No. 06-2627

IN THE

United States Court of Appeals for the First Circuit

UNITED STATES OF AMERICA EX REL. DR. PETER ROST,

Plaintiff-Appellant,

v.

PFIZER, INC.; PHARMACIA CORPORATION,

Defendants-Appellees.

On Appeal from the United States District Court
for the District of Massachusetts

BRIEF FOR AMICI CURIAE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND AMERICAN HOSPITAL ASSOCIATION IN SUPPORT OF DEFENDANTS-APPELLEES

Of Counsel:

Diane E. Bieri
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
950 F Street, N.W., Suite 300
Washington, D.C. 20004
(202) 835-3405

Melinda Reid Hatton
Maureen D. Mudron
AMERICAN HOSPITAL ASSOCIATION
325 Seventh Street, N.W., Suite 700
Washington, D.C. 20004
(202) 638-1100

Jonathan L. Diesenhaus*
Catherine E. Stetson
Jessica L. Ellsworth
Jake M. Shields
HOGAN & HARTSON L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-5600

*Admission pending

Counsel for Amici Curiae

June 7, 2007

RULE 26.1 CORPORATE DISCLOSURE

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, amicus curiae Pharmaceutical Research and Manufacturers of America ("PhRMA") states that no corporation or publicly held company owns 10 percent or more of the stock of PhRMA, and amicus curiae the American Hospital Association ("AHA") states that no corporation or publicly held company owns 10 percent or more of the stock of AHA.

TABLE OF CONTENTS

TABLE OF CONTENTS—Continued

TABLE OF AUTHORITIES

Page

CASES:

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

IN THE

United States Court of Appeals for the First Circuit

No. 06-2627

UNITED STATES OF AMERICA EX REL. DR. PETER ROST,

Plaintiff-Appellant,

v.

PFIZER, INC.; PHARMACIA CORPORATION,

Defendants-Appellees.

On Appeal from the United States District Court
for the District of Massachusetts

BRIEF FOR AMICI CURIAE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND AMERICAN HOSPITAL ASSOCIATION IN SUPPORT OF DEFENDANTS-APPELLEES

Pursuant to Federal Rule of Appellate Procedure 29, amici curiae Pharmaceutical Research and Manufacturers of America ("PhRMA") and American Hospital Association ("AHA") respectfully submit this brief in support of Defendants-Appellees.

INTEREST OF AMICI CURIAE

PhRMA is an association whose membership comprises the country's leading research-based pharmaceutical and biotechnology companies. PhRMA

members invested an estimated $43 billion in 2006 in discovering and developing new medicines that help patients live longer, healthier and more productive lives.

AHA is the national advocacy organization for U.S. hospitals. It represents approximately 5,000 hospitals, health care systems, and other health care organizations, as well as 37,000 individual members. AHA leads, represents, and serves health care organizations that provide care to their communities 24 hours a day, seven days a week, 365 days a year.

Proper interpretation of the False Claims Act ("FCA"), 31 U.S.C. §§ 3730 et seq., and in particular its public disclosure bar, is crucially important to amici's members. FCA lawsuits have proliferated over the past two decades, and the largest subset of FCA suits purport to target health care fraud. See GAO, Letter to Hon. F. James Sensenbrenner, Jr., Hon. Chris Cannon, and Hon. Charles E. Grassley, Information on False Claims Act Litigation 28 (Jan. 31, 2006) ("GAO 2006 Report") (noting that 45.98 percent of qui tam cases involved alleged health care fraud).

The United States government declines to intervene in nearly two-thirds of these lawsuits, leaving them to be prosecuted by relators alone. A large percentage of declined qui tam cases allege violations involving federal health care funds, including cases against amici's members. See id. at 29 (noting that 754 of 1770 declined cases since 1987 were in the health care field). The overwhelming

majority of these declined health care qui tam cases produce no recovery for the United States (or the relator) and a substantial number of those cases are dismissed, but only after burdensome and expensive pre-trial litigation. See, e.g., United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 227-228 (1st Cir. 2004); United States ex rel. Clausen v. Laboratory Corp. of Am., Inc., 290 F.3d 1301, 1315 (11th Cir. 2002); United States ex rel. Hess v. Sanofi-Synthelabo, Inc., 2006 WL 1064127, at *12 (E.D. Mo. Apr. 21, 2006).[1]

Litigation under the public disclosure bar ordinarily arises in declined qui tam cases, as this case exemplifies. Because a great number of declined qui tam cases are health care cases, the scope of the public disclosure bar is especially important to health care businesses—providers and manufacturers alike. The Court's decision in this case will clarify application of the public disclosure bar, and thereby the rules governing who can properly claim to litigate on behalf of the United States. Reversal of the lower court's decision will also preserve important

[1] One hospital's story is an illuminating example. In early 2003, the FBI raided Good Shepherd Medical Center in Hermiston, Oregon—a non-profit, 25-bed hospital—after a relator filed a sealed qui tam complaint alleging wide-ranging irregularities in the hospital's practices. See Letter from Dennis E. Burke, President, Good Shepherd Health Care System, to Senator Ron Wyden (Aug. 23, 2006) (http://www.aha.org/aha/content/2006/pdf/wydenltr.pdf). During an arduous three-year investigation, the alleged irregularities—"unbundling," kickbacks, over-coding, billing for services not provided, among others—dropped away one by one until the federal government discontinued its fraud investigation. Id. at 2. By that time, the hospital had incurred over one million dollars in fees and costs relating to the investigation. Id.

incentives for providers, manufacturers and others to self-report wrongdoing to law enforcement. In contrast, an interpretation of the public disclosure bar that exposes health care business to an increased likelihood that they will be sued by relators—even where they have made full disclosure and the government ultimately sees no reason to prosecute—will not encourage voluntary disclosure and will not serve the interests of the government or patients.

PhRMA's and AHA's members have a strong interest in ensuring that courts rigorously apply jurisdictional and pleading rules to insure that the statutory license to litigate on behalf of the United States is invoked only by legitimate relators with knowledge of actual frauds to guide them. FCA lawsuits based on speculation alone divert precious resources away from the core mission of amici's members—researching and developing medications and providing the care that allows people to live longer, healthier, and more productive lives—and toward defending costly litigation the alleged victim of the fraud (the government) has elected not to pursue.[2] Amici respectfully submit that this Court should vacate the holding of the

[2] In the past two decades, the health care field has been subjected to hundreds of declined qui tam actions by relators who are unsupervised at best and unscrupulous at worst. Defense of these frequently meritless claims drains the health care industry of badly needed resources. See Riley v. St. Luke's Episcopal Hosp., 252 F.3d 749, 767 n.24 (5th Cir. 2001) (Smith, J., dissenting) (noting that "[o]f the 1,966 [of all qui tam] cases that the government has refused to join, only 100 have resulted in recoveries (5%)"); see also GAO 2006 Report at 36 (noting that the median recovery in declined qui tam cases is just over $22,000). But given the risk of huge per-claim penalties and the inevitable high cost of protracted

District Court and remand with instructions to dismiss for lack of subject matter jurisdiction or, alternatively, affirm the decision below.

SUMMARY OF ARGUMENT

The District Court's decision undermines government pronouncements that companies who discover wrongdoing committed in their name should disclose those violations to law enforcement and take steps to remedy any resulting harm. To encourage a corporation's self-disclosure to law enforcement—which preserves the government's prosecutorial and investigative resources while imposing the costs, risks, and burdens of disclosure on the company—the government offers some predictability of pace, outcome, and coordination of remedies in exchange for corporate cooperation. In this case, Pfizer and Pharmacia accepted that offer and disclosed to the government certain marketing and distribution irregularities. If allowed to stand as precedent, however, the District Court's decision—holding that a formal voluntary disclosure to law enforcement officials is not a public disclosure under the FCA—will significantly alter the incentives to self-report. The only Court of Appeals until now to have addressed this issue has held that voluntary disclosure to officials charged with the authority to vindicate society's

---

litigation, health care manufacturers and providers all too often opt to settle these cases despite the absence of any fraud—simply as a rational business decision. See Keith D. Barber et al., Prolific Plaintiffs or Rabid Relators? Recent Developments in False Claims Act Litigation, 1 Ind. Health L. Rev. 131, 172 (2004).

interests will trigger the public disclosure bar. See United States v. Bank of Farmington, 166 F.3d 853, 861 (7th Cir. 1999). This Court should reach the same conclusion.

At the heart of the FCA's public disclosure bar is one basic premise: the value of whistleblower litigation is outweighed by its cost when federal law enforcement officials who are "strangers to the fraud" already have access to the essential information demonstrating that it occurred. See Rockwell Int'l Corp. v. United States, 127 S. Ct. 1397, 1409-11 (2007). When officials charged with the authority to enforce the FCA already know all of the information underlying an allegation of fraud, the government has no need for a "whistleblower" to alert it to the allegation. And inevitably, the whistleblower will claim as a bounty a portion of any recovery—despite Congress' intent, under these circumstances, to retain full recovery in the treasury. There is only one narrow exception to this principle: a relator who initially puts the government on notice of false or fraudulent claims subsequently disclosed to the public, and thereby enables the government to make an informed decision about whether and how to exercise its prosecutorial discretion. The statute dubs such a relator an "original source" and exempts their claims from the jurisdictional bar. Id.

Here, by the time the relator filed his qui tam suit, the defendants had already self-reported to the government, and disclosed to public officials

authorized to enforce the FCA (and each of the other statutes implicated by the conduct) all of the key facts that formed the basis of the relator's subsequent lawsuit. Those federal officials already had commenced an investigation of the conduct. There was nothing left for a whistleblower to disclose—no whistle to be blown. Because the FCA's public disclosure bar applied, the District Court lacked jurisdiction and the relator's complaint should have been dismissed.

Instead, the District Court rendered a tortured reading of multiple aspects of the public disclosure bar, watering down this fundamental predicate to a qui tam claim and significantly expanding federal courts' jurisdiction under the FCA. If that interpretation remains in place, qui tam defendants will face increased exposure to exactly those whistleblower suits Congress intended to foreclose: ill-supported FCA lawsuits pursued by opportunistic relators who cannot contribute direct and independent knowledge to aid the government's investigation or prosecution.

First, the public disclosure bar applies whenever there has been a disclosure to "strangers to the fraud"—including, especially, disclosures to public officials with authority to prosecute the misconduct or fraud. The District Court's holding to the contrary flies in the face of the FCA jurisdictional provision's text and purpose. Nothing in the text of the FCA suggests that disclosure to these public officials is insufficient to trigger the bar. The whole purpose of the statute is to get

information into the hands of law enforcement authorities who have prosecutorial discretion over how, whether, and when to pursue validly stated FCA allegations. The District Court's refusal to apply the "public disclosure bar" when a defendant has voluntarily disclosed alleged misconduct to law enforcement does not further the FCA's goals of encouraging prompt disclosure by whistleblowers with direct factual knowledge that would prompt a government investigation while discouraging qui tam actions based solely on speculation or indirect information. See United States ex rel. S. Prawer & Co. v. Fleet Bank of Maine, 24 F.3d 320, 327 (1st Cir. 1994).

Second, the District Court erred in its reading of the phrase "based upon the public disclosure." As the majority of courts have held, the public disclosure bar is properly interpreted to bar relator claims involving the same facts that have already been disclosed, regardless of a relator's actual reliance on that disclosure.

Third, the District Court's finding that Rost qualified as an "original source"—i.e., one with "direct and independent knowledge" of fraud—stands in stark tension with its finding that Rost failed to actually plead the submission of a single fraudulent claim to the government—and Rost's own admission that he specifically lacked any knowledge of any such claim. Under the Supreme Court's recent decision in Rockwell, this finding must be reversed.

While the District Court never should have reached the question of failure to state a claim, its analysis and application of Rule 9(b) was absolutely correct. Under a straightforward application of this Court's decision in Karvelas, Rost's failure to include "the particulars of any of his allegations concerning the presentation of false claims to the government" compelled dismissal. 360 F.3d at 233 n.17.

ARGUMENT

I. VOLUNTARY DISCLOSURE TO A PUBLIC OFFICIAL WITH DISCRETION TO PROSECUTE TRIGGERS THE "PUBLIC DISCLOSURE BAR."

The critical issue in this appeal is whether a relator may bring a qui tam suit after a company voluntarily has disclosed to the appropriate law enforcement officials all of the essential facts on which the qui tam suit is based. The District Court found that lawsuit permissible and exercised jurisdiction over the relator's claims. That was error. Corporations—like Pfizer—that learn of wrongdoing and promptly report it to those with law enforcement authority in the government, and then cooperate with and assist those public officials in investigating the scope of the problem, are taking precisely the action that the government and society expect and encourage. Leaving such corporations exposed to all sorts of qui tam actions, and removing the predictability of a global resolution with the United States, does not further the goals of the FCA and could significantly weaken the incentives that

encourage corporations to act expeditiously and forthrightly when they discover violations of law.

A. Public Disclosure Includes Disclosure To Public Officials.

1) Disclosure to a "stranger to the fraud"—including a public official—is sufficient to trigger the public disclosure bar under a plain reading of the statute.

The District Court's holding that disclosure to a public official will not trigger the public disclosure bar flies in the face of a plain reading of the statute. Section 3730(e)(4)(A) states:

> 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 [GAO] 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.

The statute sets no restriction on the identity of the party to whom the disclosure must be made; it draws no distinction between disclosures made to public officials and those made to private citizens. Rather, the only limitations set forth in the statute relate to the context in which the disclosure was made. The bar is triggered by disclosures made in: 1) a governmental hearing or investigation; 2) a governmental report; or 3) in the news media. Two of these contexts—governmental hearings/investigations and governmental reports—involve

disclosures made necessarily to public officials, but only potentially to private citizens.

Rather than focusing on whether the disclosure in this case was made in one of these contexts, the District Court fixated on whether the disclosure was somehow "public-enough."[3] It found that only disclosures to the "general public" would trigger the jurisdictional bar. Rost Addendum ("Add.") 17. That finding makes little sense and is contrary to the holdings of numerous courts of appeals. Although "public" refers to "members of the community," nothing about the term requires that it refer to all members of the community. As the government acknowledges, disclosure to even "a few members of the public is sufficient." Gov't Br. 17.[4]

The crucial question is whether the facts underlying the allegations of fraud have been disclosed to a stranger to the fraud—i.e., someone other than the perpetrator and the agency or agent victim of the fraud. Numerous courts of

---

[3] As Pfizer explains in its brief, it made these disclosures in an administrative investigation. Pfizer Br. 29-30.

[4] Viewed in the context of the District Court's decision and its own position on appeal, the government's acknowledgement leads to the odd conclusion that a disclosure to a government investigator does not trigger the public disclosure bar unless and until that investigator discloses information about the ensuing investigation to a private citizen in the course of an investigation or audit. It seems unlikely that Congress would have intended the statute so clearly to render the government's investigative file essential to jurisdictional discovery.

appeals have held that no minimum threshold applies to the number of people who receive disclosed information before it is sufficiently "public." See, e.g., United States ex rel. Fine v. Advanced Sciences, Inc., 99 F.3d 1000, 1005-06 (10th Cir. 1996); United States ex rel. Doe v. John Doe Corp., 960 F.2d 318, 323 (2d Cir. 1992); United States ex rel. Stinson v. Prudential Ins. Co., 944 F.2d 1149, 1158 (3d Cir. 1991). Rather, a "public disclosure" occurs when any person who is a "stranger[] to the fraud" is informed of the allegedly fraudulent acts. Doe, 960 F.2d at 322; see Fine, 99 F.3d at 1005; Stinson, 944 F.2d at 1155; see United States ex rel. Ramseyer v. Century Healthcare Corp., 90 F.3d 1514, 1521 (10th Cir. 1996) ("public disclosure occurs only when the allegations or fraudulent transactions are affirmatively provided to others not previously informed thereof"); United States ex rel. Foust v. Group Hospitalization & Med. Servs., Inc., 26 F. Supp. 2d 60, 71-72 (D.D.C. 1998) (citing Doe and Fine). Federal law enforcement officials are strangers to the fraud, and disclosure to them triggers the bar.

The only appellate court to have considered this precise question has so held. In Farmington, 166 F.3d at 861, the Seventh Circuit held that disclosure of evidence of a fraud to a "public official responsible for a claim" naturally is a "public disclosure." The court reasoned that "[t]he point of public disclosures of a false claim against the government is to bring it to the attention of authorities, not merely to educate and enlighten the public at large about the dangers of

misappropriation of their tax money." Id. Thus, the reason that "[d]isclosure to the public at large" triggers the bar is "precisely because it is likely to alert the authorities about the alleged fraud." Id. Because disclosure to enforcement officials eliminates the need for middlemen, such disclosure can, and should, trigger the bar; public officials with a charge to protect the public interest are no less members of the public than private citizens with no such responsibility. Id. (the term "public" includes one who is "authorized by, acting for, or representing the community") (quoting 12 Oxford English Dictionary 779 (2d ed. 1989)).

This straightforward construction of the statute makes sense. The contrary construction proffered by the government in this appeal strains its clear meaning. Gov't Br. 17-18. By that construction, if a Pfizer executive published a confession of improper conduct in a rural Chinese newspaper that had no U.S. subscribers, she would have made a "public disclosure" of that information sufficient to trigger the bar and preclude suits by non-original source relators. But if that employee, acting on behalf of the corporation, were to disclose violations to the specific public officials authorized to investigate and prosecute the wrongdoing, relators would not be barred from bringing suit and sharing in any recovery the government receives.

No reasonable reading of the statute would allow for such an absurd result. The provision should be interpreted to preserve and promote that which the qui tam

statute clearly values—disclosure of misconduct to public officials empowered to investigate and prosecute violations of federal law.

2) Recognizing that voluntary disclosures are public disclosures does not restore the "government knowledge" defense.

The District Court and the government wrongly conclude that dismissal of Rost's claim under the public disclosure bar would be tantamount to resurrecting a repealed defense that barred qui tam actions based on information the government had in its possession somewhere, regardless of who was the source of that information, what individual within the government had that information, and whether that person was tasked with acting on it. See Add. 17-19; Gov. Br. 14-15. In 1986, in the wake of the Seventh Circuit's decision in United States ex rel. Wisconsin v. Dean, 729 F.2d 1100 (7th Cir. 1984), Congress jettisoned this "government knowledge" defense and enacted the public-disclosure-bar-plus-original-source-exception. In Dean, the State of Wisconsin had brought a qui tam action after it uncovered a scheme to defraud Medicaid; but the case was dismissed because Wisconsin informed the federal government of the fraud before filing suit. 728 F.2d at 1102-04. The court reasoned that a qui tam action is barred "whenever the government has knowledge of the essential information upon which the suit is predicated before the suit is filed, even when the plaintiff is the source of that

knowledge." Id. at 1103 (emphasis added). After this decision, "there was once again a perception that the qui tam provisions were in need of alteration." Prawer, 24 F.3d at 326; see United States ex rel. Springfield Terminal Ry. v. Quinn, 14 F.3d 645, 650 (D.C. Cir. 1994) (noting that Congress "responded" to pleas " 'urging [it] to rectify the unfortunate result' of the Dean case") (quoting S. Rep. No. 345, at 13 (1986)).

The result in Dean reinforced the importance of an original source exception, which Congress adopted as part of a larger overhaul of the FCA. See Quinn, 14 F.3d at 651 (Congress "enact[ed] the 'original source' exception that had somehow slipped through the crack in 1943").[5] Congress recognized that the exception was important to achieving the desired balance between encouraging whistleblowers to come forward while preventing parasitic qui tam litigation. Prawer, 24 F.3d at 327; Quinn, 14 F.3d at 651 (noting that in 1986 Congress "left in place barriers to parasitic lawsuits"). Once some member of the public knows of the fraud, that information can make its way (directly or indirectly) to the government; and once the government is aware of the fraud and the essential facts

[5] Congress had considered an original source exception in 1943 when it enacted the government knowledge defense. Prawer, 24 F.3d at 325 ("the Senate bill would have precluded suits which were based upon information already in the government's possession unless the information underlying the suit was original with the person bringing the suit") (citing Quinn, 14 F.3d at 650 and 89 Cong. Rec. 510, 744 (daily ed. Dec. 16, 1943)). But, as enacted, the bill ommited an "original source" exception. Id.

relating to it, it is "in a position to vindicate society's interests, and a qui tam action would serve no purpose." United States ex rel. Feingold v. AdminaStar Fed., Inc., 324 F.3d 492, 495 (7th Cir. 2003).

As the Seventh Circuit found in Farmington, disclosure to a public official with "managerial responsibility for the claim" is significantly more "public" than disclosure to a government employee who was either indifferent to the information or had an incentive to not investigate the fraud. 166 F.3d at 861-862. The Court concluded that the latter was insufficient in part because it "fails to . . . encourage the exposure and punishment of fraud." Id. at 862. While interpreting the bar as triggered by disclosure to government personnel without responsibility to prosecute the claim might resurrect the government knowledge defense, finding the bar triggered by a disclosure to law enforcement does not.

The public disclosure bar and its original source exception restrict the license granted to litigate claims of the United States when the proverbial whistle has already been blown and the government can recover its losses without the aid of a non-original source relator. Under the District Court and the government's reading in this case, Congress's purpose would be frustrated since the government's recovery would actually decrease because a relator could step in where a disclosure had been made and, despite any ongoing investigation, claim a share of that recovery. Congress could not have intended such a result.

3) Failure to apply the "public disclosure bar" here will undermine federal self-reporting programs and corporate compliance plans.

HHS's law enforcement authority—the Office of Inspector General ("OIG")—implemented a "Self-Disclosure Protocol" nearly a decade ago for health care entities to disclose federal health care program abuses. HHS, Office of Inspector General, Provider Self-Disclosure Protocol,[6] 63 Fed. Reg. 58,399 (Oct. 30, 1998) ("Self-Disclosure Protocol" or "Protocol"). In creating the Protocol, OIG noted that it "has long stressed the role of the health care industry in combating health care fraud," and offered its "belie[f] that health care providers" can "play a cooperative role in identifying and voluntarily disclosing program abuses." Id. Providers and manufacturers are urged to use the Protocol in order "to work openly and cooperatively with the OIG to efficiently quantify a particular problem" and to "promote a higher level of ethical and lawful conduct throughout the health care industry." Id.

The Protocol's declared goal is "to encourage . . . voluntary disclosures." Id. 58,400. The Protocol is part of OIG's "commitment to promote an environment of openness and cooperation." OIG News Release, OIG Issues Guidance on Voluntary Disclosure of Health Care Fraud (Oct 21, 1998), at 2.[7] As OIG explains

---

[6] Available at http://oig.hhs.gov/authorities/docs/selfdisclosure.pdf.

[7] Available at http://oig.hhs.gov/fraud/docs/complianceguidance/dispress.pdf.

it, the Protocol seeks to "enlist[]" the health care industry in "win[ning] the battle against health care fraud." Id. And OIG touts that "full disclosure and cooperation generally benefits the individual or company." Id.[8]

Just last year, in fact, OIG supplemented the Protocol with a "self-disclosure initiative" that "serves as an additional opportunity for providers to work collaboratively with the OIG." Daniel R. Levinson, HHS Inspector General, An Open Letter to Health Care Providers (Apr. 24, 2006).[9] This new initiative specifically applies to self-disclosure of violations of the federal physician self-referral law (42 U.S.C. § 1395nn) and the federal anti-kickback statute (42 U.S.C § 1320a-7b). In announcing the new initiative, OIG confirmed its view that "[e]ffective compliance systems are key to strengthening the integrity of the health care system." Id. at 1. And it stressed that "detection and prompt disclosure of potential fraud are evidence of an effective compliance program." Id. at 2.

The Self-Disclosure Protocol is incorporated into several Compliance Program Guidances ("CPGs") OIG has developed for each segment of the health care industry. CPGs provide direction for adopting and maintaining voluntary

---

[8] A party disclosing misconduct under the Protocol may also request the participation of the Department of Justice "in order to resolve potential liability under the False Claims Act or other laws." Protocol, 63 Fed. Reg. 58,401.

[9] Available at http://oig.hhs.gov/fraud/docs/openletters/Open%20Letter%20to%20Providers%202006.pdf.

compliance and reporting programs. See, e.g., CPG for Clinical Laboratories, 63 Fed. Reg. 45,076 (Aug. 24, 1998); CPG for Hospitals, 63 Fed. Reg. 8,987 (Feb. 23, 1998), supplemented, 70 Fed. Reg. 4,858 (Jan. 31, 2005); CPG for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003). Self reporting is an element of each CPG:

> Where the compliance officer, compliance committee, or a member of senior management discovers credible evidence of misconduct from any source and, after a reasonable inquiry, believes that the misconduct may violate criminal, civil, or administrative law, the company should promptly report the existence of misconduct to the appropriate federal and state authorities within a reasonable period, but not more than 60 days, after determining that there is credible evidence of a violation.

See, e.g., CPG for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23,742.[10]

The CPGs are in sync with other law enforcement pronouncements and incentives concerning self reporting. The CPGs rely heavily on the definition of effective compliance programs propounded by the United States Sentencing Commission. See id. at 23,731; United States Sentencing Commission, Guidelines Manual, § 8B2.1(b) (Nov. 2006). The Commission's guidelines have become a touchstone for corporations intent on demonstrating their commitment to compliance with the law. And the principle embodied in those guidelines—that

---

[10] The CPG for Pharmaceutical Manufacturers specifically lists as appropriate authorities for self-reporting misconduct those with law enforcement authority over the misconduct at HHS, the Department of Justice, and FDA—the very public officials to whom Pfizer made its voluntary disclosure. See id. at 23,743.

law abiding corporations recognize obligations both to prevent and detect illegal conduct and to respond promptly once problems are detected—is reflected in the CPGs. See id., Ch. 8, intro ("[t]he two factors that mitigate the ultimate punishment of an organization are: (i) the existence of an effective compliance and ethics program; and (ii) self-reporting, cooperation, or acceptance of responsibility"); id. § 8C2.5(f)(1) (culpability score to be reduced if the corporate defendant has an effective compliance program).

Pfizer followed the requirements of the Self-Reporting Protocol and the principle of promoting voluntary disclosure of misconduct embodied in that document, the CPG, and the Sentencing Guidelines. In the end, the very federal officials who prosecuted the voluntarily disclosed misconduct noted that Pfizer "acted responsibly when it self-disclosed to various federal government agencies . . . Pharmacia's unlawful promotion of human growth hormone." U.S. Justice Dep't Press Release at 1 (Apr. 2, 2007).[11]

Nothing further can be gained from a relator's complaint after voluntary disclosure of this type. Quite the contrary: The District Court's interpretation of the public disclosure bar will erode the incentives of entities in the health care industry to quickly and forthrightly disclose evidence of misconduct carried out in

[11] Available at http://www.usdoj.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Apr2007/Pharmacia-Information-Settlement.html.

their name. The net effect can only frustrate achievement of the FCA's primary goal: " 'enhanc[ing] the Government's ability to recover losses sustained as a result of fraud against the Government.' " Prawer, 24 F.3d at 326 (citation omitted). Self disclosure offers an efficient means to accomplish that goal; the District Court's decision here discourages responsible parties from doing just that.

B. The Relator's Law Suit Was "Based Upon" A Public Disclosure.

An action is "based upon" a public disclosure when its allegations are "similar to" or share an "identity with" the allegations that have been disclosed. On this point, both the government and Pfizer have it exactly right. Gov't Br. 19-24; Pfizer Br. 31(noting that seven Courts of Appeals have so held). Beyond the case law discussed in those briefs, two canons of construction support that reading.

First, it is well-settled that "[a]ll words and provisions of statutes are intended to have meaning and are to be given effect, and no construction should be adopted which would render statutory words or phrases meaningless, redundant or superfluous." United States v. Ven-Fuel, Inc., 758 F.2d 741, 751-752 (1st Cir. 1985). The District Court interpreted the public disclosure bar to apply only when a relator's suit is "derived from" the public disclosure. Add. 22. That rule creates a bar under which original source status could never be achieved. As a matter of simple logic, any relator whose suit is derived from the publicly disclosed information will never have "direct and independent knowledge" of the allegations

because the relator's knowledge will stem from the public disclosure, not personal experience or direct observation. The original source exception—which can be invoked only by one with "direct and independent knowledge"—would thus unacceptably be rendered superfluous.

Second, "[i]t is a fundamental interpretive principle that identical words or terms used in different parts of the same act are intended to have the same meaning." United States v. Nippon Paper Indus. Co., 109 F.3d 1, 4 (1st Cir. 1997). This " 'basic canon of statutory construction' " applies whether the words "appear in different paragraphs or sentences of a single section" of a statute. Id. at 5 (citing Estate of Cowart v. Nicklos Drilling Co., 505 U.S. 469, 479 (1992)). Here, the phrase "based upon" appears twice: Section 3730(e)(3) states that no person may bring an action "which is based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party" and Section 3730(e)(4) states that a court lacks jurisdiction over an action that is "based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or [GAO] report, hearing, audit, or investigation, or from the news." This Court has already construed "based upon" as used in Section

3730(e)(3) to mean shares an "identity" with, see Prawer, 24 F.3d at 328, and it should construe that same term in Section 3730(e)(4) in the same manner.[12]

This Court should hold—like seven other Circuits—that an action is "based upon" a public disclosure when the allegations are "similar to" or share an "identity with" the allegations that have been disclosed. The allegations in Rost's complaint plainly satisfy that standard.

C. The Relator Did Not Qualify As An "Original Source."

1) Speculative predictions do not constitute "direct and independent knowledge" of false claims.

The public disclosure bar contains an exception that permits jurisdiction when the relator "is an original source of the information," i.e., one who has "direct and independent knowledge of the information on which the allegations are based." 31 U.S.C. § 3730(e)(4). The District Court correctly recognized that the statute requires that a relator like Rost have direct and independent knowledge of the fraud alleged in his complaint. But it then curiously held that Rost satisfied

---

[12] The similar term "based on" appears in the first-to-file bar, which precludes subsequent relators from bringing a cause of action "based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). There, the phrase "based on the facts" has been interpreted to mean subsequent causes of action encompassing the same "essential facts." See, e.g., United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 232-233 (3d Cir. 1998). This interpretation comports with the principle that "[o]nce the government is put on notice of its potential fraud claim, the purpose behind allowing qui tam litigation is satisfied." Grynberg v. Koch Gateway Pipeline Co., 390 F.3d 1276, 1279 (10th Cir. 2004).

this standard because he had direct and independent knowledge of the defendants' alleged regulatory misconduct. Add. 29-30.

The court failed to appreciate the distinction between knowledge of regulatory violations and knowledge of false claims within the FCA's scope. Rost claimed to know of regulatory misconduct by virtue of his management position, but tellingly admitted that he had no direct knowledge of a single false claim submitted for government reimbursement. Rost instead offered only his prediction that the misconduct would have "inevitably" resulted in the submission of some false claims somewhere by someone. Rost Br. 21. This type of speculation cannot qualify as direct and independent knowledge of fraud. See, e.g., United States ex rel. Aflatooni v. Kitsap Phys. Servs., 163 F.3d 516, 526 (9th Cir. 1999) ("pure speculation" by a relator does not meet the test for direct knowledge).

The Supreme Court's decision this term in Rockwell held that a prediction "does not qualify as 'direct and independent knowledge" in determining original source status under the FCA. 127 S. Ct. at 1410. In finding the relator there was not an original source, the Court emphasized that the relator did not "know" of a problem, he simply "predicted" it. Id. (emphasis in original). And because the premise of the relator's prediction was inaccurate, the Court found that his prediction "assuredly" did not qualify as direct and independent knowledge and the relator could not qualify as an original source. Id.

Rost's status as a qui tam relator is doomed for the reasons stated in Rockwell. Rost does not "know" of any false claims. According to the District Court, Rost merely "speculate[d] that Defendants' marketing activities must have caused physicians to prescribe Genotropin for off-label uses and that some of these prescriptions were inevitably reimbursed by federal and state government health care programs." Add. 37 (emphasis added). After an extensive investigation, however, the United States never alleged any FCA violations by Pharmacia, and neither Pharmacia nor Pfizer admitted any such violations. Pfizer Br. 48. And moreover, even Rost's predictions of "inevitable" false claims appear to rest on the faulty premise that off-label uses of growth hormones for anti-aging, cosmetic, or athletic purposes would lead to claims for reimbursement. The government—which investigated this matter for years—concluded to the contrary that in "most, if not all, instances" patients taking Genotropin for off-label uses paid for the drug "out-of-pocket without reimbursement from any public or private third-party payors." Id. (quoting Agreement between United States Attorney's Office for the District of Massachusetts and Pharmacia & Upjohn Company, L.L.C., Mar. 27, 2007, Appendix A ¶ 18).

Given the purpose of the qui tam provisions—"to encourage individuals with true 'knowledge' of alleged wrongdoing to come forward"—the Ninth Circuit concluded that "allowing a relator to maintain a qui tam suit based on pure

speculation or conjecture" is inappropriate. Aflatooni, 163 F.3d at 526. Karvelas strongly suggested the same result, holding that detailed descriptions of procedures allegedly used by the hospital to submit false claims did "not permit [the Court] to speculate that false claims were in fact submitted." 360 F.3d at 235. This Court should find the same here.

2) Any relator who lacks the information to state a claim under Rule 9(b) cannot qualify as an original source.

While claiming original source status—as one with purported "direct and independent knowledge" of fraud—Rost now admits that he lacks any evidence of actual false "claims" and any "information" essential to enabling him to identify them. Rost's admissions come as he brazenly seeks discovery and leave to amend his complaint thereafter. Rost Br. 27. Rost cannot have it both ways. The qui tam statute is intended to encourage the disclosure of wrongdoing by individuals with knowledge of actual fraudulent claims; it does not exist as a means for those without knowledge to troll for evidence.

In its discussion of Rule 9(b), the District Court correctly found that Rost failed to allege a single false claim for government reimbursement, compelling dismissal with prejudice under the pleading requirements of Rule 9(b). Add. 37. The tension between this holding and its predicate holding that Rost possessed the requisite "direct and independent knowledge" of actual fraudulent conduct is readily apparent. Other courts have avoided this tension in numerous cases by

examining the standards of direct and independent knowledge and Rule 9(b) together. See, e.g., United States ex rel. Joshi v. St. Luke's Hosp., Inc., 441 F.3d 552, 560 (8th Cir. 2006); United States ex rel. Kinney v. Stoltz, 327 F.3d 671, 674 (8th Cir. 2003); United States ex rel. Westerfield v. University of San Francisco, 2006 WL 2884331, at 3 (N.D. Cal. Oct. 10, 2006); United States ex rel. Detrick v. Young, 909 F. Supp. 1010, 1019 (E.D. Va. 1995). Any failure to plead with specificity under Rule 9(b) "provides strong evidence that a relator does not qualify as an original source." 1 John T. Boese, Civil False Claims And Qui Tam Actions § 4.02[D][1], at 4-95 (3d ed. 2007).

Finally, this Court has observed that the definition of an original source "excludes individuals who must rely upon information already in the possession of the government to adequately state their claim." Karvelas, 360 F.3d at 230. The same logic should apply to qui tam plaintiffs who must acquire information in the hands of third parties. Any relator lacking the information to allege false claims with particularity should not qualify as an original source with direct and independent knowledge of the fraud.

Because the District Court lacked jurisdiction over relator Rost's claims, its judgment should be vacated and the case remanded with instructions to dismiss Rost's claims for lack of jurisdiction. Doing so will restore the government's incentive and encouragement that companies embrace self-disclosure as a means of

achieving a global settlement with the government addressing wrongdoing a company becomes aware was committed in its name.

II. THE RELATOR'S COMPLAINT FAILED TO STATE A CLAIM UNDER RULE 9(b).

The stringent pleading standard articulated in Rule 9(b) applies to FCA claims, just as it applies to any allegation of fraud. This Court's decision in Karvelas governs the inquiry here, as the Government and Pfizer argue and as the District Court properly held below. Add. 32-37; Gov't Br. 29; Pfizer Br. 41-43.

In Karvelas, the relator's complaint was dismissed for failure to allege "the particulars of any of his allegations concerning the presentation of false claims to the government." 360 F.3d at 233 n.17. The glaring omission in that complaint was its failure to "specif[y] the dates or content of any particular false or fraudulent claim allegedly submitted for reimbursement." Id. at 233 (emphasis added). As the Court emphasized, allegations of regulatory noncompliance are not enough; specific allegations of the purported fraud (i.e., details of the false claims submitted for payment or the false statements made to get a false claim paid) are the only allegations that can serve as the premise for a FCA violation. Id. at 234.

Like Karvelas, Rost lacks any detailed knowledge of fraud. He recycles the argument soundly rejected by this Court in Karvelas—that allegations of regulatory non-compliance should be enough. Rost Br. 16-17, 24-26. Rule 9(b) requires more, as Karvelas makes clear. Only FCA complaints that plead details of

the alleged fraud meet Rule 9(b); allegations based on regulatory misconduct that "inevitably" would lead to submissions of some false claim somewhere by someone are not enough. Rost Br. 21, 25. An actual false claim submitted to the government is "the sine qua non of a False Claims Act violation," and without details about the submission of a false claim, no FCA cause of action is stated. Clausen, 290 F.3d at 1311, 1313; see also Joshi, 441 F.3d at 557; United States ex rel. Atkins v. McInteer, 470 F.3d 1350, 1359 (11th Cir. 2006); Corsello v. Lincare, Inc., 428 F.3d 1008, 1013 (11th Cir. 2005).[13]

Enforcing the strict pleading standard of Rule 9(b) is necessary to further specific policies and purposes in the FCA context and to "protect defendants against spurious charges." Ziemba v. Cascade Int'l, Inc., 256 F.3d 1194, 1202 (11th Cir. 2001); see Karvelas, 360 F.3d at 226; Clausen, 290 F.3d at 1313 n.24. If a relator's complaint does not identify fraud with particularity, it must be dismissed. See United States ex rel. Thompson v. Colombia/HCA Healthcare

---

[13] Rost cannot escape the shortcomings in his complaint by alleging that the information on false claims was in the defendants' possession rather than his own. See United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah, 472 F.3d 702, 727-728 (10th Cir. 2006) (relying on Karvelas to reject just such an argument by a relator); Rost Br. 27-28. And the strict pleading standard is equally important with respect to Rost's "false record" claims under § 3729(a)(2), since there is no liability for a false statement under that section "unless it is used to get [a] false claim paid." United States v. Southland Mgmt Corp., 326 F.3d 669, 675 (5th Cir. 2003). See United States ex rel. Totten v. Bombardier Corp., 380 F.3d 488, 498-502 (D.C. Cir. 2004) (same).

Corp., 125 F.3d 899, 903 (5th Cir. 1997) ("At a minimum, Rule 9(b) requires that a plaintiff set forth the 'who, what, when, where, and how' of the alleged fraud.") (internal quotation omitted).

CONCLUSION

For the foregoing reasons, as well as those in defendants-appellees' brief, the Court should vacate the judgment and remand with instructions to dismiss for lack of jurisdiction. In the alternative, the Court should affirm the decision below for failure to state a claim.

Respectfully submitted,

Of Counsel:

Diane E. Bieri
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
950 F Street, N.W., Suite 300
Washington, D.C. 20004
(202) 835-3405

Melinda Reid Hatton
Maureen D. Mudron
AMERICAN HOSPITAL ASSOCIATION
325 Seventh Street, N.W., Suite 700
Washington, D.C. 20004
(202) 638-1100

Jonathan L. Diesenhaus*
Catherine E. Stetson
Jessica L. Ellsworth
Jake M. Shields
HOGAN & HARTSON L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-5600

*Admission pending

June 7, 2007

Counsel for Amici Curiae

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), I hereby certify that this brief is proportionally spaced, has a typeface of 14 points using Microsoft Word 2003 and contains 6,994 words.

_____

Jonathan L. Diesenhaus

CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of June, 2007, two copies of the Brief for Amici Curiae Pharmaceutical Research and Manufacturers of America and American Hospital Association in Support of Defendants-Appellees were served by overnight delivery on:

Peter D. Keisler
Assistant Attorney General
Michael J. Sullivan
United States Attorney
Douglas N. Letter
Michael D. Granston
Jamie Ann Yavelberg
Attorneys
Civil Division, Room 9144
U.S. DEPARTMENT OF JUSTICE
601 D Street, N.W.
Washington, D.C. 20004
(202) 514-6514

Mark I. Labaton
Megan Benett
Hilary B. Taylor
KREINDLER & KREINDLER LLP
707 Wilshire Boulevard, Suite 5070
Los Angeles, CA 90017
(213) 622-6469

Ethan M. Posner
Carolyn F. Corwin
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 662-6000

_____
Jonathan L. Diesenhaus