PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 12-2431

UNITED STATES ex rel. BARRY ROSTHOLDER; BARRY ROSTHOLDER, individually,

Plaintiffs - Appellants,

and

STATE OF CALIFORNIA; STATE OF DELAWARE; STATE OF FLORIDA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF LOUISIANA; STATE OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MONTANA; STATE OF NEW HAMPSHIRE; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NEVADA; STATE OF TENNESSEE; STATE OF TEXAS; STATE OF VIRGINIA; COOK COUNTY, ILLINOIS; DISTRICT OF COLUMBIA; CITIES OF CHICAGO AND NEW YORK; STATE OF GEORGIA; STATE OF NEW JERSEY; STATE OF OKLAHOMA; STATE OF RHODE ISLAND; STATE OF WISCONSIN,

Plaintiffs,

v.

OMNICARE, INCORPORATED, a Delaware Corporation; OMNICARE DISTRIBUTION CENTER, LLC, f/k/a Heartland Repack Services, LLC, a Delaware Limited Liability Company, jointly and severally,

Defendants – Appellees.

Appeal from the United States District Court for the District of Maryland, at Baltimore. Catherine C. Blake, District Judge. (1:07-cv-01283-CCB)

Argued: December 10, 2013 Decided: February 21, 2014

Before NIEMEYER, SHEDD, and KEENAN, Circuit Judges.

Affirmed by published opinion. Judge Keenan wrote the opinion, in which Judge Niemeyer and Judge Shedd joined.

ARGUED: Gerald C. Robinson, GERALD ROBINSON LAW FIRM PLLC, Minneapolis, Minnesota, for Appellants. James Christopher Martin, REED SMITH LLP, Pittsburgh, Pennsylvania, for Appellees. **ON BRIEF**: Jay P. Holland, JOSEPH, GREENWALD & LAAKE, PA, Greenbelt, Maryland, for Appellants. Colin E. Wrabley, Pittsburgh, Pennsylvania, Eric A. Dubelier, Lawrence S. Sher, Katherine J. Seikaly, REED SMITH LLP, Washington, D.C., for Appellees.

BARBARA MILANO KEENAN, Circuit Judge:

Relator Barry Rostholder (relator) filed this qui tam action under the False Claims Act (FCA), 31 U.S.C. §§ 3729 through 3733, against his former employer, Omnicare, Inc., and its affiliated companies. Relator alleged that the defendants violated a series of Food and Drug Administration (FDA) safety regulations requiring that penicillin and non-penicillin drugs be packaged in complete isolation from one another, which violations resulted in a legal presumption of penicillin cross-contamination. According to relator, these contaminated drugs were not eligible for reimbursement by Medicare and Medicaid and, therefore, any claims presented to the government for reimbursement for these drugs were false under the FCA.

The district court granted Omnicare's motion to dismiss the complaint under Federal Rule of Civil Procedure 12(b)(6). Because relator already had filed two amended complaints, the court denied any further leave to amend. Upon our review, we hold that relator's complaint failed to allege that the defendants made a false statement or that they acted with the necessary scienter. We also conclude that the district court did not abuse its discretion in denying relator's request to file a third amended complaint. We therefore affirm the district court's judgment.

I.

Omnicare provides certain pharmaceutical services to senior citizens through its drug repackaging and pharmacy facilities. As alleged in relator's second amended complaint, Omnicare owned Heartland Repack Services, LLC (Heartland), the drug repackaging operation at issue in this case located in Toledo, Ohio (the Toledo building). Heartland repackaged drugs into convenient units for patient use. Omnicare also operated hundreds of pharmacies nationwide, including a pharmacy that shared the Toledo building with Heartland. Such pharmacies "primarily" served nursing homes owned by Omnicare's partner, Health Care Resources.

Although Heartland repackaged non-penicillin drugs for distribution, the Omnicare pharmacy that shared the Toledo building processed penicillin products. The pharmacy and the repackaging operations were located in the Toledo building, and were separated by "rolling" garage-type doors. Within the building, employees of both the repackaging and pharmacy units shared "break" areas, entrances, and exits. The Toledo building also had a single ventilation and heating/cooling system.

From 1997 until 2006, relator, a licensed pharmacist, was employed at Heartland. Relator's job responsibilities included "overseeing repackaging, quality assurance, regulatory affairs, and wholesale and distribution." In 2004, Omnicare executive

and relator's supervisor, Denis Holmes, suggested that Heartland begin repackaging penicillin products. Relator informed Holmes that any repackaging of penicillin drugs would constitute a violation of FDA regulations requiring the separate processing of penicillin and non-penicillin products.

Relator conducted further research regarding the FDA's penicillin isolation requirements and stated his conclusions in a memorandum that he provided to Holmes. Relator also contacted the pharmacy manager in the Toledo building, who informed relator for the first time that the pharmacy frequently repackaged penicillin, despite sharing the building with Heartland's non-penicillin drug packaging operation (the Heartland facility). At Holmes' request, relator researched and recommended ways in which Heartland could repackage penicillin in compliance with FDA regulations.

In February 2006, relator resigned from Heartland due to his concerns about the facility's quality control efforts. Several months after his resignation, relator notified the FDA of Heartland's "improper repackaging practices." Based on this information, FDA investigators visited the Heartland facility and were advised by employees that "no penicillin was being repackaged in the Repackaging Division." Based on these representations, the investigators left the Heartland facility.

Relator later participated in an interview with FDA officials, during which "[h]e described the specific details of the penicillin exposure" at the Heartland facility. In the summer of 2006, the FDA conducted another inspection of the Heartland facility and discovered that penicillin was being repackaged in the Toledo building. Testing "revealed the presence of penicillin throughout the building," including in the Heartland facility. As a result, the FDA issued a warning letter to Omnicare (the warning letter), outlining numerous violations of FDA regulations, both related and unrelated to Omnicare's practices of handling penicillin. The warning letter explained that Omnicare's failure to adhere to the FDA's Current Good Manufacturing Practice regulations (the CGMPs) caused the drugs to be "adulterated."

Rather than quarantining and conducting tests on its products, Omnicare disposed of nearly $19 million worth of inventory. According to the complaint, Omnicare at that time had not recalled any of its drugs due to suspected penicillin contamination, nor had Omnicare reimbursed the government for amounts already paid for the contaminated drugs.

In May 2007, relator filed this action under the FCA, 31 U.S.C. § 3729(a)(1), (a)(2), and (a)(7) (2006),[1] and similar state statutes, against Omnicare and its affiliated companies (collectively, Omnicare).[2] Relator alleged that Omnicare "knowingly and/or recklessly repackaged drugs at [the Toledo building] in violation of applicable laws, including [the CGMPs], which rendered [the drugs] presumptively unsafe under [the CGMPs], and therefore adulterated and misbranded, and therefore not in their FDA-approved form, and thus ineligible for coverage under government programs." The government declined to intervene in the action.

The district court granted Omnicare's motion to dismiss, holding that relator had failed to allege that Omnicare made a false statement to the government or engaged in fraudulent conduct. The court also held that relator had not adequately alleged the details of any false claims that had been submitted to the government for reimbursement. After the court denied relator's motion for leave to amend his complaint, relator timely appealed.

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[1] The 2009 amendments to the FCA resulted in a renumbering of these sections. See Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1617. We refer to the pre-amendment numbering system as cited in the complaint.

[2] The second amended complaint was filed in October 2010.

II.

A.

Before addressing the merits of relator's arguments on appeal, we first consider Omnicare's assertion that the district court lacked subject matter jurisdiction over this action due to the "public disclosure bar" in the FCA. We review this jurisdictional question de novo, and examine the district court's jurisdictional findings of fact for clear error. U.S. ex rel. Vuyyuru v. Jadhav, 555 F.3d 337, 350 (4th Cir. 2009); U.S. ex rel. Grayson v. Advanced Mgmt. Tech., Inc., 221 F.3d 580, 582 (4th Cir. 2000); see also Gaines Motor Lines, Inc. v. Klaussner Furniture Indus., 734 F.3d 296, 301 (4th Cir. 2013) (noting our "obligation to assure ourselves of our jurisdiction").

The version of the public disclosure bar in place at the time of the relevant events[3] provided:

[3] The public disclosure bar provision was amended in 2010. See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010). The disclosures at issue in this case occurred in 2006, and relator filed the original complaint in 2007. The amendments to the public disclosure bar are not retroactive, and neither party argues that the amended statute should apply. See Graham Cnty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson, 559 U.S. 280, 283 n.1 (2010). Accordingly, like the district court, we apply the pre-amendment version of the statute and our precedent interpreting that version.

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

31 U.S.C. § 3730(e)(4) (2006) (emphasis added). Omnicare argues that the public disclosure bar divested the district court of jurisdiction because relator's complaint is "based upon" the warning letter and Omnicare's "Form 10-Ks" filed with the Securities and Exchange Commission (SEC).[4] Omnicare also asserts that relator is not an "original source" of the information in the complaint. We disagree with Omnicare's arguments.

Under this Court's precedent, "a qui tam action is based upon publicly disclosed allegations only if the qui tam plaintiff's allegations were actually derived from the public

[4] Publicly traded companies must submit to the SEC a "Form 10-K" annually. The form "provides a comprehensive overview of the company's business and financial condition and includes audited financial statements." U.S. Securities and Exchange Commission, Form 10-K, available at http://www.sec.gov/answers/form10k.htm (last accessed Feb. 20, 2014).

disclosure itself." U.S. ex rel. Wilson v. Graham Cnty. Soil & Water Conservation Dist., 528 F.3d 292, 308 (4th Cir. 2008), rev'd on other grounds by 559 U.S. 280 (2010) (emphasis in original). A qui tam action will "not be barred if the plaintiff's claims are similar or even identical to the publicly disclosed allegations, so long as the plaintiff had independent knowledge of the facts and did not derive his allegations from the public disclosure itself."[5] Id.

We conclude that relator's FCA complaint was not "based upon" the warning letter or SEC filings, despite Omnicare's objection to the "substantial similarities" between the allegations in the complaint and the public disclosures. The complaint makes clear that relator discovered the penicillin-related violations of the CGMPs during his employment at Heartland. Relator's knowledge was based on his conversations with other employees in the Toledo building, his personal familiarity with the repackaging operations, and his own independent research. Relator also alleged that he twice informed the FDA of the penicillin exposure issues at Heartland,

[5] We note that under the amended version of the statute, the public disclosure bar applies "if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed," unless the plaintiff was an original source. 31 U.S.C. § 3730(e)(4).

which precipitated the FDA investigations and resulted in the FDA's issuance of the warning letter.

Also in his complaint, relator alleged that Omnicare supplied drugs to patients residing in nursing care facilities who primarily were insured by government health care programs. These allegations illustrate relator's independent knowledge, apart from the SEC filings regarding Omnicare's revenue, that Omnicare caused claims to be submitted to the government for payment. See Vuyyuru, 555 F.3d at 353.

For the same reasons, we conclude that relator has sufficiently alleged that he had "direct and independent knowledge of the information on which the allegations are based," thereby entitling him to original source status. See 31 U.S.C. § 3730(e)(4)(B) (2006). Accordingly, we hold that the public disclosure bar did not divest the district court of jurisdiction over relator's FCA claims.

B.

We next consider relator's primary argument on appeal, namely, that the district court erred in dismissing relator's complaint on the ground that he did not adequately allege a false statement or a fraudulent course of conduct as required for an FCA claim. We review de novo the district court's dismissal of relator's complaint under Rule 12(b)(6). U.S. ex

rel. Nathan v. Takeda Pharms. N. Am., Inc., 707 F.3d 451, 455 (4th Cir. 2013).

The FCA is designed to prevent fraud and reflects Congress' broad goal "to protect the funds and property of the government." U.S. ex rel. Owens v. First Kuwaiti Gen. Trading & Contracting Co., 612 F.3d 724, 728 (4th Cir. 2010) (citation and quotation marks omitted). Under 31 U.S.C. § 3729(a)(1), a person is liable to the United States government if he "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." To plead an FCA claim, a relator must plausibly allege four distinct elements: "(1) [] there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter [knowledge]; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due (i.e., that involved a 'claim')."[6] Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 788 (4th Cir. 1999).

Relator contends that he adequately alleged the elements of an FCA claim in this case. He asserts that by failing to comply with the CGMPs, Omnicare's repackaged drugs were "adulterated"

[6] These elements similarly apply to FCA claims brought under § 3729(a)(2) and (a)(7). See Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 784-88 (4th Cir. 1999); U.S. ex rel. Sanders v. N. Am. Bus Indus. Inc., 546 F.3d 288, 297, 299 (4th Cir. 2008).

and prohibited from interstate commerce and, therefore, ineligible for reimbursement by Medicare and Medicaid. Relator thus maintains that any claim for reimbursement for these drugs under government programs was false or fraudulent within the meaning of the FCA.

To determine whether relator's allegations in his second amended complaint were sufficient to withstand Omnicare's motion to dismiss under Rule 12(b)(6), we first consider the general regulations and the statutory provisions on which relator's FCA claim is based. FDA regulations set forth the "Current Good Manufacturing Practices" related to the handling of penicillin. The CGMPs require that "[o]perations relating to the manufacture, processing, and packing of penicillin" be "performed in facilities separate from those used for other drug products for human use," and additionally mandate "completely separate" "air-handling systems" for such operations involving penicillin and other types of drugs. 21 C.F.R. §§ 211.42, 211.46(d).

The regulations require that non-penicillin drugs be tested for the presence of penicillin "[i]f a reasonable possibility exists" that the non-penicillin drug has been exposed to penicillin cross-contamination. 21 C.F.R. § 211.176. The non-penicillin drug may not be marketed "if detectable levels [of penicillin] are found when tested." Id. Drugs that do not

comply with the CGMPs are considered "adulterated" within the meaning of the Food, Drug, and Cosmetic Act (FDCA), and are not permitted in interstate commerce. 21 U.S.C. §§ 331, 351(a)(2)(B); see also 21 C.F.R. 210.1 (failure to comply with the CGMPs renders a drug "adulterated").

Relator's assertion that Omnicare fraudulently made claims for payment for "adulterated" drugs is based on the statutes governing reimbursement under Medicare and Medicaid. Those statutes define "covered outpatient drugs" as those "approved for safety and effectiveness" under the FDCA, 21 U.S.C. § 355. See 42 U.S.C. § 1396r-8(k)(2)(A)(i) (Medicaid); 42 U.S.C. § 1395w-102(e) (Medicare Part D); see also 42 C.F.R. § 423.100 (defining Medicare "Part D" drug). The FDA's approval process for new drugs under 21 U.S.C. § 355 requires that an application for approval describe "the methods used in, and the facilities and controls used for, the manufacture, processing, and packing" of the drug. 21 U.S.C. § 355(b). The FDA may refuse an application or withdraw a previously approved application if these methods or facilities "are inadequate to preserve [the drug's] identity, strength, quality, and purity." Id. § 355(d), (e). A new drug may not be introduced into interstate commerce unless an approved application is in effect. 21 U.S.C. § 355(a).

According to relator, because the Medicare and Medicaid statutes refer to the FDCA's requirements for new drug approval and marketing set forth in Section 355, Medicare and Medicaid do not authorize reimbursement for any drugs that are "adulterated" due to non-compliance with the CGMPs. Relator acknowledges, however, that the Medicare and Medicaid statutes do not expressly prohibit reimbursement for drugs that have been adulterated. Moreover, those statutes do not require compliance with the CGMPs or any other FDA safety regulations as a precondition to reimbursement.

To qualify as a "covered outpatient drug" as defined in the Medicare and Medicaid statutes, a drug merely must be approved by the FDA. The relevant statutes do not provide that when an already-approved drug has been produced or packaged in violation of FDA safety regulations, that particular drug may not be the proper subject of a reimbursement request under Medicare and Medicaid. Therefore, we conclude that once a new drug has been approved by the FDA and thus qualifies for reimbursement under the Medicare and Medicaid statutes, the submission of a reimbursement request for that drug cannot constitute a "false" claim under the FCA on the sole basis that the drug has been adulterated as a result of having been processed in violation of FDA safety regulations.

Relator maintains, nevertheless, that he adequately has pleaded a false claim because compliance with the CGMPs is material to the government's decision to provide reimbursement for regulated drugs. However, relator must allege both materiality and a "false statement or fraudulent course of conduct" as distinct elements of an FCA claim. See Harrison, 176 F.3d at 788; Owens, 612 F.3d at 729. Here, because compliance with the CGMPs is not required for payment by Medicare and Medicaid, Omnicare has not falsely stated such compliance to the government, as contemplated by the FCA.[7] Thus, relator's allegations of regulatory violations fail to support FCA liability. See Harrison, 176 F.3d at 786-87 (discussing U.S. ex. rel. Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 902 (5th Cir. 1997), and stating that FCA liability based on a false certification to the government "will lie only if compliance with the statutes or regulations was a prerequisite to gaining a benefit, and the defendant affirmatively certified such compliance"). As we previously

[7] Because adulterated drugs are subject to reimbursement by Medicare and Medicaid and therefore any claim for payment cannot be "false," we do not separately address relator's arguments for FCA liability under "implied certification" or "worthless services" theories. See generally United States v. Sci. Applications Int'l Corp., 626 F.3d 1257, 1266-71 (D.C. Cir. 2010) (discussing various versions of the implied certification theory); U.S. ex. rel. Mikes v. Straus, 274 F.3d 687, 702-03 (2d Cir. 2001) (describing worthless services theory).

have explained, the correction of regulatory problems is a worthy goal, but is "not actionable under the FCA in the absence of actual fraudulent conduct." Mann v. Heckler & Koch Def., Inc., 630 F.3d 338, 346 (4th Cir. 2010) (emphasis added and citation omitted). In the present case, relator has not identified any false statement or other fraudulent misrepresentation that Omnicare made to the government.

Were we to accept relator's theory of liability based merely on a regulatory violation, we would sanction use of the FCA as a sweeping mechanism to promote regulatory compliance, rather than a set of statutes aimed at protecting the financial resources of the government from the consequences of fraudulent conduct. When an agency has broad powers to enforce its own regulations, as the FDA does in this case, allowing FCA liability based on regulatory non-compliance could "short-circuit the very remedial process the Government has established to address non-compliance with those regulations." U.S. ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 310 (3d Cir. 2011).

Under the provisions of the FDCA, the Secretary of Health and Human Services may suspend or withdraw FDA approval of a drug if the packaging process is "inadequate to assure and preserve [the drug's] identity, strength, quality, and purity." 21 U.S.C. § 355(e). In the present case, the FDA pursued

numerous regulatory actions against Omnicare, including conducting multiple inspections of the Toledo building and issuing the warning letter. The FDA also threatened seizure of Heartland products, use of injunctive remedies, and action recommending "disapproval of any new applications listing [Heartland] as a manufacturer of drugs." The existence of these significant remedial powers of the FDA buttresses our conclusion that Congress did not intend that the FCA be used as a regulatory-compliance mechanism in the absence of a false statement or fraudulent conduct directed at the federal government.

For the same reasons that relator has failed to plead the existence of a false statement or fraudulent conduct, he cannot plausibly allege that Omnicare acted with the requisite scienter when submitting claims to the government for drugs not in compliance with the CGMPs. Liability under the FCA requires that the defendant acted "knowingly," which by definition requires actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(a), (b)(1). Because the Medicare and Medicaid statutes do not prohibit reimbursement for drugs packaged in violation of

the CGMPs, Omnicare could not have knowingly submitted a false claim for such drugs.[8]

We also conclude that the district court did not abuse its discretion in denying relator's request to file a third amended complaint. In seeking leave to amend, relator did not comply with the District of Maryland's local rules, which require that a plaintiff attach to a motion to amend "the proposed amended pleading." D. Md. Local Rule 103(6)(a). Relator's failure to comply with this rule justified the district court's denial of leave to amend. See Francis v. Giacomelli, 588 F.3d 186, 197 (4th Cir. 2009). Moreover, any amendment would have been futile in light of our holding that adulterated drugs are not barred from reimbursement by Medicare and Medicaid and, therefore, claims for reimbursement for these drugs cannot be "false" under the FCA.

Finally, we emphasize that we do not condone Omnicare's disregard of FDA safety regulations that apparently occurred in this case. Nevertheless, we remain convinced that the submission of claims for payment for drugs packaged at the

[8] Because we conclude that relator failed to plead the existence of a false statement and the scienter required for an FCA claim, we do not address Omnicare's alternative argument that relator did not allege the presentment of a false claim with particularity under Federal Rule of Civil Procedure 9(b) and our decision in Nathan, 707 F.3d 451.

Heartland facility did not constitute fraud on the government, and we are confident that the FDA's use of its regulatory enforcement powers may be exercised fully to ensure further compliance with applicable safety standards.

III.

In sum, we conclude that the district court properly exercised jurisdiction over this action, but that relator failed to plead the existence of a false statement and scienter as required by the FCA. Accordingly, we affirm the district court's judgment.

AFFIRMED