No. _____

In The
Supreme Court of the United States

UNITED STATES EX REL. HELEN GE, M.D.,

Petitioner,

vs.

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

Respondents.

**On Petition For A Writ Of Certiorari
To The United States Court Of Appeals
For The First Circuit**

PETITION FOR WRIT OF CERTIORARI

MICHAEL L. BAUM
Counsel of Record
R. BRENT WISNER
BAUM HEDLUND ARISTEI
& GOLDMAN, P.C.
12100 Wilshire Blvd., Suite 950
Los Angeles, California 90025
Telephone: (310) 207-3233
Facsimile: (310) 207-4204
MBaum@baumhedlundlaw.com

MICHAEL SULLIVAN
THE ASHCROFT GROUP
1 Post Office Square,
Suite 3750
Boston, Massachusetts
02109
Telephone: (617) 573-9400
Facsimile: (617) 573-9400
MSullivan@
ashcroftlawfirm.com

Counsel for Petitioner

COCKLE LEGAL BRIEFS (800) 225-6964
WWW.COCKLELEGALBRIEFS.COM

QUESTION PRESENTED

It is black letter law that a district court should freely give leave to amend under Federal Rule of Civil Procedure 15(a) unless there is an apparent or explained reason why amendment should be disallowed. *Foman v. Davis*, 371 U.S. 178, 181-82 (1962). Liberal amendment ensures litigants obtain decisions on the merits and restricts a court's inclination to turn pleading into "a game of skill in which one misstep by counsel may be decisive to the outcome[.]" *Id.* at 181. A problem arises, however, when the liberal amendment standard of Rule 15(a) is applied after the entry of judgment. The policy favoring decisions on the merits runs into the practical consideration of preserving the finality of judgments. This tension has led to divisions among the courts of appeals. Thus, the question presented is:

Whether the "freely given" standard embodied in Rule 15(a), and espoused in *Foman*, applies to a motion to amend timely filed after the entry of judgment, as held by the Third, Fourth, Fifth, Sixth, and Tenth Circuits, or whether the entry of judgment categorically forecloses any application of Rule 15(a), as held by the First, Seventh, Ninth, and Eleventh Circuits.

PARTIES TO THE PROCEEDING

Petitioner Helen Ge, M.D., was relator-plaintiff in the district court and relator-appellant in the court of appeals. Respondents Takeda Pharmaceutical Company, Ltd. and Takeda Pharmaceutical North America, Inc. were defendants in the district court and appellees in the court of appeals.

TABLE OF CONTENTS

TABLE OF CONTENTS – Continued

TABLE OF CONTENTS – Continued

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES – Continued

Page

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

PETITION FOR A WRIT OF CERTIORARI

Petitioner Helen Ge, M.D., respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the First Circuit in this case.

OPINIONS BELOW

The court of appeals' opinion, filed December 6, 2013, is reported at 737 F.3d 116 (1st Cir. 2013). (Appendix ["App."] 3-28.) The First Circuit's January 10, 2014 order denying rehearing and rehearing *en banc* was not published in the official reports. (App. 45-47.)

The district court's November 1, 2012 memorandum and order dismissing the underlying complaints was not published in the official reports. (App. 29-44.)

JURISDICTION

The First Circuit filed its opinion on December 6, 2013. (App. 3.) Petitioner timely petitioned for rehearing and rehearing *en banc* and, on January 10, 2014, the First Circuit denied the petition. (App. 47.) This Court has jurisdiction under 28 U.S.C. § 1254(1) to review on writ of certiorari the First Circuit's December 6, 2013 decision.

STATUTORY PROVISIONS AND RULES AT ISSUE

Relevant portions of the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* and the Federal Rules of Civil Procedure are set forth in the Appendix. (App. 48-49.)

STATEMENT OF THE CASE

In *Foman v. Davis*, the Court directed lower courts to heed the mandate of Federal Rule of Civil Procedure 15(a) and allow litigants to freely amend their complaint unless there was an *apparent* or *expressed* reason to the contrary. 371 U.S. 178, 181-82 (1962). In *Foman*, a Massachusetts district court dismissed a complaint on a motion to dismiss and entered judgment in favor of the defendant. *Id.* at 179. The plaintiff subsequently filed a motion pursuant to Rule 15(a), seeking leave to file an amended complaint. *Id.* at 179-80. The district court denied the plaintiff's motion without explanation. *Id.* On appeal, the First Circuit affirmed. *Id.*

This Court reversed, holding that the district court's refusal to consider a request to amend constituted an abuse of discretion since there was no attempt to determine whether the proposed amendment was made in bad faith, would prejudice the parties, or would be futile:

> It is too late in the day and entirely contrary to the spirit of the Federal Rules of Civil Procedure for decisions on the merits to be

avoided on the basis of such mere technicalities. "The Federal Rules reject the approach that pleading is a game of skill in which one misstep by counsel may be decisive to the outcome and accept the principle that the purpose of pleading is to facilitate a proper decision on the merits." *Conley v. Gibson*, 355 U.S. 41, 48 (1957). The Rules themselves provide that they are to be construed "to secure the just, speedy, and inexpensive determination of every action." Fed. R. Civ. P. 1.

The Court of Appeals also erred in affirming the District Court's denial of petitioner's motion to vacate the judgment in order to allow amendment of the complaint. As appears from the record, the amendment would have done no more than state an alternative theory for recovery.

Rule 15(a) declares that leave to amend 'shall be freely given when justice so requires'; this mandate is to be heeded. *See generally*, 3 Moore, Federal Practice (2d ed. 1948), 15.08, 15.10. If the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits. In the absence of any apparent or declared reason – such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc. – the leave sought should,

> as the rules require, be 'freely given.' Of course, the 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.

Id. at 181-82.

In the fifty years since *Foman*, the courts of appeals have developed conflicting rules about when a district court abuses its discretion in denying leave to amend. This is particularly true when the request to amend is made after judgment. The Third, Fourth, Fifth, Sixth, and Tenth Circuits hold "that 'a post-judgment motion to amend is evaluated under the same legal standard' – grounded on Rule 15(a) – 'as a similar motion filed before judgment was entered.'" *Matrix Capital Mgmt. Fund, LP v. BearingPoint, Inc.*, 576 F.3d 172, 193 (4th Cir. 2009) (quoting *Laber v. Harvey*, 438 F.3d 404, 428 (4th Cir. 2006)); *accord Cureton v. Nat'l Collegiate Athletic Ass'n*, 252 F.3d 267, 272 (3d Cir. 2001); *Rosenzweig v. Azurix Corp.*, 332 F.3d 854, 864 (5th Cir. 2003); *Morse v. McWhorter*, 290 F.3d 795, 799 (6th Cir. 2002); *Glenn v. First Nat. Bank in Grand Junction*, 868 F.2d 368, 371 (10th Cir. 1989). The First, Seventh, Ninth, and Eleventh Circuits, however, hold that "Fed. R. Civ. P. 15(a) has no application once the district court has dismissed the complaint and entered final judgment for the

defendant." *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1361, n.20 (11th Cir. 2006); *accord United States ex rel. Ge v. Takeda Pharm. Co. Ltd.*, 737 F.3d 116, 128 (1st Cir. 2013) (App. 27); *First Nat. Bank of Louisville v. Cont'l Ill. Nat. Bank & Trust Co. of Chicago*, 933 F.2d 466, 468 (7th Cir. 1991); *Lindauer v. Rogers*, 91 F.3d 1355, 1357 (9th Cir. 1996). And, in yet another approach, the Second and Eighth Circuits appear to apply a middle ground, balancing the interests of finality of judgment against the purpose of the federal rules to promote resolution on the merits. *See Williams v. Citigroup Inc.*, 659 F.3d 208, 212 (2d Cir. 2011); *United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 824 (8th Cir. 2009).

These conflicting interpretations of Rule 15 and its application to post-judgment motions to amend are problematic. They result in inconsistent application of Rule 15 in federal courts, which runs afoul of the purpose of uniformity and undermines the integrity of the federal court system. Litigants in different circuits should not systematically receive different access to the courts. And yet, in the fifty years since *Foman* was issued, that is exactly what is happening. Litigants' ability to have a case decided on the merits turns not on the judicious application of the Federal Rules, but on the happenstance of where they filed their lawsuit.

The court of appeals' decision below presents an excellent vehicle for the Court to resolve these circuit conflicts and clarify how *Foman* and Rule 15 should

be understood and uniformly applied. Absent the Court's review of this matter, litigants in different circuits will continue to receive materially different access to the courts, which in turn, leads to different levels of due process.

I. THE DISTRICT COURT PROCEEDING

A. The Complaints

Relator-Petitioner Dr. Helen Ge ("Dr. Ge") filed two *qui tam* actions pursuant to the Civil False Claims Act ("FCA"), 31 U.S.C. §§ 3729, *et seq*.,[1] in the United States District Court for the District of Massachusetts. The complaints alleged that, while

[1] Under the FCA, any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment" to the government, is liable for a civil penalty, "plus 3 times the amount of damages[.]" 31 U.S.C. § 3729(a). The FCA "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). Unlike other civil enforcement statutes, the FCA contains a *qui tam* provision, which allows individuals with specific knowledge of the fraud to file a suit on behalf of the United States. 31 U.S.C. § 3730(b). The government receives the majority of any resulting judgment, but the *qui tam* plaintiff, also called the "relator," is entitled to a smaller portion of the recovered funds. *Id.* The purpose of the *qui tam* provision is to bolster FCA enforcement, even in cases where the government, for whatever reason, does not have the motivation or wherewithal to pursue an otherwise meritorious claim. *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 547 (1943).

working as a contract physician for Takeda,[2] Dr. Ge observed Takeda conceal serious health risks associated with Actos,[3] Uloric,[4] Kapidex/Dexilant, and Prevacid[5] ("Subject Drugs") from the U.S. Food and Drug Administration ("FDA"), patients, and prescribers. As a result, patients and prescribers were misled about the safety profile of the drugs, believing them to be safer than they actually were. This manipulated understanding of safety led to the submission of claims to various government healthcare programs to

---

[2] Helen Ge received her medical degree from First Medical University of Shanghai and originally worked as a Clinical Research Fellow at the University of Pittsburgh School of Medicine and Harvard Medical School. Dr. Ge later became an Associate Medical Director at the Harvard Medical Clinical Research Institute. In September 2008, Dr. Ge accepted a position with Takeda as a Contract Physician of Drug Safety, where she performed medical reviews of adverse event reports to ascertain the seriousness of the events associated with Actos, Uloric, and Kapidex/Dexilant.

[3] 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. Actos is used primarily to treat Type II diabetes. 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").

[4] Uloric (febuxostat), which was approved by the FDA in 2009, is a urate lowering prescription medication designed to treat gout by suppressing the excess production of uric acid.

[5] Kapidex/Dexilant (dexlansoprazole) and Prevacid (lansoprazole) are both proton-pump inhibitors. They are designed to inhibit the stomach's production of certain acids and are used to treat gastroesophageal reflux disease.

pay for these drugs and the medical care for the misreported adverse events – claims that would never have been submitted but for the fraud. Accordingly, the basic theory of Dr. Ge's FCA allegations is that Takeda, by misleading patients and doctors about the risks associated with the Subject Drugs, induced the submission of claims to the government, which would never have been submitted absent the fraud.

These allegations are best illustrated by Takeda's failure to properly amend the Actos drug label to reflect an association with bladder cancer. By 2005 (if not earlier), Takeda learned that Actos significantly increased the risk of bladder cancer in humans. Instead of disclosing this information to physicians and patients, Takeda concealed it by misreporting adverse events, withholding clinical trial data, and not updating the label. Between 2005 and 2010, because Actos was able to downplay bladder cancer risks, it was able to beat out its competitor Avandia with an artificially inflated safety profile. This allowed Takeda to dominate the insulin sensitizer market, where about half of all prescriptions were paid for with government funds.

In 2010, evidence of the bladder cancer risk was published and the FDA issued a statement that it would be investigating the possible link between bladder cancer and Actos. The alert, by itself, caused sales of Actos to plummet over 60%. Then, in 2011, the FDA completed its investigation and added an official bladder cancer warning. Sales continued to plummet until the drug finally went generic in

August 2012. Joel W. Hay, Ph.D., a Professor and Founding Chair of Pharmaceutical Economics and Policy at the University of Southern California, estimates that had the bladder cancer warnings been issued in 2005, when Takeda first learned of the statistically significant bladder cancer risk to humans, sales to patients receiving government healthcare benefits would have been reduced by approximately $6.24 billion.[6] In other words, Takeda was able to secure over $6 billion in payments from the government by misleading patients and prescribers about the safety of Actos.

Dr. Ge filed two complaints. The first centered on Takeda's fraudulent conduct involving Actos. The

---

[6] 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 ("Actos MDL"). *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. In total, several thousand personal injury and wrongful death claims have been filed relating to bladder cancer caused by Actos. The Actos MDL recently completed a bellwether jury trial on April 7, 2014, wherein the jury returned a verdict of $1.475 million in compensatory damages and, versus Takeda, *$6 billion* in exemplary damages. This, along with three other jury trials that have occurred in various state courts around the country, has led to the disclosure of numerous documents that directly support Dr. Ge's allegations and show that Takeda willfully misled patients, doctors, and the FDA about the risks associated with Actos. Should Dr. Ge ever be allowed to amend her complaint, many of the facts contained in these documents will be included.

second involved similar conduct regarding Uloric, Kapidex/Dexilant, and Prevacid. Both complaints were originally filed under seal pursuant to 31 U.S.C. § 3730(b)(2) so the United States could investigate Dr. Ge's claims and decide whether it would intervene. During the government's twenty-month investigation, and before the complaints were served on Takeda, Dr. Ge amended the complaints once to include updated allegations based on events that had occurred since the filing, i.e., the bladder cancer warning for Actos. (App. 54-55.) Then, shortly after the complaints were unsealed and served on Takeda, Dr. Ge amended the complaints once again without leave of the district court pursuant to Rule 15(a)(1).[7] (App. 55.)

B. The Dismissal

Takeda moved to dismiss the complaints pursuant to Fed. R. Civ. P. 12(b)(6) and 9(b). Takeda argued, in part, that the complaints failed to plead with sufficient particularity those claims rendered false because of Takeda's alleged misconduct.[8] In opposing

---

[7] *Qui tam* cases will often undergo numerous amendments before the defendant is served with the final complaint so those facts uncovered during the United States' investigation and/or included in the accompanying disclosure memorandum can be incorporated.

[8] Whether a relator must identify specific false claims submitted to the government to satisfy Rule 9(b)'s pleading requirements for an FCA claim is a hotly litigated issue and has led to disagreement among the courts of appeals. *See United*

(Continued on following page)

Takeda's motion, Dr. Ge argued that the complaints alleged a fraudulent scheme such that it was "beyond mere possibility" that false claims were submitted to the government for payment.

Recognizing that this issue was in dispute among circuits (and arguably within the First Circuit), Dr. Ge requested that should the court find that the complaints fail to satisfy Rule 9(b)'s pleading requirements, she should be given an opportunity to cure those deficiencies with an amended complaint. (App. 66.) This request was made in a separate section in her opposition brief, and it read:

REQUEST FOR LEAVE TO AMEND

> If the Court were to determine that Relator's Complaints are deficient in any regard,

---

States ex rel. Nathan v. Takeda Pharm. N. Am., Inc., 707 F.3d 451, 457 (4th Cir. 2013), *cert. denied*, 12-1349, 2014 WL 1271321 (U.S. Mar. 31, 2014) (describing different Rule 9(b) standards applied to FCA claims). Indeed, the case law in the First Circuit appears to be contradictory. *Compare United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007) (holding that a complaint satisfies Rule 9(b) when it contains factual or statistical evidence to strengthen the inference of fraud beyond possibility.") *and United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13, 30 (1st Cir. 2009), *cert. denied*, 130 S. Ct. 3454 (2010) (holding that allegations concerning eight specific medical providers describing the general claims that were submitted was a "close call" but satisfied Rule 9(b)) *with United States ex rel. Ge v. Takeda Pharm. Co. Ltd.*, 737 F.3d 116, 125 (1st Cir. 2013) (citing approvingly of *Nathan*'s requirement that a relator must allege specific false claims, conflicting with the central holding in *Rost* and *Duxbury*) (App. 18-19.).

> Relator respectfully requests that this Court afford her an opportunity to amend her complaint. 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 v. Hyatt Hotels of P.R.*, 357 F.3d 152, 154 (1st Cir. 2004); [*U.S. ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733-34 (1st Cir. 2007)] (same); *see also Foman v. Davis*, 371 U.S. 178, 182 (1962) (leave to amend should be "freely given").

(App. 66.)

Dr. Ge made this request relying on *United States ex rel. Rost v. Pfizer, Inc.*, an FCA case involving similar allegations of the fraudulent inducement of false claims for a pharmaceutical product. 507 F.3d 720, 723 (1st Cir. 2007). In *Rost*, the First Circuit affirmed the dismissal of a complaint pursuant to Rule 9(b), but reversed the district court for failing to allow the relator an opportunity to cure those deficiencies with amendment. *Id.* at 731-34. The First Circuit noted that the relator made a request to amend the complaint as part of his opposition to the motion to dismiss, thus invoking the liberal amendment considerations of Rule 15.[9] *Id.* at 733-34.

---

[9] The request to amend in *Rost* was found in footnote 135, and stated: "Moreover, if there should be any deficiency in plaintiffs [sic] complaint, which there is not, he should be allowed leave to amend. *See, e.g., Koehler v. The Bank of Bermuda (New York) Ltd.*, 209 F.3d 130, 138 (2nd Cir. 2000)." *United States ex*

(Continued on following page)

The defendant argued that the relator had "waived his opportunity to amend by making only a 'passing reference' to a request for leave to amend in his briefs to the district court." *Id.* at 734. The First Circuit, however, flatly rejected this argument, stating "*[t]hat is not our law.* This court has treated many similar requests to be sufficient invocations for leave to amend under Rule 15(a)." *Id.* (emphasis added). Dr. Ge believed, based on *Rost*, that a request in an opposition brief asking for an opportunity to cure deficiencies through amendment was sufficient to invoke Rule 15.

Ultimately, the district court dismissed Dr. Ge's complaints for, in part, failing to plead with sufficient particularly under Rule 9(b).[10] The district court stated that "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." (App. 39.) Relying on *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13, 30 (1st Cir. 2009) *cert. denied* 130 S. Ct. 3454 (2010), wherein

---

rel. Rost v. Pfizer, 2006 WL 1033403 (March 13, 2006) (Relator's Opposition Brief).

[10] The district court also dismissed the complaints for failure to plead how the claims submitted as a result of Takeda's alleged fraud were rendered false or fraudulent. (App. 41-43.) Since the court of appeals did not address this issue (*see* App. 5), Dr. Ge does not address it here.

"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[,]" the district court held that Dr. Ge's complaints failed to identify "specific claimants or government program payors." (App. 39.)

The district court did not, however, address Dr. Ge's request to amend the complaint nor make a finding of undue delay, bad faith, dilatory motive, repeated failures to cure through amendment, or futility. Indeed, the district court's order did not even specify whether the dismissal was with prejudice.

Instead, concurrently with its order dismissing the complaints, the district court filed a separate one page order dismissing the cases in their entirety, thereby rendering a final judgment in favor of Takeda.[11] (*See* App. 58, Dkt. 46.) In the order dismissing the cases, there was no mention of Dr. Ge's request to amend, no finding of futility, and no reason given for dismissing the case, as opposed to just the complaints. The documents, dated November 1, 2012, contained a single sentence: "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

[11] This effectively made the district court's dismissal under Rule 9(b) with prejudice.

be dismissed." (*United States ex rel. Ge v. Takeda Pharm. Co. Ltd.*, 10-CV-11043-FDS (D. Mass.) at Dkt. 46, 11-CV-10343-FDS at Dkt. 44.)[12]

C. Post-Judgment Request to Amend Complaints

Shortly after the district court entered judgment in favor of Takeda, Dr. Ge filed a timely motion pursuant to Rule 59(e),[13] seeking reconsideration of the district court's order and requesting leave to cure the deficiencies identified by the district court pursuant to Rule 15(a)(2). Attached to the motion were:

(1) Two proposed amended complaints;

(2) Affidavits from eight Actos patients identifying the "who, what, where, and when" of specific claims submitted to the government as a result of Takeda's alleged misconduct; and

---

[12] At the time the case was dismissed, the parties had never appeared before the district court and no discovery had been conducted. The case was in the nascent stages of litigation.

[13] The court of appeals stated that Dr. Ge's motion for reconsideration and motion to amend were "late." (App. 24.) Federal Rule of Civil Procedure 59(e) provides that a motion to amend or alter judgment "must be filed no later than 28 days after entry of judgment." The district court entered judgment on November 1, 2012. (App. 57-58, Dkts. 45, 46.) Dr. Ge filed her Rule 59(e) motion on November 29, 2012, within 28 days of entry of judgment. (App. 58, Dkt. 47.) It is unclear what the court of appeals meant by "late" in describing this motion.

(3) Expert testimony of Dr. Joel W. Hay, a pharmaceutical economist, calculating the amount of government money spent on prescriptions and medical care because of Takeda's alleged misconduct.

(App. 58-59, Dkt. 48.) These affidavits and expert testimony were specifically gathered to cure the deficiencies identified by the district court's dismissal order.

Shortly after Dr. Ge filed her motion, the district court denied Dr. Ge's motion without explanation by entering an electronic docket entry that stated "ELECTRONIC ORDER entered DENYING 47 Motion for Reconsideration and DENYING 47 Motion to Amend." (App. 60.) No document was attached to the district court's order. No explanation was provided for why the district court was denying Dr. Ge's motion. No finding of undue delay, bad faith, dilatory motive, repeated failures to cure through amendment, or futility of amendment was made.

II. THE COURT OF APPEALS' DECISION

The court of appeals affirmed "the district court on its Rule 9(b) and denial of amendment rulings[.]"[14]

[14] Dr. Ge is not petitioning for review of the court of appeals' Rule 9(b) ruling, even though this is an issue of great importance and implicates conflicting rulings by the courts of appeals. Regardless of which 9(b) standard applies, Dr. Ge's proposed amended complaints were sufficient. And, since Dr. Ge's proposed amended complaints were never considered by the

(Continued on following page)

(App. 5.) Regarding the district court's refusal to allow amendment (or give any explanation why amendment would not be permitted), the court of appeals applied different standards in reviewing Dr. Ge's first request to amend, which was made in opposition to Takeda's motion to dismiss, and Dr. Ge's second request to amend, which was made following the district court's dismissal. (App. 23-28.)

Regarding Dr. Ge's first request, the court of appeals stated that "[w]hen a motion to amend is properly made before entry of judgment, the district court is to evaluate that motion under the 'liberal standard of Fed. R. Civ. P. 15(a).'" (App. 24-25.) However, the court of appeals found that Dr. Ge's first request to amend "was not properly made" because it consisted of "boilerplate" language and did not include the components of a formal motion to amend. (App. 25-26). *But see, e.g.*, *Rost*, 507 F.3d at 733-34. Accordingly, the district court was free to disregard Dr. Ge's first request without explanation because, according to the court of appeals, no "real" request was made.

Regarding Dr. Ge's second request, the court of appeals held that "the liberal leave to amend language

---

district court or court of appeals, the relevant error of law centers on the refusal, without explanation, to allow any post-ruling amendment, even though requests to amend were made and even though neither the district court nor court of appeals held that amendment was futile.

of Rule 15(b)[15] does not apply" to requests to amend made "after judgment[.]" (App. 27.) According to the court of appeals, therefore, the district court's refusal to provide any justification for denying Dr. Ge's second request was not an abuse of discretion since the "freely given" standard of Rule 15 did not apply. (App. 27.) Instead, since the request to amend was brought after judgment, the court of appeals held that Dr. Ge would only have been entitled to file an amended complaint if she could meet the stringent requirements of Rule 59 and present "newly acquired evidence" or a "manifest error of law[.]" (App. 25, 27.) The court of appeals then explained that the evidence presented with Dr. Ge's motion to amend the complaint was not "newly acquired" because, even though no discovery had been performed and the case involved contested issues of law under Rule 9(b), "Dr. Ge could have sought the testimony of an expert witness and/or subject drug users much earlier." (App. 27.) Similarly, the court of appeals held that Dr. Ge could not "plausibly identify some 'manifest error of law' committed by the district court." (App. 27.) Therefore, according to the court of appeals, the district court's unjustified denial of Dr. Ge's post-judgment motion to amend was not an abuse of discretion, even though no discretion was exercised.

---

[15] The court of appeals probably meant Rule 15(a)(1)(B), which contains the liberal amendment language, not Rule 15(b), which involves amendments during and after trial.

Absent from the court of appeals' decision, much like the district court's order, was any finding that amendment would be futile. This is not surprising. Dr. Ge's proposed amended complaints, which were attached to her motion to amend, provided detailed allegations of specific claims rendered false because of Takeda's alleged fraud, including eight affidavits from actual patients and statistical evidence from a renowned pharmaceutical economist. To date, these proposed amended complaints have never been considered by the district court or the court of appeals, nor has any court determined that Dr. Ge would not be able to cure the deficiencies identified by the district court. More importantly, there is no evidence that there was undue "delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed,[16] undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc." – the only permissible reasons a request to amend should be denied. *Foman*, 371 U.S. at 182.

[16] The court of appeals alluded, but did not directly state, that Dr. Ge made repeated failures to cure deficiencies in prior amendments. (App. 27.) This is simply not true. None of the amendments that Dr. Ge made prior to Takeda's only motion to dismiss were via leave of court. They were done as a matter of right, before any responsive pleading or motion to dismiss was filed. The first pleading that suggested Dr. Ge's complaints were defective was Takeda's motion to dismiss.

REASONS FOR GRANTING THE PETITION

This case raises an issue that sharply divides the courts of appeals, i.e., whether the liberal amendment standard embodied in Rule 15(a), and espoused in *Foman*, should be applied to a post-judgment motion to amend a complaint. While the issue, itself, is technical in nature, its impact on the rights of litigants is very real. Rule 15 represents "one of the basic policies of the federal rules – that pleadings are not an end in themselves but are only a means to assist in the presentation of a case to enable it to be decided on the merits." 6 C. Wright, A. Miller & M. Kane, *Federal Practice and Procedure,* § 1473 (3d ed. 2010). In an age where pleadings standards are more rigid than ever, *see Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), Rule 15 operates as a safety valve, allowing for flexibility in pleading practice and ensuring that cases are resolved on the merits, not technicalities. *Foman*, 371 U.S. at 181-82. Application of the liberal amendment standard of Rule 15 is, therefore, an issue that materially affects every litigant. And, when that standard varies from circuit to circuit, it undermines the integrity of the federal court system.

The issue raised in this petition is simple, even though it has broad implications: Does the liberal amendment standard of Rule 15(a)(2), as espoused in *Foman*, apply to a timely motion to amend the complaint brought after judgment has been entered? In the decision below, the court of appeals departed from a plurality of sister circuits and held that a

post-judgment motion to amend does not invoke Rule 15's liberal amendment policy. (App. 27.) In so doing, the court of appeals deepened an existing conflict among the circuits concerning whether Rule 15 should govern a post-judgment request to amend. It also, arguably, directly undermines the reasoning of *Foman*, where this Court held that the draconian application of the rules must yield to a policy favoring decisions on the merits, i.e., leave to amend should be freely given.

Since this case contains a clean record, where there is no apparent or expressed reason to deny leave to amend other than a refusal by the lower courts to apply Rule 15's liberal amendment policy, and since the underlying proposed amended complaints clearly corrected the pleading defects raised by the district court, this case provides an excellent vehicle for reviewing the issue.

I. THE DECISION BELOW DEEPENS ENTRENCHED CIRCUIT CONFLICTS OVER WHETHER A LITIGANT IS ENTITLED TO THE LIBERAL AMENDMENT STANDARD OF RULE 15(a) IN A POST-JUDGMENT MOTION TO AMEND

In the decision below, the court of appeals held that a district court need not apply the liberal amendment standard of Rule 15(a) to a motion to amend made after judgment has already been entered. (App. 27.) The court of appeals reasoned that since "a district court cannot allow an amended

pleading where a final judgment has been rendered unless that judgment is first set aside or vacated pursuant to Fed. R. Civ. P. 59 or 60" the liberal amendment standard of Rule 15 is subsumed by the more stringent standard applicable to Rules 59 and 60. (App. 25, 27 (quoting *Maldonado v. Dominguez,* 137 F.3d 1, 11 (1st Cir. 1998)).) Under Rules 59 and 60, a judgment will only be set aside when there is newly acquired evidence or a manifest error of law. (App. 27.) Therefore, a post-judgment motion to amend will only be allowed when the proposed amendment is based on newly acquired evidence or a manifest error of law. (App. 27.)

The court of appeals then concluded that a district court does not abuse its discretion for refusing to explain why it denied a post-judgment motion to amend since, regardless of whether amendment could cure the purported deficiencies in the complaint, the district court is not bound by the liberal amendment standard of Rule 15(a). (App. 27.) In other words, Rule 15(a)'s liberal amendment standard is only applicable to pre-judgment motions to amend. (App. 27.)

This ruling leads to troubling results. When a district court dismisses a complaint and enters judgment simultaneously, as the district court did in this case, the only period where a litigant could have invoked the liberal amendment standard of Rule 15(a) would have been before a ruling on the motion to dismiss. This means, as a practical matter, a plaintiff will need to simultaneously oppose a motion

to dismiss and, separately, seek leave of the court to amend the complaint, or else lose any opportunity to invoke the liberal amendment standard of Rule 15(a).[17] Furthermore, litigants will not be able to consider the district court's guidance in amending the complaint since once the court rules on the motion to dismiss and enters judgment, the ability to amend the complaint is foreclosed. This is particularly problematic when the parties are fighting over a contested issue of law, such as the pleading requirements of an FCA claim. *See, e.g., Pruell v. Caritas Christi*, 678 F.3d 10, 15 (1st Cir. 2012) ("Nevertheless, we think the motion to amend should be allowed. The precedents on pleading specificity are in a period of transition, and precise rules will always be elusive because of the great range and variations in causes of action, fact-patterns and attendant circumstances."); *see also* John T. Boese & Douglas W. Baruch, *By Denying Certiorari in Duxbury and Hopper, Supreme Court Maintains the Circuit Split Status Quo on Important Original Source and Rule 9(b) Questions*, 2 Fin. Fraud Law Report 649 (2010) (explaining how the issue of FCA pleading requirements under Rule 9(b) are in dispute).

---

[17] It is difficult to imagine how an opposition to a motion to dismiss would look where, in one section, the plaintiff argues that the operative complaint pleads a plausible cause of action and then, in another section, concedes that the operative complaint is deficient and proposes how amendment would cure those deficiencies. The court of appeals would require litigants to "plead with forked tongue."

A. The Court of Appeals' Decision Conflicts with the Standard Applied in the Third, Fourth, Fifth, Sixth, and Tenth Circuits

The court of appeals' ruling, which accords similar rulings by the Seventh and Eleventh Circuits, *see First Nat. Bank of Louisville*, 933 F.2d at 468 (7th Cir.); *Atkins*, 470 F.3d at 1361 n.20 (11th Cir.), is in direct conflict with the Third, Fourth, Fifth, Sixth, and Tenth Circuits. *See Cureton*, 252 F.3d at 272 (3d Cir.); *Matrix*, 576 F.3d at 193 (4th Cir.); *Rosenzweig*, 332 F.3d at 864 (quoting *Dussouy v. Gulf Coast Inv. Corp.*, 660 F.2d 594, 597 n.1 (5th Cir. 1981)); *Morse*, 290 F.3d at 799 (6th Cir.); *Glenn*, 868 F.2d at 371 (10th Cir.).

The Third, Fourth, Fifth, Sixth, and Tenth Circuits hold that when a motion to amend is brought post-judgment pursuant to Rule 59 and 15, "[a] conclusion that the district court abused its discretion in denying a motion to amend . . . is sufficient grounds on which to reverse the district court's denial of a Rule 59(e) motion." *Laber*, 438 F.3d at 428; *accord Cureton*, 252 F.3d at 272 ("Where a timely motion to amend judgment is filed under Rule 59(e), the Rule 15 and 59 inquiries turn on the same factors."); *Morse*, 290 F.3d at 799 (same, quoting *Cureton*); *Rosenzweig*, 332 F.3d at 864 ("Thus the disposition of the plaintiff's motion to vacate under rule 59(e) should be governed by the same considerations controlling the exercise of discretion under rule 15(a)."); *Glenn*, 868 F.2d at 371 ("After a motion to dismiss has

been granted, plaintiffs must first reopen the case pursuant to a motion under Rule 59(e) or Rule 60(b). . . . In that event, in accordance with Rule 15, 'leave shall be freely given when justice so requires.'" (quoting *Foman*, 371 U.S. at 181-82)). This holding is predicated on *Foman* and "the federal policy in favor of resolving cases on their merits instead of disposing of them on technicalities." *Laber,* 438 F.3d at 426. Thus, in these circuits, a "request to amend should only be denied if one of three facts is present: 'the amendment would be prejudicial to the opposing party, there has been bad faith on the part of the moving party, or amendment would be futile.'" *Mayfield v. Nat'l Ass'n for Stock Car Auto Racing, Inc.*, 674 F.3d 369, 379 (4th Cir. 2012) (quoting *Matrix*, 576 F.3d at 193). Thus, a district court's refusal or failure to make "determinations about prejudice, bad faith, or futility with respect to" a post-judgment motion to amend "constitute[s] an abuse of discretion." *Matrix*, 576 F.3d at 193 (citing *Foman,* 371 U.S. at 182). *Cf. Cureton*, 252 F.3d at 274 (affirming district court's denial of post-judgment request to amend because "[t]he court carefully analyzed plaintiffs' proffered reasons for delay, the prejudice to the NCAA, and the substance of the amended complaint.").

B. The Court of Appeals' Decision Conflicts with the Standard Applied in the Second and Eighth Circuits

The court of appeals' decision is also in conflict with the Second Circuit. *See Williams*, 659 F.3d at

212 (2d Cir.); *Roop*, 559 F.3d at 822 (8th Cir.). Although the Second Circuit does not consider a post-judgment motion for leave to amend to be completely governed by Rule 15(a), it also does not reject its application in the post-judgment setting. In *Williams*, the district court denied a post-judgment motion to amend pursuant to Rules 59 and 15 because the plaintiff did "not explain why she should be granted leave to replead at this stage when she failed to request an opportunity to replead in the first instance." 659 F.3d at 212-13. On appeal, the Second Circuit examined whether Rule 15's liberal amendment standard applies to a post-judgment motion to amend. *Id.* at 212-14. The court took note that there were two competing interests at stake – the interest of finality attendant to the entry of judgment and the interest of having a case resolved on the merits. *Id.* at 213.

After surveying Second Circuit case law, the court concluded that "postjudgment motions for leave to replead must be evaluated with due regard to both the value of finality and the policies embodied in Rule 15." *Id.* With this consideration in mind, the court turned to the district court's denial of the plaintiff's post-judgment motion to amend and concluded that the district court's reason for denying the plaintiff's motion was improper. *Id.* The Second Circuit explained:

> [T]he district court applied a standard that cannot be reconciled with the Supreme Court's holding in *Foman*. The district court

> apparently believed that a motion for leave to replead is not timely unless made "in the first instance." The court did not explain precisely what it meant by "in the first instance." In the circumstances of this case, however, it can only have meant one of two things: that the plaintiff was under obligation to seek leave to replead either immediately upon answering the motion to dismiss the complaint (without yet knowing whether the court will grant the motion, or, if so, on what ground), or immediately upon receipt of the court's ruling granting the motion and prior to the entry of judgment thereupon. Regardless which of the two the court had in mind, *Foman* makes unmistakably clear there is no such rule. The plaintiff in *Foman* did not seek leave to replead either together with her response to the motion to dismiss, or indeed prior to the district court's entry of judgment. The motion was made postjudgment. Nonetheless, the Supreme Court, identifying "undue delay" as an appropriate reason that might be given for denial of such a motion, ruled that the district court abused its discretion and violated the liberal spirit of Rule 15 by denying the motion. ***The Foman holding cannot be reconciled with the proposition that the liberal spirit of Rule 15 necessarily dissolves as soon as final judgment is entered.***

Id. (emphasis added). Thus, although the Second Circuit does not conflate Rule 15(a)'s liberal amendment standard with a post-judgment request to

amend, like the Third, Fourth, Fifth, Sixth, and Tenth Circuits, it does not completely reject the application of Rule 15(a) like the court of appeals did in this case. This is yet another example of how the courts of appeals are divided on this issue.

The court of appeals' decision below is also in conflict with the Eighth Circuit. *See Roop*, 559 F.3d at 823-24. In *Roop*, the Eighth Circuit confronted the same issue presented in this petition, and posed its own question:

> [W]hen a complaint is dismissed for failure to state a claim, and plaintiff files a post-judgment motion for leave to file an amended complaint, is that motion reviewed under the liberal "freely give" standard of Rule 15(a)(2), or under the more restrictive standards applicable to post-judgment motions under Rules 59(e) and 60(b)?

Id. at 823. Similar to the Second Circuit in *Williams*, the Eighth Circuit began its evaluation by comparing the interests of finality against the liberal amendment policy espoused in *Foman*. *Id.* The court noted that it found "two circuits that have addressed this question" and they came out on different sides. *Id.* The court then reviewed Eighth Circuit case law, and stated that:

> From this survey of prior case law, we conclude that district courts in this circuit have considerable discretion to deny a post-judgment motion for leave to amend because such motions are disfavored, ***but may not***

> ***ignore the Rule 15(a)(2) considerations that favor affording parties an opportunity to test their claims on the merits, particularly when a fraud complaint has been dismissed for failure to comply with the pleading requirements of Rule 9(b).***

Id. at 824 (emphasis added). Thus, much like the Second Circuit in *Williams*, the Eighth Circuit's interpretation of Rule 15 in a post-judgment context conflicts with the court of appeals' decision in this case because the Eighth Circuit refuses to completely disregard Rule 15(a)'s liberal amendment considerations.

C. The Court of Appeals' Decision Conflicts with the Reasoning Espoused in *Foman v. Davis*

In many ways, this case sits squarely in the shadow of *Foman*. The basic facts are the same: A Massachusetts district court grants a motion to dismiss and enters judgment for the defendant. The plaintiff files a post-judgment motion for leave to file an amended complaint. The district court denies the motion without explanation. On appeal to the First Circuit, the court refuses to apply the liberal amendment standard embodied in Rule 15(a), and affirms the summary dismissal. *See Foman v. Davis*, 292 F.2d 85, 87 (1st Cir. 1961). The only real difference between *Foman* and this case is that in the fifty years since *Foman*, courts of appeals have chipped away at

Foman's central holding, and found ways to substitute rigorous evaluation on the merits with rigid application of the rules.

In the decision below, the First Circuit held that "[t]here was also no abuse in denying Dr. Ge's second request. It came after judgment, when the liberal leave to amend language of Rule 15[(a)] does not apply." (App. 27.) To support this proposition, the court of appeals cites *Foman*. This is inexplicable. In *Foman*, this Court applied the liberal pleading standard of Rule 15(a) to a request made *post-judgment*. 371 U.S. at 181-82. It does not stand for the proposition that Rule 15 cannot be applied to a post-judgment request to amend. In fact, it holds the *exact opposite*. *Id.*; *see Williams*, 659 F.3d at 213 ("The *Foman* holding cannot be reconciled with the proposition that the liberal spirit of Rule 15 necessarily dissolves as soon as final judgment is entered."). This leads to yet another reason why this Court should grant this petition: the court of appeals' decision conflicts with this Court's holding in *Foman*.

In her opposition to Takeda's motion to dismiss, Dr. Ge requested leave to file an amended complaint should the district court grant Takeda's motion. (App. 66.) In the district court's order dismissing Dr. Ge's complaints, the district court did not provide any indication about whether Dr. Ge would be afforded an opportunity to amend.

Subsequently, Dr. Ge filed a motion for reconsideration under Rule 59(e) and requested, again, the

opportunity to amend the complaints. (App. 62-64.) In her motion, Dr. Ge explained why she should be afforded an opportunity to amend the complaints and supplied affidavits and expert testimony to support her proposed changes. (App. 62-64.) The district court, however, summarily denied Dr. Ge's request and provided no explanation. (App. 60.) Under *Foman*, this is reversible error because "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." 371 U.S. at 182.

D. Review by the Court Is the Only Practical Way to Resolve These Conflicts

Whether litigants are allowed to have their cases resolved on the merits may depend entirely on where the suit is filed. Indeed, had Dr. Ge filed her lawsuit in the Third, Fourth, Fifth, Sixth, or Tenth Circuits (and probably the Second, Eighth, and Ninth Circuits[18]), her proposed amended complaints would have

---

[18] Indeed, in the Ninth Circuit, before judgment would have been entered, the district court would have been required to evaluate whether it would be possible to cure the complaints' deficiencies with amendment. *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000). As the Ninth Circuit held in a *qui tam* case against another pharmaceutical company:

> Although we agree that [relator] did not comply with Rule 9(b), we hold that the district court erred in denying him leave to amend. A district court's

(Continued on following page)

been allowed and the merits of her claims considered. Instead, Dr. Ge filed her complaints in the First Circuit under what appeared at the time to be a more liberal amendment standard under *Rost*, where she was given *one* chance to plead a proper FCA claim at the outset, without the district court's guidance, or else see her claims dismissed with prejudice.[19] The application of a federal statute should not turn on the happenstance of geography. The conflict regarding this issue will not resolve itself. And, as explained below, the issue is too important to remain unreviewed by this Court.

> discretion to deny leave to amend a complaint is not absolute. We consistently have held that leave to amend should be granted unless the district court 'determines that the pleading could not possibly be cured by the allegation of other facts.' *Lopez,* 203 F.3d at 1127 (internal quotation marks and citations omitted).

United States ex rel. Lee v. SmithKline Beecham, Inc., 245 F.3d 1048, 1052 (9th Cir. 2001); *see also Firestone v. Firestone*, 76 F.3d 1205, 1209 (D.C. Cir. 1996) ("Failure to plead fraud with particularity likewise does not support a dismissal with prejudice. To the contrary, leave to amend is 'almost always allowed to cure deficiencies in pleading fraud.' ") (quoting *Luce v. Edelstein,* 802 F.2d 49, 56 (2d Cir. 1986)).

[19] This case stands in stark contrast with *United States ex rel. Conrad v. Abbott Labs., Inc.*, CIV.A. 02-11738-RWZ (D. Mass.), which also involved a *qui tam* action against a pharmaceutical company. In *Conrad*, the relator was allowed to file nine different amended complaints over eleven years before the district court finally dismissed the case. *See Conrad*, 02-11738-RWZ (D. Mass.) at Dkt. 195.

II. THIS ISSUE CONCERNS AN IMPORTANT AND RECURRING QUESTION OF FEDERAL LAW THAT IMPACTS NEARLY ALL LITIGATION

The issue presented in this petition implicates the basic right of every litigant to have their claims resolved on the merits. It speaks to both the importance of pleading requirements, in general, and the fundamental policy that cases be decided on their merits, not technicalities. "Pleadings are intended to serve as a means of arriving at fair and just settlements of controversies between litigants. They should not raise barriers which prevent the achievement of that end. . . . Proper pleading is important, but its importance consists in its effectiveness as a means to accomplish the end of a just judgment." *Maty v. Grasselli Chem. Co.*, 303 U.S. 197, 200-01 (1938). Resolution of the issue presented in this petition will allow for a uniform application of the rules and ensure that the due process available in a district court in Los Angeles resembles the due process available in the same court in Boston. *Wright v. N. Carolina*, 415 U.S. 936, 94 (1974) (Douglas, J., dissenting) ("Because of the present conflict, the extent of one's federal constitutional rights varies according to the State or Circuit in which the question is presented. I would grant *certiorari* in order to resolve the issue and provide uniformity.").

Furthermore, the importance of Rule 15, and the ability of a litigant to amend a pleading post judgment, is even more important in light of the Court's

decision in *Iqbal*, 556 U.S. at 678-80. The Court has ushered in a new standard for fact pleading in federal court, requiring plausibility over possibility in pleading causes of action. As the standard for pleading a cause of action becomes more demanding, the opportunity to correct deficiencies post judgment should become more forgiving. To hold otherwise undermines the spirit of the Federal Rules of Civil Procedure, and will only result in abrogation of a litigant's right to have their case decided on the merits.

The importance of the issue presented in this petition is highlighted by the frequency with which it recurs. For example, in the last three months, at least seven district courts[20] and one circuit court[21] have been asked to evaluate a post-judgment motion to amend in the context of Rules 15, 59, and 60. In each case, the court applied the standard applicable to their circuit. Moreover, the numerous appellate decisions on all sides of the conflict, and the numerous district

---

[20] *See Deleston v. United States*, CIV. 14-558 RHK/SER, 2014 WL 1272551, at *2 (D. Minn. Mar. 27, 2014); *C.H. v. Asheville City Bd. of Educ.*, 1:12-CV-000377-MR, 2014 WL 1092290, at *2-5 (W.D.N.C. Mar. 18, 2014); *Bolden v. McCabe, Weisberg & Conway, LLC*, CIV.A. DKC 13-1265, 2014 WL 994066, at *1-2 (D. Md. Mar. 13, 2014); *Graves v. One W. Bank, FSB*, CIV.A. DKC 13-3343, 2014 WL 994366, at *1-2 (D. Md. Mar. 13, 2014); *DeVaul v. TK Mining Servs. L.L.C.*, No. 13-CV-02632-PAB-KMT, 2014 WL 585347, at *2-3 (D. Colo. Feb. 14, 2014); *Haynes v. City of Chicago*, 12 C 2980, 2014 WL 274107, at *1-2 (N.D. Ill. Jan. 24, 2014).

[21] *Kuyat v. BioMimetic Therapeutics, Inc.*, ___ F.3d ___, 13-5602, 2014 WL 1259607, at *8-9 (6th Cir. Mar. 28, 2014).

court decisions confronting the issue, attest to its significance. This issue is important and divisive. Review is warranted.

III. THE DECISION BELOW PROVIDES AN APPROPRIATE VEHICLE FOR REVIEW

At base, this petition asks the Court to draw a bright line regarding the application of Rule 15(a) to post-judgment motions to amend. Specifically, when a litigant timely files a motion to amend a complaint after the entry of judgment and can show (1) there would be no prejudice, (2) it is not being done in bad faith, and (3) amendment would not be futile, leave must be "freely given" as provided in Rule 15(a). This is the rule applied in the Third, Fourth, Fifth, Sixth, and Tenth Circuits. *E.g., Mayfield*, 674 F.3d at 379. It is not the rule the First Circuit applied in this case.

This case presents an excellent vehicle for resolving this circuit conflict. *First*, this case has an undeveloped record. The complaints were in the early stages of litigation when the district court entered judgment, so there had been no discovery or prior rulings by the district court. Thus, there is no indication that Takeda would suffer any prejudice should Dr. Ge be permitted to file amended complaints. *O'Donnell v. Robert Half Int'l, Inc.*, 429 F. Supp. 2d 246, 251 (D. Mass. 2006) ("This litigation remains in the early stages and is not nearly ready for trial. Thus, amendment of the complaint by the plaintiffs will not prejudice the defendants.").

Second, the underlying record demonstrates that Dr. Ge would have been able to cure the deficiencies identified by the district court with an amended complaint. There is no indication that amendment would be futile. The district court outlined why Dr. Ge's complaints failed to plead with sufficient particularity and Dr. Ge met those requirements in her proposed amended complaints. This fact is supported by a conspicuous lack of any finding of futility by the district court and court of appeals.

Third, should the Court grant review, and reverse the court of appeals' decision below, this case would be remanded to the district court where Dr. Ge would be allowed to raise several of the arguments regarding her theory of liability that the court of appeals deemed waived. (*See* App. 18-23.) This would provide Dr. Ge with an opportunity to have the merits of her claims addressed, one way or the other, instead of being stuck in a procedural quagmire.

Fourth, and most importantly, resolution of the issue presented in this case does not turn on the specific facts of Dr. Ge's claims. Rather, the issue presented in this petition is a pure question of law – one that was applied (or rather not applied) by the court of appeals. If, as Dr. Ge contends, the court adopts the bright-line rule proposed – that leave to amend must be granted post judgment if a litigant can show there is no prejudice, bad faith, or futility – then Dr. Ge will be entitled to remand since the court of appeals and district court applied the incorrect standard.

Accordingly, the Court should grant review and resolve whether the liberal amendment standard of Rule 15(a) applies to motions to amend filed post judgment.

CONCLUSION

The petition for writ of certiorari should be granted.

Dated: April 10, 2014

Respectfully submitted,

MICHAEL L. BAUM
Counsel of Record
R. BRENT WISNER
BAUM HEDLUND ARISTEI
& GOLDMAN, P.C.
12100 Wilshire Blvd., Suite 950
Los Angeles, California 90025
Telephone: (310) 207-3233
Facsimile: (310) 207-4204
MBaum@baumhedlundlaw.com

MICHAEL SULLIVAN
THE ASHCROFT GROUP
1 Post Office Square, Suite 3750
Boston, Massachusetts 02109
Telephone: (617) 573-9400
Facsimile: (617) 573-9400
MSullivan@ashcroftlawfirm.com

Counsel for Petitioner

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 INDIANA; STATE OF MICHIGAN; 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.

No. 13-1089

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 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.

APPEALS FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

[Hon. F. Dennis Saylor IV, *U.S. District Judge*]

App. 3

Before

Lynch, *Chief Judge*,
Stahl and Howard, *Circuit Judges*.

Michael Sullivan, with whom The Ashcroft Group, Michael L. Baum, Bijan Esfandiari, R. Brent Wisner, and Baum, Hedlund, Aristei & Goldman, P.C. were on brief, for appellant.

Brian J. Murray, with whom Morgan R. Hirst, Marron A. Mahoney, Christopher M. Morrison, Joseph B. Sconyers, and Jones Day were on brief, for appellees.

Melissa N. Patterson, Attorney, Appellate Staff, Civil Division, with whom Stuart F. Delery, Acting Assistant Attorney General, Carmen M. Ortiz, United States Attorney, and Michael S. Rabb, Attorney, Appellate Staff, Civil Division, were on brief, for the United States of America as Amicus Curiae.

December 6, 2013

LYNCH, *Chief Judge*. In June 2010 Dr. Helen Ge originally filed these two qui tam actions against her former employer, Takeda Pharmaceutical Company Ltd. and its subsidiary Takeda Pharmaceutical North America, Inc. (collectively, "Takeda"), under the federal False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.,* and various analogous state statutes. The two actions concern different drugs. She has since

amended each of her complaints twice. The United States has declined to enter the case as a party. In a successful qui tam action, the relator collects a portion of the award to the government regardless of whether the government intervenes. *See United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.* ("*Duxbury I*"), 579 F.3d 13, 16 (1st Cir. 2009).

Dr. Ge has alleged in her second amended complaints that Takeda had failed to disclose adequately the risks associated with four of its drugs and generally that this failure resulted in the submission of false claims by various third-party patients and physicians for government payment through, for example, Medicare or Medicaid reimbursement.

On Takeda's motions to dismiss, the district court dismissed both of Dr. Ge's actions under Federal Rule of Civil Procedure 9(b) for failure to plead fraud with particularity and, in addition, under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. *United States ex rel. Ge v. Takeda Pharm. Co. Ltd.,* Nos. 10-11043-FDS, 11-10343-FDS, 2012 WL 5398564 (D. Mass. Nov. 1, 2012). Dr. Ge proposed to amend the second amended complaint yet again, asserting still more theories of FCA liability. The district court declined to allow further amendment.

Dr. Ge now appeals, making three levels of arguments: (1) as to the Rule 9(b) dismissal, that her complaints contain sufficient allegations concerning "the who, what, where, and when" of Takeda's misconduct to satisfy Rule 9(b)'s particularity requirement, *see Duxbury I,* 579 F.3d at 30 (quoting *Rodi v.*

S. New Eng. Sch. of Law, 389 F.3d 5, 15 (1st Cir. 2004)) (internal quotation mark omitted), (2) the district court abused its discretion in rejecting without opinion two requests, one pre-judgment and one post-judgment, by Dr. Ge to amend her complaints again, and (3) as to Rule 12(b)(6), that the district court's analysis relies on an overly restrictive conception of FCA liability.

This opinion concerns the first two arguments. We affirm the district court on its Rule 9(b) and denial of amendment rulings, and do not reach the 12(b)(6) issue.

I.

In September 2008, Dr. Ge took a position with Takeda as a contract physician, contracting to perform medical reviews of adverse event reports. Dr. Ge was responsible for reports of adverse events, including those concerning four specific drugs for specific diseases: Actos (type 2 diabetes), Uloric (gout), Kapidex/Dexilant (gastroesophageal reflux disease), and Prevacid (same). Takeda sells all four drugs and each required Food and Drug Administration ("FDA") approval for these uses. Dr. Ge's tasks included ascertaining the seriousness of a reported event, determining whether the associated drug was causally responsible for that event, and determining whether that event constituted a "safety signal," that is whether the reported event signaled the need for additional safety warnings. Dr. Ge worked for Takeda until January 2010. She asserts that when she

complained about improper reporting at Takeda, her contract was summarily terminated.

On June 18, 2010, Dr. Ge filed an FCA complaint under seal against Takeda pertaining to Actos. *United States ex rel. Helen Ge v. Takeda Pharmaceutical Co., et al,* 10-11043-FDS. On March 1, 2011, Dr. Ge filed a second complaint under seal pertaining to Uloric, Kapidex/Dexilant, and Prevacid. *United States ex rel. Helen Ge v. Takeda Pharmaceutical Co., et al,* 11-10343-FDS. In Dr. Ge's complaints, she alleged on behalf of the United States[1] that three FCA sections were violated: (a) 31 U.S.C. § 3729(a)(1)(A), which imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," (b) § 3729(a)(1)(B), which 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," and (c) § 3729(a)(1)(C), which imposes liability on any person who conspires to commit a violation of, among other things, § 3729(a)(1)(A) or § 3729(a)(1)(B).

[1] Dr. Ge's complaints also brought claims on behalf of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, 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, alleging violations by Takeda of similar state statutes. Michigan is only a party to the Actos appeal.

In late 2011 and early 2012, Dr. Ge filed amended complaints in both cases while both complaints were still under seal. Between late March and early April 2012, Dr. Ge filed a second set of amended complaints after the complaints were unsealed. Dr. Ge's second amended complaints are the ones directly at issue on appeal.

Dr. Ge alleged Takeda had failed to report promptly and accurately to the FDA a number of post-approval adverse events associated with the four subject drugs. The FDA is responsible for the approval of drugs for commercial marketing. *See* 21 U.S.C. § 355. The FDA is authorized after approval to continue to evaluate the safety and effectiveness of the drug and, where appropriate, to withdraw approval or require a change in labeling. *See id.* § 355(k). FDA regulations require prompt, accurate reports of adverse drug events by drug manufacturers. 21 C.F.R. §§ 314.80, 314.81. The receipt of an adverse report does not in and of itself show a causal relationship between a drug and the illness mentioned in a report. *N.J. Carpenters Pension & Annuity Funds v. Biogen Idec, Inc.,* 537 F.3d 35, 53 (1st Cir. 2008).

It is undisputed that Takeda did submit adverse event reports and there is no specific allegation that any of the events which are the subject of the complaint were not eventually reported in some form to the FDA. As to the drug Actos, Dr. Ge alleged that she was asked by Takeda to *misreport* adverse events including incidences of heart failure, renal failure, pancreatic cancer, and, most notably, bladder cancer.

Dr. Ge alleged that she complied with those directions on certain occasions after having made known her objections. In addition, Dr. Ge alleged that she had discovered *systematic under-reporting* by Takeda of the incidence of bladder cancer in adverse event reports.

The FDA did receive information on bladder cancer risk because in June 2011, 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." *FDA Drug Safety Communication: Update to ongoing safety review of Actos (pioglitazone) and increased risk of bladder cancer* (June 15, 2011), http://www.fda.gov/Drugs/Drug Safety/ucm259150.htm. The FDA also mandated a label change. *FDA Drug Safety Communication: Updated drug labels for pioglitazone-containing medicines* (Aug. 4, 2011), http://www.fda.gov/drugs/drugsafety/ucm266555.htm. But it also issued a supplemental approval of Actos after knowing of the bladder cancer risk. Dr. Ge alleges that after the labeling change the sales of Actos plummeted.

As to the drugs Uloric, Kapidex/Dexilant, and Prevacid, Dr. Ge alleged that Takeda pressured her to falsify her medical conclusions, asking her to classify events as "non-serious" or to change her causality assessment to "unrelated" so as to avoid "reporting within 15 days" as required by FDA regulation. *See* 21 C.F.R. § 314.80(c)(1)(i) (requiring report of "serious and unexpected" adverse event within 15 days).

Specifically, Dr. Ge alleged that she was directed to alter her analysis of reported adverse events involving the interactions between the three drugs and other medications likely to be taken by senior citizens. Dr. Ge did not clearly allege that she complied with Takeda's directions. Dr. Ge did allege, however, that on various occasions Takeda officials altered her assessments directly.

As to Uloric, at some point Takeda submitted a Supplemental New Drug Application to update the Adverse Reactions section of the Uloric label. The FDA approved this supplemental application on January 28, 2011.[2]

As to all four drugs Dr. Ge asserts that Takeda should have reported adverse events earlier, and that Takeda consistently took actions to resist label changes through under-reporting.

On May 11, 2012, Takeda filed its motion to dismiss. Dr. Ge filed a memorandum in opposition on July 17, 2012. At the end of her memorandum but not as a separate motion, Dr. Ge requested leave to amend her complaints a third time, if the court was inclined to dismiss, and supported it with a declaration from one of her attorneys that included an attachment providing the total expenditures by the

[2] At times Dr. Ge's complaint appears to be directed against the FDA for its failure to require greater warnings on labels, such as for Prevacid.

federal government for Actos. On August 27, 2012, Takeda filed a motion to strike that declaration.

On November 1, 2012, the district court dismissed in a written order Dr. Ge's claims under Rule 9(b), reasoning that "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." *Takeda,* 2012 WL 5398564, at *4. The district court noted that Dr. Ge had attempted to cure this defect by referring to her attorney's declaration, which attached the total aggregate expenditure data by the government for Actos. *Id.* The district court held, however, that even assuming it was permissible for the court to consider the Actos data, such aggregate expenditure data did not satisfy Rule 9(b)'s particularity requirement. *Id.* The district court contrasted Dr. Ge's pleadings with the pleadings of the relator in *Duxbury I*, which identified eight specific medical providers who allegedly submitted false claims, the rough time periods, locations, and amounts of the claims, and the specific government programs to which the claims were made. *Takeda,* 2012 WL 5398564, at *4 (citing *Duxbury I,* 579 F.3d at 29-30).

From the absence of such specifics in Dr. Ge's complaints, the district court inferred that Dr. Ge meant to assert that *all* claims for the subject drugs during the relevant time period were rendered false by Takeda's alleged misconduct. *Id.* at *5. The district

court held that Dr. Ge had not provided the specific factual allegations necessary to support the inference that the FDA would have withdrawn approval from all four drugs immediately upon receiving the withheld information. *Id.; see also* 21 C.F.R. §§ 314.80(j), 314.81(d) ("If an applicant fails to establish and maintain records and make reports required under this section, FDA *may* withdraw approval of the application and, thus, prohibit continued marketing of the drug product that is the subject of the application.") (emphasis added). The district court went beyond that to point out that even were it to accept the unsubstantiated premise that drugs would have been taken off the market, there were still no allegations about how the fraudulent reporting would render false those claims which were filed before the adverse events occurred.

In the same November 1, 2012 order, the district court also dismissed Dr. Ge's claims under Rule 12(b)(6) for failure to state a claim, holding that Dr. Ge had not adequately established that compliance with adverse-event reporting requirements was a "material precondition" to the payment of the claims at issue. *Takeda,* 2012 WL 5398564, at *6; *see also United States ex rel. Hutcheson v. Blackstone Med., Inc.,* 647 F.3d 377, 392 (1st Cir. 2011) (holding that FCA liability exists where claims submitted "misrepresented compliance with a precondition of payment so as to be false or fraudulent" and where "those misrepresentations were material"). The district court observed that it is within the FDA's discretion

to respond to violations of adverse-event reporting requirements in a number of ways, only the harshest of which is the withdrawal of drug approval. *Takeda,* 2012 WL 5398564, at *6. The district court noted in addition that the FDA's enforcement procedures provide the opportunity for citizens to petition the FDA to bring action against specific violators. *Id.* (citing 21 C.F.R. § 10.30). The district court reasoned that "[i]t 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." *Id.*

Finally, the district court dismissed in that same order Dr. Ge's various state-law claims both because they failed to state a claim under state law and because they failed to plead with specificity the details of any claims for payment made to any of the states. *Id.* The district court did not address Dr. Ge's request for leave to amend. Judgment was entered for defendants on November 1, 2012.

On November 29, 2012, Dr. Ge filed a formal motion for reconsideration pursuant to Rule 59(e) along with a motion for leave to amend her complaint. Dr. Ge's motions were supported by (a) an economic model constructed by a pharmaceutical economics professor from the School of Pharmacy at the University of Southern California purporting to show the amount of claims for Actos that would not have been submitted for government payment but for Takeda's alleged misconduct, and (b) the declarations of eight individuals attesting that an individual

patient would not have submitted his or her claim if Takeda had promptly and accurately disclosed the link between Actos and bladder cancer. On December 18, 2012, the district court denied Dr. Ge's motions without opinion. On January 14, 2013, Dr. Ge filed a timely notice of appeal.[3]

II.

We review de novo the district court's dismissal order for failure to comply with Rule 9(b). *United States ex rel. Gagne v. City of Worcester,* 565 F.3d 40, 45 (1st Cir. 2009). Rule 9(b) provides: "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b).

---

[3] Appearing as amicus curiae in support of neither party, the United States makes a limited argument that the district court erred in its Rule 12(b)(6) analysis to the extent that it reasoned (1) the availability of alternative administrative remedies precludes FCA liability, and (2) the failure to comply with FDA post-approval reporting requirements is per se immaterial to the Government's decision whether to reimburse a claim and hence could under no circumstances serve as a basis for FCA liability. According to the United States, failure to comply with FDA post-approval reporting requirements could serve as a basis for FCA liability only in "rare circumstances." It was objecting only to a per se approach. The United States takes no position as to whether Dr. Ge's complaints contain sufficient allegations to state a claim for purposes of Rule 12(b)(6). Nor does the United States take a position as to whether Dr. Ge's pleadings satisfy the particularity requirement of Rule 9(b).

The district court correctly cited the relevant pleading requirements: Relators are required to set forth with particularity the "'who, what, when, where, and how' of the alleged fraud." *United States ex. rel Walsh v. Eastman Kodak Co.,* 98 F. Supp. 2d 141, 147 (D. Mass. 2000) (quoting *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.,* 125 F.3d 899, 903 (5th Cir. 1997)); *see also Arruda v. Sears, Roebuck & Co.,* 310 F.3d 13, 18-19 (1st Cir. 2002).

As we noted a few months ago in *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.* ("*Duxbury II*"), 719 F.3d 31, 33 (1st Cir. 2013):

> "Although [the FCA's] financial incentive encourages would-be relators to expose fraud," *United States ex rel. Poteet v. Bahler Med., Inc.,* 619 F.3d 104, 107 (1st Cir. 2010), it also attracts "'parasitic' relators who bring FCA damages claims based on information within the public domain or that the relator did not otherwise discover," *United States ex rel. Rost v. Pfizer, Inc.,* 507 F.3d 720, 727 (1st Cir. 2007).

For those reasons, there are a number of limitations on qui tam actions, including the particularity requirements of Rule 9(b).

As we explained in *United States ex rel. Karvelas v. Melrose-Wakefield Hospital,* 360 F.3d 220 (1st Cir. 2004):

> [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 those 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 a 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 232-33 (quoting *United States ex rel. Clausen v. Lab. Corp. of Am.,* 290 F.3d 1301, 1312 n.21 (11th Cir. 2002)). *Karvelas* also rejects the notion that the Rule 9(b) pleading standard is relaxed for FCA claims. *See id.* at 228-31.

In a qui tam action in which the defendant is alleged to have induced third parties to file false claims with the government, a relator can satisfy this requirement by "providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility' without necessarily providing details as to

each false claim." *Duxbury I,* 579 F.3d at 29 (quoting *Rost,* 507 F.3d at 733).

Because FCA liability attaches only to false *claims, Karvelas,* 360 F.3d at 225, merely alleging facts related to a defendant's alleged *misconduct* is not enough, *Rost,* 507 F.3d at 732-33. Rather, a complaint based on § 3729(a)(1)(A) must "sufficiently establish that false claims were submitted for government payment" as a result of the defendant's alleged misconduct. *Rost,* 507 F.3d at 733.

We will assume that the district court was correct that, as to the allegations of fraud on the FDA, the alleged misconduct suffices. Dr. Ge has, however, alleged next to no facts in support of the proposition that Takeda's alleged misconduct resulted in the submission of false claims or false statements material to false claims for government payment. Dr. Ge alleges a conclusion that numerous claims for the four subject drugs would not have been submitted for government payment but for Takeda's misconduct, but alleges no more than that. What is missing are any supporting allegations upon which her conclusion rests and any particulars. Dr. Ge's pleadings fall far short of what was found barely adequate in *Duxbury I, see* 579 F.3d at 29-30, and are far less particular than those there whose sufficiency was deemed a "close call," *id.* at 30.

There, this court reversed the district court's dismissal under Rule 9(b) of some of the relator's claims, reasoning that the relator's identification of

eight specific medical providers who allegedly submitted false claims, plus rough time periods, locations, and amounts of the claims, and the specific government programs to which the claims were made, were just enough to constitute a pleading of fraud with particularity. *Id.* at 30.[4] Here, by contrast, Dr. Ge provided in response to the motions to dismiss, at most, aggregate expenditure data for one of the four subject drugs, with no effort to identify specific entities who submitted claims or government program payers, much less times, amounts, and circumstances.

Dr. Ge thus made no attempt in her complaints to allege facts that would show that some *subset* of claims for government payment for the four subject drugs was rendered false as a result of Takeda's alleged misconduct. And any theory that all claims submitted during this period were false has even less basis to survive. Dr. Ge attempts to satisfy the Rule 9(b) requirements with a per se rule that if sufficient allegations of misconduct are made, it necessarily follows that false claims and/or material false information were filed. We reject that approach, which violates the specificity requirements of Rule 9(b).

---

[4] After discovery, those very claims were dismissed on summary judgment as unsupported. *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.,* No. 03-12189-RWZ, 2012 WL 3292870 (D. Mass. Aug. 13, 2012), *aff'd,* 719 F.3d 31 (1st Cir. 2013).

On appeal, Dr. Ge articulates three new theories purporting to support the notion that all claims submitted during the relevant period for the four subject drugs must have been rendered false by Takeda's alleged misconduct; and that allegations of falsity would per se suffice to constitute compliance with Rule 9(b). All three theories are waived, however, not having been raised properly before the district court.

We do not rule on whether, had they not been waived, any of these theories under any subsection would have added the needed specificity under Rule 9(b), and merely say it is doubtful.[5] *See Clausen,* 290 F.3d at 1311 (commenting that Rule 9(b) does not permit an FCA plaintiff "merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the [g]overnment"); *see also United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.,* 707 F.3d 451,

[5] We recognize that, under *Allison Engine Co. v. United States ex rel. Sanders,* 553 U.S. 662 (2008), as construed in *Gagne,* 565 F.3d at 46 & n.7, the "presentment" requirement applies only to her subsection (a)(1)(A) claims and not her subsection (a)(1)(B) or subsection (a)(1)(C) claims. However, Rule 9(b)'s particularity requirement applies with full force to all three subsections. *See Gagne,* 565 F.3d at 42, 45. Here, Dr. Ge has not alleged in her second amended complaints, with specificity, facts that comply with Rule 9(b) as to any of her claims. In any event, as discussed infra, her new theories of FCA liability were waived.

457 (4th Cir. 2013) ("[We] hold that when a defendant's actions, as alleged and as reasonably inferred from the allegations, *could* have led, but *need not necessarily* have led, to the submission of false claims, a relator must allege with particularity that specific false claims *actually were presented* to the government for payment." (emphasis added)); *United States ex rel. Atkins v. McInteer,* 470 F.3d 1350, 1359 (11th Cir. 2006) ("[Relator] has described in detail what he believes is an elaborate scheme for defrauding the government by submitting false claims. . . . [Relator] fails to provide the next link in the FCA liability chain: showing that the defendants *actually submitted* reimbursement claims for the services he describes.").

A. Implied Warranty

Dr. Ge's first additional theory of per se ineligibility for federal reimbursement of all claims for the four drugs rests on the assertion that the subject drugs were not "as safe as Takeda purported them to be." Dr. Ge contends that through labels and participation in the adverse event reporting process, Takeda represented to all patients, doctors, and the government that the subject drugs possessed certain risks and benefits. Dr. Ge alleges, however, that the subject drugs "did not possess the safety profile Takeda claimed they would." And from this Dr. Ge infers that she has adequately stated that all claims submitted to the government for those drugs were false.

Dr. Ge's first theory is waived, having been raised only in "cursory fashion" before the district court. *See Rodríguez v. Municipality of San Juan,* 659 F.3d 168, 175 (1st Cir. 2011) ("It should go without saying that we deem waived claims not made or claims adverted to in a cursory fashion, unaccompanied by developed argument."). Dr. Ge asserted to the district court only that Takeda's alleged fraudulent conduct led to the submission of claims that would not have otherwise occurred, without providing any specificity, and alleging nothing more. But that is inadequate; courts should not be asked to guess the contents of a theory of liability. "[I]ssues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived." *United States v. Zannino,* 895 F.2d 1, 17 (1st Cir. 1990).

Dr. Ge did offer a bit more argumentation in her Rule 59(e) motion for reconsideration. That was too late. "To the extent that appellants' reconsideration motion sought to raise an argument waived at the trial stage, it must necessarily fail." *DiMarco-Zappa v. Cabanillas,* 238 F.3d 25, 34 (1st Cir. 2001).

B. "Reasonable and Necessary"

Dr. Ge on appeal invokes 42 U.S.C. § 1395y(a)(1)(A), which prohibits Medicare payments for treatments that are not "reasonable and necessary."[6] According to

[6] Various state statutes and regulations governing Medicaid reimbursement impose similar restrictions. *See, e.g.,* 130 Mass.

(Continued on following page)

Ge, as a result of Takeda's alleged misconduct, certain reimbursement claims were rendered false under the FCA because they impliedly – and incorrectly – certified that the subject drugs were "reasonable and necessary."

No such theory was properly presented to the district court before dismissal. Dr. Ge concedes that she did not cite or discuss 42 U.S.C. § 1395y(a)(1)(A) before the district court in her memorandum in opposition to Takeda's motions to dismiss. Dr. Ge did provide a bare citation of § 1395y(a)(1)(A) in her second amended complaints. However, Dr. Ge did not allege in those complaints *that* Takeda's alleged misconduct rendered claims for the four subject drugs "[un]reasonable" or "[un]necessary." Nor did she make any effort to explain *why* that would be so. *See Pan v. Gonzales,* 489 F.3d 80, 87 (1st Cir. 2007) ("We long have held that legal theories advanced in skeletal form, unaccompanied by some developed argumentation, are deemed abandoned.").

C. "Misbranded"

On appeal Dr. Ge newly argues that false claims must have been submitted to the government for the four drugs on the theory that Takeda's failure to properly update the subject drugs' labels caused those

---

Code Regs. 450.204 ("The MassHealth agency will not pay a provider for services that are not *medically necessary*. . . .") (emphasis added).

drugs to be "misbranded" for purposes of the federal Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 352(a), and so they were ineligible to enter interstate commerce, *id.* § 331(a). Consequently, she now says they were ineligible for reimbursement. At best, there was a gesture to Dr. Ge's "misbranding" theory before the trial court, and it is waived.

Dr. Ge rejoins that she did adequately raise a "misbranding" argument before the district court. Her second amended complaints alleged that Takeda failed to update the label for Actos to accurately reflect the drug's risks, as required by the FDCA. However, as to ineligibility, Dr. Ge's complaints state only: "[The FDCA] forbids 'misbranding' and provides a range of civil and criminal enforcement mechanisms against inaccurate product labeling." Dr. Ge made no mention of ineligibility for interstate commerce, let alone of ineligibility for reimbursement on that basis. At most, a footnote in her memorandum opposing dismissal referred to misbranding but nothing more. The argument was waived. *See City of Bangor v. Citizens Commc'ns Co.,* 532 F.3d 70, 95 n.11 (1st Cir. 2008) (deeming waived argument "presented only in a passing fashion in a footnote"). The mention of misbranding in Dr. Ge's Rule 59(e) motion was too little, too late. *See Cochran v. Quest Software, Inc.,* 328 F.3d 1, 11 (1st Cir. 2003) ("Litigation is not a game of hopscotch. It is generally accepted that a party may not, on a motion for reconsideration, advance a new argument that could (and should)

have been presented prior to the district court's original ruling.").

To sum up: Dr. Ge waived all of her new arguments to the effect that the four subject drugs were per se ineligible for government reimbursement during the relevant period on these varying theories. Dr. Ge's claims on all theories which were presented fail under Rule 9(b).

III.

This court reviews the district court's denial of an appellant's motion to amend and for reconsideration for abuse of discretion. *Fábrica de Muebles J.J. Álvarez, Incorporado v. Inversiones Mendoza, Inc.,* 682 F.3d 26, 31 (1st Cir. 2012); *Torres-Alamo v. Puerto Rico,* 502 F.3d 20, 25 (1st Cir. 2007).

Dr. Ge argues that she could have cured any defects in her complaints had she been provided with leave to amend the two times she asked. She had already twice amended both of her complaints in the 21 months after the filing of her initial complaint. The first request, after Takeda filed its motion to dismiss in 2012, was in her memorandum in opposition to Takeda's motion to dismiss and conditionally did state that if the court was inclined to dismiss,

then she would like to amend.[7] The district court did not explicitly discuss the request, but did discuss the additional appended material on Actos and said it did not cure the deficiencies in the pleading.

The second of her requests came in the form of a motion to amend, filed post-judgment on November 29, 2012 in conjunction with her motion for reconsideration under Rule 59(e) of the judgment of dismissal. The district court dismissed this late motion without opinion in its December 18, 2012 order.

When a motion to amend is *properly* made before entry of judgment, the district court is to evaluate that motion under the "liberal standard of Fed. R. Civ. P. 15(a)." *Palmer v. Champion Mortg.,* 465 F.3d 24, 30 (1st Cir. 2006). "Amendments may be permitted pre-judgment, even after a dismissal for failure to state a claim, and leave to amend is 'freely given

---

[7] There, Dr. Ge's conditional request to amend consisted just of two sentences:

> If the Court were to determine that Relator's Complaints are deficient in any regard, Relator respectfully requests that this Court afford her an opportunity to amend her complaint. 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 v. Hyatt Hotels of P.R.,* 357 F.3d 152, 154 (1st Cir. 2004); *Rost,* 507 F.3d at 733-34 (same); *see also Foman v. Davis,* 371 U.S. 178, 182 (1962) (leave to amend should be "freely given").

when justice so requires.'" *Id.* (quoting Fed. R. Civ. P. 15(a)). The "request" was not properly made.

By contrast, as to post-judgment motions "a district court cannot allow an amended pleading where a final judgment has been rendered unless that judgment is first set aside or vacated pursuant to Fed. R. Civ. P. 59 or 60." *Maldonado v. Dominguez,* 137 F.3d 1, 11 (1st Cir. 1998). "The granting of a motion for reconsideration is 'an extraordinary remedy which should be used sparingly.'" *Palmer,* 465 F.3d at 30 (quoting 11 Charles Alan Wright et al., *Federal Practice and Procedure* § 2810.1 (2d ed. 1995)). The moving party "must 'either clearly establish a manifest error of law or must present newly discovered evidence.'" *Marie v. Allied Home Mortg. Corp.,* 402 F.3d 1, 7 n.2 (1st Cir. 2005) (quoting *Pomerleau v. W. Springfield Pub. Schs.,* 362 F.3d 143, 146 n.2 (1st Cir. 2004)). A motion for reconsideration "certainly does not allow a party to introduce new evidence or advance arguments that could and should have been presented to the district court prior to the judgment." *Aybar v. Crispin-Reyes,* 118 F.3d 10, 16 (1st Cir. 1997) (quoting *Moro v. Shell Oil Co.,* 91 F.3d 872, 876 (7th Cir. 1996)).

Dr. Ge relies on *Foman v. Davis,* 371 U.S. 178 (1962), which stated:

> Of course, the 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.

Id. at 182. Dr. Ge contends that the district court's denials without a statement of reasons for her two requests amounted to just the sort of "outright refusal . . . without any justifying reason" that *Foman* proscribes.

As explained in *Silverstrand Investments v. AMAG Pharmaceuticals, Inc.,* 707 F.3d 95, 107-08 (1st Cir. 2013), where, as here, a request to file an amended complaint consists of nothing more than "boilerplate sentences stating the well-settled 'freely given' standard under which a request for leave to amend is generally analyzed," a district court "act[s] well within its discretion when completely disregarding the request."[8] Indeed, in *Gray v. Evercore Restructuring LLC,* 544 F.3d 320 (1st Cir. 2008), a case involving a nearly identical request, this court explained that except perhaps in "exceptional circumstances," a bare request in an opposition to a motion to dismiss *does not constitute* a motion to amend for purposes of Rule 15(a). *Id.* at 327 ("Although a court's denial of a

[8] Dr. Ge argues that *Silverstrand* is inapposite because her post-dismissal request for leave to amend consisted of several pages of argument and was accompanied by two proposed amended complaints and statistical and anecdotal evidence of the effects of Takeda's alleged misconduct. Dr. Ge's second request is neither here nor there with respect to whether the district court's rejection of her *first,* "boilerplate" request amounted to an abuse of discretion.

motion to amend is typically reviewed for an abuse of discretion, in this case the district court neither granted nor denied a motion to amend. . . . As [plaintiff] failed to request leave to amend, the district court cannot be faulted for failing to grant such leave *sua sponte*."); *accord Fisher v. Kadant, Inc.,* 589 F.3d 505, 509-10 (1st Cir. 2009). And even at that, *Foman* identifies "repeated failure to cure deficiencies by amendments previously allowed" as reason for denying a motion for leave to amend under the permissive Rule 15(a) standard. 371 U.S. at 182.

There was also no abuse in denying Dr. Ge's second request. It came after judgment, when the liberal leave to amend language of Rule 15(b) does not apply. *Id.* In order to grant Dr. Ge's second request, the district court would have had first to set aside its judgment pursuant to Dr. Ge's motion to reconsider under Rule 59(e). It did not and did not abuse its discretion.

Her argument, in any event, has no legs. Dr. Ge could hardly contend that the so-called "newly discovered evidence" accompanying her second request was "not previously available." *Palmer,* 465 F.3d at 30. Dr. Ge could have sought the testimony of an expert witness and/or subject drug users much earlier. Nor could Dr. Ge plausibly identify some "manifest error of law" committed by the district court. *Id.*

The district court's dismissal order identified the evidentiary defects in Dr. Ge's complaints after Dr. Ge had twice amended her complaints and after having

considered arguendo Dr. Ge's contested declaration and accompanying expenditure data. As this court has stated previously:

> To require the district court to permit amendment here would allow plaintiffs to pursue a case to judgment and then, if they lose, to reopen the case by amending their complaint to take account of the court's decision. Such a practice would dramatically undermine the ordinary rules governing the finality of judicial decisions, and should not be sanctioned in the absence of compelling circumstances.

James v. Watt, 716 F.2d 71, 78 (1st Cir. 1983) (Breyer, J.). So too, here.

IV.

We *affirm* the district court's orders dismissing relator Dr. Ge's claims and denying leave to amend her second amended complaints. Costs are awarded to Takeda.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

MEMORANDUM AND ORDER ON MOTIONS TO DISMISS

(Filed Nov. 1, 2012)

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 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

[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.

reflect this. (Uloric Compl. ¶ 3). Furthermore, Takeda avoided properly reporting to the FDA serious adverse events caused by these interactions. (Uloric Compl. ¶ 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 Compl. ¶¶ 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,

---

[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.

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 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. ParkeDavis,* 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 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

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

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

[4] S*ee, 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

(Continued on following page)

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

---

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.").

United States Court of Appeals

For the First Circuit

No. 13-1088

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

Plaintiff-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 PHARMACEUTICA [sic] NORTH AMERICA, INC.

Defendants-Appellees

No. 13-1089

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

Plaintiff-Appellant

STATE OF CALIFORNIA; STATE OF DELAWARE; STATE OF FLORIDA; STATE OF GEORGIA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF LOUISIANA; 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 PHARMACEUTICA [sic] NORTH AMERICA, INC.

Defendants-Appellees

Before

Lynch, *Chief Judge,*
Torruella, Stahl, Howard,
Thompson and Kayatta,
Circuit Judges.

ORDER OF COURT
Entered: January 10, 2014

The petition for rehearing having been denied by the panel of judges who decided the case, and the petition for rehearing en banc having been submitted to the active judges of this court and a majority of the judges not having voted that the case be heard en banc, it is ordered that the petition for rehearing and the petition for rehearing en banc be *denied*.

By the Court:

/s/ Margaret Carter, Clerk

RELEVANT STATUTORY PROVISIONS AND RULES

1. The False Claims Act, 31 U.S.C. § 3729 *et seq.,* provides in relevant part:

§ 3729. False claims

(a) Liability for certain acts. –

(1) In general. – Subject to paragraph (2), any person who –

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

* * *

is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-4101), plus 3 times the amount of damages which the Government sustains because of the act of that person.

* * *

RULE 15. AMENDED AND SUPPLEMENTAL PLEADINGS

(a) AMENDMENTS BEFORE TRIAL.

(1) *Amending as a Matter of Course.* A party may amend its pleading once as a matter of course within:

(A) 21 days after serving it, or

(B) if the pleading is one to which a responsive pleading is required, 21 days after service of a responsive pleading or 21 days after service of a motion under Rule 12(b), (e), or (f), whichever is earlier.

(2) *Other Amendments.* In all other cases, a party may amend its pleading only with the opposing party's written consent or the court's leave. The court should freely give leave when justice so requires.

(3) *Time to Respond.* Unless the court orders otherwise, any required response to an amended pleading must be made within the time remaining to respond to the original pleading or within 14 days after service of the amended pleading, whichever is later.

United States District Court
District of Massachusetts (Boston)
CIVIL DOCKET FOR CASE #: 1:10-cv-11043-FDS

* * *

Date Filed	#	Docket Text
06/18/2010		ELECTRONIC NOTICE of Case Assignment. Judge Patti B. Saris assigned to case. If the trial Judge issues an Order of Reference of any matter in this case to a Magistrate Judge, the matter will be transmitted to Magistrate Judge Marianne B. Bowler. (Hurley, Virginia) (Entered: 06/18/2010)
06/18/2010	1	COMPLAINT against Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceutical Company Limited, filed by United States of America. (Attachments: # 1 Part 2, # 2 Part 3, # 3 Part 4, # 4 Civil Cover Sheet)(Patch, Christine) (Entered: 06/22/2010)
06/18/2010	2	MOTION to Seal Case by United States of America. (Patch, Christine) (Entered: 06/22/2010)
06/21/2010		Filing fee/payment: $ 350.00, receipt number BST 017965 for 1 Complaint (Patch, Christine) (Entered: 06/22/2010)
06/23/2010		Judge Patti B. Saris: ELECTRONIC ORDER entered granting 2 Motion to Seal Case (Patch, Christine) (Entered: 06/24/2010)

06/30/2010	3	MOTION for Leave to Appear Pro Hac Vice for admission of Michael L. Baum, Ronald L.M. Goldman, Bijan Esfandiari, and A. Ilyas Akbari by Helen Ge, MD. (Attachments: # 1 Affidavit Michael L. Baum, # 2 Affidavit Ronal [sic] L.M. Goldman, # 3 Affidavit Bijan Esfandiari, # 4 Affidavit Ilyas Akbari)(Patch, Christine) (Entered: 07/01/2010)
07/01/2010		Payment: $ 200.00, receipt number BST018111 for 3 MOTION for Leave to Appear Pro Hac Vice for admission of Michael L. Baum, Ronald L.M. Goldman, Bijan Esfandiari, and A. Ilyas Akbari (Patch, Christine) (Entered: 07/01/2010)
07/01/2010		Judge Patti B. Saris: ELECTRONIC ORDER entered granting 3 Motion for Leave to Appear Pro Hac Vice Added Michael L. Baum, Ronald L.M. Goldman, Bijan Esfandiari, and A. Ilyas Akbari. **Attorneys admitted Pro Hac Vice must register for electronic filing. To register go to the Court website at www.mad.uscourts.gov. Select Case Information, then Electronic Filing (CM/ECF) and go to the CM/ECF Registration Form.** (Patch, Christine) (Entered: 07/01/2010)
08/17/2010	4	MOTION for Extension of Time to 8/18/11 to Consider Election to

		Intervene by United States of America. (Patch, Christine) (Entered: 08/18/2010)
08/17/2010	5	MEMORANDUM in Support re 4 MOTION for Extension of Time to 8/18/11 to Consider Election to Intervene filed by United States of America. (Patch, Christine) (Entered: 08/18/2010)
08/30/2010	6	Judge Patti B. Saris: ORDER entered granting 4 Motion for Extension of Time to Consider Election to Intervene. (Patch, Christine) (Entered: 08/31/2010)
10/18/2010	7	NOTICE of Filing by State of Montana (Patch, Christine) (Entered: 10/19/2010)
10/18/2010	8	NOTICE of Election to Decline Intervention at this Time, by State of Montana (Patch, Christine) (Entered: 10/19/2010)
10/29/2010	9	Judge Patti B. Saris: ORDER entered re 8 Notice of Election to Decline Intervention at this Time, filed by State of Montana (Patch, Christine) (Entered: 11/01/2010)
03/15/2011		ELECTRONIC NOTICE of Reassignment. Judge F. Dennis Saylor, IV added. Judge Patti B. Saris no longer assigned to case. (Abaid, Kimberly) (Entered: 03/15/2011)
08/23/2011	10	MOTION for Extension of Time for six months up to and including

		February 18, 2012 to intervene by United States of America. (Attachments: # 1 Text of Proposed Order)(Jones, Sherry) (Entered: 08/23/2011)
08/23/2011	11	MEMORANDUM in Support re 10 MOTION for Extension of Time to six months up to and including February 18, 2012 to intervene filed by United States of America. (Jones, Sherry) (Entered: 08/23/2011)
09/02/2011		Judge F. Dennis Saylor, IV: ELECTRONIC ORDER entered granting 10 Motion for Extension of Time to intervene. (Castles, Martin) (Entered: 09/02/2011)
09/30/2011	12	AMENDED COMPLAINT against All Defendants, filed by Commonwealth of Massachusetts, Commonwealth of Virginia, District of Columbia, Helen Ge, MD, State of California, State of Delaware, State of Florida, State of Georgia, State of Hawaii, State of Illinois, State of Indiana, State of Louisiana, State of Michigan, 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, United States of America. (Jones, Sherry)(DISK INCLUDED) Modified on 9/30/2011 (Jones, Sherry). (Main Document 12 replaced on 10/4/2011) (Jones, Sherry). (Entered: 09/30/2011)
02/22/2012	13	NOTICE of Election to Decline Intervention by United States of America. (Attachments: # 1 Text of Proposed Order)(Anderson, Jennifer) (Entered: 02/22/2012)
02/24/2012	14	Judge F. Dennis Saylor, IV: ORDER entered. re 13 Notice of Election to Decline Intervention filed by United States of America. (Jones, Sherry) (Entered: 02/24/2012)
02/29/2012	15	Summons Issued as to Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc .. **Counsel receiving this notice electronically should download this summons, complete one for each defendant and serve it in accordance with Fed.R.Civ.P. 4 and LR 4.1. Summons will be mailed to plaintiff(s) not receiving notice electronically for completion of service.** (Jones, Sherry) (Entered: 02/29/2012)
02/29/2012		Clerk shall regenerate electronic notices of Entries # 1 complaint, 12

		amended complaint, 13 notice of election to decline intervention, 14 Judge Saylor's Order. (Jones, Sherry) (Entered: 02/29/2012)
03/27/2012	16	AMENDED COMPLAINT against Defendants, filed by Helen Ge, MD. (Attachments: # 1 Supplement Assented to Filing of Second Amended Complaint)(Sullivan, Michael) Modified on 3/27/2012 (Jones, Sherry). (Entered: 03/27/2012)
03/28/2012		Notice of correction to docket made by Court staff. Correction: docket entry 16 is restricted because: the document was filed in wrong case. (Burgos, Sandra) (Entered: 03/28/2012)
04/05/2012	17	AMENDED COMPLAINT against All Defendants, filed by Helen Ge, MD. (Attachments: # 1 Supplement Assented to Filing of Second Amended Complaint)(Sullivan, Michael) (Entered: 04/05/2012)
		* * *
05/01/2012	24	MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM by Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc..(Morrison, Christopher) (Entered: 05/11/2012)
05/11/2012	25	MEMORANDUM in Support re 24 MOTION TO DISMISS FOR

		FAILURE TO STATE A CLAIM *(Jointly filed in 11-10343-FDS)* filed by Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc.. (Morrison, Christopher) (Entered: 05/11/2012)
05/11/2012	26	MOTION to Strike 17 Amended Complaint *(bladder cancer-related allegations set forth in paragraphs* 8 *and 98-114*) by Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc.. (Morrison, Christopher) (Entered: 05/11/2012)
05/11/2012	27	MEMORANDUM in Support re 26 MOTION to Strike 17 Amended Complaint *(bladder cancer-related allegations set forth in paragraphs 8 and 98-114*) filed by Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc.. (Morrison, Christopher) (Entered: 05/11/2012)
05/11/2012	28	DECLARATION re 27 Memorandum in Support of Motion, by Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc.. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Exhibit

		E, # 6 Exhibit F) (Morrison, Christopher) (Entered: 05/11/2012)
		* * *
07/17/2012	35	MEMORANDUM in Opposition re 24 MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM filed by Helen Ge, MD. (Attachments: # 1 Affidavit Declaration of Bijan Esfandiari, # 2 Exhibit 1, # 3 Exhibit 2, # 4 Exhibit 3, # 5 Exhibit 4, # 6 Exhibit 5, # 7 Exhibit 6, # 8 Exhibit 7, # 9 Exhibit 8, # 10 Exhibit 9, # 11 Exhibit 10, # 12 Exhibit 11, # 13 Exhibit 12, # 14 Exhibit 13, # 15 Exhibit 14, # 16 Exhibit 15, # 17 Exhibit 16, # 18 Exhibit 17)(Esfandiari, Bijan) (Main Document 35 replaced on 7/18/2012) (Burgos, Sandra). (Entered: 07/17/2012)
		* * *
07/17/2012	40	REPLY to Response to 24 MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM *AND* 26 *MOTION TO STRIKE* filed by Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc.. (Morrison, Christopher) (Entered: 08/27/2012)
		* * *
11/01/2012	45	Judge F. Dennis Saylor, IV: ORDER entered. MEMORANDUM AND ORDER. 24 MOTION TO DISMISS

		FOR FAILURE TO STATE A CLAIM is GRANTED. 26 MOTION to Strike Amended Complaint and 41 MOTION to Strike the Declaration of Bijan Esfandiari are terminated as MOOT. (Cicolini, Pietro) (Entered: 11/01/2012)
11/01/2012	46	Judge F. Dennis Saylor, IV: ORDER entered. ORDER DISMISSING CASE. (Cicolini, Pietro) (Entered: 11/01/2012)
11/29/2012	47	MOTION for Reconsideration re 46 Order Dismissing Case, 45 Memorandum & ORDER, MOTION to Amend 17 Amended Complaint (Responses due by 12/13/2012) by Helen Ge, MD.(Esfandiari, Bijan) (Entered: 11/29/2012)
11/29/2012	48	MEMORANDUM in Support re 47 MOTION for Reconsideration re 46 Order Dismissing Case, 45 Memorandum & ORDER, MOTION to Amend 17 Amended Complaint filed by Helen Ge, MD. (Attachments: # 1 Affidavit Declaration of Bijan Esfandiari, # 2 Exhibit A to Esfandiari Decl., # 3 Exhibit B to Esfandiari Decl., # 4 Affidavit of Joel W. Hay, PhD, # 5 Appendix A to Joel Hay Affid, # 6 Appendix B to Joel Hay Affid, # 7 Appendix C to Joel Hay Affid, # 8 Affidavit of Erma Kern, # 9 Affidavit of Karen Cole, # 10 Affidavit of Adelita Maestas,

		# 11 Affidavit of Robert Kehr, # 12 Affidavit of Alvin C. Gerard, # 13 Affidavit of Melvin Rosoff, # 14 Affidavit of David Mallow, # 15 Affidavit of Kenneth G. Johnson) (Esfandiari, Bijan) (Entered: 11/29/2012)
11/29/2012	49	Proposed Document(s) submitted by Helen Ge, MD. Document received: Proposed Third Amended False Claims Act Complaint. (Attachments: # 1 Exhibit 1 – to Proposed 3rd Amended Complaint, # 2 Exhibit 2 – to Proposed 3rd Amended Complaint) (Esfandiari, Bijan) (Entered: 11/29/2012)
12/13/2012	50	MEMORANDUM in Opposition re 47 MOTION for Reconsideration re 46 Order Dismissing Case, 45 Memorandum & ORDER, MOTION to Amend 17 Amended Complaint filed by Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc .. (Morrison, Christopher) (Entered: 12/13/2(12)
12/13/2012	51	AFFIDAVIT of Christopher M. Morrison in Opposition re 47 MOTION for Reconsideration re 46 Order Dismissing Case, 45 Memorandum & ORDER, MOTION to Amend 17 Amended Complaint filed by Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals

		North America, Inc.. (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibit 3, # 4 Exhibit 4, # 5 Exhibit 5, # 6 Exhibit 6)(Morrison, Christopher) (Entered: 12/13/2012)
12/18/2012	52	Judge F. Dennis Saylor, IV: ELECTRONIC ORDER entered DENYING 47 Motion for Reconsideration and DENYING 47 Motion to Amend (Cicolini, Pietro) (Entered: 12/18/2012)

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

United States Of America, et al. ex rel. Helen Ge, M.D. Plaintiffs And Relator, v. Takeda Pharmaceutical Company Limited, And Takeda Pharmaceuticals U.S.A., Inc., f/k/a Takeda Pharmaceuticals North America, Inc. Defendants	Civil Action No. 10-11043-FDS
United States Of America, et al. ex rel. Helen Ge, M.D. Plaintiffs And Relator, v. Takeda Pharmaceutical Company Limited, And Takeda Pharmaceuticals U.S.A., Inc., f/k/a Takeda Pharmaceuticals North America, Inc. Defendants	Civil Action No. 11-10343-FDS

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF RELATOR HELEN GE, M.D.'S MOTION FOR RECONSIDERATION OF THIS COURT'S NOVEMBER 1, 2012 ORDERS AND ALTERNATIVE MOTION FOR LEAVE TO FILE THE ACCOMPANYING PROPOSED THIRD AMENDED COMPLAINTS

(Filed Nov. 29, 2012)

* * *

IV. DR. GE SHOULD HAVE BEEN GRANTED AT LEAST ONE POST-RULING OPPORTUNITY TO AMEND HER COMPLAINT AND HEREBY MOVES FOR LEAVE TO AMEND

In her Opposition Brief, Dr. Ge specifically requested that, in the event the Court felt her complaint was deficient in any regard, she be allowed an opportunity to amend her complaint. See Docket No. 35, Opp. Br. at 36. The Court, however, never ruled on Dr. Ge's request for leave to amend and dismissed her claims. Dr. Ge respectfully re-asserts her request for leave to amend and asks that she be allowed to file the attached proposed Third Amended Complaint which cures the factual deficiencies the Court ruled were lacking in her previous complaint.

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 v. Hyatt Hotels of P.R.*, 357 F.3d 152, 154 (1st Cir.2004). Grounds for denial generally involve undue delay, bad faith, dilatory

motive of the requesting party, repeated failure to cure deficiencies, and futility of amendment. *Foman v. Davis,* 371 U.S. 178, 182 (1962). In this case, Dr. Ge has never been afforded any post-ruling opportunity to amend her complaint, she has not acted in bad faith, and has not engaged in any dilatory conduct. More importantly, as the attached proposed amended complaint confirms, her ability to amend the complaint will not be futile. Notably, in granting Takeda's motion to dismiss, the Court held that the complaint did not provide any sampling of specific claims similar to *Duxbury.* See Order at 8-9. Through the newly discovered evidence, Dr. Ge has cured these deficiencies by providing affidavits from eight patients who filled Actos prescriptions and which, as discussed *supra* at pages 6-7, provide all of the information the Court claimed was lacking. The information obtained from these eight patient declarations has now been alleged in the attached proposed amended complaint. Moreover, to lend further support to her allegations, Dr. Ge is also providing the expert declaration of Joel Hay, Ph.D. who has performed a statistical analysis of the monetary damages suffered by the government as a result of Takeda's fraud. The discovery and inclusion of these new facts and statistical analysis confirm that, if Dr. Ge is afforded leave to amend her complaint, it will not be futile.

Rost is instructive. In *Rost,* like the present case, the district court granted defendant's motion to dismiss and never addressed relator's request for leave to amend. The First Circuit reversed and held

that the relator should have been given a post-ruling opportunity to attempt to cure/amend his complaint. *Rost,* 507 F.3d at 733-34. The *Rost* court further held that the relator (who, like Dr. Ge, had made his request for leave to amend in his opposition brief) had not waived his rights to amend his complaint. *Rost,* 507 F.3d at 734; *see also Epstein v. C.R. Bard, Inc.,* 460 F.3d 183, 190-91 (1st Cir. 2006) (request for leave to amend made in opposition to motion to dismiss treated as motion to amend pursuant to Rule 15(a)); *Rodi v. S. New Eng. Sch. of Law,* 389 F.3d 5, 20 (1st Cir.2004) (request to amend contained in motion for reconsideration treated as Rule 15(a) motion).

In light of the aforementioned authority, if the Court does not grant her reconsideration motion, Dr. Ge respectfully requests that the Court grant her request for leave to amend and allow her to file the attached proposed Third Amended Complaint.

* * *

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

United States Of America, et al. ex rel. Helen Ge, M.D. Plaintiffs And Relator, v. Takeda Pharmaceutical Company Limited, And Takeda Pharmaceuticals U.S.A., Inc., f/k/a Takeda Pharmaceuticals North America, Inc. Defendants	Civil Action No. 10-11043-FDS **LEAVE TO FILE 40 PAGES GRANTED 7/16/12** **ORAL ARGUMENT REQUESTED**
United States Of America, et al. ex rel. Helen Ge, M.D. Plaintiffs And Relator, v. Takeda Pharmaceutical Company Limited, And Takeda Pharmaceuticals U.S.A., Inc., f/k/a Takeda Pharmaceuticals North America, Inc. Defendants	Civil Action No. 11-10343-FDS

RELATOR'S OPPOSITION TO DEFENDANTS' JOINT MOTION TO DISMISS RELATOR'S SECOND AMENDED QUI TAM COMPLAINTS

* * *

REQUEST FOR LEAVE TO AMEND

If the Court were to determine that Relator's Complaints are deficient in any regard, Relator respectfully requests that this Court afford her an opportunity to amend her complaint. 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 v. Hyatt Hotels of P.R.,* 357 F.3d 152, 154 (1st Cir.2004); *Rost,* 507 F.3d at 733-34 (same); *see also Foman v. Davis,* 371 U.S. 178, 182 (1962) (leave to amend should be "freely given").

* * *