg, Feb. 15, 2013, *available at* http://www.bloomberg.com/news/2013-02-15/takeda-worried-about-actos-s-cancer-link-filing-shows.html. These documents reveal that Takeda engaged in a strategy to prevent the disclosure of bladder cancer risks because Takeda knew, based on internal surveys, that if doctors were advised of a bladder tumor link, they would not prescribe it.

generally involve undue delay, bad faith, dilatory motive of the requesting party, repeated failure to cure deficiencies, and futility of amendment. *Villanueva v. United States*, 662 F.3d 124, 127 (1st Cir. 2011).

As a threshold matter, the district court did not provide *any* reason for denying De. Ge's request to file amended complaints. This fact, alone, demonstrates an abuse of discretion. The United States Supreme Court explained:

> [T]he grant or denial of an opportunity to amend is within the discretion of the District Court, but outright refusal to grant the leave without any justifying reason appearing for the denial is not an exercise of discretion; it is merely abuse of that discretion and inconsistent with the spirit of the Federal Rules.

Foman v. Davis, 371 U.S. 178, 182 (1962). Thus, the district court's refusal to provide any justifying reason for denying Dr. Ge's request was, itself, an abuse of discretion, and demands reversal.

Moreover, Dr. Ge was never afforded a post-ruling opportunity to amend her complaints, has not acted in bad faith, and has not engaged in any dilatory conduct. There is no indication that Dr. Ge's request for leave to amend is untimely. More importantly, amendment would not be futile since, as demonstrated by the filings submitted with Dr. Ge's motion for reconsideration, any purported deficiencies can be cured through amendment. *See Rost*, 507 F.3d at 733-34 (holding that relator failed to plead FCA claim with particularity but remanding to give

relator an opportunity to amend). Accordingly, the district court abused its discretion in denying Dr. Ge's request to amend the Actos and Uloric Complaints.

CONCLUSION

Underlying this appeal is a simple viewpoint—pharmaceutical companies should not be allowed to collect government money by deceiving and misleading the FDA, the medical community, and patients about important health risks associated with a drug. A pharmaceutical company's fraud, which induces the submission of false claims to the government, should be actionable under the FCA. As it stands, however, the district court's interpretation of the FCA will have a profound impact on whether pharmaceutical companies can manipulate the federal regulatory framework to turn an improperly gained profit. Ultimately, the district court's narrow reading of the FCA undercuts the law's rationale and discourages whistleblower suits for fraudulent conduct that clearly costs the government, and taxpayers, money.

The district court committed reversible error in its dismissal of Dr. Ge's complaints and for disallowing any post-ruling amendment. Accordingly, Dr. Ge respectfully requests that this Court vacate the order of dismissal below and remand for further proceedings.

Dated: June 13, 2013

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH RULE 32(A)

(1) This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 13,964 words, excluding the parts of the brief exempted by Federal Rule of AppelOplate Procedure 32(a)(7)(B)(iii).

(2) This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally-spaced typeface using Microsoft Word 2007 in New Century Schoolbook, 14-point font.

June 13, 2013

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CERTIFICATE OF SERVICE

I hereby certify that on June 13, 2013, I electronically filed the foregoing document with the accompanying addendum with the United States Court of Appeals for the First Circuit by using the CM/ECF system. I certify that the following parties or their counsel of record are registered as ECF Filers and that they will be served by the CM/ECF system:

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ADDENDUM

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Addendum - A

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.").

Addendum - B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

United States of America et al,
Plaintiffs,

v.

Takeda Pharmaceutical Co. Ltd. et al,
Defendants.

CIVIL ACTION

NO. 10-11043-FDS

ORDER OF DISMISSAL

Saylor, D. J. **November 01, 2012**

In accordance with the Court's Memorandum and Order issued on November 01, 2012, granting the defendants' motion to dismiss, it is hereby ORDERED that the above-entitled action be dismissed.

So Ordered.

F. DENNIS SAYLOR, IV
UNITED STATES DISTRICT JUDGE

By the Court: **/s/ Pietro Cicolini**
Deputy Clerk