No. 09-654

IN THE

Supreme Court of the United States

ORTHO BIOTECH PRODUCTS, L.P.,
Petitioner,

v.

UNITED STATES EX REL.
MARK EUGENE DUXBURY,
Respondent.

On Petition for Writ of Certiorari To the United States Court of Appeals For the First Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Amicus curiae addresses the following issue only:

Whether, in a *qui tam* suit filed under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, a relator alleging that the defendant induced a third party to submit false or fraudulent claims, can satisfy Rule 9(b) of the Federal Rules of Civil Procedure without identifying a single false or fraudulent claim, but merely by alleging facts sufficient "to strengthen the inference of fraud beyond possibility."

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE IN SUPPORT OF PETITIONER

INTERESTS OF *AMICI CURIAE*

The Washington Legal Foundation is a public interest law and policy center with supporters in all 50 States.[1] WLF devotes a substantial portion of its resources to promoting limited and accountable government, supporting the free enterprise system, and opposing abusive enforcement actions and civil litigation by the government and private litigants.

To that end, WLF has appeared before this Court and other federal courts in numerous cases raising significant issues regarding the civil False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.* *See, e.g., Graham County Soil & Water Conservation Dist. v. United States ex rel. Wilson*, No. 08-304 (U.S., dec. pending); *Allison Engine Co. v. United States ex rel. Sanders*, 128 U.S. 2123 (2008); *Rockwell Int'l Corp. v. United States*, 549 U.S. 457 (2007); *Hopper v. Solvay Pharmaceuticals, Inc.*, ___ F.3d ___, 2009 U.S. App. LEXIS 26381 (11th Cir., Dec. 4, 2009); *United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11 (D. Mass. 2008).

WLF is concerned that over the last two decades,

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief. More than ten days prior to the due date, counsel for WLF provided counsel for Respondent with notice of its intent to file this brief. All parties have consented to the filing of this brief. Letters of consent have been lodged with the Court.

excessive FCA activity has spawned abusive punitive litigation against businesses, both large and small, to the detriment of those businesses, their employees, their shareholders, and the public at large. Respondent's complaint focuses on his allegations that Petitioner Ortho Biotech Products, L.P. improperly promoted sales of its products. But the issue in this case is whether Petitioner violated the FCA, not whether it improperly promoted its products. The complaint cannot state a cause of action under the FCA given its failure to allege with particularity even a single false claim submitted to the federal government for payment. WLF is concerned that if complaints of this sort are deemed sufficient to survive motions to dismiss, the business community will be forced: (1) to settle even insubstantial FCA claims in order to avoid the prohibitive costs of pre-trial discovery; and (2) to refrain from speaking truthfully to doctors and their patients for fear that the plaintiffs' bar will allege that the speech induced violations of the FCA.

WLF has no direct interest, financial or otherwise, in the outcome of this case. It is filing its brief due solely to its interest in enforcing reasonable restraints on FCA litigation. WLF agrees with Petitioner that review is warranted on the first question presented: whether Respondent should qualify as an "original source" despite his failure to provide relevant information to the government until after that information was publicly disclosed. However, this brief addresses only the second question presented: whether the complaint was adequate under Fed.R.Civ.P. 9(b).

STATEMENT OF THE CASE

The FCA's *qui tam* provisions encourage private individuals with knowledge of fraud perpetrated against the United States Treasury to come forward and sue on behalf of the United States. To encourage whistleblowers (known as *qui tam* relators) to come forward and expose such fraud, the federal government pays a bounty of up to 30% of all recoveries. In other words, the FCA's *qui tam* provisions essentially allow the government to "purchase" from private individuals the information they may have about fraud on the United States Treasury. *United States ex rel. Russell v. Epic Healthcare Mgmt. Group*, 193 F.3d 304, 309 (5th Cir. 1999).

The potential bounties available under the FCA's *qui tam* provisions make this mechanism susceptible to abuse by opportunistic bounty hunters masquerading as true whistleblowers. One of the most effective checks on such parasitic lawsuits is Fed.R.Civ.P. 9(b), which provides that any complaint alleging fraud or mistake (as all FCA complaints must do) "must state with particularity the circumstances constituting fraud or mistake." An FCA complaint that fails to comply with Rule 9(b)'s "particularity" requirement is subject to dismissal under Fed.R.Civ.P. 12(b)(6). A central issue in this petition concerns what an FCA plaintiff must plead to meet the "particularity" requirement.

Respondent Mark Duxbury was employed by Petitioner Ortho Biotech Products, L.P. ("OBP") from 1992 to 1998 in a sales capacity. Duxbury's amended complaint (filed in 2006) did not allege that OBP itself

submitted any false claims to the federal government. Rather, he alleged that OBP promoted sales of one of its oncology drugs, Procrit, in a manner that encouraged others to submit false claims to the federal government under the Medicare program.

Duxbury's allegations regarding this improper encouragement fell generally into two categories. First, Duxbury alleged that OBP violated the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, by promoting the use of Procrit for "off-label" uses (*i.e.*, uses for which the Food and Drug Administration (FDA) has not granted marketing authority). Duxbury conceded that the FDCA does not interfere with the authority of doctors and other practitioners to prescribe an FDA-approved drug for any use they deem medically appropriate, even uses that have not been explicitly approved by FDA. Duxbury nonetheless alleged that at least some Procrit off-label prescriptions written during 1992-1998 were not properly reimbursable under Medicare and that practitioners falsely sought (and obtained) Medicare reimbursement for those prescriptions. Duxbury alleged that various of OBP's promotional activities caused practitioners to submit these false claims and/or to get the claims paid, and that OBP should be held civilly liable under 31 U.S.C. § 3729(a)(1) & (2).

Second, Duxbury alleged that OBP paid "kickbacks" to health care practitioners for the purpose of inducing them to prescribe Procrit.[2] These kickbacks

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[2] The federal anti-kickback statute makes it a serious felony to solicit or receive:

allegedly took the form of "free samples, off-invoice discounts, rebates, consulting fees, educational grants, payments to participate in studies or trials and advisory board honoraria." Pet. App. 49a (citing Am. Compl. ¶ 228).

Duxbury alleged that there were several reasons why these alleged kickbacks violated the FCA. First, the reimbursements paid by Medicare for Procrit were based on the drug's Average Wholesale Price (AWP). Duxbury alleged that the AWP for Procrit was calculated without taking into account the alleged secret kickbacks paid by OBP. Duxbury alleged that information provided by OBP (including its failure to disclose the kickbacks) caused Procrit's AWP to be inflated and thereby caused Medicare to pay inflated reimbursements to health care practitioners. Second, Duxbury alleged that health care practitioners could only have obtained reimbursement for Procrit purchases by falsely certifying to federal officials that they had not received kickbacks. Third, health care practitioners allegedly violated the FCA (at OBP's encouragement) by wrongfully seeking "reimbursement" for the free samples they were given by OBP.

> any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program . . .

42 U.S.C. § 1320a-7b(b)(1). Subsection (b)(2) makes it a felony to *pay* a kickback under similar circumstances.

In January 2008, the district court dismissed all of Duxbury's FCA claims under Fed.R.Civ.P. 12(b). Pet. App. 44a-78a. It dismissed the off-label marketing claims under the first-to-file rule of 31 U.S.C. § 3730(b)(5). The court held that Duxbury's claims were barred because another *qui tam* relator had filed a substantially similar FCA claim before Duxbury filed his first amended complaint. *Id.* at 63a-72a. The court dismissed the kickback-related claims under Rule 9(b), finding that Duxbury had failed to state those claims with sufficient particularity. *Id.* at 72a-77a. It faulted the complaint for failing to identify any specific false claim with particularity (*e.g.*, the date and amount of the claim and the identity of those involved with the billing). *Id.*

The First Circuit affirmed the dismissal of Duxbury's off-label claims but reversed and remanded with respect to the kickback-related claims. *Id.* at 1a-43a. The appeals court conceded that the adequacy of the kickback-related claims was a "close call," in light of Duxbury's failure to "identify any specific claims" submitted by a health care practitioner to Medicare officials. *Id.* at 35a-36a. But the appeals court held that the district court should have applied a "more flexible standard" in determining whether Rule 9(b)'s particularity requirement had been met. *Id.* at 35a. It held that Duxbury met that "flexible" standard because even though the first amended complaint did not identify any specific false claims, it named specific health care providers and included allegations suggesting that OBP's alleged kickbacks had caused those providers to file false claims. *Id.* at 32a-39a.

REASONS FOR GRANTING THE PETITION

This petition raises issues of exceptional importance. Doctors and their patients are well-served when pharmaceutical manufacturers are permitted to speak truthfully about their products. Courts have recognized the public health benefits of permitting the free flow of truthful information about medical products and have recognized broad First Amendment rights both to disseminate and to receive such information. *See, e.g., Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000).

The free flow of such information is in serious jeopardy, however, as a result of lawsuits such as this one, which seek to impose massive liability on pharmaceutical companies based on their promotional activities. The plaintiffs' bar has filed a torrent of lawsuits seeking to impose FCA liability on those companies based on claims that the promotional activities – which often involve nothing more than speaking truthfully about off-label uses of their products and providing doctors with free samples of those products – are causing others to submit false claims to the federal government. Review is warranted to determine whether Congress really intended to impose FCA liability under these circumstances.

The court below determined that Respondent Duxbury's amended complaint met the heightened pleadings standards of Fed.R.Civ.P. 9(b), despite its failure to identify any specific false claims submitted by a health care practitioner. It did so on the basis of a

"flexible" pleading standard that took into account that relators who do not work for a health care practitioners are highly unlikely to have access to the practitioners' billing records and thus cannot easily obtain information about the submission of specific false claims. As the Petition thoroughly documents, the First Circuit's standard for judging compliance with Rule 9(b)'s "particularity" requirement conflicts sharply with the standards adopted by at least three other federal appeals courts. WLF writes separately to note that the day after the Petition was filed, the Eleventh Circuit issued a decision that rendered the conflict just that much sharper. In a case raising claims virtually identical to those raised by Respondent Duxbury, the Eleventh Circuit affirmed dismissal of the FCA lawsuit against a pharmaceutical manufacturer because the relator failed to identify any specific false claim that was filed as a result of the manufacturer's alleged promotional activities. *Hopper v. Solvay Pharmaceuticals, Inc.*, __ F.3d __, 2009 U.S. App. LEXIS 26381 (Dec. 4, 2009). Review is warranted to resolve the conflict.

Review is also warranted because of the recurring nature of the issue. Virtually every pharmaceutical and medical device company is facing or has faced FCA claims of the type at issue here. Although there is substantial reason to question the validity of many of these suits, the difficulty and expense of defending against FCA claims of this nature mean that defendants – if they cannot prevail on a motion to dismiss – often feel compelled to settle, sometimes for very substantial sums. Clarification of the Rule 9(b) pleading standards in cases of this sort is urgently needed, so that

manufacturers can know how to conform their conduct to the requirements of the FCA. WLF notes, for example, that for valid promotional reasons, pharmaceutical manufacturers annually give away to health care practitioners billions of dollars of free samples of their products. Under the First Circuit's Rule 9(b) standard, allegations that a manufacturer has given away free samples of a drug with the intent that the recipient bill Medicare for the samples are sufficient to withstand a motion to dismiss, notwithstanding the relator's failure to identify a specific false claim submitted for any of the samples. If that is the correct standard, manufacturers may feel compelled to cut back drastically on their use of free samples as a promotional tool.

This case presents a particularly good vehicle for addressing the issue. The outcome of this case unquestionably turns on which Rule 9(b) standard is applied to the amended complaint. Even under the relaxed Rule 9(b) standard it employed, the First Circuit conceded that this case presented a "close call." Because the amended complaint did not specifically identify even one false claim that OBP allegedly caused to be submitted to Medicare officials, there can be little question that the complaint would have been dismissed under the standard adopted by the Sixth, Eighth, and Eleventh Circuits.

Finally, review is warranted because the First Circuit's decision is so clearly at odds with Rule 9(b) and congressional limitations on who may serve as a relator in an FCA suit. Where, as here, the substance of the complaint's allegations was publicly disclosed before

the complaint was filed, the FCA provides that the only proper relators are those who have "direct and independent knowledge of the information on which the allegations are based." 31 U.S.C. § 3730(e)(4)(B). That requirement indicates that Congress expected relators to be able to spell out the alleged fraud with the "particularity" demanded by Rule 9(b) – including information about specific false claims submitted to the federal government for payment. By applying a relaxed Rule 9(b) standard that excused Respondent Duxbury's failure to specifically identify *any* false claim, the First Circuit ignored § 3730(e)(4)(B). It is difficult to comprehend how a relator could be deemed to have "direct and independent knowledge" regarding false claims when he cannot identify even one such claim with "particularity."

I. THE DECISION BELOW CONFLICTS WITH RULE 9(b) STANDARDS ADOPTED BY AT LEAST THREE OTHER CIRCUITS, AND A POST-PETITION DECISION INTENSIFIES THE CONFLICT

The Petition explains in detail the direct conflict between the Rule 9(b) standard laid down by the First Circuit's decision and the standards adopted by the Sixth, Eighth, and Eleventh Circuits. Pet. 24-31 (citing *Yuhasz v. Brush-Wellman, Inc.*, 341 F.3d 559, 566 (6th Cir. 2003); *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552 (8th Cir. 2006); *United States ex rel. Clausen v. Laboratory Corp. of America*, 290 F.3d 1301 (11th Cir. 2002). *See also United States ex rel. Marlar v. BYXT Y-12, L.L.C.*, 525 F.3d 439, 444-45 (6th Cir. 2008) ("Where the complaint alleges a complex and

far-reaching fraudulent scheme, then that scheme must be pleaded with particularity and the complaint must also provide examples of specific fraudulent conduct."). WLF will not repeat the Petition's cogent explanation; WLF agrees that review is warranted to resolve the conflict among the federal appeals courts identified by the Petition.

WLF writes separately to call attention to an Eleventh Circuit decision issued the day after the Petition was filed; the decision renders the conflict just that much sharper. In a case raising claims virtually identical to those raised by Respondent Duxbury, the Eleventh Circuit affirmed dismissal of an FCA lawsuit against a pharmaceutical manufacturer because the relator failed to identify any specific false claim that was filed as a result of the manufacturer's alleged promotional activities. *Hopper v. Solvay Pharmaceuticals, Inc.*, __ F.3d __, 2009 U.S. App. LEXIS 26381 (Dec. 4, 2009).

The *qui tam* relator in *Hopper* alleged that a pharmaceutical company caused health care providers to submit false claims for reimbursement to government-run health care programs by: (1) promoting widespread off-label use of the company's drug; and (2) giving kickbacks to health care providers to induce them to write prescriptions for the drug. 2009 U.S. App. LEXIS 26381 at *6. The Eleventh Circuit acknowledged that the complaint offered "detailed allegations of an illegal scheme to cause the government to pay amounts it did not owe" and a "highly compelling statistical analysis that renders inescapable the conclusion that a huge number of claims for ineffective off-label uses of" the

drug were submitted to the federal government for payment. *Id.* at *14. The appeals court nonetheless upheld dismissal of the complaint for failure to meet Rule 9(b)'s "particularity" requirement:

> Rule 9(b) requires that actual presentment of a claim be pled with particularity. Because the relators' complaint fails to assert the 'who,' 'what,' 'where,' 'when,' and 'how' of fraudulent submissions to the government, the district court did not err by concluding that the complaint failed to plead fraud with particularity.

Id. at *17-*18 (citations omitted).

The Rule 9(b) standard adopted in *Hopper* directly conflicts with the Rule 9(b) standard adopted in this case. The First Circuit held that when an FCA relator does not allege that the defendant itself submitted false claims but rather induced others to submit false claims, a "more flexible" Rule 9(b) standard is applicable and the complaint need not specifically identify any false claims submitted to the government. Pet. App. 32a-35a. In contrast, although *Hopper* (as here) involved a claim that the defendant caused *others* to submit false claims, the Eleventh Circuit applied the same strict Rule 9(b) standard it had previously applied to cases in which the defendant itself was alleged to have submitted the false claims. Dismissal of the complaint was upheld in the absence of allegations regarding the who, what, where, when, and how of fraudulent submissions to the government. *Hopper* at *17-*18.

The amended complaint filed by Respondent Duxbury met only the "who" component: it stated the names of several health care providers alleged to have been induced by OBP to submit false claims. Amended Compl. ¶ 211, Pet. App. 96a-101a. But he has not supplied answers to the what, where, when, and how components. Not for even a single "false claim" are details provided regarding the date on which the claim was submitted, how it was submitted, how much money was sought, and how much money was paid. The First Circuit held that the amended complaint met Rule 9(b)'s particularity requirement; *Hopper* indicates that the Eleventh Circuit would have reached the opposite conclusion. Review is warranted to resolve the direct conflict between the First and Eleventh Circuits.[3]

II. REVIEW IS WARRANTED IN LIGHT OF THE IMPORTANCE OF THE QUESTION PRESENTED AND ITS RECURRING NATURE

Review is also warranted in light of the importance to health care delivery of the issues raised by the petition. Virtually every pharmaceutical and

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[3] The Eleventh Circuit's *Hopper* decision included a brief discussion of the First Circuit's decision in this case. The Eleventh Circuit explained that *Duxbury* was distinguishable with regard to one factual issue: in contrast to the defendant in *Hopper*, Respondent Duxbury had alleged facts sufficient to give rise to an inference that OBP had intended to cause the submission of false claims. *Hopper*, at *29-*30. But that statement does nothing to lessen the conflict between the First and Eleventh Circuits on the central issue: the degree of "particularity" required by Rule 9(b) in alleging the submission and payment of actual false claims.

medical device company is facing or has faced FCA claims of the type at issue here. Moreover, there is no reason to delay review of the issue; the conflict among the federal appeals courts is already pronounced and shows no sign of abating on its own.

Coming up with a precise tally of the number of improper-promotion FCA lawsuits filed in recent years against pharmaceutical companies is a difficult task in light of confidentiality provisions embedded in the FCA. Any FCA lawsuit filed by a private relator must be filed in camera and remains under seal until the federal government has sufficient time (usually, well in excess of a year) to determine whether it will intervene in the action and conduct the action in its own name. *See* 31 U.S.C. § 3730(b). Nonetheless, press accounts confirm that there has been a torrent of such suits in which the promotional activities of pharmaceutical companies are alleged to have induced others to file false claims with Medicare and Medicaid officials. *See, e.g.*, Richard C. Ausness, *"There's Danger Here, Cherie!" Liability for the Promotion and Marketing of Drugs and Medical Devices for Off-Label Uses*, 73 BROOKLYN L. REV. 1253 (2008). Prominent FCA cases of this nature that have led to reported, substantive decisions include (in addition to this case and *Hopper*): *United States ex rel. Rost v. Pfizer*, 507 F.3d 720 (1st Cir. 2007); *United States ex rel. Hess v. Sanofi-Synthelabo*, No. 05-570, 2006 WL 1064127 (E.D. Mo. Apr. 21, 2006); and *United States ex rel. Franklin v. Parke-Davis,* 147 F. Supp. 2d 39 (D. Mass. 2001). In every one of these case, the central issue was whether the relator had alleged the submission of false claims with sufficient "particularity" to satisfy Rule 9(b)'s heightened pleadings standards.

In numerous other instances, pharmaceutical companies have decided to settle FCA claims (often for substantial sums) rather than incurring the massive costs of defending such suits and risking the possibility that an unfavorable decision could result in imposition of ruinous liability. Recent settlements of FCA suits filed by relators have included $800 million paid by Eli Lilly & Co. in January 2009 (marketing of Zyprexa); $671 million paid by Merck & Co. in February 2008 (alleged kickbacks to doctors); $668 million paid by Pfizer in October 2009, plus another $331 million under state FCA laws (off-label marketing practices); $515 million paid by Bristol-Myers Squibb in September 2007 (alleged kickbacks and off-label promotion); $425 million paid by Cephalon in November 2007 (marketing of Actiq, Provigil, and Gabitril); $400 million paid by Abbott Laboratories in July 2003 (marketing of "enteral" products); $311 million paid in September 2007 by four manufacturers of hip and knee surgical implant products (payment of consulting fees to surgeons); and $266 million paid by AstraZeneca Pharmaceuticals in June 2003 (marketing of Zoladex). *See generally,* U.S. Dep't of Justice, "More Than $1 Billion Recovered by Justice Department in Fraud and False Claims in Fiscal Year 2008" (Nov. 10, 2008), *available at* www.justice.gov/opa/pr/2008/November/08-civ-992.html.

WLF does not mean to suggest that there was no merit in any of the settled FCA cases filed against pharmaceutical companies based on their alleged improper marketing. Indeed, most of the cases involving large settlements were ones in which the federal government investigated the private relators'

claims and found those claims sufficiently meritorious that it decided to intervene. Rather, we cite the above cases simply as evidence that FCA lawsuits challenging the marketing practices of pharmaceutical companies are a widespread and growing phenomenon. In all such cases – particular where, as here, the federal government has investigated the allegations and has declined to intervene – a threshold issue is whether a health care provider has actually been induced by the defendants' promotional activities to file a false claim.[4] Thus, the Rule 9(b) issue is of critical importance. If an FCA relator can survive a motion to dismiss despite failing to specifically identify a single false claim submitted to Medicare or Medicaid officials, then numerous pharmaceutical companies can be expected to settle even non-meritorious FCA suits rather than incur the costs of discovery.[5]

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[4] Although Rule 9(b) prevents a private relator from engaging in fishing expeditions in an effort to establish his FCA claims, the federal government is not similarly constrained. Even before filing suit, the Attorney General is empowered to demand the production of all documents and testimony relevant to an investigation into possible FCA violations. *See* 31 U.S.C. § 3733(a).

[5] There is considerable reason to doubt the merit of many of the current wave of FCA suits. For example, many of the suits hinge on a claim that payments/discounts offered by a drug manufacturer to health care practitioners are improper unless explicitly reflected in the manufacturer's Average Wholesale Price (AWP), and thus that all requests for reimbursement on the basis of AWP constitute "false claims." A recent decision by the Alabama Supreme Court calls that theory into question; the court noted that federal and state Medicaid/Medicare officials are well aware that AWP does *not* reflect any discounts. *AstraZeneca LP v. State of Alabama*, 2009 Ala. LEXIS 244 (Ala., Oct. 16, 2009) (overturning several hundred million dollars in common law fraud judgments

Clarification of the Rule 9(b) pleading standards is particularly important in cases of this sort, so that manufacturers can know how to adjust their marketing techniques in order to minimize the number of private FCA lawsuits they are likely to face. WLF notes, for example, that for valid promotional reasons, pharmaceutical manufacturers annually give away to health care practitioners billions of dollars of free samples of their products. *See, e.g.*, Andrew Zajac, "A Prescription for Snooping," *Los Angeles Time* (Dec. 14, 2009) at E1 (the retail value of free samples provided in the U.S. by pharmaceutical companies in 2004 was $15.9 billion, according to a Kaiser Family Foundation study). Under the First Circuit's Rule 9(b) standard, allegations that a manufacturer has given away free samples of a drug with the intent that the recipient bill Medicare for the samples are sufficient to withstand a motion to dismiss, notwithstanding the relator's failure to identify a specific false claim submitted for any of the samples. If that is the correct standard, manufacturers may feel compelled to cut back drastically on their use of free samples as a promotional tool.

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against three pharmaceutical manufacturers).

WLF is similarly skeptical of Duxbury's claim that OBP's management provided free samples to health care providers with the understanding that the providers would seek "reimbursement" from Medicare for the supposed cost of those samples. It is a serious violation of the FDCA for anyone to sell or offer to sell any drug sample. *See* 21 U.S.C. § 353(c)(1). Drug manufacturers have so many legitimate promotional reasons for wanting to distribute drug samples that it is difficult to believe that they would choose to use the distribution process for the additional purpose of aiding and abetting crimes by health care providers, particularly when manufacturers do not stand to gain financially from the crime.

This case presents a particularly good vehicle for addressing the issue. The outcome of this case unquestionably turns on which Rule 9(b) standard is applied to the amended complaint. Even under the relaxed Rule 9(b) standard it employed, the First Circuit conceded that this case presented a "close call." Because the amended complaint did not specifically identify even one false claim that OBP allegedly caused to be submitted to Medicare officials, there can be little question that the complaint would have been dismissed under the standard adopted by the Sixth, Eighth, and Eleventh Circuits. Moreover, if review is denied, OBP will have lost all opportunity for review of the Rule 9(b) issue. Denial of review may well, of course, force OBP to settle as a less expensive alternative to enduring discovery. But even if the case is litigated to judgment, appellate review will turn on the evidence presented at trial, not on the adequacy of allegations contained in the initial complaint.

In sum, review is warranted in light of the importance of the issues raised, their recurring nature, and the inability to obtain review of the question presented at any later stage of the case.

III. REVIEW IS WARRANTED BECAUSE THE DECISION BELOW IS INCONSISTENT WITH LIMITATIONS IMPOSED BY CONGRESS ON PRIVATE FCA SUITS

Review is also warranted because the First Circuit's decision is so clearly at odds with Rule 9(b) and congressional limitations on who may serve as a relator in an FCA suit.

The history of the FCA evidences Congress's attempt to balance the encouragement of true whistleblower activity and the discouragement of opportunistic behavior. Congress established the public disclosure bar in 1986 for the purpose of preventing parasitic lawsuits by *qui tam* relators bringing suits based on information that has already been disclosed and thus is readily available to government investigators. *See Rockwell Int'l Corp. v. United States*, 549 U.S. 457 (2007). When, as here, the information contained in an FCA complaint was publicly disclosed before the complaint was filed, the suit is jurisdictionally barred unless the relator qualifies as an "original source" of the information. 31 U.S.C. § 3730(e)(4)(A). An individual is an "original source" if, *inter alia*, he has "direct and independent knowledge of the information on which the allegations are based." 31 U.S.C. § 3730(e)(4)(B). Thus, Duxbury's right to maintain this action hinges on his assertion that he has "direct and independent knowledge of the information" on which his allegations against OBP are based.

Even today, seven years after filing his lawsuit, Duxbury plainly does know all the information on which his allegations against OBP are based. He concedes that he is unaware of the details of even a single false claim submitted to and/or paid by the federal government as a result of OBP's alleged misconduct. *See* Amended Compl. ¶ 232, Pet. App. 102a. Yet, the First Circuit excused that lack of knowledge, reasoning that Rule 9(b)'s "particularity" requirement does not require the pleading of such information – at least where, as here, the FCA suit is based on an allegation that the defendant did not file its own false claims but rather

caused others to do so. *Id.* at 32a-35.

That conclusion is plainly at odds with Congress's intent in establishing the public disclosure bar and the "original source" exception thereto. When it adopted the requirement that an "original source" have "direct and independent knowledge of the information on which the allegations are based," 31 U.S.C. § 3730(e)(4)(B), Congress expressed its expectation that relators would to be able to spell out the alleged fraud with the "particularity" demanded by Rule 9(b) – including information about specific false claims submitted to the federal government for payment. By applying a relaxed Rule 9(b) standard that excused Respondent Duxbury's failure to specifically identify *any* false claim, the First Circuit ignored § 3730(e)(4)(B). It is difficult to comprehend how a relator could be deemed to have "direct and independent knowledge" regarding false claims when he cannot identify even one such claim with "particularity."

The First Circuit's decision to excuse Respondent Duxbury's lack of knowledge appears to be based on a "sporting chance" theory of litigation. It would not be fair to dismiss FCA suits filed by relators situated as was Duxbury, the First Circuit apparently reasoned, because otherwise such relators would never be able to avoid dismissal of their FCA suits – since employees of pharmaceutical companies are unlikely to have inside knowledge of the billing practices of health care providers to whom the pharmaceutical companies sell their products. But Congress did not establish the *qui tam* provision to give every relator a sporting chance of winning his lawsuit. Rather, the *qui tam* provision was

adopted to allow the government to "purchase" from private individuals the information they may have about fraud on the United States Treasury. *United States ex rel. Russell v. Epic Healthcare Mgmt. Group*, 193 F.3d 304, 309 (5th Cir. 1999). Because Duxbury does not have any information demonstrating that the Treasury was actually defrauded (but rather has simply made an educated guess that fraud occurred), § 3730(e)(4)(B) makes clear that Congress did not intend to permit Duxbury to seek a cash bounty by using the discovery process in an attempt to uncover actual evidence of fraud.

Review is warranted to correct the First Circuit's clear misinterpretation of the Rule 9(b) "particularity" requirement.

CONCLUSION

Amicus curiae Washington Legal Foundation respectfully requests that the Court grant the petition for a writ of certiorari.

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