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 PHARMACEUTICAL 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 PHARMACEUTICAL NORTH AMERICA, INC.

Defendants – Appellees.

BRIEF FOR DEFENDANTS-APPELLEES

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Appellees provide the following statement identifying any parent corporation and any publicly traded company owning 10 percent or more of their stock:

Takeda Pharmaceutical Company Limited, a Japanese corporation with its principal place of business in Japan, is publicly traded on the Tokyo Stock Exchange. Takeda Pharmaceutical Company Limited has no parent company and no publicly traded company owns 10 percent or more of its stock.

Takeda Pharmaceuticals U.S.A., Inc. (formerly known as Takeda Pharmaceuticals North America, Inc.), a Delaware corporation with its principal place of business in Illinois, is wholly owned by Takeda America Holdings, Inc., which is wholly owned by Takeda Pharmaceutical Company Limited.

/s/ Brian J. Murray
Brian J. Murray

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PRELIMINARY STATEMENT

Relator Helen Ge worked as an outside contractor for Takeda for a little over a year. She performed medical reviews of adverse event reports for four drugs: Actos®, Uloric®, Dexilant®, and Prevacid® (collectively the "subject drugs"). Ge apparently believes that Takeda should have reported certain adverse events for these drugs to the U.S. Food and Drug Administration ("FDA") differently than it did, and updated the warning labels for those drugs.

Adverse event reporting and labeling for drugs are governed by federal statutes and regulations, which FDA has the exclusive authority to enforce. Ge does not dispute that all (or nearly all; her complaints aren't entirely clear) of the supposed adverse events identified in her complaints were reported to FDA. Indeed, FDA reviewed these events, in some instances leading to new label warnings. Nor can Ge dispute that, notwithstanding these adverse event reports, all of these drugs are still FDA-approved and on the market today. Indeed, FDA issued its supplemental approval for Actos® over a year after Ge filed her first complaint in this case despite knowing of the bladder cancer adverse events underlying her FCA claims.

Ge tried to parlay her views of how Takeda should have reported adverse events and updated drug labels into multiple lawsuits, with the United States and twenty-five different states as plaintiffs. But she was never able to fit the square pegs of adverse event reporting and labeling into the round hole of the False Claims Act ("FCA"). Her theories evolved through three sets of complaints, then changed again in briefing on Takeda's motion to dismiss. But ultimately, none could sustain her FCA claims. The district court accordingly dismissed her complaints. Ge then sought reconsideration, attaching voluminous materials to her motion that she could and should have pled in her first three complaints. The court denied that motion as well.

On appeal, Ge has changed gears yet again, jettisoning the FCA theories she argued to the district court and arguing three new ones for the first time. The waiver problems with that tactic are plain. Besides, the new theories are no better than the old. The fundamental problem for Ge is that adverse event reporting and labeling for drugs are multiple steps removed from claims for government payment for those drugs. Indeed, the United States as *amicus* before this Court concedes that compliance with these FDA

regulations is not a precondition of payment under Medicare or Medicaid.[1] All Ge offers to bridge the gap is layer upon layer of unfounded speculation—if Takeda had acted differently, then FDA might have withdrawn approval for the drugs, and prescribing physicians might have changed their prescribing habits, which might (somehow) lead to fewer claims for the subject drugs being paid by the government. Accordingly, she cannot establish falsity of the claims, or materiality, both crucial elements of FCA claims.

Ge tellingly fails to cite a single authority imposing FCA liability in this way. And for good reason. FDA's enforcement powers are broad and exclusive; not even courts can second-guess FDA's refusal to institute enforcement actions under the Administrative Procedure Act. It would therefore be passing strange if a relator, like Ge, could impose massive liability on pharmaceutical companies like Takeda based on nothing more than her personal opinion—never endorsed by either FDA or any other authority—of Takeda's compliance with FDA regulations.

[1] In her Second Amended Complaints, Ge also asserted FCA claims based on reimbursement claims submitted to the TRICARE program, 10 U.S.C. § 1079 *et seq.*, but on appeal she focuses solely on the Medicare and Medicaid programs.

Indeed, to accept such a sweeping expansion of FCA liability would allow relators to effectively (and retroactively) nullify FDA approval of drugs, undermining both that agency's authority and the complex statutory and regulatory mechanisms in place to assure the continued development of safe and effective pharmaceutical products. There is nothing in the law or logic to recommend that result. The district court was correct to so conclude, and its judgment of dismissal should be affirmed.

STATEMENT OF THE ISSUES

1. Whether Ge waived (a) all of her three new liability theories by never presenting them—and in one case expressly disavowing it—before to the district court, and (b) any arguments related to her state law claims by never raising them in her opening brief;

2. Whether the district court correctly dismissed Ge's complaints (a) under Rule 12(b)(6) because they failed to allege that Takeda's accused actions resulted in false claims for reimbursement which misrepresented compliance with a material precondition of payment, and (b) under Rule 9(b) because they

failed to plead with particularity any facts related to the allegedly false reimbursement claims; and

3. Whether the district court properly rejected Ge's request for leave to amend her complaints a third time when that request was merely a boilerplate recitation of the legal standard, and any amendment would have been futile.

STATEMENT OF FACTS

A. The Legal Framework For Adverse Event Reporting, Labeling, and FDA Enforcement.

1. Adverse Event Reporting.

By Act of Congress, FDA is the exclusive expert agency charged with regulating prescription drugs. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973). FDA oversees the Federal Food, Drug, and Cosmetic Act ("FDCA"), and its implementing regulations, which together form a complex and comprehensive framework governing the development, approval, and ongoing review of pharmaceutical products. *See* 21 U.S.C. §§ 301 *et seq.*; 21 C.F.R. §§ 1.1 *et seq.*

Under this framework, a drug manufacturer may not market a new drug unless it has submitted a New Drug Application ("NDA")

to FDA and received the Agency's approval. 21 U.S.C. § 355(a). FDA "will approve an [NDA] after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling." 21 C.F.R. § 314.105(c),(d). This determination includes a "strict and demanding" review of the NDA, *Weinberger*, 412 U.S. at 619, and is based "on a comprehensive scientific evaluation of the product's risks and benefits." 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006). Or course, reviewing whether a particular drug complies with the statutory standard "demand[s] flexibility." 21 C.F.R. § 314.105(c). So FDA "is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards." *Id.*

After approval of a NDA, FDA remains responsible for monitoring the drug's safety and efficacy. Manufacturers must review and file post-marketing reports of "[a]dverse drug experience[s]" with the agency. 21 C.F.R. § 314.80. This requirement casts a broad net: reportable "adverse drug experiences" include "[*a*]*ny* adverse event associated with the use of a drug in humans, *whether or not* considered drug related[.]" 21

C.F.R. § 314.80(a) (emphasis added). Thus, the submission of an adverse event report does not establish either that an adverse event actually occurred or that the event was caused by a drug. *See, e.g.*, S. Rep. No. 109-324, at 6 (2006) ("The fact of a report of an adverse event is not determinative that the event occurred or that the event was caused by a consumer's use of the product."); *N.J. Carpenters Pension & Annuity Funds v. Biogen Idec Inc.*, 537 F.3d 35, 53 (1st Cir. 2008) ("[T]he receipt of an adverse report does not in and of itself show a causal relationship between a drug and the illness mentioned in the report." (quoting *In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d 36, 41 (2d Cir. 2000)); *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005) (recognizing adverse event reports offer "one of the least reliable sources to justify opinions about both general and individual causation").

Adverse event reports fall into two categories: "alert reports" and "periodic reports." 21 C.F.R. § 314.80(c)(1)(i), (c)(2). Alert reports are required only for those adverse events which are both "serious and unexpected"; they must be provided to FDA within 15 calendar days from the initial receipt of relevant information. 21 C.F.R. § 314.80(c)(1)(i). "Serious" adverse events include "[d]eath, a

life-threatening adverse drug experience,[2] inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect." 21 C.F.R. § 314.80(a). In addition, other "[i]mportant medical events" may fall within the "serious" event category "when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition." *Id.* "Unexpected" adverse events are "[a]ny adverse drug experience that is not listed in the current labeling for the drug product." *Id.*

All other previously known adverse events, including serious events already accounted for on a drug's label, are reported via periodic reports, submitted either quarterly or annually to FDA. 21 C.F.R. § 314.80(c)(2).

Both types of reports require the manufacturer to provide details regarding the reported adverse event. 21 C.F.R.

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[2] A "[l]ife-threatening adverse drug experience" is "[a]ny adverse drug experience that places the patient, in the view of the initial reporter, at immediate risk of death from the adverse drug experience as it occurred, i.e., it does not include an adverse drug experience that, had it occurred in a more severe form, might have caused death." 21 C.F.R. § 314.80(a).

§ 314.80(c)(1)(iii), (c)(2)(ii). In addition to these adverse reports, companies may also file regular reports of other field experiences and any information that "might affect the safety, effectiveness, or labeling of the drug." 21 C.F.R. § 314.81.

FDA also maintains its own safety monitoring database: the Sentinel System, "a national, integrated, electronic system for monitoring medical product safety." FDA, *The Sentinel Initiative: National Strategy for Monitoring Medical Product Safety* at 4 (2008).[3] The system expands the data available to FDA beyond adverse event reports to databases run by private health plans, insurers, and government agencies, thereby enhancing the agency's ability to observe and respond to potential safety issues. *See id.* at 4, 18-24. The system currently tracks drug safety events in nearly 100 million patients, covering over 2.9 billion prescriptions. FDA's "Mini-Sentinel" safety pilot program also "is up and running,

[3] *Available at* http://www.fda.gov/downloads/Safety/FDAsSentinelInitiative/UCM124701.pdf.

demonstrating rapid analysis of medical products safety questions."[4]

2. Drug Labeling.

FDA also regulates the labeling of prescription drugs. Under 21 C.F.R. § 201.57(c)(7), for example, the "adverse reactions" section of the label must "describe the overall adverse reaction profile of the drug based on the entire safety database." A labeled "adverse reaction," however, is narrower than an "adverse event" for reporting purposes: "This definition does not include all adverse events observed during the use of a drug." *Id.* Instead, the "adverse reactions" only include "those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event." *Id.* Similarly, 21 C.F.R. § 201.80(e) requires that a manufacturer revise its labels to "include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug."[5]

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[4] *Available at* http://www.fda.gov/downloads/Safety/FDAsSentinelInitiative/UCM268035.pdf; *see also* Mini-Sentinel, http://mini-sentinel.org (last visited Sept. 16, 2013).

[5] 21 C.F.R. § 201.80 applies to older drugs as defined in 21 C.F.R § 201.56(b)(1)-(2).

3. FDA Enforcement Authority.

The United States has the exclusive authority to enforce the FDCA. 21 U.S.C. § 337(a); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4, 352 (2001). FDA is exclusively authorized to investigate violations of the FDCA. 21 U.S.C. § 372. When it finds such violations, FDA is authorized to pursue a variety of sanctions, including withdrawing its approval of a drug, injunctive relief, civil monetary penalties for submission of false or misleading information, and criminal prosecution of the manufacturer. 21 U.S.C. §§ 332, 333(a), 333(f)(3)(A), 355(e); 21 C.F.R. § 314.80(j) ("If an applicant fails to establish and maintain records and make reports required under this section, FDA *may withdraw* approval of the application . . . .") (emphasis added). In short, FDA "has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Administration." *Buckman*, 531 U.S. at 349. As important, these enforcement provisions "commit complete discretion to the Secretary to decide how and when they should be exercised." *Heckler v. Chaney*, 470 U.S. 821, 835 (1985). Accordingly, the Agency's decision not to take enforcement action is not subject to judicial review under the

Administrative Procedure Act. *Id.*; *see Cmty. Nutrition Inst. v. Young*, 818 F.2d 943, 950 (D.C. Cir. 1987) (per curiam) ("FDA enjoys complete discretion not to employ the enforcement provisions of the FDC Act, and those decisions are not subject to judicial review."). And indeed, besides basic procedural protections and a limited right of federal court review for manufacturers, FDA's power here is essentially total. *See* 21 U.S.C. § 355(e)-(h); 21 C.F.R. § 314.200; *Weinberger*, 412 U.S. at 620.

B. The Subject Drugs And Relevant FDA Action.

The four subject drugs in this action—Actos®, Uloric®, Dexilant®, and Prevacid®—were all approved by FDA through the comprehensive NDA procedures.

Actos® is used to treat type 2 diabetes. (Actos® Compl.[6] ¶¶ 11-12.) Actos® first received FDA approval on July 15, 1999. (*Id.* ¶ 12; FDA, NDA Approval Letter (July 15, 1999).)[7] Just two years ago (one month before Ge filed her First Amended Complaint in the

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[6] "Actos® Complaint" refers to Ge's Second Amended Complaint in Case No. 10-cv-11043, which is included at Appendix 12-127.

[7] *Available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/99/021073A_Actos_appltr.pdf.

Actos® action), after Takeda had sufficient data to substantiate a request to amend the drug's label to warn for bladder cancer, Actos® received supplemental FDA approval on August 4, 2011, approving the manufacturer-amended label warnings for bladder cancer. FDA, Supplement Approvals (Aug. 4, 2011).[8]

Uloric® is used to treat gout and first received FDA approval on February 13, 2009. (Uloric® Compl.[9] ¶ 2; FDA, NDA Approval (Feb. 13, 2009).)[10] Almost three years ago, Uloric® received supplemental FDA approval on January 28, 2011. Again, when Takeda had sufficient data to justify the request, it submitted a Supplemental New Drug Application updating the Adverse Reactions section on the Uloric® label with additional post-

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[8] *Available at* http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/021073Orig1s043s044-021842Orig1s014s015-022024Orig1s008s007-021925Orig1s010s011ltr.pdf.

[9] "Uloric® Complaint" refers to Ge's Second Amended Complaint in Case No. 11-cv-10343, which is included at Appendix 128-250.

[10] *Available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2009/021856s000_Approv.pdf.

marketing safety information. FDA, Supplemental Approval: Fulfillment of Postmarketing Requirement (Jan. 28, 2011).[11]

Prevacid® and Dexilant® are proton pump inhibitors used to treat gastroesophageal reflux disease. (Uloric® Compl. ¶ 2.) Prevacid® first received FDA approval on May 10, 1995. *See* FDA, NDA Approval (May 10, 1995).[12] Dexilant® received FDA approval on January 30, 2009. *See* FDA, NDA 22-287 Approval (Jan. 30, 2009).[13]

None of the four subject drugs has ever had its FDA approval suspended or withdrawn.

C. The FCA And Ge's Evolving Theories Of Liability.

Any person who believes that a pharmaceutical company is violating the FDCA can petition FDA to bring action against the

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[11] *Available at* http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/021856s003ltr.pdf.

[12] *Available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/pre96/020406_s000_part1.pdf.

[13] *Available at* http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2009/022287s000ltr.pdf. At the time Dexilant® was approved it was sold under the name Kapidex®. To avoid naming confusion with other pharmaceuticals with similar names, the name was changed to Dexilant® in 2010.

offender. 21 C.F.R. § 10.30. But Ge did not use this mechanism to raise her concerns with Takeda's adverse event reporting or drug labeling. Instead, since all four of the subject drugs are reimbursable by the federal government under Medicare and Medicaid, (Actos® Compl. ¶¶ 39-42; Uloric® Compl. ¶¶ 140-143), she attempted to bring claims under the FCA.

1. The Statutory Framework.

The FCA, 31 U.S.C. §§ 3729 *et seq.*, prohibits the submission of false or fraudulent claims for payment to the federal government. "Enacted in 1863 in response to cases of contractor fraud perpetrated on the Union Army during the Civil War," S. Rep. No. 99-345 (1986), *reprinted at* 1986 U.S.C.C.A.N. 5266, 5269, the FCA was intended to protect the government from being "bill[ed] for nonexistent or worthless goods, charged exorbitant prices for goods delivered, and generally robbed in purchasing the necessities of war." *United States v. McNinch*, 356 U.S. 595, 599 (1958). The FCA thus provides a civil penalty for each false claim of "not less than $5,000 and not more than $10,000," in addition to "3 times the amount of damages" the government has sustained. 31 U.S.C. §§ 3729(a); 1986 U.S.C.C.A.N. at 5274. Under 31 U.S.C. § 3730(b),

a private individual (i.e., a relator, like Ge) can file suit on behalf of the government and is entitled to a portion of the recovery, with that amount varying depending on whether the government decides to intervene in the action. *See generally* 31 U.S.C. § 3730(d).

As relevant to Ge's appeal, the FCA imposes liability on any person who "(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or] (C) conspires to commit a violation" of the Act. 31 U.S.C. § 3729(a)(1)(A)-(C).[14]

The key limitation of the False Claims Act is apparent from its title. For while "a false claim may take many forms," 1986 U.S.C.C.A.N. at 5274, "[n]ot all fraudulent conduct gives rise to liability under the FCA," *U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 225 (1st Cir. 2004); *see also U.S. ex rel. Rost v.*

[14] The Fraud Enforcement and Recovery Act ("FERA"), Pub. L. No. 111-21, 123 Stat. 1617 (2009), amended subsection 2729(a) of the FCA. FERA provides that amendments to the FCA take effect upon enactment except for the amendment to the old § 3729(a)(2), 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. Ge does not dispute that the post-FERA version of the FCA applies to her claims. (*See* RelatorBr. 18-19; R.35 at 13 n.8.)

Pfizer, Inc., 507 F.3d 720, 732 (1st Cir. 2007) (explaining that allegedly "illegal practices" "are not a sufficient basis for an FCA action" unless they "involve claims for government reimbursement"). Instead, liability only attaches to a false or fraudulent "claim," defined by the Act as "any request or demand … for money or property," either presented to the United States or to a "contractor, grantee, or other recipient," where the government "provides" or "will reimburse" any part of the money or property requested. 31 U.S.C. § 3729(b)(2); *see also Karvelas*, 360 F.3d at 225; *Rost*, 507 F.3d at 732.

And there are other limitations. "Knowingly," as defined by the FCA, requires that a person "(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the trust or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). Additionally, this Court reads a materiality requirement into the statute generally, even though it is only expressly included in §3729(a)(1)(B) & (G). *U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 388 & n.13 (1st Cir. 2011); *U.S. ex rel. Loughren v. Unum Group*, 613 F.3d 300, 307 & n.8 (1st Cir. 2010). An act is "material" only if

it has a "natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." § 3729(b)(4); *Loughren*, 613 F.3d at 307.

Accordingly, numerous courts have recognized that the FCA is not intended to impose liability for all regulatory violations.[15] Instead, as explained by the Senate Judiciary Committee's Report accompanying the 1986 amendments to the FCA, the FCA "defend[s] the Federal treasury against unscrupulous contractors and grantees," with the "most common" types of claims giving rise to liability being "for goods or services not provided, or provided in violation of contract terms, specification, statute, or regulation." 1986 U.S.C.C.A.N. at 5269, 5274.

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[15] *U.S. ex rel. Hobbs v. MedQuest Assocs., Inc.*, 711 F.3d 707, 713 (6th Cir. 2013) ("[B]ecause [the Medicare regulations] are not conditions of payment, they do not mandate the extraordinary remedies of the FCA and are instead addressable by the administrative sanctions available . . . ."); *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 310-11 (3d Cir. 2011) (declining to "permit[] qui tam plaintiffs to file suit [under the FCA] based on the violation of regulations which may be corrected through an administrative process and which are not related directly to the Government's payment of a claim"); *Mann v. Heckler & Koch Defense, Inc.*, 630 F.3d 338, 346 (4th Cir. 2010) ("Correcting regulatory problems may be a laudable goal, but one not actionable under the FCA in the absence of actual fraudulent conduct." (quoting *U.S. ex rel. Hopper v. Anton*, 91 F.3d 1261, 1269 (9th Cir. 1996))).

2. The Evolution Of Ge's FCA Claims.

At their core, Ge's FCA claims turn on two key factual assertions. *First*, although Takeda reported all (or nearly all, the complaints are not entirely clear) of Ge's identified adverse events to FDA,[16] it should have reported those events earlier pursuant to the "alert reports" procedures of 21 C.F.R. § 314.80(c)(1). And *second*, although all (or nearly all) of the supposed adverse events identified in her complaints were already the subject of FDA review or drug label warnings (*see, e.g.*, Actos® Compl. ¶¶ 60, 99, 103-106; Uloric® Compl. ¶¶ 62-63, 74, 76, 79, 88, 111, 118-119, 123-125, 127), she contends that Takeda "systematically resist[ed] label changes" based on her personal opinion of FDA labeling requirements. *See, e.g.*, 21 C.F.R. § 201.57(c)(7); § 201.80(e).

More specifically, related to adverse event reporting for Actos®, Ge contends, for example, that Takeda "had been systematically

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[16] (*See* Actos® Compl. ¶ 66 (Takeda reported all congestive heart failure ("CHF") events as "serious" adverse events prior to May 23, 2007 and reported all post-May 23, 2007 CHF events requiring hospitalization as "serious" and all other CHF events as standard adverse events.); Uloric® Compl. ¶¶ 31, 42, 58, 69, 72, 92-93, 96, 100-102, 104-105, 124-125, 127, 131 (alleging Uloric®, Prevacid® and Dexilant® adverse events were transmitted to FDA and available via FDA's Adverse Event Reporting System ("AERS") database/MedWatch forms).)

underreporting the incidence of bladder cancer in adverse event reports." (RelatorBr. 7 (citing Appendix 48-54).) But the allegations in the cited pages of the Actos® Complaint do not identify any instance where Takeda failed to report an adverse bladder cancer event to FDA. (*See* Appendix at 48-54; *see also supra* n.16 (addressing other alleged underreporting).)

As to reporting for Uloric®, Dexilant®, and Prevacid®, Ge similarly asserts that Takeda "systematically underreport[ed] adverse events" associated with these drugs. (RelatorBr. 11.) What Ge fails to mention is that this alleged "underreporting" includes reporting as "expected" (i.e., labeled) drug-drug interactions that actually were listed on the labels. (*See* Uloric® Compl. ¶¶ 62, 75-78, 109-10.) Ge believes that these events technically were "unlabeled," and therefore should have been classified as "unexpected," because Takeda never sponsored any clinical trials demonstrating the drug-drug interaction. (*See id.* ¶¶ 62, 75-78, 109-10.) But, as Ge alleges, FDA actually instructed Takeda to include certain contraindications if it did not undertake the studies. (*See, e.g.*, *id.* ¶ 63 ("Without these studies, co-administration of Uloric with . . . . azathioprine will need to be contraindicated."

(quoting October 14, 2005 letter from FDA Director of Drug Evaluation to Takeda)); *see also id.* ¶ 78.)

For labeling, Ge contends Takeda "systematically resist[ed] label changes" with respect to Actos® and bladder cancer. (RelatorBr. 8.) But as Ge alleges, the 1999 label for Actos® actually warned that bladder cancer was observed in the pre-clinical animal studies. (*See* Actos® Compl. ¶ 106 (recognizing that the 1999 label for Actos® included the warning that "[d]rug-induced tumors were not observed in any organ except for urinary bladder.").) And in 2006—prior to the claims at issue here—FDA required Takeda to change the Actos® label to include the bladder cancer results from the first post-marketing study. (*See id.*)[17] Then, in August 2011, FDA issued its supplemental approval for Actos, which updated the

[17] Ge also implies that Takeda withheld from FDA information from the Actos® pre-clinical and clinical trials. (*See* RelatorBr. 7-8 ("Dr. Ge further learned that there were pre-clinical and clinical trials performed by Takeda indicating Actos® caused bladder cancer. Dr. Ge discovered that Takeda had suppressed this information . . . .").) But as the Actos® Complaint alleges, information from these trials, including the incidents of bladder cancer, was disclosed to FDA in the Actos® NDA. (*See* Actos® Compl. ¶ 103.)

labeling to warn of an increased "relative risk of developing bladder cancer." FDA, Supplement Approvals (Aug. 4, 2011).[18]

Ge similarly contends that Uloric®'s, Dexilant®'s, and Prevacid®'s labels "were misleading because they failed to warn about serious and fatal drug interactions." (*See* RelatorBr. 12 (citing Appendix 147-48, 178, 180).) As to Uloric®, for example, Ge maintains that the label's warnings about a Uloric®/Warfarin interaction were misleading because the warnings did not address the results of an initial Takeda study. (*See* Uloric® Compl. ¶¶ 37-38.) But as Ge admits, FDA reviewed this initial study and nevertheless approved the label. (*See id.*)

The other adverse events Ge identifies also were reported to FDA and appeared in FDA's Adverse Event Reporting System ("AERS"). (*See id.* ¶¶ 123-124, 127.) And she does not allege that Takeda misreported any of these allegedly adverse events. (*See id.*)[19]

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[18] *See supra* n.8.

[19] Ge also discusses certain FCA settlements involving pharmaceutical companies, implying that those settled FCA claims had merit—and that hers do as well. (RelatorBr. 17.) But such reliance on settlement agreements "to prove . . . the validity . . . of a disputed claim" is impermissible under Federal Rule of Evidence

From these facts, Ge argues that *every* claim for reimbursement for the subject drugs under the federal healthcare programs, regardless of whether the claim was made prior to any of these alleged adverse events, was false. (*See, e.g.,* RelatorBr. 40 ("[T]his fraudulent conduct rendered all claims to Medicare and Medicaid false and fraudulent.").)

(a) Ge's FCA Theories Before The District Court.

In opposing Takeda's motion to dismiss in the district court, Ge attempted to package these factual allegations into two theories of FCA liability: a "primary theory" and an "[a]lternative[]" theory. (R.35 at 19-20.) The primary theory, to which Ge devoted most of her briefing, was that Takeda falsely certified in the subject drugs' new drug and supplemental new drug applications that it would comply with FDA's mandatory reporting requirements. (*Id.* at 19.) Had Takeda not made this false certification, the argument goes, its applications for the subject drugs "would never been approved" in the first instance. (*Id.*)

(continued…)

408. And the "Takeda" settlement actually involved a joint venture not joined here. (*See* Actos® Compl. ¶ 32.)

Ge's "alternat[e]" theory was skeletal, presented in a paragraph. (*See id.* at 20.) But essentially, this theory contends that had Takeda complied with its reporting obligations and "provided prompt warnings" "then its warnings would have resulted in diminished sales/prescriptions and resulted in fewer reimbursable claims." (*Id.*)

Ge also represented that she "[was] *not* alleging that, once Takeda failed to comply with its reporting obligations, FDA would have exercised its discretion to punish or withdraw the approval of the implicated drugs." (*Id.* at 19 (emphasis added).)

(b) The District Court's Disposition of Ge's FCA Claims.

On November 1, 2012, the district court granted Takeda's Motion to Dismiss Ge's FCA claims pursuant to both Federal Rules of Civil Procedure 9(b) and 12(b)(6).[20] With respect to Rule 12(b)(6), the court found that the complaints adequately alleged that Takeda knowingly caused providers to submit claims for payment of the subject drugs. Accordingly, the court reasoned, "the sufficiency of

[20] Takeda also moved to strike certain allegations the Actos Complaint based on the FCA's public disclosure provisions, 31 U.S.C. § 3730(e)(4). (R.26.) The district court denied this motion as moot based on its dismissal of Ge's claims. (*See* R.45.)

the complaints turns on whether the claims at issue were false or fraudulent." (Addendum 73.) And, since the claims were not false on their face (they sought payment for FDA-approved drugs actually dispensed), the issue really was whether they "misrepresented compliance with a material precondition of payment," which would render them false under the FCA. (*Id.*)

That, the court held, was where the complaints failed. For they did not explain how providers' claims for payment for the subject drugs misrepresented Takeda's compliance with FDA reporting requirements. (*Id.*) Nor, the court continued, could Ge show that Takeda's compliance with adverse-event reporting requirements was an implied material precondition of payment. Ge's assertions that, but for alleged misreporting and mislabeling, FDA would have withdrawn approval, required too many layers of speculation—for "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." (*Id.* at 74.)

The court also concluded that the complaints did not plead fraud with particularity under Rule 9(b) because they "failed to

allege the specific details of any claims that were allegedly rendered 'false' as a result" of Takeda's alleged misreporting or mislabeling. (*Id.* at 71.) Nor had Ge identified providers who submitted false claims; the rough time periods, locations, and amounts of the claims; or the specific government programs to which the claims were made. (*Id.* at 71-72.) The court specifically rejected Ge's theory that all of the claims for the subject drugs were false based on Takeda's adverse event reporting, and further found that she failed to specifically allege that FDA would have withdrawn approval for the drugs after receiving the adverse events. (*Id.* at 72.) And, besides, she had not explained how any fraudulent reporting could render false any reimbursement claims that were filed *prior to* the occurrence of the alleged adverse events. (*Id.*)

Finally, the court dismissed Ge's various state-law claims both because they "failed to state a claim under state law," and because they "fail[ed] to plead with specificity the details of any claims for payment made to any of the states." (*Id.* at 75.)

Ge then sought reconsideration under Rule 59(e), relying for the first time on several declarations and other documents which she had never disclosed in her three sets of complaints or in

opposition to Takeda's motion. (R.47.) The district court denied this motion without opinion on December 18, 2012. (R.52.)

(c) Ge's FCA Theories On Appeal.

On appeal, Ge abandons her "primary theory" and advances three new theories instead—including the one she told the district court she was *not* pursuing. They include:

1. Because Takeda allegedly failed to comply with FDA's reporting and labeling requirements, the labels on the subject drugs did not accurately reflect their safety risks. That, Ge contends, makes provider claims for reimbursement false or fraudulent because the products were "substandard." (RelatorBr. 28-37.)

2. Provider claims for reimbursement were "false" because, based on Takeda's alleged regulatory violations, they misrepresented that the prescribed drugs were "reasonable and necessary," which is a requirement for payment under Medicare and Medicaid. (*Id.* at 37-40.)

3. Because Takeda allegedly failed to comply with adverse event reporting and labeling requirements, FDA could have withdrawn approval for the subject drugs. Thus, Ge argues, all provider claims for reimbursement "were false and fraudulent

because the drugs were fraudulently on the market." (*Id.* at 40.) This is the very theory Ge told the district court she was *not* pursuing. (*Compare id.* at 44 (It was only "because Takeda was able to conceal the safety risks associated with the [subject] drugs . . . [that] it was able to maintain access to the pharmaceutical market," so "[a]ny claims submitted to Medicare and Medicaid were, therefore, false and fraudulent.") *with* R.35 at 19 ("Relator is not alleging that . . . FDA would have exercised its discretion to punish or withdraw the approval of the implicated drugs.").)

SUMMARY OF ARGUMENT

Ge's ever-evolving theories of liability would expand the FCA's reach well beyond any of her cited authority, and threaten to undermine FDA's exclusive authority in policing regulatory compliance. For the following reasons, the district court's judgment should be affirmed:

First, unable to articulate a coherent theory of FCA liability, Ge abandons the primary theory she previously argued in the district court and now advances three new theories for the first time on appeal—including the one that she expressly disavowed. All are waived.

Second, the district court correctly dismissed all of Ge's FCA claims under Rule 12(b)(6). Like her original theories, Ge's latest theories not only are based upon multiple layers of speculation but also fail to allege that any claims submitted for reimbursement under the government programs misrepresented a material precondition of payment such that they were false. As the government concedes, compliance with FDA labeling and reporting requirements is not a precondition of payment under the federal health care plans. And at all times, the drugs have been FDA-approved, leaving the government without any discretion to deny claims for reimbursement. On these facts, Ge cannot state an FCA claim.

Third, the district court did not err in dismissing Ge's claims for failure to plead fraud with particularity under Rule 9(b). Ge's complaints are devoid of any factual or statistical evidence demonstrating beyond mere possibility that fraudulent claims were submitted to the government. Nor can Ge rely on belatedly produced evidence from her motion for reconsideration to bolster her claims. The district court properly denied that motion because none of her "new evidence" was previously unavailable to her, and

she has not argued on appeal that this denial amounted to an abuse of discretion.

Fourth, Ge has not challenged the district court's dismissal of her state law claims and any future arguments she makes with respect to those claims are waived.

Finally, the district court did not abuse its discretion in denying Ge's request for leave to amend her complaints a third time. Ge offered no justification for an amendment—no facts, no legal argument, and no explanation of how she planned to salvage her pleadings. She only set out only a handful of boilerplate sentences quoting the applicable legal standard. The district court acted well within its discretion in disregarding this undeveloped request. And besides, any attempt to replead would be futile.

The judgment of the district court should, therefore, be affirmed in its entirety.

ARGUMENT

I. THE THREE THEORIES OF FCA LIABILITY ADVANCED ON APPEAL WERE NOT PRESENTED TO THE DISTRICT COURT AND ARE THEREFORE WAIVED.

Ge's opening brief before this Court quite remarkably asserts that the district court "fundamentally misunderstood how the

allegations in the [relevant] [c]omplaints stated a claim under the FCA." (RelatorBr. 32.) This seems particularly uncharitable, given that none of the three theories of FCA liability Ge advances before this Court were presented to the district court.

It is, of course, black-letter law that one cannot assign as error to a district court that which the court was never asked to consider. *See, e.g.*, *Tobin v. Liberty Mut. Ins. Co.*, 433 F.3d 100, 105 n.3 (1st Cir. 2005) ("Theories not raised in the district court cannot be raised for the first time on appeal."). Nor may a litigant "merely . . . mention a possible argument in the most skeletal way, leaving the court to do counsel's work," *United States v. Zannino*, 895 F.2d 1, 17 (1st Cir. 1990), for "it is well settled that arguments made in a perfunctory manner below are deemed waived on appeal," *Rodriguez-Pinto v. Tirado-Delgado*, 982 F.2d 34, 41 (1st Cir. 1993); *see Lawson Prods., Inc. v. Avnet, Inc.*, 782 F.2d 1429, 1439-40 (7th Cir. 1986) ("[P]arties should keep in mind that their opportunity before the district court is the main event rather than a tryout for the road. The situation is no different if there is a live performance or just a mountain of paper.") (internal quotations omitted).

This makes sense. As this Court explained just a few months ago:

> On the one hand, 'busy judges, faced with lengthy and growing dockets, necessarily must rely on litigants to present the relevant facts and law governing the disputes that the judges are asked to resolve.' And on the other, federal litigation 'is less a game of blind man's bluff and more a fair contest with the basic issues [of] facts [and law] disclosed to the fullest practicable extent,' so as to give each party a meaningful opportunity to present its case.

Silverstrand Invs. v. AMAG Pharms., Inc., 707 F.3d 95, 107-08 (1st Cir. 2013) (internal citations omitted).

Before the district court, Ge's primary theory of FCA liability was that Takeda falsely certified in its new drug and supplemental new drug applications for the subject drugs that it would comply with FDA's mandatory reporting requirements. (R.35 at 19.) That argument appears nowhere in Ge's brief to this Court.

Ge also tried to raise an alternative theory before the district court. In a single paragraph of her 36-page brief, she sketched out that if Takeda had complied with its reporting obligations and "provided prompt warnings," "then its warnings would" (somehow) "have resulted in diminished sales/prescriptions and resulted in

fewer reimbursable claims." (*Id.* at 20.) But she never developed this theory. For example, although an FCA claim requires allegations of both falsity and materiality, *Hutcheson*, 647 F.3d at 388 n.12, both were notably absent from Ge's analysis.

Before this Court, in contrast, Ge raises three entirely new theories. The first turns on the assertion that Takeda's alleged adverse-event reporting and labeling conduct defrauded not the government but the "medical community and patients about the safety of" the subject drugs, making them "substandard" products. (RelatorBr. 28-33.) But neither the lead case on which this argument turns, *U.S. ex rel. Westrick v. Second Chance Body Armor, Inc.*, 685 F. Supp. 2d 129 (D.D.C. 2010), nor even the phrase "substandard product" appears anywhere in Ge's opposition to the motion to dismiss. Accordingly, this theory is waived. *Rodriguez-Pinto*, 982 F.2d at 41 ("[I]t is well settled that arguments made in a perfunctory manner below are deemed waived on appeal.").

Ge's second theory is that Takeda's alleged conduct made the subject drugs not "reasonable and necessary" for treatment, making claims for payment for the drugs false. (RelatorBr. 37-40.) This argument hinges on 42 U.S.C. § 1395y(a)(1)(A), *Heckler v. Ringer*,

466 U.S. 602 (1984), and *Strom ex rel. U.S. v. Scios, Inc.*, 676 F. Supp. 2d 884 (N.D. Cal. 2009). Again, the "reasonable and necessary" theory, *Heckler*, and the relevant statutory provision appear nowhere in Ge's opposition to the motion to dismiss. And she only addressed *Strom* in connection with her Rule 9(b) pleading arguments, not in explaining her substantive liability theories in opposition to Takeda's Rule 12(b)(6) motion. This theory is also waived.

Finally, in her third theory, Ge contends that "Takeda violated the FCA by using fraud to maintain access to and eligibility in the prescription drug market" for the subject drugs (RelatorBr. 40), because "[f]ailure to comply with [applicable] reporting requirements can lead FDA to 'withdraw approval of the application and, thus, prohibit continued marketing of the drug,'" (*id.* at 41). This theory is not just waived. It was expressly forfeited. Not only did Ge not raise this theory in the district court, she *affirmatively represented* that she "[was] *not* alleging that, once Takeda failed to comply with its reporting obligations, the FDA would have exercised its discretion to punish or withdraw the approval of the implicated drugs." (R.35 at 19 (emphasis added).) It is easy to see how the

district court could have "fundamentally misunderstood" Ge's current arguments when it was told she wasn't making them. (Relator.Br. 32.) But the blame for that belongs to Ge, not the district court.

Because none of the three FCA theories Ge advances on appeal was presented to the district court, none can justify reversal before this Court. On this ground alone, the judgment of the district court can, and should, be affirmed.

II. THE DISTRICT COURT CORRECTLY DISMISSED GE'S CLAIMS UNDER RULE 12(b)(6).

Even if Ge's new FCA theories were not all waived (and they are), they would still fail to state a claim under Rule 12(b)(6). To survive a Rule 12(b)(6) motion, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "If the factual allegations in the complaint are too meager, vague, or conclusory to remove the possibility of relief from the realm of mere conjecture, the complaint is open to dismissal." *SEC v. Tambone*, 597 F.3d 436, 442 (1st Cir. 2010) (en banc). And of course, this

Court may affirm dismissal "on any basis made apparent from the record." *Rocket Learning, Inc. v. Rivera-Sanchez*, 715 F.3d 1, 8 (1st Cir. 2013).

On appeal, Ge asserts FCA liability under each of 31 U.S.C. § 3729(1)(A), (B), and (C). As this Court has squarely recognized, however, "Not all fraudulent conduct gives rise to liability under the FCA." *Karvelas*, 360 F.3d at 225. Instead, liability under the FCA attaches "'not to the underlying fraudulent activity or to the government's wrongful payment, *but to the claim for payment.*'" *Id.* (quoting *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995)) (emphasis added). Thus, the irreducible minimum requirements for a cause of action under the FCA are (1) "claims" that "misrepresented compliance with a precondition of payment so as to be false or fraudulent"; and (2) that the "misrepresentations were material." *Hutcheson*, 647 F.3d at 392. None of Ge's three new theories meets these requirements.

A. Ge's Theories Do Not Establish Claims That Misrepresented Compliance With A Precondition Of Payment.

To begin with, none of Ge's three theories can establish that claims for payment for the subject drugs submitted by providers

"misrepresented compliance with a precondition of payment so as to be false or fraudulent." *Id.* To demonstrate that "the claims at issue misrepresented compliance with a precondition of payment so as to be false or fraudulent," Ge must:

- identify the purported "precondition of payment" under the relevant government healthcare programs;
- allege facts supporting the reasonable inference that the reimbursement claims represented compliance with this precondition; and
- show that this representation was "false."

New York v. Amgen, Inc., 652 F.3d 103, 111 (1st Cir. 2011) ("The question here is whether claims submitted to the . . . Medicaid programs misrepresented compliance with a precondition of payment recognized by those particular programs."); *see also U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 307 (3d Cir. 2011) ("[A] plaintiff must show that if the Government had been aware of the defendant's violations of the Medicare laws and regulations that are the bases of a plaintiff's FCA claims, it would not have paid the defendant's claims.").

Here, Ge's three theories do not, and cannot, allege that Takeda's compliance with FDA's adverse-event reporting and labeling requirements is a precondition of payment under Medicare

or Medicaid. The district court recognized as much in the context of the different theories Ge presented there. (Addendum 74 (Ge did not "demonstrate that compliance with" these requirements "was a material precondition of payment.").) And even the United States, as *amicus* in this appeal, candidly admits:

> Compliance with the adverse event reporting requirements is not, in itself, a material precondition of payment under Medicare or Medicaid; reimbursement for prescription drugs is not conditioned on a pharmaceutical company's compliance with these requirements.

(U.S.Br. 20.) This key legal point distinguishes this case from all the FCA paradigms on which Ge relies.

As Ge concedes, preconditions for payment are "typically found in an underlying contract, a statute or regulation, or [are] implied in the transaction itself." (RelatorBr. 23.) Quite so. And that sets this case apart from the various scenarios she cites, including anti-kickback violations, off-label marketing, and bid-rigging. *See, e.g.*, *Amgen*, 652 F.3d 103 (anti-kickback statutes are express condition of payment); *Hutcheson*, 647 F.3d 377 (same); *U.S. ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39 (D. Mass. 2001) ("on-label" use is express condition of payment); *Murray &*

Sorenson v. United States, 207 F.2d 119, 123-24 (1st Cir. 1953) (bid-rigging violates "implied false representation" that bids are competitive). Here, the reporting and labeling violations alleged simply are not preconditions to payment—express, statutory, implied, handshake, or otherwise.

In its *amicus* brief, the United States does contend that a reimbursement claim could be ineligible for reimbursement in "rare instances" where the "concealed events are so serious and unexpected that FDA, would have, for example, withdrawn its approval of the drug for all indications had it known about the concealed information." (U.S.Br. 19, 21.) It is not surprising that the Government would try to preserve its enforcement prerogatives for extreme cases. But tellingly, it cites not a single statutory or regulatory authority in support. Besides, the United States does not maintain that this case involves such a "rare circumstance." (*Id.* at 23.) Nor could it, since FDA never withdrew approval for the subject drugs despite being informed of the adverse events.

And Ge's three new liability theories similarly fall outside the framework of the FCA.

1. As to her "substandard" product theory, Ge effectively contends that every claim for payment for an FDA-approved drug is conditioned on the product being as safe or effective as the manufacturer "purported it to be" in the drug's labeling—whatever that means. (*See* RelatorBr. 29-30.) But this makes no sense. Safety and efficacy are established through extensive review by FDA, not by a relator's subjective views on how that review should have gone. *See* 21 C.F.R. § 314.105(c),(d). Same with establishing a drug's labeling. *See* 21 C.F.R. § 201.56. More fundamentally, this theory only works if the federal health care programs conditioned payment on the drugs having a certain safety profile. *Amgen*, 652 F.3d at 115. Ge identifies no authority suggesting this is the case.

Indeed, none of *Bornstein*, *Aerodex*, or *Westrick*, all cited by Ge (*See* RelatorBr. 28-32), stand for the proposition that every claim for government reimbursement inherently includes a representation that the provided product or service satisfies an unspecified standard of quality. Rather, all of these cases involved government contracts which included certain specifications or warranties for the purchased products. *See United States v. Bornstein*, 423 U.S. 303,

307 (1976) (defendant's products did not meet "certain specifications" in the contract and were "falsely marked" as being "of the required quality"); *United States v. Aerodex*, 469 F.2d 1003, 1005 (5th Cir. 1972) ("The bearings delivered were not those specified in the contract."); *Westrick*, 685 F. Supp. 2d at 137 ("[E]ach . . . vest sale and each consequent invoice submission" was "predicated" on a "fraudulently represented five-year warranty."). In all these cases, therefore, the specified quality of the products was an express precondition of payment.[21]

And courts have rejected similar FCA theories where relators base their claims on an implied warranty of merchantability without "articulat[ing] some court opinion or regulation that imports such warranties into the government's contracts." *U.S. ex rel. Steury v. Cardinal Health, Inc.*, No. 12-20314, 2013 U.S. App. LEXIS 17381,

[21] Ge's reliance on *Mann v. Heckler & Koch Def., Inc.*, 630 F.3d 338, 346 (4th Cir. 2010), a case which found *no* FCA violation, is likewise misplaced. In *Mann*, as in Ge's other cases, the government's contract solicitation "detail[ed] the specifications" for the requested product. *Id.* at 341. And notably the court found no FCA violation because, while the plaintiff disputed whether a part used in his employer's bid submission satisfied the government's requirements, the bid submission "[did] not even discuss the quality of the [part]" provided to the government. *Id.* at 346. Where, as here, the plaintiff "opposed nothing more than [the employer's] non-fraudulent business decision," the FCA did not apply. *Id.*

at *12-13 (5th Cir. Aug. 21, 2013) (affirming dismissal of FCA claim based on an "implied warranty of merchantability" theory which the court described as an "implied certification of an implied contract provision that is an implied prerequisite to payment").

Franklin, 147 F. Supp. 2d 39, and *Strom*, 676 F. Supp. 2d 884, both off-label drug cases, also cited by Ge, are similarly inapposite. Relying on these cases, Ge contends that any fraudulent representation related to a drug's safety and efficacy automatically renders a reimbursement claim false. (*See* RelatorBr. 29.) But again, like Ge's other cited authority, in these cases the defendants' conduct was linked to a precondition of payment. In *Franklin*, it was undisputed that under the Medicaid regulations, the government would not reimburse for the promoted off-label uses, and the false claim resulted "not from unlawful off-label marketing activity itself—but from the submission of Medicaid claims for uncovered off-label uses induced by Defendant's fraudulent conduct." 147 F. Supp. 2d at 52. And in *Strom*, the court relied on Medicare's "reasonable and necessary" requirement under 42 U.S.C. § 1395y (the basis for Ge's second theory, discussed below)

to determine whether the claim for off-label reimbursement was false. 676 F. Supp. 2d at 891.

Here, Ge has not alleged that the Medicare or Medicaid programs condition payment on the prescription drugs having a particular safety profile. *Amgen*, 652 F.3d at 115. Nor has she alleged that the doctors, pharmacies, or other third-parties that allegedly submitted claims for reimbursement somehow certified that the subject drugs' labeling accurately reflected their safety.

2. As to Ge's "reasonable and necessary" theory, Ge correctly states that under 42 U.S.C. § 1395y(a)(1)(A), Medicare and Medicaid may not pay "for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury." And as Ge concedes, "[t]ypically, the prescribing doctor determines whether a drug is reasonable and necessary." (RelatorBr. 37.) Again, quite so. And Ge has not pled that Takeda's alleged reporting and labeling violations (somehow) made its drugs not "reasonable and necessary for the diagnosis or treatment of illness or injury."

Indeed, unlike other FCA complaints alleging improper government reimbursement of pharmaceutical products, Ge does

not and cannot allege that the subject drugs were: (i) not FDA-approved; (ii) subject to adverse FDA action; or (iii) otherwise ineligible for payment at the time claims were allegedly submitted to government payors. Nor can she allege that any health provider submitted a claim seeking payment for a subject drug (i) without actually providing the drug to a patient, (ii) seeking payment of sums other than that allowed under a government healthcare program, or (iii) seeking reimbursement for a non-indicated ("off-label") or unnecessary use of the drug.

Ge, however, contends that "when a drug company fraudulently promotes the safety and efficacy of a drug," that makes prescriptions of the drugs "not reasonable and necessary." (RelatorBr. 38.) The only case she cites for this broad proposition is *Strom ex rel. U.S. v. Scios, Inc.*, 676 F. Supp. 2d 884 (N.D. Cal. 2009), an off-label use case, which does not support her expansive interpretation of the "reasonable and necessary" requirement to capture Takeda's alleged conduct here.

Whether an item or service is "reasonable and necessary" under 42 U.S.C. § 1395y(a)(1)(A) must be addressed in light of the surrounding statutory and regulatory requirements. *See U.S. ex rel.*

Hobbs v. MedQuest Assocs., Inc., 711 F.3d 707, 715-16 (6th Cir. 2013) (limiting scope of "reasonable and necessary" under § 1395y(a)(1)(A) based on corresponding regulations and holding that claims did not violate this condition of payment). For prescription drugs, the statutory scheme for the federal healthcare programs expressly addresses the conditions of reimbursement. *See United States v. King-Vassel*, No. 12-3671, 2013 U.S. App. LEXIS 17989, *21-22 (7th Cir. Aug. 28, 2013) (explaining federal statutory scheme for prescription drug reimbursement). Only "covered outpatient drugs" receive reimbursement, and such drugs exclude any drugs "used for a medical indication which is not a medically accepted indication." *Id.* at *21; 42 U.S.C. §§ 1396b(i)(10), 1396r-8(a)(3), 1396r-8(k)(3). "Medically accepted indication" in turn "refers to a prescription purpose approved by the [FDCA] or 'supported by' any of several identified 'compendia.'" *King-Vassel*, 2013 U.S. App. LEXIS, at *22 (citing 42 U.S.C. §§ 1396r-8(k)(6), 1396r-8(g)(1)(B)(i)). When a prescription is "off-label," as in *Strom*, the drug is "not prescribed for an indication covered under the FDCA" and therefore does not meet the first indicia of "medically accepted indication." *Id.* Thus, a prescription for an off-label use is not reimbursable

unless it is used for a "medically accepted indication" as supported by one of the identified compendia. *Id.*; § 1396r-8(k)(6).

When viewed through the lens of the relevant statutory provisions, the distinctions between the alleged off-label use in *Strom* and the on-label uses alleged by Ge in this case are evident. In *Strom*, the court did not hold that a mere misrepresentation of a product's level of safety or efficacy renders it not "reasonable and necessary" for treatment. Rather, the drug in *Strom* was alleged *to be ineffective* when used for the prescribed off-label purpose, 676 F. Supp. 2d at 891—which would render the claim ineligible for reimbursement. Because the off-label use was not subject to reimbursement, the court reasoned, any claim for reimbursement arguably misrepresented compliance with the "reasonable and necessary" requirement.

But here, in contrast, Ge has not alleged that any of the prescribed uses for the subject drugs was either off-label, or for any other use that was not a "medically accepted indication" that would render them ineligible for reimbursement under the "reasonable and necessary" test. Instead, FDA has approved the uses of the subject drugs under the FDCA, making them used for a "medically

accepted indication" and therefore reimbursable. *King-Vassel*, 2013 U.S. App. LEXIS, at *21-22. Ge simply believes that the drugs were not "reasonable and necessary" because, in her opinion, they are not as safe as their labels purport them to be—despite FDA never finding the subject drugs in violation of any labeling or adverse event reporting regulations. The "reasonable and necessary" requirement simply has not and cannot be stretched so far.

3. Finally, Ge's most extreme theory—that because FDA *could have* withdrawn marketing approval for the subject drugs based on Takeda's failure to comply with FDA regulations, *every* claim for the subject drugs was "false or fraudulent because the drugs were fraudulently on the market"—is even further off the mark. (RelatorBr. 40.) As the district court recognized, while FDA could have withdrawn FDA approval were Ge's allegations true, it equally could have "take[n] a number of different actions." (Addendum 74.) Indeed, "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. (*Id.* (citing *Cutler v. Hayes*, 818 F.2d 879, 893 (D.C. Cir. 1987) ("The [FDCA] imposes no clear duty upon FDA to bring

enforcement proceedings[.]")).) And again, even with the adverse reports in hand and labels changed over time, all of the subject drugs are still on the market and are FDA approved, *see supra* 12-14—which means that FDA had no discretion not to pay for them.[22] Indeed, expanding Ge's theory to its logical conclusion, FCA liability would attach to alleged violations of countless statutory and regulatory provisions, even when they bear no relationship to the provided products or services. For example, under Ge's theory, any time a food manufacturer fails to comply with local health department regulations—regardless of how marginal the infraction—it faces a potential FCA suit: Because the health department *could have* shut down the manufacturer's operations until the violations are corrected, all products sold during that

[22] *See* 42 U.S.C. §§ 1395w-101, 1395w-115 (Medicare makes periodic capitated payments to private insurance plans—known as Prescription Drug Plans—who, in turn, must reimburse network pharmacies for their services.); 42 C.F.R. § 423.100 (defining "Covered Part D drug"); 42 U.S.C. § 1396r-8 (Medicaid program requires coverage for the "medically accepted indication" of "any covered outpatient drug"); *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 684-85 (2003) ("[A] State that has elected to offer prescription drug coverage must cover the drug under its state plan unless it complies with one of the Medicaid Act's provisions that permits a State to exclude or restrict coverage.") (O'Connor, J. concurring in part, dissenting in part).

period theoretically were fraudulently on the market. To the extent that the government paid for any of these products via its Supplemental Nutrition Assistance Program, 7 U.S.C. § 2013, the FCA would impose draconian liability and civil penalties. Nothing recommends, let alone requires, that result.[23]

B. Ge's Theories Do Not Otherwise Establish False Or Fraudulent Claims.

Additionally, Ge has not otherwise established that any of the claims submitted for the subject drugs were rendered "false or fraudulent" under the FCA by Takeda's alleged adverse-event

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[23] Nor do *Hendow*, *Main*, *Westinghouse*, or *Bierman*, cited by Ge, support this novel FCA liability theory. (*See* RelatorBr. 42-44.) All involved programs or contracts that expressly conditioned program participation on compliance with certain statutes, regulations, or certifications. *See U.S. ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1168 (9th Cir. 2006) (participation in subsidy program required agreement to "abide by a panoply of statutory, regulatory, and contractual requirements" including a "ban on incentive compensation"); *U.S. ex rel. Main v. Oakland City Univ.*, 426 F.3d 914, 916 (7th Cir. 2005) (participation in federal subsidy program "condition[ed]" on "commitment to refrain from paying recruiters contingent fees for enrolling students"); *U.S. ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 916 (4th Cir. 2003) (contract between contractor and government required contractor to submit a "no organizational conflict" certification); *U.S. ex rel. Bierman v. Orthofix Int'l*, 748 F. Supp. 2d 123, 127 (D. Mass. 2010) (Medicare program participation required that participant certify that it "agree[d] to abide by the Medicare laws, regulations and program instructions").

reporting and labeling violations. Again, Ge does not dispute that all (or nearly all) of the alleged adverse events were reported to FDA. *See supra* 19-22. She just thinks that Takeda should have reported them differently (i.e., as either "serious" or "unexpected") and disclosed them sooner in 15-day alert reports. *See id.*[24] Yet despite having knowledge of these adverse events, FDA has not withdrawn its approval for the subject drugs. All claims for reimbursement, therefore, were for drugs that continue to receive full and unequivocal FDA approval.

Similarly, as to the subject drugs' labeling, she does not allege that FDA ever deemed the subject drugs "misbranded" or found Takeda in violation of its labeling regulations. *See supra* 12-14. And her Second Amended Complaints do not identify a single physician who allegedly would not have prescribed the subject drugs had the labels contained Ge's proposed warnings.

Her only attempt to span the chasm between the alleged violations and a false or fraudulent claim is with multiple layers of

[24] Again, Ge also does not dispute that several of the drug-drug interactions she accuses Takeda of misreporting as "expected" (i.e., "labeled") actually were listed on the labels per FDA's instruction. *See supra* 20-21.

unsupported speculation as to how FDA, or doctors, or patients, *would have reacted* had Takeda reported the alleged adverse events earlier as 15-day alert reports or updated the subject drugs' labels in accord with Ge's personal interpretation of FDA regulations. Such speculative allegations, however, are too "conclusory to remove the possibility of relief from the realm of mere conjecture." *Tambone*, 597 F.3d at 442. They do not satisfy Rule 12(b)(6).

Besides, allowing a relator to predicate a FCA action on alleged violations of FDA adverse event reporting and labeling regulations, where, as here, FDA never found a violation occurred, both undermines FDA's exclusive authority and discretion to decide how and whether to enforce these regulations, *Buckman*, 531 U.S. at 349, and effectively provides judicial review of FDA's discretionary decision to decline enforcement, even though such review is otherwise unavailable under the Administrative Procedure Act, *Heckler*, 470 U.S. at 835, 837-38.

Such usurpation of FDA's authority is especially unwarranted here because the allegedly violated regulations necessarily implicate FDA discretion in determining whether a violation has occurred. Under 21 C.F.R. § 314.80(a), for example, certain adverse events are

only "serious" if "when, *based upon appropriate medical judgment*, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the [above] outcomes." 21 C.F.R. § 314.80(a) (emphasis added). Similarly, a manufacturer need only update its label to report "those adverse events for which there is *some basis to believe there is a causal relationship* between the drug and the occurrence of the adverse event." 21 C.F.R. § 201.57(c)(7) (emphasis added).

But as Ge would have it, even when FDA—employing its expertise in this area—finds no fault with a manufacture's reporting or labeling, judges and juries can second-guess that judgment, leading to the incongruous result of a pharmaceutical company facing exorbitant penalties, including treble damages, for conduct wholly condoned by FDA. This is not hypothetical—it is exactly what Ge is trying to do in this case.

As legions of courts have already recognized, the FCA should not be expanded so dramatically as to undermine the complex

administrative procedures already in place to police compliance with FDA regulations.[25] This Court should join them.

Ge's final contention, that even if Takeda did not violate any FDA regulations FCA liability can still apply because FDA approval does not discharge a manufacturer's duty to properly label a product (*See* RelatorBr. 33 n.8, 41), is particularly unavailing. The only authority she cites, *Wyeth v. Levine*, 555 U.S. 555 (2009), involved failure-to-warn, products-liability tort claims based on

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[25] *See Wilkins*, 659 F.3d 295 at 310 ("[I]f we allowed appellants . . . to bring suit based on [defendant's] non-compliance with marketing regulations, we would short-circuit the very remedial process the Government has established to address non-compliance with those regulations."); *U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1222 (10th Cir. 2008) ("It would . . . be curious to read the FCA, a statute intended to protect the government's fiscal interests, to undermine the government's own regulatory procedures."); *see also Hobbs*, 711 F.3d at 713 ("[B]ecause these regulations are not conditions of payment, they do not mandate the extraordinary remedies of the FCA and are instead addressable by the administrative sanctions available, including suspension and expulsion from the Medicare program."); *U.S. ex rel. Hopper v. Anton*, 91 F.3d 1261, 1267 (9th Cir. 1996) (holding that FCA may not be used as a substitute for administrative remedies where the regulatory compliance is "not a sine qua non [for the] receipt of state funding"); *U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999) (holding that a qui tam plaintiff may not use the FCA to "preempt" a federal agency's "discretionary decision not to pursue regulatory penalties" and stating that "the FCA is not an appropriate vehicle for policing technical compliance with administrative regulations").

common-law negligence and strict liability. *Id.* at 559-60. The FCA, however, includes a scienter requirement, *see* 31 U.S.C. §3729(a)(1)(A)-(B), which "cabins" the breadth of a "false" claim, *Hutcheson*, 647 F.3d at 388. Ge does not explain how, in the absence of an allegation that Takeda violated FDA's reporting and labeling requirements, Takeda could have at the very least "act[ed] in reckless disregard of the truth or falsity of the information," §3729(b)(1)(A), that was allegedly represented in the claim for reimbursement.

C. Ge's Theories Do Not Satisfy The FCA's Materiality Requirement.

To state a claim under the FCA, Ge was required to allege that the false claims were "material" to the government's decision to pay the claim. *Hutcheson*, 647 F.3d at 394; *Loughren*, 613 F.3d at 307. A statement is material if it "represent[s] compliance with a material condition of payment that was not in fact met." *Hutcheson*, 647 F.3d at 379. The materiality requirement, as this Court has recognized, is a means of "cabin[ing] the breadth of the phrase 'false or fraudulent'" under the FCA. *Amgen*, 652 F.3d at 110 (quoting *Hutcheson*, 647 F.3d at 388-89).

Here, the district court correctly concluded that Ge's theories could not satisfy the materiality requirement. All of Ge's allegations involve payment of claims for FDA-approved drugs. The government had no discretion to deny claims for payment for those drugs under some hypothetical theory of an alleged, unproven FDA violation. *See supra* n.22. Moreover, as the district court correctly recognized, Ge's claims involve alleged regulatory violations within the exclusive jurisdiction of FDA. Because FDA has several remedies at its disposal to enforce its regulations, including declining to institute any enforcement proceedings at all, *see Heckler*, 470 U.S. at 835, 837-38, the district court correctly held that a violation of these regulations could not be material to the government's payment decision.

Ge's new three liability theories on appeal fare no better. Her lead contention, that materiality is "fact-intensive and context specific" (RelatorBr. 34), is true but irrelevant. Ge had to plead those facts, and she did not. *In re New Motor Vehicles Canadian Export Antitrust Litig.*, 533 F.3d 1, 6 n.3 (1st Cir. 2008) ("Plaintiffs appear to confuse what they plead in their complaints with what they argue in their briefs before this court . . . . [I]t is the fact-

pleading in the complaints that controls [for reviewing a motion to dismiss].").

Ge also argues that the district court was wrong to assess materiality from the vantage point of the government as opposed to the doctors and patients. (RelatorBr. 33-34.) Wrong. *U.S. ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39 (D. Mass. 2001), the only FCA case she cites for this proposition, actually focused its materiality analysis on the government, not some third party. There, the court found that the relator adequately alleged materiality, because, as the defendant in *Franklin* did not dispute, "the government would not have paid the claims if it had known of the use for which they were being submitted." *Id.* at 53.

And pertinent authority is actually against Ge, holding that the proper inquiry focuses on whether the conduct had a natural tendency to influence or was capable of influencing the *government's* decision to pay the claim. *See Amgen*, 652 F.3d at 110 (recognizing that FCA plaintiff "must show that the claims at issue . . . misrepresented compliance with a *material* precondition of Medicaid payment") (emphasis added); *Loughren*, 613 F.3d at 307 ("[W]e will find that the statement . . . was material if it had a

natural tendency to influence or was capable of influencing the [Social Security Administration's] decision whether or not to award [Social Security Disability Insurance] benefits."); *Hutcheson*, 647 F.3d at 394 (addressing whether the alleged misrepresentations were "capable of influencing Medicare's decision to pay the claims").[26]

At bottom, Ge's inability to plead materiality is a problem inherent in her effort to stretch the FCA to cover this case. The mine run of FCA cases finding materiality are where falseness or fraud gives the government the legal right not to pay a claim. *See, e.g.*, *Amgen*, 652 F.3d 103; *Hutcheson*, 647 F.3d 377. That, of course, is not this case.

Some courts, in decisions on which Ge and the government as *amicus* rely, have also extended FCA coverage to situations where falseness or fraud gives the government discretion not to pay a claim. In *U.S. ex rel. Harrison v. Westinghouse Savannah River Co.*,

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[26] Ge's reliance on tort cases recognizing the presumption that a physician will heed an adequate warning in a "failure to warn" suit, and on *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011), is similarly misplaced (*see* RelatorBr. 34-35); again, the materiality inquiry focuses on the party making the ultimate payment decision.

352 F.3d 908, 916-17 (4th Cir. 2003), for example, the court held that a qui tam plaintiff need not prove that the false statement "*actually* influenced the government not to pay a particular claim." (emphasis added). FCA liability could attach, the court reasoned, even though "a government entity might choose to continue funding the contract despite earlier wrongdoing by the contractor." (*See* U.S.Br. 14 (citing *Harrison*, 352 F.3d at 917)); *see also U.S. ex rel. Feldman v. Van Gorp*, 697 F.3d 78, 96 (2d Cir. 2012); *United States v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008); *United States v. President & Fellows of Harvard Coll.*, 323 F. Supp. 2d 151, 186 (D. Mass. 2004). But these cases are also not helpful here.

While Ge attempts to elide the difference, these decisions addressing the government's "discretion" dealt strictly with discretion afforded to its *decision to pay the claim*, not to an unrelated administrative agency's discretionary decision of *how to enforce its regulations*, which might in the future impact how claims may or may not be paid. That conduct could give the government the choice to pay or not suggests materiality. That conduct could give an unrelated administrative agency the choice to bring an enforcement action, and to then choose which consequence to

impose out of a number of options, where one of those potential consequences might, in the future, affect the government's obligation to pay, is a bridge too far. That is why courts have routinely declined to extend FCA liability to claims implicating an administrative agency's enforcement of its regulations. *See supra* n.25 (citing *Wilkins*, 659 F.3d at 310; *U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1222 (10th Cir. 2008); *Hobbs*, 711 F.3d at 713; *U.S. ex rel. Hopper v. Anton*, 91 F.3d 1261, 1267 (9th Cir. 1996); *U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999)). The result here should be no different.

Somewhat less directly, the government argues that the district court erred to the extent that it relied on the availability of other administrative remedies to address the alleged fraud—namely, FDA's citizen-petition provisions. But the government's authority actually underscores the distinction between the alleged regulatory violations in this case (which are multiple levels removed from any precondition of payment) and those in cases where courts found the plaintiff sufficiently pled an FCA claim.

The government cites *U.S. ex rel. Onnen v. Sioux Falls Independent School District No. 49-5*, 688 F.3d 410 (8th Cir. 2012),

for the proposition that FCA liability should not "turn on whether the alleged conduct might also be addressed through regulatory schemes." (U.S.Br. 18.) But *Onnen* expressly recognized that the presence of other regulatory remedies *is relevant* where, as here, the materiality of the regulatory non-compliance to the claim for reimbursement is disputed. As the court put it: "The scope of regulatory requirements and sanctions may affect the fact-intensive issue of whether a specific type of regulatory non-compliance resulted in a *materially* false claim for a specific government payment." *Id.* at 414 (emphasis added).

Besides, the district court did not do what the government accuses it of doing; it based its Rule 12(b)(6) dismissal on Ge's failure to allege how the providers' claims misrepresented compliance with FDA reporting requirements, and on the FDA's discretion in enforcing its regulations, including the multiple enforcement remedies at its disposal. (*See* Addendum 74.) And even the government does not argue for reversal of the Rule 12(b)(6) dismissal.

Finally, as a backstop, Ge also points to a variety of "expert" evidence she attached to her motion for reconsideration. (*See*

RelatorBr. 35-36.) But this cannot salvage her claims. "What matters . . . is what plaintiff[] pled in [her] complaints." *New Motor Vehicles*, 533 F.3d at 5. These matters should have been pled somewhere in Ge's first three sets of complaints—or at least raised in her opposition to Takeda's motion to dismiss. It is well-established that reconsideration based on new facts is available only where the movant "offer[s] a convincing explanation as to why [s]he could not have proferred the crucial evidence at an earlier stage of the proceedings." *Karak v. Bursaw Oil Corp.*, 288 F.3d 15, 19-20 (1st Cir. 2002). The district court correctly rejected Ge's attempt to inject new (but previously available, (*see* R.50 at 13-18)) evidence belatedly. Ge has not challenged that ruling, and even if she had it would be reviewed only for abuse of discretion, which she has not remotely shown. *Palmer v. Champion Mortg.*, 465 F.3d 24, 30 (1st Cir. 2006). So this scattershot "expert" evidence is unavailing.

For all of these reasons, the district court was correct to dismiss Ge's complaints under Rule 12(b)(6), and its judgment can be affirmed on that ground, too.

III. THE DISTRICT COURT CORRECTLY DISMISSED GE'S CLAIMS FOR FAILURE TO PLEAD FRAUD WITH PARTICULARITY AS REQUIRED BY RULE 9(b).

The district court also dismissed Ge's FCA claims on the independent ground that they failed to satisfy Rule 9(b)'s particularity requirements. To meet this standard, a "complaint must specify 'the time, place, and content of an alleged false representation.'" *Rost*, 507 F.3d at 731 (citation omitted). More specifically, because FCA liability only attaches to false *claims*, *Karvelas*, 360 F.3d at 225, merely alleging facts related to the defendant's allegedly illegal practices is not enough, *Rost*, 507 F.3d at 733. A complaint must "sufficiently establish that false claims were submitted for government payment." *Id.*

To be sure, as this Court recently recognized, where an FCA action involves allegations that the "defendant induced *third parties* to file false claims with the government," a complaint need not "necessarily provide[] details as to *each* false claim." *U.S. ex rel. Duxbury v. Ortho Biotech Prods.*, 579 F.3d 13, 29 (1st Cir. 2009). But the complaint must do more than merely "suggest fraud was possible." *Rost*, 507 F.3d 733; *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006) ("Rule 9(b) 'does not permit a

False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply . . . that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government.'" (quoting *U.S. ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002)). At a minimum, it must provide "factual and statistical evidence to strengthen the inference of fraud beyond possibility." *Rost*, 507 F.3d 733; *Duxbury*, 579 F.3d at 29. In *Duxbury*, for example, which this Court described as a "close call," the complaint survived Rule 9(b) where it identified (1) eight specific medical providers who allegedly submitted false claims; (2) information about the dates and amounts of those claims; and (3) the government healthcare plan to which the claims were submitted. 579 F.3d at 28-32.

This standard is demanding, and for good reason: The rule both protects defendants against unsupported allegations of fraud because "the mere accusation often causes harm," and also "discourages plaintiffs from filing allegations of fraud merely in the hopes of conducting embarrassing discovery and forcing settlement." *Rost*, 507 F.3d at 733. Indeed, these "purposes may

apply with particular force in the context of the [FCA], given the potential consequences flowing from allegations of fraud by companies who transact business with the government." *U.S. ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, 707 F.3d 451, 456 (4th Cir. 2013). Accordingly, although Ge neglects to mention it, this Court has declined invitations to apply a relaxed pleading standard like the one Ge proposes, (RelatorBr. 48), just because a relator believes "the fraud at issue" to be "complex." *Karvelas*, 360 F.3d at 231 n.14. And it has expressly rejected requests like Ge's (*see* RelatorBr. 52-53) to apply a lower standard in the hopes that discovery might reveal more facts to plead. *Id.* at 231 ("[W]e hold that a qui tam relator may not present general allegations in lieu of the details of actual false claims in the hope that such details will emerge through subsequent discovery."); *see also Rost*, 507 F.3d at 732.

Measured against this standard, as the district court found, Ge's Second Amended Complaints are woefully insufficient. They focus solely on Takeda's allegedly illegal practices and allege no specific facts related to:

1. The allegedly false claims for reimbursement, including no "factual or statistical evidence" suggesting "beyond possibility" that any such claims were in fact submitted, *Rost*, 507 F.3d at 733; *Duxbury*, 579 F.3d at 29;

2. Ge's hypothetical scenario of what either FDA or certain physicians *might have done* if Takeda had either expedited the reporting of certain adverse events or updated its labels sooner, *see U.S. ex rel. Roop v. Hypoguard USA, Inc.,* 559 F.3d 818, 825 (8th Cir. 2009) (rejecting under Rule 9(b) "[t]he conclusory allegation that unidentified government agents 'would not have reimbursed through Medicare individuals submitting claims for Hypoguard systems if they had known of the defects and failure to comply with the rules and regulations of the FDA'" or that certain products "'would have been recalled' had Hypoguard complied with the [Medical Device Reporting] regulations"); or

3. How the allegedly false representations of compliance would have been capable of influencing the government's payment decisions. *See id.* (affirming Rule 9(b) dismissal of FCA claim which did not allege "how any product defect or failure to submit [Medical Device Reporting] reports to the FDA was material to—that is

'capable of influencing'—the government's decision to pay countless unidentified Medicare reimbursement claims").

More specifically, and in sharp contrast to the complaint in *Duxbury*, Ge's complaints fail to identify:

1. A single physician who was allegedly induced to prescribe any of the subject drugs or whose independent judgment was somehow compromised by Takeda's alleged post-marketing reporting;

2. When any prescriptions were made;

3. When any prescriptions were filled by a pharmacy;

4. When and if a claim was submitted for reimbursement;

5. The amount of any alleged claims;

6. Whether a claim was submitted to the government or instead to a private payor for reimbursement;

7. What government healthcare program any claims were submitted to; and

8. Whether the government made a payment on any of the subject drugs.

The district court was thus correct to dismiss these claims under Rule 9(b) because Ge "failed to allege the specific details of any claims." (Addendum 71.)

On appeal, Ge spends the first half of her Rule 9(b) argument patting herself on the back for her allegations about "the fraud perpetrated by Takeda." (RelatorBr. 50-53.) That is telling, as the district court conceded that she had "alleged facts that would demonstrate a 'fraud-on-the-FDA.'" (Addendum 71.) In striking contrast, she cannot point to any allegations in her Second Amended Complaints related to a single false claim for government reimbursement. (*See* RelatorBr. 53-57.)

Instead, Ge first contends that she satisfied Rule 9(b) because Takeda is "on notice of what categories of government claims are at issue." (*Id.* at 52.) Not so. Her allegations only give notice related to Takeda's alleged conduct, not to any false claims. That is not enough. *Rost*, 507 F.3d at 733 (complaint failed to provide notice under Rule 9(b) because it only alleged facts related to defendant's illegal conduct, not to any false claims). Besides, as set forth above, "notice is not the only reason for the requirement of Rule 9(b)." *Id.* Notice does nothing to solve other concerns that gave rise to Rule

9(b), including potential reputational damages and undue settlement leverage. This case is a poster-child for those concerns.

As a fallback, Ge suggests that even if the complaints fall short of the pleading requirement, the additional information she provided in her motion for reconsideration should suffice. (RelatorBr. 54-57.) But, as set out above, those materials came far too late. *See supra* 60-61.

Thus, district court was correct to hold that Ge's claims did not satisfy Rule 9(b)'s heightened pleading requirements. On this ground, too, dismissal may be affirmed.

IV. GE WAIVED ANY ARGUMENT THAT THE DISTRICT COURT ERRED IN DISMISSING HER STATE LAW CLAIMS.

The district court also dismissed all of Ge's state law claims under both Rules 9(b) and 12(b)(6). Ge has not challenged this dismissal on appeal. As a result, because she "did not raise the issue in [her] opening brief . . . it is deemed waived." *Ouk v. Keisler*, 505 F.3d 63, 66 n.3 (1st Cir. 2007).

V. THE DISTRICT COURT DID NOT ABUSE ITS DISCRETION IN DENYING GE LEAVE TO FILE THIRD AMENDED COMPLAINTS.

Finally, Ge's request for a remand to file a fourth set of complaints should be rejected out of hand.

Ge requested leave to file an amended complaint at the end of her opposition to Takeda's motion to dismiss. This is the entirety of that two-sentence request:

> 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").

(R.35 at 36.) The district court did not separately address this request in its dismissal order.

On appeal, Ge first claims that the district court's not providing a reason for denying her request is, standing "alone," sufficient grounds for reversal. Continuing, Ge's brief represents that only such extreme grounds as undue delay, bad faith, dilatory motive, and repeated failure to cure deficiencies can justify denying

leave to amend, relying principally on a 50-year-old case. (RelatorBr. 58). But she does not even cite this Court's controlling decision, issued seven months ago, in *Silverstrand Investments v. AMAG Pharmaceuticals, Inc.*, 707 F.3d 95, 107 (1st Cir. 2013).

Silverstrand is fatal to Ge's contentions. In that case, plaintiffs assigned as error the district court's denial of leave to amend, and asked this Court to give them leave to replead. There, as here, "[p]laintiffs included their request for another attempt at making a plausible claim on this front within their submission opposing dismissal, but failed to provide the district court with the reasons supporting their request and with the substance of possible amendments." *Id.* Instead, as here, plaintiffs relied on "boilerplate sentences stating the well-settled 'freely given' standard under which a request for leave to amend is generally analyzed." *Id.* (Indeed, in *Silverstrand*, plaintiffs' included four boilerplate sentences, compared to Ge's two.) And there, as here, "[t]he district court never addressed the request, and Plaintiffs believe[d] that that constituted a reversible error." *Id.*

This Court flatly rejected these arguments because they "failed to abide by our oft-quoted maxim that litigants should not seriously

expect to obtain a remedy without doing the necessary leg work first"—specifically, they must "set forth the factual and legal predicate for the remedy sought." *Id.* The Court therefore affirmed, explaining: "Truncated at the factual end, Plaintiffs' request for leave to amend ran afoul of both of these principles. The district court therefore acted well within its discretion when completely disregarding the request." *Id.* at 108; *see also Epstein v. C.R. Bard, Inc.*, 460 F.3d 183, 191 (1st Cir. 2006). This case is on all fours with *Silverstein*, which requires affirmance.

Besides, even Ge concedes that leave to replead should be denied when it would be futile. And, as explained above, no matter how Ge might try she cannot jam the square peg of her allegations against Takeda into the round hole of the FCA. That required dismissal under Rule 12(b)(6), and nothing she could plead would change that.

CONCLUSION

The judgment of the district court should be affirmed.

Dated: September 17, 2013

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 13,890 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Office 2007 in Bookman Old Style 14pt.

Dated: September 17, 2013

/s/ Brian J. Murray
Brian J. Murray

CERTIFICATE OF SERVICE

I hereby certify on this 17th day of September, 2013, I electronically filed the foregoing with the Clerk of the Court of the United States Court of Appeals for the First Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ Brian J. Murray
Brian J. Murray