United States Court of Appeals
For the Eighth Circuit

No. 12-2979

In re: Baycol Products Litigation

United States of America, ex rel Laurie Simpson

Plaintiff

Laurie Simpson

Plaintiff Relator - *Appellant*

v.

Bayer Healthcare, doing business as Bayer Healthcare Pharmaceuticals; Bayer Pharmaceuticals Corporation; Bayer Corporation; Bayer A.G.

Defendants - Appellees

Appeal from United States District Court
for the District of Minnesota - Minneapolis

Submitted: June 12, 2013
Filed: October 15, 2013

Before LOKEN, BRIGHT, and BYE, Circuit Judges.

BRIGHT, Circuit Judge.

Laurie Simpson appeals the dismissal of the *qui tam* action she brought against Bayer Healthcare under the False Claims Act (FCA), 31 U.S.C. §§ 3729–3733. Simpson alleged Bayer defrauded the United States government through its marketing and sale of the cholesterol-lowering drug Baycol. She claimed Bayer fraudulently caused the government to make reimbursements for Baycol prescriptions through federal health insurance programs such as Medicare and Medicaid; she also claimed Bayer fraudulently induced the Department of Defense (DoD) to enter into two contracts for the purchase of Baycol. The district court dismissed Simpson's claims, concluding she failed to plead fraud with the particularity required by Rule 9(b) of the Federal Rules of Civil Procedure. We affirm the dismissal relating to federal health insurance programs but reverse as to the DoD contract claims and remand for further proceedings.

I.

In early 1998, Bayer began marketing Baycol to compete with other cholesterol-lowering "cerivastatin" or "statin"[1] drugs. Certain studies concluded Baycol was less effective at lowering cholesterol than competing drugs when Baycol was prescribed at the dosage initially approved by the Food and Drug Administration (FDA). Bayer then sought and obtained approval from the FDA to sell Baycol at higher dosage levels. Doctors began to report, however, that patients who were prescribed Baycol developed rhabdomyolysis, a rare but serious muscle disorder in which destroyed muscle cells release into the bloodstream. The likelihood of this warned-about side effect appeared to increase when Baycol was prescribed at higher doses, or in conjunction with gemfibrozil, another cholesterol-lowering drug. In July

[1]Statins are a class of drugs which inhibit HMG-CoA reductase, an enzyme that plays a central role in the production of cholesterol in the liver.

2001, the FDA asked Bayer to address these concerns about Baycol. Bayer voluntarily withdrew Baycol from the market in August 2001.

Laurie Simpson worked at Bayer from 1998 through 2004 as a manager of market research. While at Bayer, Simpson's work involved marketing Baycol. In October 2006, relying in large part upon information to which she was privy during her time at Bayer, Simpson filed a *qui tam* action against Bayer as a relator on behalf of the government. She alleged Bayer knew about, but downplayed, the risks of developing rhabdomyolysis through the use of Baycol. She also alleged Bayer misrepresented Baycol's efficacy when compared to competing cholesterol-lowering drugs sold by other manufacturers (such as Lipitor), and paid illegal kickbacks to physicians to increase Bayer's share of the market for statin drugs.

Part of Simpson's initial lawsuit was dismissed for lack of jurisdiction on the grounds Simpson was not the original source of her allegations. See 31 U.S.C. § 3730(e)(4)(A) (indicating courts lack jurisdiction over an FCA claim unless the relator is "an original source of the information"). Some of her allegations – those involving payments the government made before October 2000 – were also dismissed because they were barred by the FCA's six-year statute of limitations. The district court initially dismissed the remainder of Simpson's suit without prejudice for failing to plead fraud with particularity, but gave Simpson a chance to cure the deficiencies by filing an amended complaint, which Simpson filed. This appeal concerns what was left of Simpson's suit.

In this second amended complaint (SAC), Simpson alleged Bayer defrauded the government in two distinct respects. First, Simpson alleged Bayer fraudulently caused the government to make reimbursements for Baycol prescriptions through federal health insurance programs such as Medicare and Medicaid, asserting that "had the Government known the full truth [about Baycol] it would not have paid the [reimbursement] claims." SAC at ¶ 266; Appellant's App. at A-128. Simpson also

alleged Bayer fraudulently induced the DoD to enter into two contracts for the purchase of Baycol to be prescribed to members of the armed services by physicians working at Military Treatment Facilities. We will first summarize Simpson's allegations regarding the DoD contracts.

A. The DoD Contracts

The DoD reached an initial agreement with Bayer for the purchase of Baycol on October 1, 1999. The initial DoD contract called for Bayer to sell Baycol to the military for an 18-month term in three different dosages (0.2 mg, 0.3 mg, and 0.4 mg) at a price of $.30 per tablet. This initial contract had an estimated base value per year of $11,505,000, and provided the military with an option to renew for two separate one-year extensions. If the DoD exercised its option to renew, the per tablet price would increase to $.31 per tablet the first year (for an estimated base value of $11,888,500), and to $.32 per tablet the second year (for an estimated base value of $12,272,000). Id. at ¶ 72; Appellant's App. at A-70.

After entering into the initial contract with Bayer, the DoD became concerned about the connection between rhabdomyolysis and Baycol, and contacted Bayer regarding those concerns. Simpson alleged that on November 10, 1999, Casimir Zygmunt, a Baycol representative at Bayer, responded to inquiries made by Lieutenant Commander Richerson, the DoD's point of contact for the DoD Statin Award Implementation Plan, about Baycol's safety with respect to the risk of rhabdomyolysis. Simpson alleged Zygmunt told the DoD there is "[n]o evidence to suggest Baycol causes more rhabdo then (sic) others – it is a class effect." Id. at ¶ 107; Appellant's App. at A-77. Simpson alleged this was "a false statement because Bayer did possess evidence at the time ***suggesting*** that Baycol did cause more rhabdomyolysis than other statins." Id. (Emphasis in original).

Paragraphs 108 through 120 of the SAC further describe the contacts between Bayer and the DoD over the latter's concern about the frequency or severity of rhabdomyolysis associated with Baycol. For example, in a letter Bayer sent to the DoD on December 3, 1999, Simpson alleges Bayer falsely stated "there are insufficient data upon which to base a dose-response relationship" between the frequency or severity of rhabdomyolysis and the use of Baycol. Id. at ¶ 112; Appellant's App. at A-78. Simpson alleged this was a false statement because "Bayer was aware at the time that there was in fact a dose-response relationship with Baycol's adverse side-effects." Id.

On January 20, 2001, the DoD renewed the original contract with Bayer and extended the period of performance from February 20, 2001, through February 19, 2002, for an estimated dollar value of $11,888,500.[2] Id. at ¶ 80; Appellant's App. at A-71. In addition, on February 20, 2001, the DoD agreed to purchase a higher dosage of Baycol from Bayer (0.8 mg tablet) under a Blanket Purchase Agreement (BPA). Under the BPA, Bayer sold 0.8 mg tablets of Baycol to the military at a discounted price of $15.00 for 30 tablets, and $45.00 for 90 tablets. Id. at ¶ 96; Appellant's App. at A-74.

Simpson alleged the January 2001 contract extension and the February 2001 BPA were fraudulently induced by the false statements Bayer made about Baycol's effectiveness and connection to rhabdomyolysis. Simpson alleged that "[i]f the DoD and other prescribers had known the truth (which DoD attempted to discover on multiple occasions), then it is unlikely the DoD would have entered into the contract with Bayer or would have extended the contract." Id. at ¶ 123; Appellant's App. at A-82.

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[2]The contract extension slightly modified the terms of the original contract, because the original contract was supposed to expire on March 31, 2001, not February 20, 2001.

Finally, as relevant to the January 2001 contract extension and February 2001 BPA, Simpson alleged that "[a]ccording to the DoD PEC [Pharmacoeconomic Center], there were approximately 400,000 Baycol prescriptions filled in MTFs [Military Treatment Facilities] during the period commencing October 2000 to the withdrawal of Baycol from the market [in August 2001]." Id. at ¶ 244; Appellant's App. at A-123. Simpson also alleged that "[f]rom October 2000 through the time of the withdrawal of Baycol from the market in August 2001, government agencies, under various contracts with Bayer for the supply of Baycol, including the DoD . . . paid Bayer at least $11,983,305.08 for their supplies of Baycol." Id. at ¶ 243. In other words, Simpson alleged Baycol was used by members of the armed services after Bayer allegedly fraudulently induced the DoD to enter into the January 2001 contract extension and February 2001 BPA, and further alleged the government made payments to Bayer pursuant to the allegedly fraudulently induced DoD contracts.

B. Federal Health Insurance Reimbursements

We next summarize Simpson's allegations regarding federal health insurance reimbursements. Simpson's SAC focused on a number of aspects of the manner in which Bayer generally marketed Baycol. Simpson alleged Bayer made false statements about Baycol's efficacy in lowering cholesterol when it introduced the drug into the general marketplace. Simpson further alleged Bayer misrepresented the risks of adverse side effects associated with Baycol. Simpson also alleged Bayer used illegal kickbacks to physicians to induce them to begin prescribing Baycol or to increase their prescriptions of Baycol.

Finally, as significant for purposes of this appeal, Simpson then alleged the general manner in which Bayer marketed Baycol was causally connected to payments the government made under Medicare, Medicaid, and the Federal Employees Health Benefits Program (FEHBP) when individuals participating in those programs received a prescription from a physician for Baycol, filled the prescription at a pharmacy, and

the pharmacy or individual submitted the prescription to the government for reimbursement through those federal health insurance programs. Simpson specifically alleged "the Government purchased and/or reimbursed significant quantities of Baycol when it would not otherwise have done so if Bayer had fully disclosed the truth regarding the safety of its drug." Id. at ¶ 266; Appellant's App. at A-128. Simpson further alleged "Bayer caused false claims to be submitted by patients and organizations because physicians relied on Bayer's assertions when they prescribed Bayer, thus causing false claims to be submitted to the Government[.]" Id.; Appellent's App. at A-129. Finally, Simpson alleged "had the Government known the full truth it would not have paid the claims." Id.

C. The Motion to Dismiss

Bayer moved to dismiss Simpson's SAC under Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure. Bayer contended in relevant part that Simpson's allegations were deficient because she did not include representative examples of false claims submitted for payment to the government. Bayer argued the particularity requirements of Rule 9(b) require a relator to allege representative false claims in order to survive a motion to dismiss, citing this court's decisions in United States ex rel. Vigil v. Nelnet, Inc., 639 F.3d 791 (8th Cir. 2001); United States ex rel. Joshi v. St. Luke's Hospital, 441 F.3d 552 (8th Cir. 2006); and United States v. ex rel. Roop v. Hypoguard USA, Inc., 559 F.3d 818 (8th Cir. 2009). The district court agreed with Bayer's arguments and granted the motion to dismiss. This timely appeal followed.

II

We apply de novo review to a district court's decision to dismiss a complaint under Rules 9(b) or 12(b)(6) of the Federal Rules of Civil Procedure. Summerhill v. Terminix, Inc., 637 F.3d 877, 880 (8th Cir. 2011).

Originally enacted in response to "unscrupulous Civil War defense contractors," Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp., 276 F.3d 1032, 1041 (8th Cir. 2002), the FCA serves a "specific function, protecting the federal fisc by imposing severe penalties on those whose false or fraudulent claims cause the government to pay money[.]" Vigil, 639 F.3d at 795–96. The Act allows private individuals (i.e., relators) to bring a civil action in the name of the United States against those who violate the Act's provisions. 31 U.S.C. § 3730(b)(1).

The FCA "is not concerned with regulatory noncompliance," but with false or fraudulent claims that cause the government to pay money. Vigil, 639 F.3d at 795-96. As a result, the FCA carefully defines the conduct it prohibits. The Act's "core provisions," id. at 796, make any person liable who "(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, 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)(1)–(2).[3] The FCA defines "claim" to include "any request or demand … for money or property which is made to a contractor, grantee, or other recipient if" the United States either "provides any portion of the money or property which is requested or demanded," or "will reimburse such [entity] for any portion of the money or property which is requested or demanded." Id. § 3729(c).

The FCA generally "attaches liability, not to the underlying fraudulent activity, but to the claim for payment." Costner v. URS Consultants, Inc., 153 F.3d 667, 677 (8th Cir. 1998). Accordingly, the general elements of a case under the FCA are "that

[3]Congress renumbered and amended § 3729(a) in response to the Supreme Court's interpretation of § 3729(a)(2) in Allison Engine Co. v. United States ex rel. Sanders, 553 U.S. 662, 665 (2008). See Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111–21, § 4(a)(1), 123 Stat. 1617, 1621–22. This amendment does not apply retroactively to this case because none of the allegedly false claims here were pending in 2008.

(1) the defendant made a claim against the United States; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." United States ex rel. Raynor v. Nat'l Rural Util. Coop. Fin. Corp., 690 F.3d 951, 955 (8th Cir. 2012).

With these general principles in mind, we turn to the two distinct theories of "false claims" Simpson alleged in her SAC – those involving the DoD contracts and those involving government reimbursements under federal health insurance programs.

A. The DoD Contracts

Simpson's SAC alleged that Bayer fraudulently induced the DoD to enter into the January 2001 contract extension, and the February 2001 BPA for 0.8 mg tablets of Baycol, by making allegedly false representations about Baycol's safety with respect to the risk of rhabdomyolysis.[4]

In granting Bayer's motion to dismiss, the district court applied the same analysis to both the allegations involving the fraudulently-induced DoD contracts and

[4]Bayer argues Simpson's SAC did not plead a claim of fraudulent inducement because she did not use the label "fraud-in-the inducement" in the complaint. We are not concerned, however, with the labels a party attaches to a claim. Instead, we focus on the substance of the underlying factual allegations. See Mut. Creamery Ins. Co. v. Iowa Nat'l Mut. Ins. Co., 427 F.2d 504, 508 (8th Cir. 1970) ("[P]leadings must be construed favorably to the pleader and judged by substance rather than form."); Kutten v. Bank of Am., N.A., 530 F.3d 669, 670 (8th Cir. 2008) ("[W]e do not rely on the names of the causes of action that the plaintiff alleges. Instead we look at the substance of the allegations, based on a fair reading."); see also Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007) (noting the importance of examining the factual allegations when addressing a Rule 12(b)(6) motion to dismiss, rather than the "labels and conclusions [or] formulaic recitation of the elements of a cause of action").

the allegations involving the federal health insurance reimbursements. In part, the district court concluded Simpson's allegations were insufficient on both claims because she did not tie her allegations of Bayer's fraud to specific fraudulent claims for payment submitted to the government. The district court reasoned:

> [T]he fact that a patient covered by a federal or state funded health care program was prescribed Baycol to lower his/her cholesterol is not, in and of itself, false or fraudulent. . . . A claim under the FCA focuses on the claims, not the underlying fraudulent activity. Because there are no allegations in the SAC that a claim submitted to the government for payment for Baycol, was – in and of itself – fraudulent or false, [Simpson] has failed to sufficiently plead a claim under the FCA.

In re Baycol Prods. Litig., No. 08-5758, 2012 WL 5358333 at *6 (D. Minn. July 19, 2012). Contrary to the district court's reasoning, a claim alleging fraud in the inducement of a government contract does focus on the false or fraudulent statements which induced the government to enter into the contract at the outset. We therefore conclude the district court's reasoning was incorrect as applied to Simpson's allegations regarding the DoD contracts.

The Supreme Court first recognized fraud-in-the-inducement as a viable theory of FCA liability in 1943 in United States ex rel. Marcus v. Hess, 317 U.S. 537 (1943). Hess involved claims submitted by government contractors who had engaged in collusive bidding. The Supreme Court found FCA liability for each claim submitted to the government under a contract so long as the original contract was obtained through false statements or fraudulent conduct:

> This fraud did not spend itself with the execution of the contract. Its taint entered into every swollen estimate which was the basic cause for payment of every dollar paid by the [government]. . . . The initial fraudulent action and every step thereafter taken, pressed ever to the

> ultimate goal—payment of government money to persons who had caused it to be defrauded.

Id. at 543-44.

The legislative history of the FCA also supports the conclusion that fraud-in-the-inducement is a recognized theory of liability under the Act. "Specifically, [in amending the FCA in 1986,] Congress noted that, under FCA case law, 'each and every claim submitted under a contract, loan guarantee, or other agreement which was originally obtained by means of false statements or other corrupt or fraudulent conduct, or in violation of any statute or applicable regulation, constitutes a false claim.'" United States ex rel. Bettis v. Odebrecht Contractors of Cal., Inc., 393 F.3d 1321, 1326 (D.C. Cir. 2005) (quoting S. Rep. No. 99–345, at 9 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5274).

Thus, when a relator alleges liability under a theory of fraud-in-the inducement, claims for payment subsequently submitted under a contract initially induced by fraud do not have to be false or fraudulent in and of themselves in order to state a cause of action under the FCA. See, e.g., United States ex rel. Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 788 (4th Cir. 1999) ("Contrary to the district court's decision, in many of the [fraud-in-the-inducement] cases cited above the claims that were submitted were not in and of themselves false. . . . False Claims Act liability attached, however, because of the fraud surrounding the efforts to obtain the contract or benefit status, or the payments thereunder."); see also Claire M. Sylvia, The False Claims Act: Fraud Against the Government § 4:29 (April 2013) ("A fraudulent effort to obtain a contract, sometimes called 'fraud in the inducement,' can constitute a false or fraudulent claim for payment or approval.").

Based upon our review of Simpson's allegations regarding the DoD contracts, we conclude her complaint sufficiently "identif[ies] the 'who, what, where, when, and

how' of the alleged fraud," Joshi, 441 F.3d at 556, to satisfy Rule 9(b)'s requirements and survive a motion to dismiss under Rule 12(b)(6). Simpson's allegations identify (1) the individuals involved in the exchange between Bayer and the DoD regarding the DoD's concerns about Baycol's safety with respect to the risk of rhabdomyolysis (i.e., Casimir Zygmunt for Bayer and Lieutenant Commander Richerson for the DoD); (2) the alleged misrepresentations regarding whether Baycol causes more rhabdomyolysis than other statins, and whether a relationship exists between prescribing Baycol at higher dosages and the frequency or severity of rhabdomyolysis; (3) the dates when the alleged misrepresentations were made (e.g., November 10, 1999 and December 3, 1999) and the manner in which the alleged misrepresentations were made; and (4) the specific reasons why the representations were alleged to be fraudulent (i.e., because Bayer allegedly possessed evidence to know the representations were false at the time they were made).

In addition, Simpson connected her allegations regarding the alleged fraud to the January 2001 contract extension and the February 2001 BPA and alleged that "[i]f the DoD and other prescribers had known the truth (which DoD attempted to discover on multiple occasions), then it is unlikely the DoD would have entered into the contract with Bayer or would have extended the contract." Finally, Simpson's complaint alleges the government made payments to Bayer under the allegedly fraudulently induced contracts, claiming there were approximately 400,000 Baycol prescriptions filled in Military Treatment Facilities between October 2000 and the withdrawal of Baycol from the market in August 2001, and the government paid Bayer at least $11,983,305.08 for their supplies of Baycol during that same time period.[5]

[5]We note the temporal relationship between Simpson's allegations and the two DoD contracts at issue is not a perfect fit. The SAC focused on the approximate ten-month period between the running of the statute of limitations in October 2000 and the withdrawal of Baycol from the market in August 2001, rather than the approximate seven-month period between the effective dates of the two DoD

We fail to see how these allegations are insufficient to state a claim for relief under a theory of fraud-in-the-inducement. We therefore reverse the district court with respect to the allegations regarding the DoD contracts, and remand for further proceedings consistent with this opinion.[6]

B. The Federal Health Insurance Reimbursements

Unlike the DoD contracts we have just discussed, there is no direct contractual relationship between the government and Bayer with respect to Simpson's allegations regarding reimbursements under federal health insurance programs. Thus, Simpson's reimbursement claims do not involve an allegedly fraudulently-induced contract

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contracts and the withdrawal of Baycol from the market. It would be unreasonable to infer, however, that *all* 400,000 prescriptions described in the SAC were filled prior to the effective dates of the two DoD contracts in early 2001, and that *no* prescriptions were filled thereafter until the withdrawal of Baycol from the market in August 2001. Likewise, it would be unreasonable to infer that *all* the government payments Simpson alleges took place in the ten-month period between October 2000 and August 2001 were made prior to the effective dates of the two DoD contracts, and that *no* funds were paid by the government after the contracts became effective. Thus, the SAC still clearly alleges Baycol prescriptions were filled at Military Treatment Facilities after the two contracts became effective, and that the government made payments to Bayer pursuant to the contracts. The lack of a perfect fit between the specific amounts alleged in the SAC and the effective dates of the DoD contracts is not fatal to the question whether Simpson stated a claim for relief.

[6]On appeal, Bayer urges us to affirm the district court's dismissal of the allegations involving the DoD contracts on a number of alternative grounds that have not yet been addressed by the district court. We believe it more prudent to allow the district court to address those issues in the first instance. See, e.g., Lafarge North Am., Inc. v. Discovery Grp. L.L.C., 574 F.3d 973, 986 fn.9 (8th Cir. 2009) ("Because we believe it would be beneficial for the district court to address these issues in the first instance, we decline to affirm on these alternative theories.").

where claims for payment subsequently submitted under a government contract initially induced by fraud do not have to be false or fraudulent in and of themselves in order to state a cause of action under the FCA. Instead, Simpson alleged Bayer's misleading marketing scheme caused third parties to submit false claims to the government. See 31 U.S.C. § 3729(a)(1)(A) (extending FCA liability to any person who "*causes* to be presented, [to a federal official] a false or fraudulent claim for payment or approval") (emphasis added); see also United States v. Hawley, 619 F.3d 886, 892 (8th Cir. 2010) (noting a claim under the FCA "need not be made directly to the government; it may include a request or demand that was originally made to a contractor, grantee, or other recipient of federal funds and then forwarded to the Government") (internal quotation marks and citation omitted); Claire M. Sylvia, The False Claims Act: Fraud Against the Government § 4:2 (April 2013) ("Subsection (a)(1)(A) imposes liability not only on a person who 'presents' a false or fraudulent claim, but also on a person who causes another to present a false or fraudulent claim.").

With respect to these reimbursement claims, the district court noted Simpson's SAC failed to identify any specific false claims submitted by Bayer to the government and explained that cases "decided by the Eighth Circuit post-Joshi reaffirm this Court's previous finding that particularized allegations of representative false claims are required to properly assert a claim under the FCA." In re Baycol, 2012 WL 5358333 at *5.

The district court also compared Simpson's SAC to the complaint found deficient in Roop, 559 F.3d 818. As explained by the district court, Roop involved a relator who alleged a defendant's manufacture and sale of defective glucose monitors and test strips caused the government to pay fraudulent reimbursement claims under Medicare. We held the relator failed to state a claim under the FCA for a number of reasons, including the circumstance that the relator "failed to . . . identify specific false or fraudulent Medicare reimbursement claims by Hypoguard

distributors[.]" Roop, 559 F.3d at 824. Roop affirmed the district court's dismissal of the complaint because the relator merely conclusorily alleged the government would not have paid Medicare reimbursement claims if they had known of the defects in the glucose monitors and test strips. Id. at 825.

The district court said Simpson's SAC was similarly deficient because she merely "asserts that had the government known of Bayer's misrepresentations and omissions concerning the risks associated with Baycol, the government would not have paid any claims submitted under . . . federal and state health insurance programs." In re Baycol, 2012 WL 5358333 at *6. The district court reasoned that Simpson failed to make any allegations connecting a government decision to pay Baycol to any alleged fraud because the mere "fact that a patient covered by a federal or state funded health care program was prescribed Baycol to lower his/her cholesterol is not, in and of itself, false or fraudulent." Id. The district court concluded "[b]ecause there are no allegations in the SAC that a claim submitted to the government for payment for Baycol, was – in and of itself – fraudulent or false, Relator has failed to sufficiently plead a claim under the FCA." Id.

With respect to Simpson's federal health insurance reimbursement claims, we agree with the district court that the pleadings in Simpson's SAC were inadequate to state a cause of action under the FCA because she did not include at least some representative examples of false claims with respect to Bayer's alleged scheme involving federal health insurance reimbursements, or show how any particular reimbursement claim was fraudulent in and of itself.

In Vigil, we said "[w]ithout sufficient allegations of materially false claims, an FCA complaint fails to state a claim on which relief may be granted." 639 F.3d at 796. As relevant to the issue of pleading representative false claims, we later stated with even more clarity in Joshi that a relator must "plead some representative examples [of false claims] within the statute of limitations." 441 F.3d at 560. Joshi

found persuasive the reasoning of the Eleventh Circuit in Corsello v. Lincare, Inc., 428 F.3d 1008 (11th Cir. 2005). That case related to an underlying fraudulent scheme where certain health care corporations were allegedly submitting false Medicare claims to the government by falsifying certificates of medical necessity or billing for unnecessary or nonexistent treatment. Similar to Simpson, the relator in Corsello relied upon his allegations of the underlying scheme to argue false claims must have been submitted to the government, but did not include allegations of specific false claims actually submitted to the government for payment. The Eleventh Circuit dismissed the relator's complaint for failure to plead fraud with the particularity required by Rule 9(b). Id. at 1013-14. Applying the same reasoning to the relator's allegations in Joshi, we concluded a relator could not rely merely upon allegations of the underlying scheme to argue all claims submitted for payment to the government pursuant to the scheme were fraudulent because "all the nurse anesthetists' work was illegal" and thus "every invoice for nurse anesthetist work was fraudulent[.]" Joshi, 441 F.3d at 556. Instead, we said

> to satisfy Rule 9(b)'s particularity requirement and to enable St. Luke's and Dr. Bashiti to respond specifically to Dr. Joshi's allegations, Dr. Joshi must provide *some* representative examples of their alleged fraudulent conduct, specifying the time, place, and content of their acts and the identity of the actors. Dr. Joshi's complaint is void of a single, specific instance of fraud, much less any representative examples. Thus, the district court properly dismissed Dr. Joshi's complaint for failure to comply with Rule 9(b).

Id. at 557. (Emphasis in original).

Finally, in Roop we dealt with allegations similar to the fraudulent scheme alleged by Simpson because the case involved a defendant who – by manufacturing and marketing a defective medical product – allegedly caused third parties to submit false Medicare reimbursement claims to the government. 559 F.3d at 820. Again, we

held that allegations regarding the underlying scheme were insufficient to state a claim for relief without pleading representative examples of some false reimbursement claims submitted to the government:

> 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. Nor did it allege with particularity how any product defect or failure to submit MDR[7] 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. 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).

Id. at 824-25 (internal citations omitted).

We conclude this case is controlled by our decisions in Joshi and Roop. Simpson alleged that all federal health insurance reimbursement claims submitted by third parties to the government for Baycol prescriptions were false or fraudulent because of the misleading and deceptive manner in which Bayer marketed Baycol. She did not, however, plead at least some representative examples of actual reimbursement claims submitted to the government pursuant to the underlying allegedly fraudulent marketing scheme, or establish how such reimbursement claims were false in and of themselves. Instead, she relied upon a general allegation that the government would not have paid any of the reimbursement claims submitted under the federal health insurance programs had it known of Bayer's underlying allegedly fraudulent marketing scheme. We conclude this allegation is indistinguishable, for

[7]Medical Device Reporting.

all material purposes, from the allegation we found lacking in Roop. We therefore affirm the district court with respect to the allegations involving federal health insurance reimbursement claims.[8]

III

We affirm the district court's dismissal of the claims relating to the federal health insurance reimbursements. We reverse the district court's dismissal of the claims involving the DoD contracts, and remand this case for further proceedings consistent with this opinion.

LOKEN, Circuit Judge, concurring in part and dissenting in part.

I concur in the court's cogent description of this dispute and its procedural history. I join Part II.B. of its opinion, which affirms the dismissal of relator's FCA claims relating to federal health insurance reimbursements. In Part II.A., I agree with the conclusions that relator sufficiently pleaded fraud in the inducement of the 2001 DoD contracts, and that fraud in the inducement is "a viable theory of FCA liability" established by the Supreme Court's decision in United States ex rel. Marcus v. Hess, 317 U.S. 537 (1943). But in my view, the court ends the analysis in Part II.A. prematurely, failing to take into account that *this particular* fraud-in-the-inducement claim suffers from the same Rule 9(b) inadequacy as the FCA complaint in United

[8]Simpson also appeals the district court's refusal to give her another chance to amend her complaint to state an actionable claim with respect to the federal health insurance reimbursement claims. We conclude the district court did not abuse its discretion in denying the request, because Simpson failed to provide the district court with a copy of her proposed third amended complaint, as required by Local Rule 15.1 of the District of Minnesota. See Drobnak v. Andersen Corp., 561 F.3d 778, 787 (8th Cir. 2009) (concluding a district court does not abuse its discretion when it denies leave to amend where a plaintiff does not comply with Local Rule 15.1 of the District of Minnesota).

States ex rel. Joshi v. St. Luke's Hospital, Inc. -- the implicit allegation "that 'every' claim submitted by [Bayer] was fraudulent lacks sufficient 'indicia of reliability.'" 441 F.3d 552, 557 (8th Cir.), cert. denied, 127 S. Ct. 189 (2006). Accordingly, I respectfully dissent from the decision to reverse the district court's dismissal of the DoD contract claims.

It is hornbook law that, to warrant recovery of damages for fraud in the inducement, "it must appear, not only that injury has been suffered, but that the fraud complained of was the proximate cause of the injury." Boatmen's Nat'l Co. v. M. W. Elkins & Co., 63 F.2d 214, 216-17 (8th Cir. 1933) (applying federal law and affirming a directed verdict for defendant on this ground). In the typical dispute between private parties, a well-pleaded claim of fraud in the inducement needs no specific allegation of injury; the fraudulently induced contract is itself harm likely entitling the plaintiff at least to the remedy of rescission. But FCA claims are not typical disputes. As the court recognizes, the FCA "generally attaches liability, not to the underlying fraudulent activity, but to the claim for payment." Supra p.8 (quotation omitted). In my view, when the underlying fraud is fraud in the inducement, this necessarily requires plaintiff to plead some nexus between the fraud that induced the contract, and the subsequent claims for payment under the contract. This is not unlike the need to plausibly allege that a false certification of compliance with the requirements of a government program was material to the government's decision to pay a particular claim. See United States ex rel. Vigil v. Nelnet, Inc., 639 F.3d 791, 799-800 (8th Cir. 2011); United States ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 308-11 (3d Cir. 2011).

The court ends its truncated analysis of this factor with the Supreme Court's ruling in Hess that the "taint [of fraudulent inducement] entered into every swollen estimate which was the basic cause for payment of every dollar paid." Supra p.10, quoting 317 U.S. at 543. But in Hess, the fraud was undisclosed collusive bidding, a fraud the very purpose of which was to ensure that the government paid inflated

claims submitted under the fraudulently induced contract. Likewise, in the few published cases that have upheld fraud-in-the-inducement FCA claims, the fraud ensured that the government would pay inflated claims, or would otherwise not receive the financial benefit of its bargain. See United States ex rel. Longhi v. Lithium Power Tech., Inc., 575 F.3d 458, 473 (5th Cir. 2009) (the government's benefit of the bargain, "to award money to eligible deserving small businesses . . . was lost as a result of the Defendant's fraud" in inducing the grants), cert. denied, 130 S. Ct. 2092 (2010); Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 791-94 (4th Cir. 1999) (fraud that allegedly induced paying more to a subcontractor survived Rule 12(b)(6) dismissal); Murray & Sorenson, Inc. v. United States, 207 F.2d 119, 123 (1st Cir. 1953) (fraud "increasing the price which the government eventually has to pay").

By contrast, the fraud in the inducement alleged by Simpson -- failing to disclose a known risk to patients prescribed Baycol -- did not *necessarily* have the effect of increasing the amounts paid for reimbursement of claims submitted under the DoD contracts. The only damage allegation relating to the DoD contracts in Simpson's 92-page Second Amended Complaint was that "the Government paid money to Bayer for a drug that it would not have purchased had it known the full truth." But that was harm resulting from the underlying fraud, not a plausible allegation that the government was harmed by paying false claims under the DoD contracts. With or without the contracts at issue, DoD physicians would have prescribed statin drugs to military personnel who needed to lower their cholesterol. There is no allegation that DoD paid more for Baycol than it would have paid for a different statin. There is no allegation that the government paid damages to DoD patients who were prescribed Baycol and developed rhabdomyolysis. For this reason, Simpson failed to state a plausible FCA claim simply by alleging fraud in the inducement. To plead *this alleged fraud* with the particularity Rule 9(b) requires, she needed to allege specific harm resulting from specific false claims submitted under the fraudulently induced DoD contracts. "[A]llegations of product defects and

consumer injury" do not cure deficiencies in an FCA complaint. United States ex rel. Roop v. Hypoguard USA, Inc., 559 F.3d 818, 824 (8th Cir. 2009).

An FCA relator such as Simpson has Article III standing only because Congress in the FCA *partially* assigned the government's damage claim for the "injury in fact" allegedly suffered when it pays a false claim. Vermont Agency of Natural Res. v. United States ex rel. Stevens, 529 U.S. 765, 773 & n.4 (2000). Here, Simpson alleged no injury in fact to the government, only that Bayer improperly benefitted from fraudulently inducing the DoD contracts. If true, that undoubtedly caused "injury to [the government's] sovereignty arising from violation of its laws." Id. at 771. But a claim for that injury lies beyond what the government assigned to Simpson in the FCA. Accord United States ex rel. Willard v. Humana Health Plan, Inc., 336 F.3d 375, 386 (5th Cir. 2003) ("[T]he government must suffer an injury in fact for there to be standing."). Accordingly, I would affirm dismissal of her DoD contract claims.
