In the

United States Court of Appeals

For the Seventh Circuit

No. 04-2566

UNITED STATES ex rel. SANFORD GROSS,

Plaintiff-Appellant,

v.

AIDS RESEARCH ALLIANCE-CHICAGO,
ROBERTA LUSKIN-HAWK, THOMAS KLEIN,
ROS SLOTTEN, NEEL FRENCH, PATRICIA DIXON,
and CATHOLIC HEALTH PARTNERS,

Defendants-Appellees.

Appeal from the United States District Court for
the Northern District of Illinois, Eastern Division.
No. 01 C 8182—**William J. Hibbler**, *Judge.*

ARGUED DECEMBER 8, 2004—DECIDED JULY 6, 2005

Before FLAUM, *Chief Judge,* and POSNER and SYKES, *Circuit Judges.*

SYKES, *Circuit Judge.* Sanford Gross was a subject in an AIDS research study funded by the National Institutes of Health ("NIH") and conducted by the AIDS Research Alliance-Chicago ("the Alliance"). Catholic Health Partners acted as the Institutional Review Board for the study. Gross brought a claim on behalf of the United States under the *qui tam* provision of the False Claims Act ("FCA"), 31

U.S.C. § 3729(a), alleging various acts of negligence and mismanagement by the Alliance, several of its participating medical professionals, and Catholic Health Partners. Gross alleged that the defendants submitted various forms and reports to the government during the course of the study and these constituted "certifications" that the study was being conducted in compliance with federal regulations, grant study protocols, and "Good Clinical Practices," when, in fact, it was not. These are the alleged "false claims" that form the basis of Gross's action under § 3729(a).

The district court dismissed the original and amended complaints for failure to plead fraud with particularity as required by Rule 9(b), and dismissed the second amended complaint pursuant to Rule 12(b)(6) for failure to state a claim. The latter ruling was based largely on what the district court saw as insufficiencies in the allegations regarding the knowledge element of a § 3729(a) claim. *See United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018-19 (7th Cir. 1999). The district court also invoked the jurisdictional bar in 31 U.S.C. § 3730(e)(4)(A), which precludes *qui tam* FCA claims premised upon publicly disclosed information unless "the person bringing the claim is an original source of the information."

We affirm, although on somewhat different reasoning. The second amended complaint fails under Rule 9(b) because it does not allege to the required degree of particularity the false statement or statements made by the defendants, with knowledge of their falsity, for the purpose of obtaining payment from the government. In addition, the second amended complaint fails under Rule 12(b)(6) because it does not allege that payment by the government was conditioned upon certification of regulatory compliance, a necessary component of a *qui tam* FCA claim premised upon false certification of compliance with federal statutes and regulations.

I. Facts

The second amended complaint is 42 pages long and contains 163 numbered paragraphs, some of which have numerous lettered subparts. We sketch only the pertinent allegations here. The NIH sponsored a research study on an "off-label investigational new drug" for the treatment of AIDS. The Alliance was one of 15 participating agencies, and Gross was a participant in the study from October 1998 to December 1999. Catholic Health Partners acted as the Institutional Review Board for Alliance's participation in the study, and the individual named defendants are participating physicians and a nurse. The Alliance was awarded approximately $3.7 million in NIH funding for its participation in the study.

The second amended complaint contains numerous allegations of negligence, mismanagement, and poor oversight of the study, including, for example: prescription of medication known to reduce the effectiveness of the study drug; allowing Gross's viral load to spike dramatically; failure to maintain adequate study records; and failure to obtain proper informed consent. These lapses caused the defendants to be noncompliant with a laundry list of federal regulations (there is no need to recite them here), various study protocols, and "Good Clinical Practices." The second amended complaint also alleges that Catholic Health Partners participated in "other federal grants" and was out of compliance with certain federal regulations in connection with these unspecified "other grants." The pleading alleges that on December 9, 2002, the Federal Drug Administration sent Catholic Health Partners a warning letter temporarily suspending its participation in an unrelated study for "violating regulations governing the composition, operation, and responsibilities of an IRB."

As to the alleged false claims in particular, the second amended complaint alleges that the defendants submitted

various "forms, written reports and study results" to the government, including (but not limited to): Form PHS 398; Form PHS 2590; Form FDA 1572; CPCRA Form 704; "Financial Service Requests"; "Consent Forms"; "DAIDS Investigator of Record Agreement"; and "initial and continuing review records." Apart from these cryptic acronyms and generalized references to form titles, the forms are not described any further; their purpose or content is not identified, nor is there any indication when they were filed vis-á-vis any grant payments. The second amended complaint does not describe how the filing of any of these forms related to payment of grant money. Instead, it alleges that '[i]ndividually, and in cumulative effect, the forms, written reports, and study results submitted by the defendants constituted certifications of compliance with all requirements and conditions of the research grant." There is also a general allegation that "[d]efendants, individually and in conspiracy, have knowingly made false or fraudulent claims and certifications to justify retention of federal funds already received and to induce payment of additional federal funds."

II. Discussion

The FCA is an anti-fraud statute and claims under it are subject to the heightened pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure. *United States ex rel. Garst v. Lockheed-Martin Corp.*, 328 F.3d 374, 376 (7th Cir. 2003) (Rule 9(b) applies "because the False Claims Act condemns fraud but not negligent errors or omissions.") As is pertinent here, the FCA imposes liability against any person who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." 31 U.S.C. § 3729(a)(2). An FCA claim under § 3729(a)(2) has three essential elements: (1) the defendant made a statement in

order to receive money from the government, (2) the statement was false, and (3) the defendant knew it was false. 31 U.S.C. § 3729(a)(2); *Lamers*, 168 F.3d at 1018. An FCA claim premised upon an alleged false certification of compliance with statutory or regulatory requirements also requires that the certification of compliance be a condition of or prerequisite to government payment. *United States ex rel. Mikes v. Strauss*, 274 F.3d 687, 697 (2d Cir. 2001); *United States ex rel. Siewick v. Jamieson Science & Engineering, Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 786-87 (4th Cir. 1999); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997); *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266-67 (9th Cir. 1996).

In *Lamers*, this court affirmed summary judgment against the FCA relator on the second and third elements of the claim, concluding that minor technical regulatory violations do not make a claim "false" for purposes of the FCA; the existence of mere technical regulatory violations tends to undercut any notion that a prior representation of regulatory compliance was knowingly and falsely made in order to deceive the government. *Lamers*, 168 F.3d at 1019; *see also United States ex rel. Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 733 (7th Cir. 1999). The district court relied on *Lamers* to conclude that the second amended complaint failed to state a claim. *Lamers* was a summary judgment case, however; here we are at the pleading stage, and the violations Gross has alleged appear on their face to go beyond the "minor technical violations" at issue in *Lamers*.

In our view, the insufficiencies in Gross's second amended complaint relate instead to the first element of the claim, which, in a nutshell, requires that the fraudulent statement's purpose must be to coax a payment of money from the government. As the statute itself puts it, liability attaches only when a false statement is used "to get a false

or fraudulent claim paid or approved by the Government." 31 U.S.C. § 3729(a)(2). Gross has failed to plead this element with the specificity required by Rule 9(b).

The false statements on which his claim is grounded are identified only by a categorical and essentially undecipherable listing of various "forms, written reports and study results" the defendants are alleged to have filed with the government at some point—the pleading does not say when—during the course of the study. As we have noted, the purpose or content of these forms is not described, nor does the second amended complaint describe how any of the forms relate to the payment of study funds. There are no specifics about how the $3.7 million in study funds were paid—whether in a lump sum when the study commenced or periodically while the study was ongoing. All we have are generalized allegations that the forms, considered "individually and in cumulative effect," constitute "certification" of regulatory compliance; and that the defendants, "individually and in conspiracy," made false certifications "to justify retention of federal funds already received" and "to induce" additional payment. These conclusory allegations shed no light on the nature or content of the individual forms or why any particular false statement would have caused the government to keep the funding spigot open, much less when any payments occurred or how much money was involved. This does not satisfy "the who, what, when, where, and how" requirement for pleading fraud under Rule 9(b). *Garst*, 328 F.3d at 376 (quoting *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990)).

Our conclusion here is bolstered by the analysis in *Garst*. There, the FCA relator faced similar pleading troubles, having suffered the district court's dismissal of his first three complaints. *Garst*, 328 F.3d at 375. The district court finally ordered the relator to file a more definite statement, but even that was "loaded with so many acronyms and cross-references to the third amended complaint (plus its

attachments) that no one could understand it without juggling multiple documents." *Id.* at 376. Ultimately we concluded that although the relator had "come closer to specific allegations of deceit," he nevertheless "fail[ed] to link them to any claim for payment." *Id.* at 378. Thus, we held that the complaint in *Garst* failed Rule 8's "short and plain statement" requirement as well as Rule 9(b)'s particularity mandate. We do not mean to suggest that Gross's second amended complaint flunks Rule 8, but we reach the same conclusion here as in *Garst* on the failure to plead fraud with particularity. *Id.* at 376-77.

In addition, Gross has failed to allege that any particular certification of regulatory compliance was a *condition* of payment of government money. In this respect the second amended complaint failed to state a claim and dismissal under Rule 12(b)(6) was justified. As we have noted, where an FCA claim is based upon an alleged false certification of regulatory compliance, the certification must be a condition of the government payment in order to be actionable. The second amended complaint makes no such allegation.

At oral argument, counsel suggested that the second amended complaint's incorporation by reference of the "regulatory framework" was enough to clarify the causal connection between false certifications and government payouts. But counsel admitted that this would be true only if the district judge had "gone out and read all those regulations quite carefully." It was not incumbent upon the district judge to become an expert in all of the regulations governing NIH grant compliance so that he could piece together a theory on why any particular form listed in the second amended complaint might have fraudulently caused the government to cut a check. False claim allegations must relate to actual money that was or might have been doled out by the government based upon actual and particularly-identified false representations. On this, the complaint is silent.

Finally, as we have noted, to the extent that Gross's claim was based upon the 2002 warning letter to Catholic Health Partners, the district court invoked the jurisdictional bar contained in § 3730(e)(4)(A). That section reads:

> No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A). The district court was entirely correct. Gross did not allege that he was an original source of the information in the warning letter. The judgment of the district court is AFFIRMED.

A true Copy:

Teste:

Clerk of the United States Court of Appeals for the Seventh Circuit