

**United States Court of Appeals**  
**FOR THE EIGHTH CIRCUIT**

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No. 07-3781

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| United States ex rel Henry Roop, | *                               |
|                                  | *                               |
| Plaintiff - Appellant,           | *                               |
|                                  | * Appeal from the United States |
| v.                               | * District Court for the        |
|                                  | * District of Minnesota.        |
| Hypoguard USA, Inc., et al.,     | *                               |
|                                  | *                               |
| Defendants - Appellees.          | *                               |

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Submitted: October 14, 2008  
Filed: March 17, 2009

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Before LOKEN, Chief Judge, JOHN R. GIBSON and MURPHY, Circuit Judges.

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LOKEN, Chief Judge.

Qui tam relator Henry Roop appeals the dismissal of his complaint alleging that his former employer, Hypoguard USA, Inc., violated the False Claims Act (“FCA”), 31 U.S.C. § 3729(a). Conceding that his initial Complaint failed to plead an FCA claim with the particularity required by Rule 9(b) of the Federal Rules of Civil Procedure, Roop argues that the district court<sup>1</sup> abused its discretion by denying him leave to amend and then denying his motion to alter or amend the judgment to permit him to file a proposed First Amended Complaint. We affirm.

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<sup>1</sup>The HONORABLE ANN D. MONTGOMERY, United States District Judge for the District of Minnesota.

Roop worked as a Medicare sales specialist for Hypoguard, a Minnesota-based manufacturer of blood glucose monitoring systems that are sold to diabetics, many of whom are eligible under Medicare for federal reimbursement of their purchases. Hypoguard sells these medical devices to distributors who submit Medicare reimbursement claims for their sales to nursing homes and individual consumers.

Roop commenced this action in March 2004 by filing a sealed complaint in the Northern District of Mississippi. The complaint alleged, *inter alia*, that Hypoguard blood glucose monitors and test strips were defective, and that Hypoguard knew they were defective and failed to file reports of defects required by the Food and Drug Administration's Medical Device Reporting ("MDR") regulations,<sup>2</sup> which caused Medicare to pay countless fraudulent reimbursement claims submitted by Hypoguard distributors. In May 2006, after a lengthy FDA investigation, the United States filed a Notice of Election to Decline Intervention. See 31 U.S.C. § 3730(b)(4)(B). Roop elected to continue the action. Hypoguard was then served and in October 2006 filed motions to dismiss and to transfer venue to the District of Minnesota.

In support of its motion to dismiss, Hypoguard argued that Roop failed to plead fraud with the specificity required by Rule 9(b) because he failed to allege "a single specific false claim or statement submitted to the government," details concerning the alleged failures to submit proper MDRs, and "what was false in any statement to the Government, why it was false, and when the allegedly fraudulent statements were made." In his Memorandum in Opposition, Roop argued at length that the complaint sufficiently pleaded an FCA claim and then concluded: "Alternatively, if this Court

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<sup>2</sup>The FDA granted pre-market approval of the Hypoguard glucose monitoring products. See 21 U.S.C. §§ 360c(f), 360e; 21 C.F.R. Part 814. The MDR regulations require a medical device manufacturer to submit an "adverse event report" to the FDA if it receives information suggesting that a device may have caused or contributed to a death or serious injury, or has malfunctioned and would likely cause or contribute to a death or serious injury if the malfunction recurred. 21 C.F.R. § 803.50(a).

finds that Plaintiff's False Claims Act claims lack specificity as required by Rule 9(b), Plaintiff should be granted leave to file an amended complaint." The Northern District of Mississippi transferred venue to the District of Minnesota in March 2007 without ruling on the motion to dismiss.

The district court held a hearing on Hypoguard's motion to dismiss on September 6, 2007. Roop had not complied with the local rule requiring that a party who moves to amend a pleading "shall attach a copy of the amended pleading to the motion." D. Minn. LR 15.1. Accordingly, at the hearing, the district court asked:

If I were to require there to be a realleging under Rule 9, what further facts do you think could be adduced to shore this up?

Counsel for Roop responded:

Well, number one, I can allege that people were injured by it. I do have evidence of that. My client as a regional sales manager was involved in some telephone conferences with groups of sales reps as well as management of Hypoguard in which people gave instances of where people were injured by the device, so I could allege that. . . .

THE COURT: Injured in the sense of requiring hospitalization --

[COUNSEL]: Yeah, and I think one person died. . . . I guess I could more clearly allege the reimbursement . . . it's not Hypoguard being reimbursed, but that they're causing reimbursements to be made. So I could more specifically allege regarding the MDRs and that they were required to be reported and not reported and provide the basis under the regulations with some evidence as to -- particular evidence as to people that were injured, or at least discussions where Hypoguard employees acknowledged that people were injured by the device.

THE COURT: Okay.

[COUNSEL]: I would like the opportunity . . . to do Rule 26 disclosures and I'd like to take the depositions of some Hypoguard employees and some ex-employees . . . . And I would like to get copies of all the MDRs they did file and just internal documents regarding the device . . . .

After the hearing, the district court issued a Memorandum Opinion and Order dismissing Roop's Complaint with prejudice and denying his request for leave to amend. United States ex rel. Roop v. Hypoguard USA, Inc., 2007 WL 2791115 (D. Minn. Sept. 24, 2007). The court concluded that all claims "failed to meet the particularity requirements of Rule 9(b)," a conclusion Roop does not challenge on appeal. Noting that Roop neither specified in his memorandum what additional facts he would plead nor submitted a proposed amended complaint, the court denied leave to amend because "the potential amendment Roop's counsel cited [at the hearing] would not cure the deficiencies in Roop's Complaint and thus would be futile."

On October 9, 2007, Roop filed a Motion to Alter or Amend the Judgment and Motion for Leave to File a First Amended Complaint, attaching a 25-page, 63-paragraph First Amended Complaint. His nine-page Memorandum in Support asserted that he "has now alleged in compliance with [Rule] 9(b) the instances of the false and fraudulent claims, and violations of FDA regulations," but he failed to provide a detailed comparison of how the lengthy First Amended Complaint cured deficiencies in the initial Complaint. The district court denied that motion in a Memorandum Opinion and Order explaining that Roop "failed to present any reason why he is entitled to relief under Rule 59(e) or 60(b)." United States ex rel. Roop v. Hypoguard USA, Inc., 2007 WL 4224074, at \*1 (D. Minn. Nov. 27, 2007).

1. On appeal, Roop first argues that the district court abused its discretion in dismissing his Complaint with prejudice and denying as futile his request for leave to amend to cure its Rule 9(b) deficiencies. Futility is a valid basis for denying leave to amend. We review the denial of leave to amend for abuse of discretion and questions

of futility *de novo*. United States ex rel. Joshi v. St. Luke's Hosp., Inc., 441 F.3d 552, 555 (8th Cir. 2006). The district court properly rejected Roop's request at the motion hearing for time to conduct discovery to satisfy Rule 9(b)'s particularity requirement. Id. at 559.

The FCA imposes liability if a defendant (1) "knowingly presents, or causes to be presented, [to a federal official] a false or fraudulent claim for payment or approval," or (2) "knowingly makes . . . a false record or statement to get a false or fraudulent claim paid or approved." 31 U.S.C. § 3729(a)(1)-(2).<sup>3</sup> Grounded in fraud, FCA claims must satisfy Rule 9(b)'s heightened pleading requirement: "[A] party must state with particularity the circumstances constituting fraud or mistake." To meet this standard and enable the defendant to respond "specifically and quickly," a complaint alleging fraud "must identify who, what, where, when, and how." United States ex rel. Costner v. United States, 317 F.3d 883, 888 (8th Cir. 2003). If it alleges a systematic practice of submitting fraudulent claims, the FCA complaint "must provide *some* representative examples of [the] alleged fraudulent conduct," specifying "the time, place, and content of the defendant's false representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result." Joshi, 441 F.3d at 556-57; accord United States ex rel. Snapp, Inc. v. Ford Motor Co., 532 F.3d 496, 506 (6th Cir. 2008). Roop concedes his original Complaint failed to meet this pleading standard.

Though the district court "should freely give leave [to amend] when justice so requires," Fed. R. Civ. P. 15(a)(2), plaintiffs do not enjoy "an absolute or automatic

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<sup>3</sup>A claim under § 3729(a)(2) requires proof "that the defendant intended that the false record or statement be material to the Government's decision to pay or approve the false claim." Allison Engine Co. v. United States ex rel. Sanders, 128 S. Ct. 2123, 2126 (2008). Neither Roop's Complaint nor his proposed First Amended Complaint alleged this element of the claim.

right to amend” a deficient FCA Complaint. United States ex rel. Lee v. Fairview Health Sys., 413 F.3d 748, 749 (8th Cir. 2005). Here, Roop’s Memorandum in Opposition, submitted almost a year before the motion hearing, argued that his initial Complaint satisfied Rule 9(b), alternatively requested leave to amend in a concluding paragraph, and failed to describe the amendments he would submit. After transfer to the District of Minnesota, he failed to comply with local Rule 15.1 for six months before the motion hearing. When the district court asked at that hearing how Roop would cure the Rule 9(b) deficiencies, counsel described additional allegations of consumer injury and non-compliance with the MDR regulations, allegations arguably relevant to a products liability case but, as the district court concluded, insufficient to satisfy the Rule 9(b) requirement that FCA fraud claims be pleaded with particularity. The court did not abuse its discretion in denying leave to amend. See Fairview Health Sys., 413 F.3d at 750, and cases cited; accord United States ex rel. Williams v. Martin-Baker Aircraft Co., 389 F.3d 1251, 1259 (D.C. Cir. 2004).

2. Roop next argues that the district court abused its discretion in denying his motion to alter or amend the judgment to allow him to file the proposed First Amended Complaint. He complains on appeal that only after the court dismissed his Complaint did he become “aware . . . of the facts which the Court believed were required to be set forth with particularity.” In a word, this is balderdash. Roop adopted a strategy of vigorously defending his initial Complaint, despite its numerous and obvious Rule 9(b) deficiencies. He now wants a judicial reprieve.

Review of this motion raises an issue of law ignored by the parties -- when a complaint is dismissed for failure to state a claim, and plaintiff files a post-judgment motion for leave to file an amended complaint, is that motion reviewed under the liberal “freely give” standard of Rule 15(a)(2), or under the more restrictive standards applicable to post-judgment motions under Rules 59(e) and 60(b)? All circuits acknowledge that post-judgment leave to amend may be granted if timely requested. That conclusion is compelled by the Supreme Court’s summary reversal of the denial

of such a motion in Foman v. Davis, 371 U.S. 178, 182 (1962). However, interests of finality dictate that leave to amend should be less freely available after a final order has been entered. As we have said in numerous cases, “[a]lthough leave to amend a complaint should be granted liberally when the motion is made pretrial, different considerations apply to motions filed after dismissal.” Briehl v. General Motors Corp., 172 F.3d 623, 629 (8th Cir. 1999). Nevertheless, the customary Rule 59(e) standard, which bars attempts to “introduce new evidence, tender new legal theories, or raise arguments which could have been offered or raised prior to entry of judgment,” Innovative Home Health Care, Inc. v. P.T.-O.T. Assoc. of the Black Hills, 141 F.3d 1284, 1286 (8th Cir. 1998), and Rule 60(b)(1), which limits relief to showings of “mistake, inadvertence, surprise, or excusable neglect,” seem ill-suited to the task of determining when a plaintiff who has failed to plead fraud with the particularity Rule 9(b) requires should be permitted, post-judgment, to try again.

We have found two circuits that have addressed this question in reviewing the denial of post-judgment motions for leave to amend an FCA complaint dismissed for failure to comply with Rule 9(b). Both held that Rule 59(e) and Rule 60(b) apply at this stage of the proceedings. But the Fifth Circuit held that, in this situation, “the considerations for a motion under Rule 59(e) are the same as those governing a motion under Rule 15(a).” United States ex rel. Hebert v. Disney, 2008 WL 4538308, at \*4 (5th Cir. Oct. 10, 2008) (unpublished), applying Rosenzweig v. Azurix Corp., 332 F.3d 854, 865 (5th Cir. 2003). On the other hand, the Sixth Circuit applied its normal, restrictive Rule 59 and Rule 60 principles, though the issue was of little importance because the court reversed the denial of leave to amend based on an intervening change in controlling law, a circumstance that customarily warrants post-judgment relief. Snapp, Inc., 532 F.3d at 507.

In Parnes v. Gateway 2000, Inc., 122 F.3d 539, 550-51 (8th Cir. 1997), we applied the “different considerations” standard and affirmed the denial of a motion for leave to amend a complaint dismissed under Rule 9(b) because plaintiffs “failed to

provide any valid reason for failing to amend their complaint prior to the grant of summary judgment against them.” We again recently applied the “different considerations” standard in Bills v. United States Steel LLC, 267 F.3d 785, 788 (8th Cir. 2001). From this survey of prior case law, we conclude that district courts in this circuit have considerable discretion to deny a post-judgment motion for leave to amend because such motions are disfavored, but may not ignore the Rule 15(a)(2) considerations that favor affording parties an opportunity to test their claims on the merits, particularly when a fraud complaint has been dismissed for failure to comply with the pleading requirements of Rule 9(b).

In this case, Roop did seek pre-judgment leave to amend his complaint, and that relief was properly denied. Thus, in denying the post-judgment motion, the district court correctly observed that “Roop’s argument regarding Rule 15’s policy for granting leave to amend is an attempt to reargue an issue already addressed by this Court.”<sup>4</sup> On appeal, Roop chides the district court for failing to undertake a detailed analysis of whether his proposed First Amended Complaint was futile, or stated viable FCA claims. But the court’s lack of patience was understandable. Though Roop corrected his pre-judgment failing by submitting a proposed pleading with his post-judgment motion, his supporting memorandum did not explain how this lengthy pleading -- on its face substantially similar to the initial Complaint -- cured the Rule 9(b) deficiencies in the initial Complaint. Roop’s Memorandum in Support gave the district court no reason to believe that the proposed First Amended Complaint was different than the insufficient amendments counsel orally described at the motion hearing. The court was not obligated to ferret out well-hidden changes in a post-judgment amended pleading without guidance from Roop. In these circumstances, there was no abuse of discretion in denying the post-judgment motion.

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<sup>4</sup>Roop’s contention that the district court’s order explaining its denial of his post-judgment motion was a “nullity” because he had already appealed the earlier dismissal order is without merit. See Fed. R. App. P. 4(a)(4)(B)(i); MIF Realty L.P. v. Rochester Assoc., 92 F.3d 752, 755 (8th Cir. 1996).

Moreover, our detailed review of the proposed First Amended Complaint confirms that it did not cure the Rule 9(b) deficiencies in the initial Complaint. The more-detailed allegations that Hypoguard failed to file required MDR reports did not identify specific false or fraudulent Medicare reimbursement claims by Hypoguard distributors, nor did Roop allege that Hypoguard falsely “certifie[d] compliance with a statute or regulation as a condition to governmental payment.” Mikes v. Straus, 274 F.3d 687, 697 (2d Cir. 2001); see United States ex rel. Hopper v. Anton, 91 F.3d 1261, 1266-67 (9th Cir. 1996). Likewise, additional allegations of product defects and consumer injury failed to cure deficiencies in the initial Complaint because sales of a defective product do not give rise to FCA liability absent proof that a party “knowingly or with deliberate ignorance charged the government for worthless services.” United States ex rel. Lee v. SmithKline Beecham, Inc., 245 F.3d 1048, 1053 (9th Cir. 2001). “In a worthless services claim, the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all.” Mikes, 274 F.3d at 703. That was not alleged, only that Hypoguard’s products, when misused, have resulted in serious adverse consequences.

The proposed First Amended Complaint did not plead with particularity the details of any false Medicare reimbursement claim presented to, or paid by, the United States or its agent. See Joshi, 441 F.3d at 556. Nor did it allege with particularity how any product defect or failure to submit MDR reports to the FDA was material to -- that is, “capable of influencing” -- the government’s decisions to pay countless unidentified Medicare reimbursement claims submitted by Hypoguard distributors. Hays v. Hoffman, 325 F.3d 982, 992 (8th Cir. 2003); see Costner, 317 F.3d at 887. The conclusory allegation that unidentified government agents “would not have reimbursed through Medicare individuals submitting claims [for Hypoguard systems] if [they] had known of the defects and failure to comply with the rules and regulations of the FDA” does not comply with Rule 9(b). Nor does the speculative allegation that Hypoguard products “would have been recalled” had Hypoguard complied with the MDR regulations.

Finally, in paragraphs 56, 60, and 62 of the First Amended Complaint, Roop alleged for the first time that Hypoguard assisted one distributor in submitting fraudulent Medicare reimbursement claims by “artificially inflating” the price of blood glucose monitors and reducing the price of blood glucose test strips. He did not even mention these deeply-buried allegations in his Memorandum in Support to the district court. Thus, the issue was not properly preserved. And in any event, a post-judgment motion for leave to assert an entirely new claim is untimely.

For these reasons, and the reasons stated by the district court in its two opinions and orders, the judgment of the district court is affirmed.

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