UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 02-11738-RWZ

UNITED STATES OF AMERICA *ex rel.* CONSTANCE A. CONRAD

v.

ABBOTT LABORATORIES, INC. *et al.*

MEMORANDUM OF DECISION

February 25, 2013

ZOBEL, D.J.

Relator Constance A. Conrad (hereinafter "relator") brings this qui tam suit on behalf of the United States against twenty-four different drug manufacturers, distributors, and labelers (collectively "defendants"). She claims that defendants fraudulently misrepresented their products as "covered outpatient drugs" eligible for Medicaid reimbursement, thereby causing the federal government to pay state Medicaid programs over $500 million for purchasing those products. Defendants now move to dismiss the complaint.

I. Background

Relator's claims are intertwined with both federal drug regulation and the Medicaid system. A brief explanation of each is therefore necessary before proceeding to the claims at issue.

A. Federal Drug Regulation

Congress enacted the Federal Food, Drug, and Cosmetic Act ("FDCA") in 1938. Ch. 675, 52 Stat. 1040. As originally enacted, the FDCA required the U.S. Food and Drug Administration ("FDA") to approve every new drug as safe. In 1962, Congress amended the FDCA to require the FDA to approve every new drug as both safe and effective. See Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780. The 1962 amendments thus created two classes of drugs relevant here: (1) drugs introduced between 1938 and 1962, which the FDA had approved only for safety, and (2) drugs introduced since 1962, which must be approved by the FDA for both safety and effectiveness.

The 1962 amendments also required the FDA to retroactively review all the drugs it had approved only for safety, and to ensure that those drugs are effective as well as safe. This FDA review process is called the Drug Efficacy Study Implementation ("DESI") program. After conducting a DESI review, the FDA may find the drug is effective for all indications, effective for some indications but not others, or less than effective for all indications. If the FDA finds the drug is less than effective for some or all indications, it must give the manufacturer a Notice Of Opportunity for Hearing ("NOOH") before making a final determination and beginning enforcement proceedings. The results of a DESI review apply not only to the specific drug reviewed, but also to all drugs identical, related, or similar to that drug.

B. Medicaid

Medicaid is a joint federal-state program that provides healthcare benefits,

including prescription drugs, for low-income Americans. Medicaid recipients can obtain covered drugs from their healthcare providers; those healthcare providers are then reimbursed by state Medicaid programs, which in turn are partly reimbursed by the federal government.

The Medicaid statutes define certain drugs eligible for Medicaid reimbursement as "covered outpatient drugs." See 42 U.S.C. § 1396r-8(k)(2). All drugs approved as safe and effective by the FDA since 1962 qualify as covered outpatient drugs. The statute also grandfathers in some other drugs introduced before the 1962 FDCA amendments.

To participate in Medicaid, a drug manufacturer must file a list of its covered outpatient drugs with the federal Centers for Medicare and Medicaid Services ("CMS"). It must also inform CMS of any covered outpatient drugs it markets that were subject to DESI review (or that are identical, related, or similar to drugs subject to DESI review), and list the outcome of that DESI review using the following numerical system:

DESI code "2" : The FDA found the drug safe and effective for all indications, or determined it did not require FDA approval.
DESI code "3" : The FDA has not yet completed its review, and no NOOH has been issued.
DESI code "4" : The FDA has approved the drug as safe and effective for some indications but not others, and issued a corresponding NOOH.
DESI code "5" : The FDA has found the drug less than effective for all indications, and issued a corresponding NOOH.
DESI code "6" : The FDA has found the drug less than effective for all indications, and the drug has been withdrawn from the market.

Drugs with DESI codes of "5" or "6" are not eligible for Medicaid reimbursement. Each drug manufacturer participating in Medicaid must update quarterly its CMS listing of

covered outpatient drugs and any relevant DESI codes.

C. Relator's Claims

Relator alleges that defendants made three types of fraudulent misrepresentations in their CMS filings: listing unapproved drugs as FDA-approved covered outpatient drugs, listing false DESI codes ("2" or "3" instead of "5"), and listing non-drug products as covered outpatient drugs. Based on those misrepresentations, relator alleges, healthcare providers sought and received reimbursement for defendants' products from state Medicaid programs, which in turn sought and received reimbursement from the federal government. In total, relator claims that the federal government spent over $500 million in erroneous reimbursements for defendants' products. She sues under the False Claims Act ("FCA"), 31 U.S.C. § 3729 et seq. The government has declined to intervene as to the claims at issue.

II. Analysis

Defendants raise several grounds for dismissal, including the threshold question of subject matter jurisdiction. "Federal courts, as courts of limited jurisdiction, must be 'scrupulous in applying the tenets that define the limits of their subject matter jurisdiction.'" United States ex rel. Ondis v. City of Woonsocket, 587 F.3d 49, 54 (1st Cir. 2009) (quoting Gabriel v. Preble, 396 F.3d 10, 16 (1st Cir. 2005)). The proponent of federal jurisdiction—here, relator—bears the burden of proving its existence by a preponderance of the evidence. United States ex rel. Poteet v. Bahler Medical, Inc., 619 F.3d 104, 109 (1st Cir. 2010); see also Ondis, 587 F.3d at 54. If jurisdiction is lacking, "the only function remaining to the court is that of announcing the fact and

dismissing the cause." Ex parte McCardle, 74 U.S. (7 Wall.) 506, 514 (1868).

Defendants challenge subject matter jurisdiction under the FCA's public disclosure bar. As relevant here, the statute provides:

> No court shall have jurisdiction over an action under [the FCA] 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.

31 U.S.C. § 3730(e)(4)(A) (amended 2010).[1] The public disclosure bar thus calls initially for a three-part inquiry, asking: (1) whether the alleged fraud has previously been publicly disclosed; (2) whether that disclosure was through one of the sources specified in the statute; and (3) whether the qui tam action was based on that prior disclosure. Poteet, 619 F.3d at 109. If the answer to all three parts of the inquiry is yes, and the action is brought by a private relator, then jurisdiction is lacking unless the "original source exception" applies. Id.

Here, defendants argue that relator's claims are based upon five qualifying publicly disclosed sources. First, there are the drug product data files published quarterly by CMS, which provide a consolidated list of all the covered outpatient drugs and any associated DESI codes that drug manufacturers have identified in their CMS filings. Second, there are the state drug utilization data files, also published by CMS;

[1] Congress amended this statutory section in 2010. However, those amendments are not retroactive and therefore do not apply in this case. Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel Wilson, 130 S. Ct. 1396, 1400 n.1 (2010). It should also be noted that "Government Accounting Office" is apparently a scrivener's error for "General Accounting Office," the agency now known as the Government Accountability Office. Id. at 1402 n.6.

these files list the products for which the federal government has provided reimbursement to the states and the amount reimbursed. Third, there is the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations, better known as the Orange Book, which lists all FDA-approved drugs. Fourth, there is the National Drug Code Directory, an FDA publication that compiles relevant information about all drugs currently being manufactured. Finally, there are Federal Register notices published every time the FDA completes a DESI review or determines that a particular drug requires FDA approval.

Relator responds that these sources did not publicly disclose the fraud alleged in her complaint, that the first two sources listed above (the CMS data files) are not qualifying sources, and that an omission is not a disclosure. I consider each point in turn.

A. Public Disclosure

Public disclosure has occurred when "the essential elements exposing the particular transaction as fraudulent find their way into the public domain." Ondis, 587 F.3d at 54. The relevant disclosure must present either a direct allegation of fraud, or else both a misrepresented state of facts and a true state of facts such that the recipient may infer fraud. Poteet, 619 F.3d at 110. The misrepresented facts and the true facts may also appear in several separate disclosures that combine to create an inference of fraud. See id. at 110 n.6.

Here, defendants do not contend that any prior public disclosure directly alleged the fraud described by relator. They argue instead that if relator's allegations are true,

then both the misrepresented facts and the true facts would have been disclosed by the five public sources listed above. The misrepresented facts would be disclosed by CMS's drug product data files and state drug utilization data files; the former files would show any false statement that defendants' products were covered outpatient drugs and any false DESI codes, while the latter would show that state Medicaid programs had relied on those misrepresentations. The true facts would be disclosed by the Orange Book, which lists all FDA-approved drugs (making defendants' unapproved drugs and non-drugs conspicuous by their absence); the Federal Register notices, which would list any DESI determinations about defendants' drugs (or about drugs identical, related, or similar to defendants'); and the NDC Directory, which provides enough information to show whether two drugs are identical, related, or similar.

Relator concedes that these sources were publicly available, but argues that they do not raise any inference of fraud. She cites a number of cases holding that public information about facially valid or innocuous transactions alone will not trigger the public disclosure bar. See, e.g., United States ex rel. Rabushka v. Crane Co., 40 F.3d 1509 (8th Cir. 1994); United States ex rel. Springfield Terminal Ry. v. Quinn,14 F.3d 645 (D.C. Cir. 1994). But in those cases, the public only saw the apparently valid (but actually fraudulent) transactions. The misrepresented facts were publicly disclosed, but the true facts were not. In this case, by contrast, both sets of facts were apparently publicly available. If relator's allegations are true, the CMS data files would show defendants claiming their products were covered outpatient drugs with appropriate DESI codes, while the other sources would show the products were not

approved drugs and/or had ineligible DESI codes. That contradiction in the publicly available information is enough to "lead to a plausible inference of fraud." Ondis, 587 F.3d at 54.

Of course, a person studying all of these sources would likely need substantial expertise in the field in order to find the alleged discrepancy. But the only question is whether the material facts exposing the alleged fraud are already in the public domain, not whether they are difficult to recognize. See Ondis, 587 F.3d at 59-60. A relator cannot bring a qui tam suit based on publicly disclosed facts, even if her expertise makes her the first to understand the alleged fraud.

B. Qualifying Sources

As applicable here, the public disclosure bar is only triggered by public disclosure "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." 31 U.S.C. § 3730(e)(4)(A) (amended 2010). The parties agree that the Orange Book, the National Drug Code Directory, and the Federal Register notices qualify as administrative reports. Defendants argue that the CMS drug product data files and state drug utilization data files, which reveal the alleged misrepresentations, are also administrative reports; relator disagrees.

These data files are available for the public to download from the CMS website.[2] They contain thousands of lines of unadorned data, organized into columns and sorted.

[2] See Medicaid Drug Rebate Program Data, MEDICAID.GOV, http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program-Data.html (last visited Feb. 21, 2013).

The CMS website also provides brief specifications that explain what each column in each data file represents. Relator argues that these unadorned data files cannot be considered administrative reports because they contain no analysis by the agency.

The Supreme Court recently faced a similar question in Schindler Elevator Corp. v. United States ex rel. Kirk, 131 S. Ct. 1885 (2011). In that case, the Court decided that an agency response to a FOIA request was an "administrative report" for purposes of the public disclosure bar.[3] The Court interpreted the term "report" to mean "something that gives information," a "notification," or an "official or formal statement of facts or proceedings." Id. at 1891. It emphasized that this "broad ordinary meaning . . . is consistent with the generally broad scope of the FCA's public disclosure bar." Id.

Relator seeks to distinguish the CMS data files from a FOIA response. She argues that a FOIA response is "an actual report by a government agency" because it represents "a review of the agency's records, and the issuance of a written response with the results of that review." Docket # 360 (Opp.) at 16. The CMS data, on the other hand, she describes as only a "raw data file." Id. at 14.

The distinction is unconvincing. First, the CMS data files summarize information in the agency's possession in exactly the same way that a FOIA response does. One could easily characterize the CMS data files as a written summary of the results of CMS's review of its records regarding drug product data and state drug utilization data. Like a FOIA response, the CMS data files represent at least some minimal preparation and synthesis

[3] Like this case, Schindler Elevator was already pending when the public disclosure bar was amended, and so the Court considered the same version of the statute that is applicable here. See 131 S. Ct. at 1889 n.1.

by the agency, since the listings from each manufacturer and each state are sorted and compiled into a usable format.

More importantly, relator's argument ignores the definition of "report" that the Supreme Court established in Schindler Elevator. The CMS data files fall clearly within that definition. Each data file is obviously "something that gives information," a "notification," and an "official or formal statement of facts." Specifically, the drug product data files notify their recipient of the covered outpatient drugs and DESI codes that each drug manufacturer has reported, while the state drug utilization data files notify their recipient of how much the federal government has reimbursed the states for each covered outpatient drug. The data files constitute official public statements by CMS regarding those facts. As such, they fall within the broad ordinary meaning of the term "report." See Schindler Elevator, 131 S. Ct. at 1891, 1893.[4]

C. Disclosure by Omission

Finally, relator argues that the public disclosure bar does not countenance disclosure by omission. Specifically, she argues that the Orange Book only lists FDA-approved drugs, and so it does not affirmatively disclose that defendants' products are not approved.[5] On this view, the public disclosure bar would only apply here if the FDA published a book listing everything that is not an approved drug, and defendants' products

[4] In a footnote of their reply brief, defendants raise the argument that the CMS data files also qualify as "news media" because they are available over the Internet. Given that the data files qualify as "administrative reports," I need not and do not reach that alternative argument.

[5] Relator's argument here apparently does not apply to her DESI code allegations, since the Federal Register notices would affirmatively state the information from which the correct DESI code could be inferred.

were affirmatively listed in that book.

The argument is clever, but not persuasive. The statute refers broadly to a "public disclosure," not narrowly to an "affirmative public disclosure." Nor is the term "disclosure" inherently restricted to affirmative disclosures. In its ordinary meaning, "disclosure" means generally "[t]he act or process of making known something that was previously unknown." Black's Law Dictionary 477 (7th ed. 1999). It does not usually require any explicit statement of the fact disclosed.[6]

Interpreting "disclosure" to mean only "affirmative and explicit disclosure" would add new words to the statute Congress enacted. See Lamie v. U.S. Tr., 540 U.S. 526, 538 (2004) (courts should not "read an absent word into the statute"). Moreover, it would conflict with the "broad ordinary meaning" of the term, and the "generally broad scope of the FCA's public disclosure bar." Schindler Elevator, 131 S. Ct. at 1891. Applying the most natural meaning of the term "disclosure," it includes disclosures by omission.

The Orange Book lists all FDA-approved drugs; in so doing, it discloses that all other products are not FDA-approved drugs. I therefore lack jurisdiction over any subsequent action based upon that disclosure. See 31 U.S.C. § 3730(e)(4).

D. Basis

Relator does not contest that her action is based upon the public disclosures defendants have cited. And rightly so. An action is considered "based upon" previous public disclosures if "the relator's allegations are substantially similar to allegations or

[6] For instance, one could disclose one's ignorance about Japanese history by saying that Toshiro Mifune won the Battle of Sekigahara. The disclosure would not require explicitly saying "I am ignorant about Japanese history."

transactions already in the public domain at the time he brings his qui tam action." Ondis, 587 F.3d at 58. Here, relator's allegations are substantially similar to the allegedly misrepresented facts disclosed in the CMS data files, and the allegedly true facts disclosed in the Orange Book, the Federal Register notices, and the National Drug Code Directory. This third part of the public disclosure inquiry is therefore satisfied.

E. Legislative Intent

Relator urges that the foregoing analysis contradicts the legislative intent behind the FCA. She emphasizes in her brief, and emphasized again at oral argument, that the federal government has recovered substantial amounts of money by settling related claims that she brought to its attention. Even if the underlying information was publicly available, she says, the government needed her hard work and her expertise to bring the fraud to light. From these facts, she argues that the public disclosure bar should not apply because the legislative intent behind the FCA is to encourage productive actions like this one.

But relator's view of the FCA's legislative intent has been contradicted by the First Circuit and by the Supreme Court. In Ondis, the First Circuit explained:

> When the material elements of a fraud are already in the public domain, the government has no need for a relator to bring the matter to its attention. To achieve its real purpose, the FCA should reward only those who come forward with original, direct, and independent knowledge of a frau

587 F.3d at 58 (citations omitted). Under that interpretation, the FCA's real purpose is to reward whistleblowers with first-hand knowledge, not hard work and expertise.

The Supreme Court took a similar approach in Schindler Elevator, noting in that case:

> [A]nyone could have filed the same FOIA requests and then filed the same suit. Similarly, anyone could identify a few regulatory filing and certification requirements, submit FOIA requests until he discovers a federal contractor who is out of compliance, and potentially reap a windfall in a qui tam action under the FCA.

131 S. Ct. at 1894. Based on those facts, the Court described the case before it as "a classic example of the 'opportunistic' litigation that the public disclosure bar is designed to discourage." Id.

Here, as in Schindler Elevator, anyone with time and the relevant expertise could have combed through the public sources identified above, discovered drug manufacturers who were out of compliance, and then filed the same suit. If Schindler Elevator was "the 'opportunistic' litigation that the public disclosure bar is designed to discourage," id., then so, too, is this suit. To the extent the legislative intent is relevant here, it supports finding that the public disclosure bar applies.

III. Conclusion

As described above, all three parts of the public disclosure inquiry are met in this case. Information giving rise to an inference of fraud was publicly disclosed, the public disclosure was through qualified sources, and the action is based on those public disclosures. Moreover, relator has not alleged that she was an original source of the relevant information. I therefore lack subject matter jurisdiction over this action. See Poteet, 619 F.3d at 109-110; Ondis, 587 F.3d at 53-54. Because I lack jurisdiction, I cannot go on to address defendants' alternative arguments for dismissal. See McCardle, 74 U.S. (7 Wall.) at 514.

Defendants' motion (Docket # 333) is ALLOWED.

February 25, 2013

DATE

/s/Rya W. Zobel

RYA W. ZOBEL
UNITED STATES DISTRICT JUDGE