United States Court of Appeals
For the First Circuit

No. 16-1382

PETER P. LAWTON, ex rel. UNITED STATES OF AMERICA; and THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DISTRICT OF COLUMBIA, DELAWARE, FLORIDA, GEORGIA, HAWAII, IOWA, ILLINOIS, INDIANA, LOUISIANA, MASSACHUSETTS, MARYLAND, MICHIGAN, MINNESOTA, MONTANA, NORTH CAROLINA, NEW JERSEY, NEW MEXICO, NEVADA, NEW YORK, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WASHINGTON, WISCONSIN,

Plaintiffs, Appellants,

v.

TAKEDA PHARMACEUTICAL COMPANY, LTD.; TAKEDA PHARMACEUTICALS U.S.A., INC., f/k/a Takeda Pharmaceuticals North America, Inc.; TAKEDA PHARMACEUTICALS INTERNATIONAL INC.; TAKEDA DEVELOPMENT CENTER AMERICAS, INC., f/k/a Takeda Global Research & Development Center Inc.; ELI LILLY AND COMPANY,

Defendants, Appellees.

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

[Hon. Mark L. Wolf, U.S. District Judge]

Before

Lynch, Stahl, and Barron,
Circuit Judges.

David E. Kovel, with whom John R. Low-Beer, Of Counsel, and Kirby McInerney LLP were on brief, for appellants.

R. Jeffrey Layne, with whom Jonathan S. Franklin, Sarah M. Cummings, and Norton Rose Fulbright US LLP were on brief, for appellees.

November 22, 2016

STAHL, **Circuit Judge**. Relator-Appellant Peter Lawton ("Lawton") brought a qui tam action against Appellees Takeda Pharmaceutical Company, Ltd. and its affiliates ("Takeda") and Eli Lilly and Company ("Eli Lilly") (collectively, "Defendants") under the False Claims Act ("FCA"), 31 U.S.C. § 3729 et seq., and the False Claims Acts of 28 different states and the District of Columbia.[1] Lawton alleges that Takeda and Eli Lilly conspired in a fraudulent marketing campaign that caused third-parties to submit false reimbursement claims to government entities for off-label uses of Actos, a treatment for Type 2 diabetes.[2]

The district court dismissed all of Lawton's claims, holding that Lawton had not pled his claims with the particularity required by Federal Rule of Civil Procedure 9(b). Lawton contests this ruling on appeal, and maintains that his allegations sufficiently plead that false claims were submitted to both federal

[1] "'Qui tam' comes from the phrase *'qui tam pro domino rege quam pro se ipso in hac parte sequitur*,' which translates as 'who pursues this action on our Lord the King's behalf as well as his own.'" United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 727 n.4 (1st Cir. 2007) (quoting Rockwell Int'l Corp. v. United States, 549 U.S. 457, 463 n.2 (2007)), overruled on other grounds by Allison Engine v. United States ex rel. Sanders, 553 U.S. 662 (2008).

[2] "Off-label uses" refer to uses for drugs that are not approved as safe and effective by the Food and Drug Administration ("FDA"). Though Medicaid reimbursement is available for certain off-label uses that are medically "essential" or recognized within one of several medical compendia, see 42 U.S.C. § 1396r-8(a)(3), (g)(1)(B)(i), (k)(6), these uses are not at issue in this case.

and state government programs. After thoroughly reviewing these allegations, we affirm.

I. Facts & Background

Since this appeal follows the granting of a motion to dismiss, we recite the relevant facts as they appear in Lawton's Second Amended Complaint. See Hochendoner v. Genzyme Corp., 823 F.3d 724, 728 (1st Cir. 2016).

Actos is a brand name drug approved by the FDA for improving blood sugar control in adults with Type 2 diabetes. The drug is manufactured, promoted, marketed, and sold by Takeda.[3]

In May 2012, Peter Lawton filed a qui tam complaint against Takeda alleging that it had engaged in an illegal off-label marketing campaign for Actos in violation of 21 U.S.C. § 321 et seq. (the "Food, Drug & Cosmetic Act"), and used illegal kickbacks to support that campaign in violation of 42 U.S.C. § 1320a-7b(b) (the "Anti-Kickback Statute").[4] Lawton -- a former

[3] In his Second Amended Complaint, Lawton named Eli Lilly as a defendant for the first time, alleging that it had entered into a partnership with Takeda to jointly market Actos from 1999 to 2006.

[4] The FDA has only approved Actos for treatment in adults with Type 2 diabetes. Physicians may prescribe Actos for non-FDA-approved treatments, but the Food, Drug & Cosmetic Act prohibits pharmaceutical companies from marketing drugs for off-label uses. The Anti-Kickback Statute, meanwhile, imposes criminal penalties on anyone who, among other things, "solicits" or "pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, to purchase or recommend purchasing any good, facility, service or item for which payment may be made in whole or in part under a federal

chemist and patent litigator at Takeda competitor GlaxoSmithKline -- further alleged that through this campaign, Takeda and Eli Lilly had knowingly caused third-parties to submit false or fraudulent claims for payment to federal and state government programs.[5] See, e.g., 31 U.S.C. § 3729(a); N.Y. State Fin. Law §§ 188-89.

Lawton made his first amendment to his complaint in February 2014, and after the United States declined to intervene and the action was unsealed, his case began in earnest. In August 2015, the district court allowed Lawton to amend his complaint again ("Second Amended Complaint"), which he filed the following month and is the subject of this appeal.

The Second Amended Complaint alleged that starting in the late 1990s and lasting until 2011, Defendants utilized a marketing scheme designed to develop and promote "quasi-scientific" bases for off-label use of Actos, specifically the

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healthcare program." 42 U.S.C. § 1320a-7b(b). Since Lawton claims Defendants violated both provisions, FCA liability would attach if Lawton proved the violations caused third-parties to submit false claims for reimbursement to government programs.

[5] Lawton claims he initially learned of Takeda's illegal conduct when, while working at GlaxoSmithKline, he met with various Takeda representatives in an intellectual property dispute concerning Actos and Avandia, GlaxoSmithKline's diabetes drug, in 2001. Subsequent to this, he claims to have learned more specifics about Takeda's strategy via internal discussions at GlaxoSmithKline between 2001 and 2003 and a series of three job interviews he had at Takeda in 2009.

treatment of prediabetes.[6] The claimed centerpiece of this campaign involved the development of dozens of pro-Actos research studies and subsequent publications substantiating these claims. The most prominent of these studies, Lawton claims, was a 2006 paper ("ACT NOW Study") on the prevention of Type 2 diabetes. Allegedly conceived and funded by Takeda but ostensibly authored by Dr. Ralph DeFronzo, the ACT NOW Study advocated for the use of Actos as an effective treatment for prediabetes. Lawton alleges that Dr. DeFronzo and other "thought leaders" and researchers like him received compensation, kickbacks, and other indirect financial inducements from Takeda for their Actos studies, related speeches, and supporting presentations. Many of these studies, however, were criticized by various academic journals, peer review panels, and the FDA.

Takeda allegedly also established a specialized Actos sales force to parallel this campaign, and tasked it with encouraging physicians to prescribe Actos as a safe and effective treatment for prediabetes. Takeda also supposedly engaged in direct marketing to the public about the off-label use of Actos and made large contributions to several educational and research organizations to gain influence over their views on prediabetes

[6] Prediabetes refers to the condition of having a high probability of developing diabetes in the future.

treatments. These efforts purportedly continued even after Takeda knew that the results of many of these studies were inconclusive.

Based on these allegations, Lawton claimed that Takeda and Eli Lilly violated the FCA and analogous state statutes by causing false claims for Actos to be presented to both federal and state government healthcare programs.

Lawton first pointed to the dramatic increase in Actos sales between 2006 ($1.5 billion) and 2011 ($3.6 billion), attributing these increased numbers to greater off-label use of Actos for patients with a prediabetes condition. Lawton then identified three non-diabetic members of the Suffolk County (NY) Health Plan who, between 2011 and 2014, were prescribed a total of 11 scripts for Actos, for which the Health Plan paid a total of $3,170.14. With respect to the federal programs, Lawton cited evidence that public sector programs like Medicaid and Medicare accounted for more than half of Actos purchases between 2003 and 2011. This evidence, he claimed, demonstrated that the Actos marketing campaign had caused violations of the False Claims Act.

Takeda and Lilly moved to dismiss the complaint on multiple grounds. On March 8, 2016, the district court granted the motion, dismissing the federal and pendant state claims with prejudice. The court reached this conclusion after finding that neither Lawton's federal nor state allegations pled fraud with the

particularity required by Federal Rule of Civil Procedure 9(b). Lawton now appeals.

II. Analysis

Lawton raises two issues on appeal, arguing that the district court erred in dismissing his federal FCA claim and associated state claims with prejudice. We review each in turn.

A. Federal Claim

Lawton first contends that the court erred when it dismissed the federal claim in Lawton's Second Amended Complaint based on his failure to plead the alleged fraud with enough particularity to satisfy Federal Rule of Civil Procedure 9(b). In such cases, we review de novo the granting of a motion to dismiss, United States ex rel. Gagne v. City of Worcester, 565 F.3d 40, 45 (1st Cir. 2009), "accepting as true all well-pleaded facts, analyzing those facts in the light most hospitable to the plaintiff's theory, and drawing all reasonable inferences for the plaintiff," United States ex rel. Hutcheson v. Blackstone Med. Inc., 647 F.3d 377, 383 (1st Cir. 2011).

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). As we have often said in these cases, relators are "required to set forth with particularity the who, what, when, where, and how of the alleged fraud." See, e.g., United States ex rel. Ge v. Takeda Pharm. Co.,

Ltd., 737 F.3d 116, 123 (1st Cir. 2013) (internal citation and quotation marks omitted); see also United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 228 (1st Cir. 2004), abrogated on other grounds by United States ex rel. Gagne v. City of Worcester, 565 F.3d 40 (1st Cir. 2009) (applying Rule 9(b) to FCA claims).

The FCA penalizes persons who present, or cause to be presented, to the federal government "a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1). Thus, Rule 9(b) requires both that the circumstances of the alleged fraud and the claims themselves be alleged with particularity. United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 727 (1st Cir. 2007), overruled on other grounds by Allison Engine v. United States ex rel. Sanders, 553 U.S. 662 (2008) ("FCA liability does not attach to violations of federal law or regulations, such as marketing of drugs in violation of the FDCA, that are independent of any false claim.").

We briefly note that Lawton cites this Court's decision in Rodi v. Southern New England School of Law for the proposition that the relevant statements about which Rule 9(b) specificity is required are not the claims filed by innocent third-parties, but rather the allegedly fraudulent statements made by Takeda. 389 F.3d 5, 15 (1st Cir. 2004) (stating "the specificity requirement [of Rule 9(b)] extends only to the particulars of the allegedly

misleading statement itself."). Rodi, however, was a case about specific fraudulent misrepresentations made by the defendant, and not one about false or fraudulent claims. Id. at 5. While it made sense for us only to require that the misleading statements be pled with particularity in that case, we will not do so here where the fraudulent act of filing false claims is distinct from actions trying to induce such filing.

That being said, we have also recognized a difference between qui tam actions alleging that the defendant made false claims to the government and those alleging that the defendant induced third-parties to file false claims with the government. See United States ex rel. Duxbury v. Ortho Biotech Products, L.P., 579 F.3d 13, 29 (1st Cir. 2009) (citing Rost, 507 F.3d at 732).

In these circumstances, we apply a "more flexible" standard such that a relator can satisfy Rule 9(b) by providing "factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each [submitted] false claim." Duxbury, 579 F.3d at 29-30. Still, the evidence necessary to achieve this inference generally requires the relator to plead, inter alia, the "'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.'" United States ex rel. Kelly v. Novartis Pharms. Corp., 827 F.3d 5, 13 (1st Cir.

2016) (quoting Ge, 737 F.3d at 124); see also Rost, 507 F.3d at 733 (rationalizing Rule 9(b)'s application to FCA claims in part because "[i]t is a serious matter to accuse a person or company of committing fraud" and the rule "discourages plaintiffs from filing allegations of fraud merely in the hopes of conducting embarrassing discovery and forcing settlement").

In Karvelas, we likewise explained that while there is no "checklist of mandatory requirements" that each allegation in a complaint must meet to satisfy Rule 9(b):

> [D]etails 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.

360 F.3d at 233.

Viewing Lawton's Second Amended Complaint against the backdrop of these guidelines, we have little trouble concluding that his allegations do not satisfy Rule 9(b).

While the complaint describes at considerable length the Takeda's marketing machinations, the Second Amended Complaint falls well short of alleging, with the requisite amount of specificity, who submitted false claims to the government, how

many false claims were submitted to the government, or how the Defendants' actions resulted in the submission of false claims.

Lawton compares his complaint to the one in Duxbury, where we concluded that the relator's complaint had met Rule 9(b)'s particularity requirement. 579 F.3d at 30. There, the relator alleged that a company paid kickbacks to eight different medical providers which induced these providers to submit false claims for reimbursement to Medicare. Id. Although a "close call," we held that the complaint satisfied Rule 9(b) because Duxbury, in addition to setting forth allegations of kickbacks, provided information concerning the dates and amounts of the false claims, who filed these false claims, the applicable time periods and locations, and how the claims were filed. Id.

We agree with the district court that Lawton's allegations are materially weaker than those seen in Duxbury. The complaint does not allege that every prescription of Actos was unlawful because it was off-label or that every claim submitted to the federal government was false. See United States ex rel. Westmoreland v. Amgen, Inc., 738 F. Supp. 2d 267, 277 (D. Mass. 2010) (holding complaint satisfied Rule 9(b), in part because it included allegations that, as a result of the defendant's inducement, a specific provider issued a "standing order" for doctors to write fraudulent prescriptions for all patients). He merely alleges that off-label prescriptions of Actos submitted to

government programs were unlawful. But Lawton, unlike the relator in Duxbury, identifies no false claims, either individual or aggregated, from particular medical providers that were submitted for reimbursement.

Instead, Lawton simply postulates that "as much as" 30% of Actos annual sales were for off-label prescriptions, points to the amounts of Medicare and Medicaid funds used to pay for Actos prescriptions between 2003 and 2012, and asks us to infer that a portion of these funds must have been used to pay unlawful claims. As Yogi Berra allegedly said, "it's like déjà vu all over again."[7] See Ge, 737 F.3d at 124 (holding, in another case concerning Actos, that "aggregate expenditure data . . . with no effort to identify specific entities who submitted claims or government program payers, much less times, amounts, and circumstances" falls short of Rule 9(b)'s requirements).

Lawton, like the relator in Rost, has "[a]t most . . . raise[d] facts suggesting fraud was possible," but his pleadings do not suffice under Rule 9(b) to show that doctors, patients, or patients' private insurers did seek out federal reimbursement for off-label Actos prescriptions. 507 F.3d at 733. Because Lawton's

[7] "This epigram is often attributed to [Berra], a man as famous for mangling the English language as for belting baseballs. Berra coined many aphorisms -- but not this one. . . . The phrase's origin is unknown." Williams v. Ashland Engineering Co., Inc., 45 F.3d 588, 589 n.1 (1st Cir. 1995).

"evidence and arguments proceed more by insinuation than any factual or statistical evidence that would strengthen the inference of fraud beyond possibility," we affirm the district court's dismissal of Lawton's complaint under Rule 9(b). See Kelly, 827 F.3d at 15.

B. State Claims

The district court similarly did not err when it dismissed Lawton's state claims with prejudice. Rule 9(b)'s heightened pleading standard generally applies to state law fraud claims brought in federal court. See Rost, 507 F.3d at 731 n.8; Universal Commc'n Sys., Inc. v. Lycos, Inc., 478 F.3d 413, 427 (1st Cir. 2007). Lawton's Second Amended Complaint only contains allegations that false claims were submitted to New York State authorities in violation of the New York State False Claims Act ("NYSFCA"). See N.Y. State Fin. Law § 187 et seq. Even these allegations, however, are not pled with the requisite particularity.

Lawton alleges that between April 2011 and March 2014, three non-diabetic members of the Suffolk County Health Plan in New York State were prescribed Actos 11 times and that the health plan paid a total of $3,170.14 for these prescriptions. The Second Amended Complaint does not, however, identify the medical providers who prescribed Actos, nor does it allege how those prescriptions resulted from Defendants' marketing campaign or

supposed kickback scheme. And given the timeframe of the allegation, it is unclear whether the prescriptions in question were issued before or after the end of the alleged marketing campaign in 2011. This is relevant because if the prescriptions were written after the campaign ended, we cannot conclude that Lawton has strengthened the inference of fraud beyond possibility.

In short, Lawton's state law claims fail to satisfy Rule 9(b) for many of the same reasons why his federal FCA claim failed. Since Lawton does not offer any new evidence on appeal that would "cure the inferential gaps" found in the Second Amended Complaint, the district court's decision to dismiss these claims with prejudice is affirmed. See Kelly, 827 F.3d at 15.

III. Conclusion

We affirm the district court's order dismissing relator Peter Lawton's claims, and because we reach this conclusion, we decline to consider whether Lawton's Second Amended Complaint is barred by the FCA's public disclosure bar, 31 U.S.C. § 3730(e)(4)(A), or the NYSFCA's public disclosure bar, N.Y. State Fin. Law § 190(9)(b).