

**IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT**

United States Court of Appeals
Fifth Circuit

FILED

November 1, 2010

No. 09-20718

Lyle W. Cayce
Clerk

UNITED STATES OF AMERICA EX REL. LESLIE STEURY,

Plaintiff - Appellant

v.

CARDINAL HEALTH, INC., formerly known as Alaris Medical
Systems, Inc.; CARDINAL HEALTH 303, INC., formerly known as
Alaris Medical Systems, Inc.; CARDINAL HEALTH SOLUTIONS, INC.,

Defendants - Appellees

Appeals from the United States District Court
for the Southern District of Texas

Before DEMOSS, BENAVIDES, and ELROD, Circuit Judges.

FORTUNATO P. BENAVIDES, Circuit Judge:

Relator Leslie Steury, on behalf of the United States, claims that defendants Cardinal Health, Inc., Cardinal Health 303 Inc., and Cardinal Health Solutions, Inc., successors to Alaris Medical Systems, Inc., sold the United States Department of Veterans Affairs defective medical equipment in violation of the False Claims Act (FCA), 31 U.S.C. § 3729(a) (2009). A magistrate judge recommended dismissing Steury's complaint for failure to state a claim under Federal Rules of Civil Procedure 9(b) and 12(b)(6), but also recommended granting Steury leave to amend. Both parties filed timely objections. After de

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novo review, the district court adopted the magistrate judge's recommendations in full. The same day, the district court entered a final judgment dismissing Steury's action. Steury appeals on grounds that she stated a claim under Rules 9(b) and 12(b)(6), and alternatively that the district court abused its discretion in denying her an opportunity to amend her complaint. We affirm the district court's decision with respect to Steury's failure to state a claim, but we vacate the final judgment and remand to give Steury an opportunity to amend.

I. BACKGROUND

According to her amended complaint, Steury marketed Cardinal's Signature Edition Infusion Device (Signature pump) to various hospitals, including hospitals operated by the Veterans Administration, from March 18, 1996 until her termination on September 28, 2001. The Signature pump is an electronic device that regulates the rate at which intravenous fluids flow into patients. Steury alleges that the Signature pump has a dangerous defect that can cause air bubbles to accumulate and ultimately release into a patient's intravenous line, potentially resulting in serious injury or death. Steury alleges that Cardinal sold Signature pumps to the Veterans Administration from 1997 until August 26, 2006, at which time Cardinal suspended production, sales, repairs, and installation of the Signature pump after certain devices were recalled by the Food and Drug Administration for a separate problem.

Steury alleges that she first became aware of the air-in-line defect in the Signature pump in October 2000. Steury asserts that Dr. Mark DiLuciano, a pediatric anesthesiologist at Children's Hospital of Akron, informed Susan Springman, another Alaris employee, that a Signature pump had injected air into his patient's intravenous line, and that a similar problem had been reported

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at Children's Hospital of Philadelphia. On May 23, 2001, Steury allegedly met with John Snow (Alaris's area manager) and nurses from Children's Hospital of Akron to discuss concerns about the Signature pump. According to Steury, Snow discredited a nurse's report of an infant mortality related to an intravenous air bubble. Steury asserts that she and various other Alaris employees again discussed the air-in-line defect during a conference call on May 25, 2001 and at a meeting on May 31, 2001.

In June 2001, Snow allegedly informed Steury that Alaris had temporarily suspended shipments of Signature pumps while it reviewed the air-in-line defect, but nonetheless directed Steury to continue marketing the Signature pump. Steury asserts that she was told to expect a final answer from Snow within 90 days. E-mails attached to Steury's complaint suggest that Children's Hospital of Akron continued to raise concerns about the Signature pump between June and September 2001. On September 28, 2001, Alaris terminated Steury's employment. According to Steury, she would have "completed filling a major order" of Signature pumps by the Veterans Administration Hospital of Ohio only five days later.

Steury sued Cardinal on May 11, 2007 for alleged violations of the FCA and a number of similar state statutes. The United States filed a notice of declination to intervene pursuant to 31 U.S.C. § 3730(b)(4)(B) on January 28, 2008. On November 26, before Cardinal answered, Steury filed an amended complaint. The amended complaint again raised claims under the FCA and similar state statutes. In addition to the above factual allegations, Steury's amended complaint asserts, in relevant part:

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51. . . . A claimant submits a false or fraudulent claim within the meaning of the FCA when he submits a claim for payment to the Government for products that contain defective parts.

52. By accepting payment from the federal Government or one of its agencies for the SE infusion pumps, Cardinal Health knowingly misrepresented that the SE infusion pumps were safe, reliable, and quality-assured.

* * *

54. A false certification occurs when the Government has conditioned payment of a claim upon the certification of compliance with, for example, a contract provision, regulation or statute. The claimant submits a false or fraudulent claim within the meaning of the FCA when he or she falsely certifies compliance with that contract provision or statute. These certifications can either be express or implied.

* * *

58. An implied false certification theory occurs when a claimant submits a false claim without expressly certifying compliance with a contract provision, statute, regulation, or governmental program. Liability is imposed on the premise of breach of contract or an implied responsibility, not a financial loss.

59. Cardinal Health is obligated to provide safe, reliable, and quality-tested products, which perform to their specifications, to the Government. By delivering and receiving payments for the SE infusion pumps, Cardinal Health is impliedly certifying compliance with the terms of its contract with the Government for the products.

Cardinal moved to dismiss Steury's complaint on February 2, 2009, and the matter was referred to a magistrate judge. On August 31, 2009, the magistrate judge issued a report and recommendation finding, inter alia, that

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Steury's allegations of fraud did not satisfy the heightened pleading requirements of Rule 9(b) and thus failed to state a claim under Rule 12(b)(6). The magistrate judge recommended that Steury's "complaint be dismissed without prejudice to the filing of an amended complaint within ten days, if this recommendation is adopted." Both parties filed timely objections. On September 25, 2009, after de novo review, the district court adopted the magistrate judge's report and recommendation in full. On the same day, the district court entered a final judgment dismissing Steury's "action." In bold letters, the district court confirmed that "THIS IS A FINAL JUDGMENT." Steury filed a timely notice of appeal on October 23, 2009.

II. STANDARD OF REVIEW

We review de novo a district court's ruling on a Rule 12(b)(6) motion. *United States ex rel. Willard v. Humana Health Plan of Tex. Inc.*, 336 F.3d 375, 379 (5th Cir. 2003). We accept all well-pleaded factual allegations as true, and we interpret the complaint in the light most favorable to the plaintiff. *Id.* The plaintiff's factual allegations must support a claim to relief that is plausible on its face and rises above mere speculation. *United States ex rel. Marcy v. Rowan Cos.*, 520 F.3d 384, 388 (5th Cir. 2008). In addition, claims brought under the FCA must comply with the particularity requirements of Rule 9(b). *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997). Rule 9(b) requires, at a minimum, "that a plaintiff set forth the 'who, what, when, where, and how' of the alleged fraud." *Id.*; see also *United States ex rel. Rafizadeh v. Cont'l Common, Inc.*, 553 F.3d 869, 872-73 (5th Cir. 2008).

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We review a district court's denial of leave to amend a pleading for abuse of discretion. *See Del Prado v. B.N. Dev. Co.*, 602 F.3d 660, 663 (5th Cir. 2010).

III. DISCUSSION

Steury has expressly limited the issues on appeal to: (1) whether Steury stated a claim under the FCA “when she alleged that the defendant sold the Veterans Administration medical equipment that it knew was defective and unsafe”; and if not, (2) whether the district court erred in granting final judgment without allowing her an opportunity to amend her complaint.

A. Failure To State A Claim

The FCA is the Government's “primary litigation tool” for recovering losses resulting from fraud. *Marcy*, 520 F.3d at 388. Under certain circumstances, the FCA permits “suits by private parties on behalf of the United States against anyone submitting a false claim to the government.” *United States ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 376 (5th Cir. 2009). Specifically, the FCA imposes civil penalties and treble damages on any person who, inter alia, “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.”¹ 31 U.S.C.

¹ Although the 2009 amendments to the FCA generally apply only to conduct on or after May 20, 2009, § 3729(a)(1)(B) applies retroactively to all claims pending on or after June 7, 2008 (that is, just before the Supreme Court's decision in *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 665 (2008)). *See* Fraud Enforcement & Recovery Act of 2009, Pub. L. 111-21, § 4(f)(1), 123 Stat. 1617, 1625 (2009); *see also* S. Rep. No. 111-10, at 10 (2009), *reprinted in* 2009 U.S.C.C.A.N. 430, 437-38 (expressing legislative intent to overrule *Allison Engine*). In *Allison Engine*, the Supreme Court held that a false record or statement implicated the FCA only when it was made with the specific “purpose of getting a false or fraudulent claim” paid by “the Government itself.” *Allison Engine*, 553 U.S. at 668-69. Steury's complaint was pending on June 7, 2008. We therefore assess Steury's claim under the current § 3729(a)(1)(B). *See United States ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94, 113 (2d Cir. 2010) (applying § 3729(a)(1)(B) to claim filed in 2005 but pending on June 7,

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§ 3729(a)(1)(B) (2009). The terms “knowing” and “knowingly” mean that a person “(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information.” *Id.* § 3729(b)(1)(A)(i)-(iii). Proof of “specific intent to defraud” is not required. *Id.* § 3729(b)(1)(B). The term “material” means “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” *Id.* § 3729(b)(4); *see also United States ex rel. Longhi v. United States*, 575 F.3d 458, 470 (5th Cir. 2009). The term “claim” means “any request or demand, whether under a contract or otherwise, for money or property . . . that . . . is presented to an officer, employee, or agent of the United States . . .” *Id.* § 3729(b)(2). We have summarized that to state a claim under the FCA, a plaintiff must allege: (1) a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that is presented to the Government. *See Longhi*, 575 F.3d at 467.

In an effort to “streamline” this appeal, Steury presses only one substantive contention: that Cardinal made a false certification (i.e., a false statement) to the Veterans Administration that the Signature pumps complied with the warranty of merchantability.² Steury does not assert that Cardinal actually (i.e., expressly) made this certification. *See Thompson*, 125 F.3d at 902

2008).

² Steury has not briefed, and indeed has expressly disclaimed, other challenges to the district court’s decision. Steury therefore has waived other potential challenges. *See, e.g.*, FED. R. APP. P. 28(a)(9)(A) (requiring appellant’s brief to include appellant’s contentions and the reasons for them); *Procter & Gamble Co. v. Amway Corp.*, 376 F.3d 496, 499 n.1 (5th Cir. 2004) (“Failure adequately to brief an issue on appeal constitutes waiver of that argument.”).

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(recognizing that when the Government expressly conditions “payment of a claim upon a claimant’s certification of compliance with, for example, a statute or regulation, a claimant submits a false or fraudulent claim when he or she falsely certifies compliance with that statute or regulation”). Instead, Steury alleges that Cardinal *impliedly*, and falsely, certified compliance with the warranty of merchantability simply by requesting payment for the Signature pumps.³

The implied-certification theory of liability under the FCA “is based on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment.” *Mikes v. Straus*, 274 F.3d 687, 699 (2d Cir. 2001). This Court has not yet recognized the implied-certification theory. *See, e.g., Marcy*, 520 F.3d at 389 (declining to resolve issue that would “require us to determine whether implied certifications may be claims under the Act”). We need not resolve the issue today, because in any event the factual allegations in Steury’s amended complaint provide no basis for implying a false certification.

³ Cardinal asserts that Steury did not base her implied-certification theory of liability specifically on the warranty of merchantability before the district court. We recognize the fundamental principle that a plaintiff may not raise an entirely new issue for the first time on appeal, *see, e.g., Martinez v. Tex. Dep’t of Criminal Justice*, 300 F.3d 567, 574 (5th Cir. 2002), but we do not find that Steury has raised an entirely new issue. As discussed above, Steury’s complaint alleges that “Cardinal Health is obligated to provide safe, reliable, and quality-tested products, which perform to their specifications, to the Government,” and that “[a] claimant submits a false or fraudulent claim within the meaning of the FCA when he submits a claim for payment to the Government for products that contain defective parts.” For its part, the district court analyzed whether “Cardinal Health violated the FCA simply by selling defective pumps.” Although Steury and the district court did not expressly refer to the warranty of merchantability by name, the issue was fairly presented to and considered by the district court. We will decide Steury’s appeal on the merits.

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The FCA is not a general “enforcement device” for federal statutes, regulations, and contracts. *Thompson*, 125 F.3d at 902; *see also Mikes*, 274 F.3d at 699 (observing that FCA “was not designed for use as a blunt instrument to enforce compliance”). Not every breach of a federal contract is an FCA problem. We have thus repeatedly upheld the dismissal of false-certification claims (implied or express) when a contractor’s compliance with federal statutes, regulations, or contract provisions was not a “condition” or “prerequisite” for payment under a contract. *See, e.g., Marcy*, 520 F.3d at 389-90 (upholding dismissal); *Willard*, 336 F.3d at 381 (same); *see also Thompson*, 125 F.3d at 902-03 (remanding for fact determination as to whether payment was “conditioned” on certification). This prerequisite requirement seeks to maintain a “crucial distinction” between punitive FCA liability and ordinary breaches of contract. *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 680 (5th Cir. 2003) (en banc) (Jones, J., specially concurring). The prerequisite requirement recognizes that unless the Government conditions payment on a certification of compliance, a contractor’s mere request for payment does not fairly imply such certification. *See Mikes*, 274 F.3d at 700 (observing that a mere claim for payment does not suggest fraud unless it can be said that the defendant submitted the claim “while knowing . . . that payment expressly is precluded because of some noncompliance by the defendant”); *United States ex rel. Siewick v. Jamieson Sci. & Eng’g, Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000) (“Courts have been ready to infer certification from silence, but only where certification was a prerequisite to the government action sought.”).

Courts have at times located the prerequisite requirement in the materiality prong of FCA analysis. *See, e.g., Marcy*, 520 F.3d at 389 (“A material

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claim is one that is required to be made in order to receive the relevant government benefit.”). Although the FCA now defines the term “material” somewhat more expansively (i.e., as having a “natural tendency to influence, or be capable of influencing, the payment or receipt of money or property”), we do not think that our false-certification precedents are obsolete. The prerequisite requirement has to do with more than just the materiality of a false certification; it ultimately has to do with whether it is fair to find a false certification or false claim for payment in the first place. As already discussed, when payment is not conditioned on a certification of compliance, it is not fair to infer such certification from a mere request for payment. Similarly, even if a contractor falsely certifies compliance (implicitly or explicitly) with some statute, regulation, or contract provision, the underlying claim for payment is not “false” within the meaning of the FCA if the contractor is not required to certify compliance in order to receive payment. *See Southland Mgmt.*, 326 F.3d at 675 (“There is no liability under this Act for a false statement unless it is used to get [a] false claim paid.”). In short, a false certification of compliance, without more, does not give rise to a false claim for payment unless payment is conditioned on compliance.⁴

In this case, we find no indication that the Government conditioned payment for the Signature pumps on a certification that the Signature pumps complied with the warranty of merchantability. Steury does not allege that the particular contracts between Cardinal and the Government impose a warranty

⁴ As we have recognized in the past, whether payment is conditioned on compliance will depend on the specific statutes, regulations, and contracts at issue in a particular case. *See Thompson*, 125 F.3d at 902-03 (remanding for factual development).

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of merchantability. Steury instead draws our attention to certain Federal Acquisition Regulations (FAR), *see* 48 C.F.R. § 12.404(a), but the regulations do not sustain her claim. Section 12.404(a) explains that the standard warranty clause in federal commercial acquisition contracts, *see id.* § 52.212-4(o), includes a warranty of merchantability and a warranty of fitness for a particular purpose. *Id.* § 12.404(a). The warranties may be excluded or limited, however, by express warranty. *Id.* § 12.404(b)(2); *see also id.* § 12.302(a) (recognizing that clauses in § 52.212-4 may be “tailor[ed] . . . to adapt to the market conditions for each acquisition”). Thus, Cardinal is not even necessarily subject to an implied warranty of merchantability under the FAR. Moreover, the FAR expressly condition payment for commercial items on *acceptance* (as opposed to compliance with the warranty of merchantability), *see id.* § 52.212-4(i) (providing that “payment shall be made for items accepted by the Government . . .”), and the FAR also permit the Government to seek a range of remedies in the event it receives noncompliant items from a contractor, including acceptance, price reduction or replacement. *See id.* §§ 46.407(b)-(d), (f), 52.246-2(k), (l). As we have recognized on previous occasions, the Government’s ability to seek a range of remedies in the event of noncompliance suggests that payment is not conditioned on a certification of compliance. *See Willard*, 336 F.3d at 382-83; *Marcy*, 520 F.3d at 389-90. That the government may accept (and pay) for noncompliant commercial items under the FAR confirms that payment is not conditioned on compliance with the warranty of merchantability. Were private litigants able to pursue FCA claims whenever the Government acquired noncompliant commercial items, the Government’s ability to pursue the range of remedies contemplated by the FAR would be substantially compromised.

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To conclude, we hold that Cardinal did not make an implied certification that the Signature pumps complied with the warranty of merchantability simply because the Government's standard commercial-acquisition contract includes a warranty of merchantability. We do not suggest, however, that a knowing delivery of defective goods to the Government will never implicate the FCA. Particular government contracts may specifically condition payment on a certification of compliance with the warranty of merchantability. Other courts have suggested that the knowing provision of "worthless" goods or services to the Government may violate the FCA. *See, e.g., Mikes*, 274 F.3d at 703; *United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 824 (8th Cir. 2009); *United States ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1053 (9th Cir. 2001). Steury has not yet pursued or briefed these theories, however, so we need not address them here. Finally, although we have held that a knowing attempt to deceive the Government about the nature of commercial items may violate the FCA, *see United States v. Aerodex, Inc.*, 469 F.2d 1003, 1008 (5th Cir. 1972) (finding that deliberate mislabeling may implicate FCA), the district court was correct in concluding that Steury has so far failed to allege this type of claim with particularity. Steury's amended complaint lacks any factual heft as to whether and how Cardinal knowingly deceived the Veterans Administration about the potential risks of the Signature pumps. *See id.* Indeed, the complaint does not even specifically allege that a Signature pump at a Veterans Administration hospital has been defective. An equally likely inference from Steury's amended complaint is that the Veterans Administration tried and tested the Signature pumps, understood their potential risks, and decided to continue purchasing and using them anyway.

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B. Amendment

A district court should “freely give leave” to amend a complaint “when justice so requires.” FED. R. CIV. P. 15(a)(2). Denial of leave to amend may be warranted for undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies, undue prejudice to the opposing party, or futility of a proposed amendment. *See Rosenblatt v. United Way of Greater Houston*, 607 F.3d 413, 419 (5th Cir. 2010) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)). We have held that a district court abuses its discretion, however, when it gives no reasons for denying a timely motion to amend, at least when the defendant would not be unduly prejudiced by the amendment. *See Griggs v. Hinds Junior Coll.*, 563 F.2d 179, 180 (5th Cir. 1977) (per curiam); *see also State of Louisiana v. Litton Mortg. Co.*, 50 F.3d 1298, 1302-03 (5th Cir. 1995) (observing that “[a] decision to grant leave is within the discretion of the court, although if the court lacks a substantial reason to deny leave, its discretion is not broad enough to permit denial” (quotations omitted)).

In this case, the district court *granted* Steury leave to amend her complaint but nonetheless entered a final judgment before her time to amend expired (or even began for that matter). The district court’s entry of final judgment may have been intentional or it may have been a mistake; either way, it was an abuse of discretion to reverse course without providing any reason whatever. It is true that Steury has already amended her complaint once, but this was done shortly after Cardinal was served and before Cardinal filed an answer. It does not appear that Steury has unduly delayed this action, or that she is pursuing it in bad faith. Cardinal has not shown that it would suffer undue prejudice if Steury were permitted to amend her complaint, and we

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cannot say that the defects in Steury's complaint are necessarily "incurable" or that amendment would be futile. *See Great Plains Trust Co. v. Morgan Stanley Dean Witter & Co.*, 313 F.3d 305, 329-30 (5th Cir. 2002). Nor do we see any other "special circumstances" that would justify dismissal of Steury's complaint without leave to amend. *Cates v. Int'l Tel. & Tel. Corp.*, 756 F.2d 1161, 1180 (5th Cir. 1985). Cardinal contends that Steury should have pursued a postjudgment motion to amend under Rule 59 or 60. *See* FED. R. CIV. P. 59, 60. This may have been a prudent and even desirable strategy, but we know of no rule requiring it instead of an appeal. *See Rosenzweig v. Azurix Corp.*, 332 F.3d 854, 864 (5th Cir. 2003) ("When a district court dismisses an action and enters a final judgment, however, a plaintiff may request leave to amend only by either appealing the judgment, or seeking to alter or reopen the judgement under Rule 59 or 60."). Accordingly, we vacate the final judgment and remand with instructions to give Steury ten days to file an amended complaint.

AFFIRMED IN PART, VACATED IN PART, AND REMANDED.