United States Court of Appeals
For the First Circuit

No. 13-1088

UNITED STATES ex rel. HELEN GE, M.D.,

Relator, Appellant,

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

Plaintiffs,

v.

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

Defendants, Appellees.

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UNITED STATES ex rel. HELEN GE, M.D.,

Relator, Appellant,

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v.

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

Defendants, Appellees.

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

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

Before

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

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

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

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

December 6, 2013

LYNCH, Chief Judge. In June 2010 Dr. Helen Ge originally filed these two qui tam actions against her former employer, Takeda Pharmaceutical Company Ltd. and its subsidiary Takeda Pharmaceutical North America, Inc. (collectively, "Takeda"), under the federal False Claims Act ("FCA"), 31 U.S.C. § 3729 et seq., and various analogous state statutes. The two actions concern different drugs. She has since amended each of her complaints twice. The United States has declined to enter the case as a party. In a successful qui tam action, the relator collects a portion of the award to the government regardless of whether the government intervenes. See United States ex rel. Duxbury v. Ortho Biotech Prods., L.P. ("Duxbury I"), 579 F.3d 13, 16 (1st Cir. 2009).

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

On Takeda's motions to dismiss, the district court dismissed both of Dr. Ge's actions under Federal Rule of Civil Procedure 9(b) for failure to plead fraud with particularity and, in addition, under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. United States ex rel. Ge v. Takeda

Pharm. Co. Ltd., Nos. 10-11043-FDS, 11-10343-FDS, 2012 WL 5398564 (D. Mass. Nov. 1, 2012). Dr. Ge proposed to amend the second amended complaint yet again, asserting still more theories of FCA liability. The district court declined to allow further amendment.

Dr. Ge now appeals, making three levels of arguments: (1) as to the Rule 9(b) dismissal, that her complaints contain sufficient allegations concerning "the who, what, where, and when" of Takeda's misconduct to satisfy Rule 9(b)'s particularity requirement, see Duxbury I, 579 F.3d at 30 (quoting Rodi v. S. New Eng. Sch. of Law, 389 F.3d 5, 15 (1st Cir. 2004)) (internal quotation mark omitted), (2) the district court abused its discretion in rejecting without opinion two requests, one pre-judgment and one post-judgment, by Dr. Ge to amend her complaints again, and (3) as to Rule 12(b)(6), that the district court's analysis relies on an overly restrictive conception of FCA liability.

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

I.

In September 2008, Dr. Ge took a position with Takeda as a contract physician, contracting to perform medical reviews of adverse event reports. Dr. Ge was responsible for reports of adverse events, including those concerning four specific drugs for

specific diseases: Actos (type 2 diabetes), Uloric (gout), Kapidex/Dexilant (gastroesophageal reflux disease), and Prevacid (same). Takeda sells all four drugs and each required Food and Drug Administration ("FDA") approval for these uses. Dr. Ge's tasks included ascertaining the seriousness of a reported event, determining whether the associated drug was causally responsible for that event, and determining whether that event constituted a "safety signal," that is whether the reported event signaled the need for additional safety warnings. Dr. Ge worked for Takeda until January 2010. She asserts that when she complained about improper reporting at Takeda, her contract was summarily terminated.

On June 18, 2010, Dr. Ge filed an FCA complaint under seal against Takeda pertaining to Actos. United States ex rel. Helen Ge v. Takeda Pharmaceutical Co., et al, 10-11043-FDS. On March 1, 2011, Dr. Ge filed a second complaint under seal pertaining to Uloric, Kapidex/Dexilant, and Prevacid. United States ex rel. Helen Ge v. Takeda Pharmaceutical Co., et al, 11-10343-FDS. In Dr. Ge's complaints, she alleged on behalf of the United States[1] that three FCA sections were violated: (a) 31 U.S.C.

[1] Dr. Ge's complaints also brought claims on behalf of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin, and the District of Columbia, alleging violations by Takeda of similar state statutes. Michigan is only a party to the Actos appeal.

§ 3729(a)(1)(A), which imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," (b) § 3729(a)(1)(B), which imposes liability on any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," and (c) § 3729(a)(1)(C), which imposes liability on any person who conspires to commit a violation of, among other things, § 3729(a)(1)(A) or § 3729(a)(1)(B).

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

Dr. Ge alleged Takeda had failed to report promptly and accurately to the FDA a number of post-approval adverse events associated with the four subject drugs. The FDA is responsible for the approval of drugs for commercial marketing. See 21 U.S.C. § 355. The FDA is authorized after approval to continue to evaluate the safety and effectiveness of the drug and, where appropriate, to withdraw approval or require a change in labeling. See id. § 355(k). FDA regulations require prompt, accurate reports of adverse drug events by drug manufacturers. 21 C.F.R. §§ 314.80, 314.81. The receipt of an adverse report does not in and of itself

show a causal relationship between a drug and the illness mentioned in a report. N.J. Carpenters Pension & Annuity Funds v. Biogen Idec, Inc., 537 F.3d 35, 53 (1st Cir. 2008).

It is undisputed that Takeda did submit adverse event reports and there is no specific allegation that any of the events which are the subject of the complaint were not eventually reported in some form to the FDA. As to the drug Actos, Dr. Ge alleged that she was asked by Takeda to misreport adverse events including incidences of heart failure, renal failure, pancreatic cancer, and, most notably, bladder cancer. Dr. Ge alleged that she complied with those directions on certain occasions after having made known her objections. In addition, Dr. Ge alleged that she had discovered systematic under-reporting by Takeda of the incidence of bladder cancer in adverse event reports.

The FDA did receive information on bladder cancer risk because in June 2011, the FDA issued an official warning "that use of the diabetes medication Actos (pioglitazone) for more than one year may be associated with an increased risk of bladder cancer." FDA Drug Safety Communication: Update to ongoing safety review of Actos (pioglitazone) and increased risk of bladder cancer (June 15, 2011), http://www.fda.gov/Drugs/DrugSafety/ucm259150.htm. The FDA also mandated a label change. FDA Drug Safety Communication: Updated drug labels for pioglitazone-containing medicines (Aug. 4, 2011), http://www.fda.gov/drugs/drugsafety/ucm266555.htm. But it

also issued a supplemental approval of Actos after knowing of the bladder cancer risk. Dr. Ge alleges that after the labeling change the sales of Actos plummeted.

As to the drugs Uloric, Kapidex/Dexilant, and Prevacid, Dr. Ge alleged that Takeda pressured her to falsify her medical conclusions, asking her to classify events as "non-serious" or to change her causality assessment to "unrelated" so as to avoid "reporting within 15 days" as required by FDA regulation. See 21 C.F.R. § 314.80(c)(1)(i) (requiring report of "serious and unexpected" adverse event within 15 days). Specifically, Dr. Ge alleged that she was directed to alter her analysis of reported adverse events involving the interactions between the three drugs and other medications likely to be taken by senior citizens. Dr. Ge did not clearly allege that she complied with Takeda's directions. Dr. Ge did allege, however, that on various occasions Takeda officials altered her assessments directly.

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

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

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

On May 11, 2012, Takeda filed its motion to dismiss. Dr. Ge filed a memorandum in opposition on July 17, 2012. At the end of her memorandum but not as a separate motion, Dr. Ge requested leave to amend her complaints a third time, if the court was inclined to dismiss, and supported it with a declaration from one of her attorneys that included an attachment providing the total expenditures by the federal government for Actos. On August 27, 2012, Takeda filed a motion to strike that declaration.

On November 1, 2012, the district court dismissed in a written order Dr. Ge's claims under Rule 9(b), reasoning that "although relator has alleged facts that would demonstrate a 'fraud-on-the-FDA' with respect to intentional under-reporting of adverse events, she has failed to allege the specific details of any claims that were allegedly rendered 'false' as a result." Takeda, 2012 WL 5398564, at *4. The district court noted that Dr. Ge had attempted to cure this defect by referring to her attorney's declaration, which attached the total aggregate expenditure data by the government for Actos. Id. The district court held, however, that even assuming it was permissible for the court to consider the Actos data, such aggregate expenditure data did not satisfy Rule 9(b)'s particularity requirement. Id. The district court

contrasted Dr. Ge's pleadings with the pleadings of the relator in Duxbury I, which identified eight specific medical providers who allegedly submitted false claims, the rough time periods, locations, and amounts of the claims, and the specific government programs to which the claims were made. Takeda, 2012 WL 5398564, at *4 (citing Duxbury I, 579 F.3d at 29-30).

From the absence of such specifics in Dr. Ge's complaints, the district court inferred that Dr. Ge meant to assert that all claims for the subject drugs during the relevant time period were rendered false by Takeda's alleged misconduct. Id. at *5. The district court held that Dr. Ge had not provided the specific factual allegations necessary to support the inference that the FDA would have withdrawn approval from all four drugs immediately upon receiving the withheld information. Id.; see also 21 C.F.R. §§ 314.80(j), 314.81(d) ("If an applicant fails to establish and maintain records and make reports required under this section, FDA may withdraw approval of the application and, thus, prohibit continued marketing of the drug product that is the subject of the application.") (emphasis added). The district court went beyond that to point out that even were it to accept the unsubstantiated premise that drugs would have been taken off the market, there were still no allegations about how the fraudulent reporting would render false those claims which were filed before the adverse events occurred.

In the same November 1, 2012 order, the district court also dismissed Dr. Ge's claims under Rule 12(b)(6) for failure to state a claim, holding that Dr. Ge had not adequately established that compliance with adverse-event reporting requirements was a "material precondition" to the payment of the claims at issue. Takeda, 2012 WL 5398564, at *6; see also United States ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 392 (1st Cir. 2011) (holding that FCA liability exists where claims submitted "misrepresented compliance with a precondition of payment so as to be false or fraudulent" and where "those misrepresentations were material"). The district court observed that it is within the FDA's discretion to respond to violations of adverse-event reporting requirements in a number of ways, only the harshest of which is the withdrawal of drug approval. Takeda, 2012 WL 5398564, at *6. The district court noted in addition that the FDA's enforcement procedures provide the opportunity for citizens to petition the FDA to bring action against specific violators. Id. (citing 21 C.F.R. § 10.30). The district court reasoned that "[i]t is through that mechanism, rather than an FCA lawsuit, that relator should have brought the reporting issues illuminated in the complaints to the attention of the FDA." Id.

Finally, the district court dismissed in that same order Dr. Ge's various state-law claims both because they failed to state a claim under state law and because they failed to plead with

specificity the details of any claims for payment made to any of the states. Id. The district court did not address Dr. Ge's request for leave to amend. Judgment was entered for defendants on November 1, 2012.

On November 29, 2012, Dr. Ge filed a formal motion for reconsideration pursuant to Rule 59(e) along with a motion for leave to amend her complaint. Dr. Ge's motions were supported by (a) an economic model constructed by a pharmaceutical economics professor from the School of Pharmacy at the University of Southern California purporting to show the amount of claims for Actos that would not have been submitted for government payment but for Takeda's alleged misconduct, and (b) the declarations of eight individuals attesting that an individual patient would not have submitted his or her claim if Takeda had promptly and accurately disclosed the link between Actos and bladder cancer. On December 18, 2012, the district court denied Dr. Ge's motions without opinion. On January 14, 2013, Dr. Ge filed a timely notice of appeal.[3]

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[3] Appearing as amicus curiae in support of neither party, the United States makes a limited argument that the district court erred in its Rule 12(b)(6) analysis to the extent that it reasoned (1) the availability of alternative administrative remedies precludes FCA liability, and (2) the failure to comply with FDA post-approval reporting requirements is per se immaterial to the Government's decision whether to reimburse a claim and hence could under no circumstances serve as a basis for FCA liability. According to the United States, failure to comply with FDA post-approval reporting requirements could serve as a basis for FCA liability only in "rare circumstances." It was objecting only to

II.

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

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

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

> "Although [the FCA's] financial incentive encourages would-be relators to expose fraud," United States ex rel. Poteet v. Bahler Med., Inc., 619 F.3d 104, 107 (1st Cir. 2010), it also attracts "'parasitic' relators who bring

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a per se approach. The United States takes no position as to whether Dr. Ge's complaints contain sufficient allegations to state a claim for purposes of Rule 12(b)(6). Nor does the United States take a position as to whether Dr. Ge's pleadings satisfy the particularity requirement of Rule 9(b).

> FCA damages claims based on information within the public domain or that the relator did not otherwise discover," United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 727 (1st Cir. 2007).

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

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

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

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

In a qui tam action in which the defendant is alleged to have induced third parties to file false claims with the

government, a relator can satisfy this requirement by "providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility' without necessarily providing details as to each false claim." Duxbury I, 579 F.3d at 29 (quoting Rost, 507 F.3d at 733).

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

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

than those there whose sufficiency was deemed a "close call," id. at 30.

There, this court reversed the district court's dismissal under Rule 9(b) of some of the relator's claims, reasoning that the relator's identification of eight specific medical providers who allegedly submitted false claims, plus rough time periods, locations, and amounts of the claims, and the specific government programs to which the claims were made, were just enough to constitute a pleading of fraud with particularity. Id. at 30.[4] Here, by contrast, Dr. Ge provided in response to the motions to dismiss, at most, aggregate expenditure data for one of the four subject drugs, with no effort to identify specific entities who submitted claims or government program payers, much less times, amounts, and circumstances.

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

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

made, it necessarily follows that false claims and/or material false information were filed. We reject that approach, which violates the specificity requirements of Rule 9(b).

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

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

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

the [g]overnment"); see also United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc., 707 F.3d 451, 457 (4th Cir. 2013) ("[We] hold that when a defendant's actions, as alleged and as reasonably inferred from the allegations, could have led, but need not necessarily have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment." (emphasis added)); United States ex rel. Atkins v. McInteer, 470 F.3d 1350, 1359 (11th Cir. 2006) ("[Relator] has described in detail what he believes is an elaborate scheme for defrauding the government by submitting false claims. . . . [Relator] fails to provide the next link in the FCA liability chain: showing that the defendants actually submitted reimbursement claims for the services he describes.").

A. Implied Warranty

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

infers that she has adequately stated that all claims submitted to the government for those drugs were false.

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

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

B. "Reasonable and Necessary"

Dr. Ge on appeal invokes 42 U.S.C. § 1395y(a)(1)(A), which prohibits Medicare payments for treatments that are not

"reasonable and necessary."[6] According to Ge, as a result of Takeda's alleged misconduct, certain reimbursement claims were rendered false under the FCA because they impliedly -- and incorrectly -- certified that the subject drugs were "reasonable and necessary."

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

C. "Misbranded"

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

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[6] Various state statutes and regulations governing Medicaid reimbursement impose similar restrictions. See, e.g., 130 Mass. Code Regs. 450.204 ("The MassHealth agency will not pay a provider for services that are not medically necessary . . . .") (emphasis added).

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

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

new argument that could (and should) have been presented prior to the district court's original ruling.").

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

III.

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

Dr. Ge argues that she could have cured any defects in her complaints had she been provided with leave to amend the two times she asked. She had already twice amended both of her complaints in the 21 months after the filing of her initial complaint. The first request, after Takeda filed its motion to dismiss in 2012, was in her memorandum in opposition to Takeda's motion to dismiss and conditionally did state that if the court was inclined to dismiss, then she would like to amend.[7] The district

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

> If the Court were to determine that Relator's Complaints are deficient in any regard, Relator respectfully requests that this Court afford her an

court did not explicitly discuss the request, but did discuss the additional appended material on Actos and said it did not cure the deficiencies in the pleading.

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

When a motion to amend is properly made before entry of judgment, the district court is to evaluate that motion under the "liberal standard of Fed. R. Civ. P. 15(a)." Palmer v. Champion Mortg., 465 F.3d 24, 30 (1st Cir. 2006). "Amendments may be permitted pre-judgment, even after a dismissal for failure to state a claim, and leave to amend is 'freely given when justice so requires.'" Id. (quoting Fed. R. Civ. P. 15(a)). The "request" was not properly made.

By contrast, as to post-judgment motions "a district court cannot allow an amended pleading where a final judgment has

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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").

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

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

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

Id. at 182. Dr. Ge contends that the district court's denials without a statement of reasons for her two requests amounted to

just the sort of "outright refusal . . . without any justifying reason" that Foman proscribes.

As explained in Silverstrand Investments v. AMAG Pharmaceuticals, Inc., 707 F.3d 95, 107-08 (1st Cir. 2013), where, as here, a request to file an amended complaint consists of nothing more than "boilerplate sentences stating the well-settled 'freely given' standard under which a request for leave to amend is generally analyzed," a district court "act[s] well within its discretion when completely disregarding the request."[8] Indeed, in Gray v. Evercore Restructuring LLC, 544 F.3d 320 (1st Cir. 2008), a case involving a nearly identical request, this court explained that except perhaps in "exceptional circumstances," a bare request in an opposition to a motion to dismiss does not constitute a motion to amend for purposes of Rule 15(a). Id. at 327 ("Although a court's denial of a motion to amend is typically reviewed for an abuse of discretion, in this case the district court neither granted nor denied a motion to amend. . . . As [plaintiff] failed to request leave to amend, the district court cannot be faulted for failing to grant such leave sua sponte."); accord Fisher v. Kadant,

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

Inc., 589 F.3d 505, 509-10 (1st Cir. 2009). And even at that, Foman identifies "repeated failure to cure deficiencies by amendments previously allowed" as reason for denying a motion for leave to amend under the permissive Rule 15(a) standard. 371 U.S. at 182.

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

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

The district court's dismissal order identified the evidentiary defects in Dr. Ge's complaints after Dr. Ge had twice amended her complaints and after having considered arguendo Dr. Ge's contested declaration and accompanying expenditure data. As this court has stated previously:

> To require the district court to permit amendment here would allow plaintiffs to

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

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

IV.

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