United States Court of Appeals
For the First Circuit

No. 06-2627

UNITED STATES OF AMERICA EX REL. PETER ROST,

Plaintiff, Appellant,

v.

PFIZER, INC.; PHARMACIA CORPORATION,

Defendants, Appellees.

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

[Hon. Joseph L. Tauro, U.S. District Judge]

Before

Torruella, Circuit Judge,
Cyr, Senior Circuit Judge,
and Lynch, Circuit Judge.

Mark I. Labaton with whom Megan Benett, Hilary B. Taylor, and Kreindler & Kreindler LLP were on brief for appellant.

Jamie Ann Yavelberg, Attorney, with whom Peter D. Keisler, Acting Attorney General, Michael J. Sullivan, United States Attorney, Douglas N. Letter, Attorney, and Michael D. Granston, Attorney, Civil Division, Department of Justice, were on brief for United States, amicus curiae.

Ethan M. Posner with whom Carolyn F. Corwin, Tara M. Steeley, Mark W. Mosier, and Covington & Burling LLP were on brief for appellees.

Mary Ita Snyder, Timothy J. Hatch, James C. Dougherty, Karen L. Manos, Minodora D. Vancea, and Gibson, Dunn & Crutcher LLP on brief for National Defense Industrial Association, amicus curiae.

Jonathan L. Diesenhaus, Catherine E. Stetson, Jessica L. Ellsworth, Jake M. Shields, Hogan & Hartson LLP, Diane E. Bieri,

Melinda Reid Hatton, and Maureen D. Mudron were on brief for Pharmaceutical Research and Manufacturers of America and American Hospital Association, amici curiae.

November 15, 2007

LYNCH, Circuit Judge. Dr. Peter Rost filed this whistleblower action against Pfizer, Inc. and its subsidiary Pharmacia Corporation under the federal False Claims Act ("FCA"), 31 U.S.C. § 3729 et seq., and analogous state statutes. The suit alleges that Pharmacia's misconduct in marketing a human growth hormone, Genotropin, for uses unapproved by the Food and Drug Administration led to claims for reimbursement to the United States for unreimbursable, off-label drug prescriptions.

The district court rejected defendants' argument that the suit be dismissed for lack of jurisdiction under 31 U.S.C. § 3730(e)(4), but granted the motion to dismiss on the ground that Rost's complaint failed to meet the pleading requirements for allegations of fraud under Federal Rule of Civil Procedure 9(b). United States ex rel. Rost v. Pfizer Inc., 446 F. Supp. 2d 6, 28 (D. Mass. 2006).

Rost's appeal urges reversal of that holding. Pfizer, supported by two sets of amici, agrees that Rost's complaint fails the pleading standard of Rule 9(b) -- but claims error by the district court in deciding the threshold issue of whether one of the FCA's jurisdictional bars, see 31 U.S.C. § 3730(e)(4), applies to Rost's suit. The United States, appearing as amicus, argues for affirmance on the jurisdictional ground and notes that the Rule 9(b) ruling is consistent with the law of this circuit. The

jurisdictional bar issue raises questions of statutory interpretation unresolved in this circuit.

We affirm the decision of the district court that § 3730(e)(4) does not bar Rost's suit. We also agree that the complaint fails to meet the heightened pleading standard for FCA claims, but remand so that the district court may consider Rost's request for leave to amend, which it did not address.

I.

Genotropin is a brand of synthetic human growth hormone originally marketed by Pharmacia. The FDA has approved Genotropin only for the treatment of three specific pediatric disorders and of adult growth hormone deficiency. Physicians may prescribe Genotropin for non-FDA-approved indications, but the Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 321 et seq., prohibits pharmaceutical companies from marketing drugs for such "off-label" uses. In addition, Medicaid generally does not reimburse patients for off-label prescriptions. See 42 U.S.C. §§ 1396b(i)(10), 1396r-8(k)(3), (k)(6).[1] There is a wide and lucrative market for off-label uses of human growth hormone. One such use is to slow the effects of aging in adults. Also, some parents request the drug to boost the growth of short children, even absent a hormonal

[1] 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). Such uses are not at issue in this case.

deficiency. Sales to the domestic market for off-label uses significantly enhance the profitability of synthetic human growth hormone.

Rost joined Pharmacia in 2001 as Vice President of Marketing in the company's Endocrine Care unit. Among his responsibilities was oversight of global marketing for Genotropin. Rost soon became concerned that subordinates in charge of marketing Genotropin within the United States were utilizing problematic tactics. Pharmacia sales representatives received incentive payments for each new patient prescribed Genotropin, whether for on- or off-label uses.

Rost also suspected Pharmacia of using a Genotropin "study program" to funnel improper payments to doctors for prescribing the drug. Every doctor that prescribed Genotropin became eligible to participate in the program, which collected data about patients with growth disorders who took Genotropin. Participating doctors would receive a cash payment for every patient to whom they prescribed Genotropin and enrolled in the study. Doctors participating in the study program also received all-expenses-paid trips to conferences at luxury resorts where, among other Genotropin-related topics, doctors would discuss off-label uses of the drug.

In addition, Rost discovered that Pharmacia granted financial incentives to distributors targeting the off-label market

for human growth hormone. These discount pricing contracts and rebates benefitted "anti-aging" clinics, internet-based vendors, and others unlikely to dispense Genotropin for its FDA-approved uses. Rost feared these incentives subsidized the off-label market for Genotropin.

The company hired physicians and others as "independent consultants" to promote Genotropin for off-label uses. For instance, Pharmacia retained a company in Canada to create marketing materials touting Genotropin's anti-aging uses. Pharmacia also made substantial payments to the director of several anti-aging clinics in Florida.

Rost believed these practices ran afoul of the FDCA. See, e.g., 21 U.S.C. §§ 331, 355 (prohibiting interstate distribution of drugs that have not undergone FDA approval process); id. § 333 (providing criminal penalties for such distribution). Rost also believed these practices were suspect under the anti-kickback statute, 42 U.S.C. § 1320a-7b(b), which criminalizes the payment of kickbacks, bribes, or other inducements to doctors in an effort to influence decisions about prescriptions that are reimbursed by a federal health care program.

Rost reported his concerns up the chain of management at Pharmacia. The company initiated an internal investigation and cut back on the problematic marketing activity. Rost, however, remained skeptical of some continuing practices.

In July 2002, Pfizer announced it would acquire Pharmacia. In meetings with Pfizer personnel during October and November of 2002, Rost and other Pharmacia employees aired their concerns about Genotropin marketing. Rost also wrote to a Pfizer marketing executive in early 2003 regarding Pharmacia's off-label sale and marketing of Genotropin.

Pfizer completed its acquisition of Pharmacia on April 16, 2003. Pfizer immediately initiated an internal investigation into the legacy marketing practices of its new subsidiary. It also moved quickly to inform the relevant federal authorities about potential problems.

On May 16, 2003, Pfizer contacted two separate offices within the Department of Health and Human Services ("HHS") regarding Pharmacia's problematic marketing practices. One was the FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC"), to which Pfizer wished to disclose information regarding the off-label marketing and distribution of Genotropin. Pfizer followed up on May 19, 2003, with a confidential letter to the DDMAC and the FDA's Office of Chief Counsel. The letter summarized Pharmacia's past off-label sales to anti-aging doctors and clinics, referring to the improper discount contracts and to sales representatives who focused their marketing efforts on the off-label market. The letter also described remedial measures taken by Pharmacia and Pfizer.

Pfizer also contacted on May 16, 2003, the HHS Office of Inspector General ("OIG"), which is charged with investigating and preventing fraud in federal health care programs such as Medicare and Medicaid. The OIG administers a voluntary disclosure program to encourage health care providers to inform the office of fraudulent conduct, and Pfizer sought to enter the program. Pfizer representatives met with OIG officials on May 21, 2003, to discuss the off-label marketing of Genotropin and various forms of improper payments to prescribing physicians. The OIG officials informed Pfizer that an investigative agent had been assigned to the matter and invited Pfizer to submit a letter requesting admission into the voluntary disclosure program. In another confidential letter sent to the OIG on June 3, 2003, Pfizer identified three areas of potential misconduct related to Pharmacia's promotion of Genotropin: first, payments made to physicians in the form of consulting contracts and "professional or educational" junkets; second, payments for participating in the Genotropin study program, which the letter acknowledged may have been motivated by "sales and marketing concerns"; and third, Pharmacia's engagement of "outside entities to provide product support services" for Genotropin to physicians. Pfizer sent a copy of the letter to the Civil Fraud Section of the Department of Justice.

Pfizer continued its internal investigation into Pharmarcia's former marketing practices after its correspondence to

the HHS but did not make any public announcement regarding Genotropin at that time. Pfizer first disclosed problems with Genotropin marketing in a publicly available document on March 10, 2004, in materials appended to a Form 10-K filed with the Securities and Exchange Commission. That document states that Pfizer "recently was notified that the U.S. Department of Justice is conducting investigations relating to the marketing and sale of Genotropin . . . . [Pfizer is] cooperating in these investigations."

In April 2007, the U.S. Attorney's Office for Massachusetts announced that Pfizer would plead guilty and pay a fine in response to a criminal charge for violating the anti-kickback statute through Genotropin-related payments to doctors. Pfizer simultaneously entered into a Deferred Prosecution Agreement with the government as to a criminal information charging the company with one count of violating the FDCA for off-label promotion and distribution of Genotropin. Pfizer paid the government a total of $34.7 million to resolve Genotropin-related investigations conducted over four years by the HHS, DOJ, and FBI.

Rost had begun considering a False Claims Act lawsuit in late 2002. Rost filed his qui tam complaint on June 5, 2003, in camera and under seal pursuant to 31 U.S.C. § 3730(b)(2). The FCA requires a private plaintiff bringing a claim under the Act to file a complaint under seal and serve the government with "the complaint

and written disclosure of substantially all material evidence and information" underlying the complaint, a procedure designed to allow the government to decide whether to intervene in the action. 31 U.S.C. § 3730(b)(2); see also United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 225 (1st Cir. 2004).

The United States spent more than two years investigating the allegations in Rost's complaint and considering whether to intervene in the action. On November 8, 2005, the United States notified the district court that it would not intervene. Two days later, the court ordered Rost's complaint unsealed and served on the defendants.

The complaint pleads claims for damages under the FCA and the statutes of ten states and the District of Columbia.[2] Rost bases those claims on marketing practices that he previously brought to the attention of Pharmacia and Pfizer management: encouraging sales representatives to promote Genotropin for off-

[2] Rost pleads state-law claims under the California False Claims Act, Cal. Gov't Code § 12651(a)(1)-(2), the Delaware False Claims and Reporting Act, 6 Del. Code Ann. tit. 6, § 1201(a)(1)-(2), the Florida False Claims Act, Fla. Stat. Ann. § 68.082(2), the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a), the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a)(1)-(2), the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12, § 5B(1)-(2), the Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.040(1)(a)-(b), the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1), the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. § 36.002, the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(1)-(2), and the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. § 2-308.14(a)(1)-(2).

label uses, making payments and other inducements to doctors through the Genotropin research program, granting discounts and rebates to distributors known to target the off-label market, and hiring physicians as "independent consultants" to promote and prescribe Genotropin for off-label uses. The complaint alleges that Pharmacia knew a significant portion of its sales were for off-label uses because it maintains a database containing information on 30,000 patients prescribed Genotropin. That information includes the identity of the prescribing doctor, the primary and secondary diagnosis, and the dosage prescribed. The complaint alleges that the database reveals that approximately sixty percent of all adult and twenty-five percent of all pediatric sales of Genotropin were for off-label uses.

The complaint does not allege Pharmacia itself ever submitted false claims. It alleges that Pharmacia knowingly caused the submission of fraudulent claims by others to the government in the form of claims for reimbursement for off-label prescriptions of Genotropin. The complaint does not identify any false claim presented by others to any government health program or any particular entity or person who actually submitted such a claim. Instead, the complaint pleads that "[t]he false claims were presented by thousands of separate entities, across the United States, and over many years. [Rost] has no control over or

dealings with such entities and [has] no access to the records in their possession."

Pfizer moved to dismiss the complaint for lack of subject matter jurisdiction and for failure to meet the Rule 9(b) pleading requirements for allegations of fraud. On the first point, Pfizer argued that its communications with government officials constituted "public disclosures" triggering the jurisdictional bar of 31 U.S.C. § 3730(e)(4)(A), and that Rost did not qualify as an "original source" for the information in his complaint so as to exempt him from the bar, see id. § 3730(e)(4)(B).

The district court held that Pfizer's confidential disclosures to the HHS and DOJ were not "public disclosures" that would trigger the FCA's jurisdictional bar but granted dismissal on the Rule 9(b) grounds. Rost, 446 F. Supp. 2d at 18, 28.

II.

The False Claims Act prohibits the knowing submission of false or fraudulent claims for payment, or causing the submission of such claims, to the federal government and prescribes fines and treble damages to penalize offenders. 31 U.S.C. § 3729(a).[3]

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[3] The Act states, in relevant part,

> Any person who --
> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval; [or]
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement

Violations of the Act may be enforced by civil actions initiated by either the Attorney General, id. § 3730(a), or a private person, id. § 3730(b). In the latter category of qui tam[4] actions, the Act affords the government an opportunity to evaluate the relator's complaint and decide whether to assume primary responsibility for prosecuting the action. Id. § 3730(b)(2), (b)(4), (c)(1). A private relator is entitled to a portion of any proceeds from the suit, whether the United States intervenes as an active participant in the action or not. If the government intervenes, the Act grants between 15 and 25% of the government's damages (or settlement amount) to the relator. Id. § 3730(d)(1). If the government does not intervene, as here, the relator is entitled to between 25 and 30% of the recovery. Id. § 3730(d)(2). In either case, the Act requires defendants to pay attorneys' fees for a successful qui tam plaintiff. Id. § 3730(d)(1)-(2).

> to get a false or fraudulent claim paid or approved by the Government;
>
> . . .
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person . . . .

31 U.S.C. § 3729(a).

[4] "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." Rockwell Int'l Corp. v. United States, 127 S. Ct. 1397, 1403 n.2 (2007).

The qui tam provisions of the FCA supplement federal law enforcement resources by encouraging private citizens to uncover fraud on the government. Karvelas, 360 F.3d at 224 & n.5. The qui tam mechanism has historically been susceptible to abuse, however, by "parasitic" relators who bring FCA damages claims based on information within the public domain or that the relator did not otherwise discover. See United States ex rel. S. Prawer & Co. v. Fleet Bank of Me., 24 F.3d 320, 324-26 (1st Cir. 1994) (summarizing history of FCA litigation and legislative amendments). Congress has tailored the FCA to "walk a fine line between encouraging whistle-blowing and discouraging opportunistic behavior." Id. at 326 (quoting United States ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 651 (D.C. Cir. 1994)). The current Act contains a series of jurisdictional bars designed in part to mediate that fine line. See 31 U.S.C. § 3730(e).

The Act does not create a cause of action against all fraudulent conduct affecting the government. Karvelas, 360 F.3d at 225. Rather, FCA liability attaches to a "false or fraudulent claim for payment" or to a "false record or statement [made] to get a false or fraudulent claim paid" by the government. 31 U.S.C. § 3729(a)(1)-(2); see also Karvelas, 360 F.3d at 225 ("Evidence of an actual false claim is 'the sine qua non of a False Claims Act violation.'") (quoting United States ex rel. Clausen v. Lab. Corp. of Am., Inc., 290 F.3d 1301, 1311 (11th Cir. 2002)). 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.

A. Jurisdictional Bar

The threshold question in a False Claims Act case is whether the statute bars jurisdiction. Rockwell Int'l Corp. v. United States, 127 S. Ct. 1397, 1405-07 (2007). The relevant bar, contained in 31 U.S.C. § 3730(e)(4)(A) and (B), provides:

> (4)(A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

Our case turns on the "public disclosure" language of § 3730(e)(4)(A). Pfizer asserts that its self-disclosure to HHS and DOJ, the appropriate investigative bodies, constitutes "public disclosure of allegations" in an appropriate government investigation setting under § 3730(e)(4)(A) and thus bars the action.

Analysis of § 3730(e)(4)(A) requires several inquiries: (1) whether there has been public disclosure of the allegations or transactions in the relator's complaint; (2) if so, whether the public disclosure occurred in the manner specified in the statute; (3) if so, whether the relator's suit is "based upon" those publicly disclosed allegations or transactions; and (4) if the answers to these questions are in the affirmative, whether the relator falls within the "original source" exception as defined in § 3730(e)(4)(B). We reach only the first question. Our case law has not previously defined the term "public disclosure."

The question here is whether self-disclosure made by a private party only to government agencies, without further disclosure, is "public disclosure."[5] In our view, a "public disclosure" requires that there be some act of disclosure to the public outside of the government. The mere fact that the disclosures are contained in government files someplace, or even that the government is conducting an investigation behind the

[5] It could be that disclosure in the form of a filing to a government body such as a court (not under seal) where all records are public could be public disclosure. See Springfield Terminal, 14 F.3d at 652; United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co., 944 F.2d 1149, 1155-56 (3d Cir. 1991). It could also be that when the government itself makes available to the public information which has been disclosed to it, say in response to a FOIA request, the later disclosure by the government constitutes a public disclosure. See United States ex rel. Schumer v. Hughes Aircraft Co., 63 F.3d 1512, 1519-20 (9th Cir. 1995), vacated on other grounds, 520 U.S. 939 (1997). These are not our case.

scenes, does not itself constitute public disclosure. Our construction of the term "public disclosure" does not turn on the fact that Pfizer requested or assumed that its disclosures to the investigating agencies would be held confidential. The United States has taken the litigation position in this action that "public disclosure" does not include the disclosure from Pfizer to the government that occurred here.[6]

Pfizer's reading is inconsistent with our understanding of the language, structure, and history of the Act. The plain language of the statute cuts against Pfizer's interpretation of the public disclosure bar for several reasons. This court has already held that "the logical reading is that the [public disclosure] subsection serves to prohibit courts from hearing qui tam actions based on information made available to the public during the course of a government hearing, investigation or audit or from the news media." United States ex rel. LeBlanc v. Raytheon Co., 913 F.2d 17, 20 (1st Cir. 1990). What Pfizer did was to make confidential disclosures to the government, which triggered an investigation. But the statute does not bar jurisdiction over qui tam actions based on disclosures of allegations or transactions to the government; it does so only for actions based on qualifying

[6] The United States also argues that the district court went too far in defining "public disclosure" as requiring that disclosure be to "all members of the community or, in other words, the general public." Rost, 446 F. Supp. 2d at 17. We agree.

disclosures made to the public. If providing information to the government were enough to trigger the bar, the phrase "public disclosure" would be superfluous.

Pfizer's reading also equates the government with the public; this is inconsistent with the rest of the statute. Government may be of the people, by the people, and for the people, but that does not mean the government and the public are the same. As the United States, in opposing Pfizer's reading, notes, the ordinary understanding of the term "public" means "something apart from the government itself." Br. for United States as Amicus Curiae Supp. Appellant 12; see also Black's Law Dictionary 1264 (8th ed. 2004) (defining "public" as "1. Relating or belonging to an entire community, state, or nation. . . . 2. Open or available for all to use, share, or enjoy."). The statute itself uses the term "Government" numerous times and does not once equate the government with the public. See, e.g., 31 U.S.C. § 3730(e)(4)(B) ("'[O]riginal source' means an individual who . . . has voluntarily provided the information to the Government . . . ." (emphasis added)). See generally id. § 3730 (delineating rights and responsibilities of "the Government" under the FCA). If Congress had wished to equate self-disclosure to the government with disclosure to the public, it easily could have done so.

To the extent there is any material ambiguity in the term "public disclosure" on these facts, we find that Pfizer's reading

is contrary to the structure of the statute as a whole, the legislative history, and the policy objectives Congress articulated at the time it enacted the language. Cf. Prawer, 24 F.3d at 327 (interpreting ambiguous provision of the FCA with reference to legislative history and congressional intent). The legislative history of the statute, particularly the 1986 amendments, see False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153, shows that Pfizer's reading is contrary to the legislative intent in several respects.

The 1986 amendments sought to achieve the two goals of discouraging "parasitic" or "free-loading" qui tam suits while also encouraging productive private enforcement suits. Springfield Terminal, 14 F.3d at 651. Pfizer's reading furthers neither purpose.

With the 1986 amendments, Congress deliberately removed a previous provision that barred jurisdiction whenever the government had knowledge of the allegations or transactions in the relator's complaint. The pre-1986 version of 31 U.S.C. § 3730(d) provided that courts had no jurisdiction over qui tam actions "based on evidence or information the Government had when the action was brought." See LeBlanc, 913 F.2d at 19 n.1. In practice, the "government knowledge" bar proved too restrictive of qui tam actions, resulting in under-enforcement of the FCA. See Prawer, 24 F.3d at 325-26. Thus, in 1986, Congress shifted the

examination away from the information in the government's possession and instead looked to whether there was public disclosure of information given to the government. "Congress thus changed the focus of the jurisdictional bar from evidence of fraud inside the government's overcrowded file cabinets to fraud already exposed in the public domain." United States ex rel. Findley v. FPC-Boron Employees' Club, 105 F.3d 675, 684 (D.C. Cir. 1997).

The effect of Pfizer's argument would be to reinstate exactly what Congress eliminated -- the "government knowledge" bar. It is an insufficient response to argue, as Pfizer does, that the government knowledge bar created by its reading is a very limited one and applies only where the government official receiving the disclosure is the appropriate investigatory official. Only one court has adopted such a reading. See United States ex rel. Mathews v. Bank of Farmington, 166 F.3d 853, 861 (7th Cir. 1999). We find no support in either the language or the history of the statute for such a reading. Indeed, Pfizer's argument runs directly contrary to our reasoning in Prawer, where we held that "Congress has explicitly deemed a 'notice' regime insufficient to protect the government against false claims (indeed it was precisely such a regime that Congress sought to abandon in enacting the 1986 amendments) . . . ." 24 F.3d at 329.

The 1986 amendments "broadened the universe of potential [qui tam] plaintiffs, with only four exclusions" enumerated in

§ 3730(e). LeBlanc, 913 F.2d at 19. Congress amended the statute to "encourage more private enforcement suits." Id. (quoting S. Rep. No. 93-345, at 23-24 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5288-89) (internal quotation marks omitted). Yet Pfizer's reading would create a new exclusion not articulated in the text. That is inconsistent with the second goal of encouraging productive private enforcement.

Pfizer's interpretation is also contrary to another legislative purpose reflected in the 1986 amendments: it was the Congressional intent, through the requirement of public disclosure, to help keep the government honest in its investigations and settlements with industry. Once allegations are made public, the government can be forced to act by public pressure. See Findley, 105 F.3d at 684 n.4.

Not only would Pfizer's argument recreate problems Congress sought to eliminate in 1986, but it fails to further Congress's purpose of discouraging "parasitic" qui tam actions. Prawer, 24 F.3d at 327. If information that could form the basis of a qui tam action is kept confidential and confined to a limited circle of government officials, there is no real danger that a private citizen who does not have "direct and independent knowledge" of that information, see 31 U.S.C. § 3730(e)(4)(B), will

bring an opportunistic qui tam suit based upon the information in the government's possession.[7]

Our conclusion is also consistent with the majority view among the circuits. The Tenth Circuit has held the public disclosure requirement "clearly contemplates that the information be in the public domain in some capacity and the Government is not the equivalent of the public domain." Kennard v. Comstock Res., Inc., 363 F.3d 1039, 1043 (10th Cir. 2004); accord United States ex rel. Schumer v. Hughes Aircraft Co., 63 F.3d 1512, 1518 (9th Cir. 1995) ("[I]nformation that was 'disclosed in private' [between government and defendant company] has not been publicly disclosed."); United States ex rel. Williams v. NEC Corp., 931 F.2d 1493, 1496 n.7 (11th Cir. 1991) ("Even if a government investigation was pending at the time [the relator] filed his qui tam complaint, such fact would not jurisdictionally bar [the FCA claim]."); see also Springfield Terminal, 14 F.3d at 653 (requiring information to be "in the public eye" for bar to apply).

Only one circuit has held that mere disclosure to the government is a public disclosure, though cabining its holding to disclosures made to appropriate investigative officials. See Mathews, 166 F.3d at 861. We simply disagree with Mathews for the

[7] Except as noted in footnote 6, we do not reach the issue of how many members of the public must receive or have access to the disclosure. Cf. Kennard v. Comstock Res., Inc., 363 F.3d 1039, 1043 (10th Cir. 2004) ("There is no requirement that a certain number of people read or receive the information.").

reasons already stated and as lucidly set forth in the district court's opinion. See Rost, 446 F. Supp. 2d at 16-18.

Two amici, industry groups for the pharmaceutical and hospital industries, argue that unless Pfizer's participation in HHS's self-disclosure program and cooperation with the government are fully protected from qui tam suits by adopting Pfizer's reading of "public disclosure," the FCA's objective -- to reduce fraud on the government -- will be undercut. The argument is misplaced and should be addressed to Congress. HHS's administrative efforts at encouraging corporate disclosure and cooperation are a more recent development, see Publication of the OIG's Provider Self-Disclosure Protocol, 63 Fed. Reg. 58399 (Oct. 30, 1998), and were not the object of Congress's concerns in adopting the 1986 amendments.

B. Rule 9(b) Requirement

The district court ultimately held that Rost failed to plead his fraud claims with sufficient specificity under Federal Rule of Civil Procedure 9(b). We affirm.

Rule 9(b) requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." The particularity requirement means that a complaint must specify "the time, place, and content of an alleged false representation." Doyle v. Hasbro, Inc., 103 F.3d 186, 194 (1st Cir. 1996) (quoting McGinty v. Beranger Volkswagen, Inc., 633 F.2d 226, 228 (1st Cir. 1980), superseded by statute on

other grounds, Private Securities Litigation Reform Act of 1995, Pub. L. No. 104-67, 109 Stat. 737). Conclusory allegations and references to "plans and schemes" are not sufficient. Id. (quoting Hayduk v. Lanna, 775 F.2d 441, 444 (1st Cir. 1985)). Rule 9(b) applies to FCA claims. Karvelas, 360 F.3d at 228. In the FCA context, this court has previously held that the rule requires relators to "provide details that identify particular false claims for payment that were submitted to the government." Id. at 232.

Rost argues that the district court overall applied too stringent a standard. He also argues that he asserted two different claims -- one under 31 U.S.C. § 3729(a)(1) for false claims, the other under § 3729(a)(2) for false statements -- and that the court erred in not analyzing the particularity requirements separately for the two subsections.[8]

In defense of the district court's ruling, Pfizer first argues this result is required by this court's decision in Karvelas. Pfizer, we think, over-reads Karvelas, which has more flexibility than Pfizer posits.

Karvelas, like this case, involved allegations of submission of false claims for medical insurance payments to

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[8] Rost also argues that the court should have separately analyzed his state law claims. The heightened pleading standard of Rule 9(b) generally applies to state law fraud claims brought in federal court. See Universal Commc'n Sys., Inc. v. Lycos, Inc., 478 F.3d 413, 427 (1st Cir. 2007); see also 5A Wright & Miller, Federal Practice and Procedure § 1297 (3d ed. 2004). The district court did not err in applying the rule to Rost's entire action.

federal health insurance programs such as Medicare and Medicaid. The FCA, Karvelas held, attaches liability not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment. 360 F.3d at 225. Karvelas held 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." Id. at 231. That principle is not at stake here.

In Karvelas, the relator worked at a hospital that allegedly submitted false claims to government health care programs for services that were "provided improperly or not at all." 360 F.3d at 223. In the context of a defendant that submits claims directly to government programs, Karvelas held that relators must provide details that identify particular false claims for payment that were actually submitted to the government. Id. at 232. Karvelas's claim failed because it provided no specifics, such as the dates of claims, identification numbers, or amounts charged to the government, that identified particular false claims. Id. at 233-35.

Nonetheless, Karvelas recognized that Rule 9(b) may be satisfied where, although some questions remain unanswered, the complaint as a whole is sufficiently particular to pass muster under the FCA. Id. at 233 n.17. Giving Rost the benefit of such

flexibility, we analyze the case with this test in mind; the claim still fails.

The fraud alleged here is in a different category than in Karvelas. Those differences both help and hurt Rost. The submission of the alleged false claims here was not by defendants Pharmacia and Pfizer; false claims were allegedly submitted by doctors who were allegedly induced and seduced by defendants into prescribing Genetropin for off-label uses to their patients, including federally insured patients. According to Rost's complaint, more than half of all adult and a quarter of all pediatric sales of Genotropin are for off-label uses. Given that, it is a possible but not a necessary or even strong inference that doctors, persuaded by Pharmacia's financial and other incentives to prescribe Genotropin for off-label uses, have written such prescriptions even if the patient was federally insured. And it is not irrational to infer that, given the large percentage of children and the elderly who are insured under federal health programs, some false claims for Genotropin reimbursement were submitted to the government.

We also note, though, that while the April 2007 criminal information against Pfizer covering off-label uses of Genotropin acknowledges that "Pharmacia earned millions of dollars for [off-label uses]," it also states that "[i]n most, if not all, instances, patients taking Genotropin [for off-label uses] paid .

. . out-of-pocket without reimbursement from any public or private third-party payors." This tends to undercut the strength of the inference that fraud on the government in fact occurred.

Rost's complaint amply describes illegal practices in which Pfizer allegedly engaged. But those practices, while illegal, are not a sufficient basis for an FCA action because they do not involve claims for government reimbursement.[9] Id. at 234. As presently pled, the complaint does not sufficiently establish that false claims were submitted for government payment in a way that satisfies the particularity requirement. Cf. id. at 233.

Rost argues that the primary purpose of pleading fraud with particularity is to give notice to Pfizer of the false claims, and that his complaint accomplishes this. The argument fails on two grounds: First, the complaint does not give notice to Pfizer of false claims submitted by others for federal reimbursement of off-label uses, only of illegal practices in promotion of the drug.

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[9] Rule 9(b)'s heightened pleading standards apply to the allegations that false claims were submitted to the government. There is a separate element to the cause of action. Under the FCA, Rost must show that Pfizer "cause[d] to be presented" a false claim for payment. 31 U.S.C. § 3729(a)(1). That there were allegedly intervening persons who actually submitted the claims does not itself necessarily break the causal connection when the claims are foreseeable. See United States ex rel. Cantekin v. Univ. of Pittsburgh, 192 F.3d 402, 416-17 (3d Cir. 1999).

In other cases, relators have pled a connecting causal link, which strengthens the inference that false claims were submitted. Cf. United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 46 (D. Mass. 2001) (describing pharmaceutical company's efforts "to coach doctors on how to conceal the off-label nature of the prescription"). No such allegations are made here.

Second, notice is not the only reason for the requirement of Rule 9(b). It is a serious matter to accuse a person or company of committing fraud, and the mere accusation often causes harm. See Doyle, 103 F.3d at 194; 5A Wright & Miller, Federal Practice and Procedure § 1296 (3d ed. 2004). Further, the rule discourages plaintiffs from filing allegations of fraud merely in the hopes of conducting embarrassing discovery and forcing settlement. See New Eng. Data Servs., Inc. v. Becher, 829 F.2d 286, 288 (1st Cir. 1987).

At most, Rost raises facts that suggest fraud was possible; but the complaint contained no factual or statistical evidence to strengthen the inference of fraud beyond possibility. It may well be that doctors who prescribed Genotropin for off-label uses as a result of Pharmacia's illegal marketing of the drug withstood the temptation and did not seek federal reimbursement, and neither did their patients. It may be that physicians prescribed Genotropin for off-label uses only where the patients paid for it themselves or when the patients' private insurers paid for it. Rost did not plead enough to satisfy the concerns behind Rule 9(b).

As for Rost's § 3729(a)(2) argument, Pfizer asserts that Rost waived the argument by not presenting it below. See 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.") We do not address the waiver issue. Our analysis -- which recognizes the role played by third parties other than Pfizer in submitting claims and making statements to the government -- undermines Rost's § 3729(a)(2) argument as well. In addition, the plain language of § 3729(a)(2) requires proof of a "false record or statement" for liability to attach under the section. Rost's complaint alleges that Pharmacia made statements in violation of federal law, but does not allege that those statements were false. Cf. Franklin, 147 F. Supp. 2d at 48-49 (describing allegations that defendant trained salespeople to "actively deceive physicians" about off-label uses of drugs). We affirm the Rule 9(b) ruling.

That does not end the matter. In dismissing the action, the district court never ruled on Rost's request that he be allowed to amend his complaint to allege fraud with particularity. If it were obvious that leave to amend should be denied, we would affirm. That level of certainty does not exist. This distinguishes our decision here from the disposition of Epstein v. C.R. Bard, Inc., 460 F.3d 183 (1st Cir. 2006).

Federal Rule of Civil Procedure 15(a) provides that leave to amend a pleading "shall be freely given when justice so requires," and reflects a liberal amendment policy. O'Connell v. Hyatt Hotels of P.R., 357 F.3d 152, 154 (1st Cir. 2004). Grounds for denial generally involve undue delay, bad faith, dilatory

motive of the requesting party, repeated failure to cure deficiencies, and futility of amendment. Foman v. Davis, 371 U.S. 178, 182 (1962). At this stage we cannot say amendment would be futile, and the district court should make the initial determination.

Pfizer says Rost has waived his opportunity to amend by making only a "passing reference" to a request for leave to amend in his briefs to the district court. That is not our law. This court has treated many similar requests to be sufficient invocations for leave to amend under Rule 15(a). See, e.g., Epstein, 460 F.3d at 190-91 (request for leave to amend made in opposition to motion to dismiss treated as motion to amend pursuant to Rule 15(a)); Rodi v. S. New Eng. Sch. of Law, 389 F.3d 5, 20 (1st Cir. 2004) (request to amend contained in motion for reconsideration treated as Rule 15(a) motion); Invest Almaz v. Temple-Inland Forest Prods. Corp., 243 F.3d 57, 71 (1st Cir. 2001) (request at oral argument on motion to dismiss for leave to amend complaint "if necessary" constituted motion to amend pursuant to Rule 15(a)). We express no views on the outcome of this issue before the district court.

The dismissal of the action is vacated. The case is remanded to the district court for further proceedings consistent with this opinion. No costs are awarded.