PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

UNITED STATES ex rel. NOAH NATHAN, On Behalf Of The United States Government and the States, *Plaintiff-Appellant,* v. TAKEDA PHARMACEUTICALS NORTH AMERICA, INCORPORATED; TAKEDA PHARMACEUTICALS AMERICA, INCORPORATED, *Defendants-Appellees.*	No. 11-2077

Appeal from the United States District Court
for the Eastern District of Virginia, at Alexandria.
Anthony J. Trenga, District Judge.
(1:09-cv-01086-AJT-JFA)

Argued: October 25, 2012

Decided: January 11, 2013

Before MOTZ and KEENAN, Circuit Judges, and
James K. BREDAR, United States District Judge
for the District of Maryland,
sitting by designation.

Affirmed by published opinion. Judge Keenan wrote the opinion, in which Judge Motz and Judge Bredar joined.

COUNSEL

ARGUED: Jeffrey A. Lamken, MOLOLAMKEN, LLP, Washington, D.C., for Appellant. William F. Cavanaugh, Jr., PATTERSON, BELKNAP, WEBB & TYLER, New York, New York, for Appellees. **ON BRIEF:** Michael G. Pattillo, Jr., Martin V. Totaro, MOLOLAMKEN, LLP, Washington, D.C., for Appellant. Susan R. Podolsky, THE LAW OFFICES OF SUSAN R. PODOLSKY, Alexandria, Virginia; Daniel S. Ruzumna, Sean H. Murray, Aileen M. McGill, PATTERSON, BELKNAP, WEBB & TYLER, New York, New York, for Appellees.

OPINION

BARBARA MILANO KEENAN, Circuit Judge:

Noah Nathan (Relator), a sales manager for Takeda Pharmaceuticals (Takeda), brought this *qui tam* action against his employer under the False Claims Act (the Act), 31 U.S.C. §§ 3729 through 3733. Relator alleges that Takeda violated § 3729(a)(1)(A) of the Act by causing false claims to be presented to the government for payment under Medicare and other federal health insurance programs.[1] After allowing Relator to file a third amended complaint (the amended complaint), the district court dismissed Relator's claims under Federal Rule of Civil Procedure 12(b)(6). In this appeal, Relator argues that the district court erred in concluding that Relator did not plausibly allege in the amended complaint that false claims had been presented to the government for payment, or that Takeda caused the presentment of any such false claims. Relator also contends that the district court abused its discretion in denying Relator's request for leave to file a fourth amended complaint.

[1]Relator does not appeal the district court's dismissal of Relator's separate claim brought under 31 U.S.C. § 3729(a)(1)(B).

Upon our review, we hold that the district court did not err in dismissing the amended complaint, because Relator failed to plausibly allege that any false claims had been presented to the government for payment. We further hold that the district court did not abuse its discretion in denying Relator leave to file a fourth amended complaint.

I.

Among other things, the Act prohibits any person from knowingly "caus[ing] to be presented" to the government false claims for payment or approval. 31 U.S.C. § 3729(a)(1)(A). A false statement is actionable under the Act only if it constitutes a "false or fraudulent *claim*." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999) (emphasis added). Importantly, to trigger liability under the Act, a claim actually must have been submitted to the federal government for reimbursement, resulting in "a call upon the government fisc." *Id.*; *see also Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1325-26 (11th Cir. 2009).

Relator alleges in the amended complaint that prescriptions written for certain medical uses, which have not been approved by the Food and Drug Administration (the FDA) or included in statutorily specified compendia, are not reimbursable under federal health insurance programs. Such uses commonly are referred to as "off-label" uses. Relator further alleges that because the cost of prescriptions for off-label uses is not subject to reimbursement by the federal government, the presentment of these types of claims for payment constitutes a violation of the Act.[2]

[2]Nevertheless, physicians are permitted to prescribe drugs for off-label uses. *See* 21 U.S.C. § 396. However, under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, pharmaceutical companies are not permitted to promote their drugs for uses not approved by the FDA. *See Wash. Legal Found. v. Henney*, 202 F.3d 331, 332-33 (D.C. Cir. 2000).

In the amended complaint, Relator additionally alleges that Takeda marketed its prescription drug Kapidex, a proton pump inhibitor used to treat various gastric conditions, for off-label uses.[3] Relator alleges that two of Takeda's marketing practices caused presentation of false claims to the government. The identified marketing practices were: (1) Takeda's promotion of Kapidex to rheumatologists, who typically do not treat patients having conditions for which Kapidex has been approved; and (2) Takeda's practice of marketing high doses of Kapidex for the treatment of conditions for which only a lower dose has been approved by the FDA.

In particular, Relator alleges that 60 mg doses of Kapidex have been approved by the FDA only for the treatment of the active condition of erosive esophagitis (EE). However, Kapidex has been approved by the FDA at a lower 30 mg dose to treat the more common condition of gastroesophogeal reflux disease (GERD), as well as for the maintenance of already "healed" cases of EE. Relator alleges that Takeda has provided doctors with samples of Kapidex exclusively in 60 mg doses, irrespective whether such physicians treat active cases of EE. As Relator further alleges, by this sampling practice, Takeda improperly implies that a 60 mg dose of Kapidex is the only available dosage of that drug, thereby causing doctors to prescribe 60 mg doses for unapproved conditions.[4] Relator also alleges that Takeda sales representatives regularly misled physicians by deflecting or dismissing their questions about proper dosages, and by making misrepresentations concerning the available dosages.

Additionally, Relator alleges that the motivation for Take-

[3]Relator alleges that Kapidex has been renamed Dexilant. Because the amended complaint refers to the drug at issue exclusively as Kapidex, we do the same here.

[4]Relator alleges that although Takeda sought government approval for higher dosages of Kapidex, including a 60 mg dose to treat GERD, the Food and Drug Administration rejected this request.

da's alleged fraudulent marketing stems from Takeda's desire to replicate the success of its previously approved drug, Prevacid, the patent for which was set to expire in 2009. Prevacid has been approved to treat 13 conditions, including GERD. Prevacid also has been approved to provide gastric protection and to treat gastric ulcers, indications relevant to rheumatology patients who regularly take anti-inflammatory pain medications. In contrast, Kapidex is not approved for these two conditions. Relator alleges that because the patent expiration date for Prevacid was approaching, Takeda promoted Kapidex to "fill the Prevacid void."

The district court dismissed the amended complaint on two independent grounds: (1) the amended complaint failed to allege the "presentment" of a false or fraudulent claim to the government for payment or approval under 31 U.S.C. § 3729(a)(1)(A); and (2) the amended complaint failed to allege adequately that Takeda "caused" the issuance of off-label prescriptions.[5] The district court also denied Relator's request to amend his complaint for a fourth time. Because we conclude that the district court properly dismissed the amended complaint based on Relator's failure to allege presentment of a false claim, we do not reach the additional question whether Relator alleged sufficient facts to support the required causation element for a claim asserted under the Act. We further hold that the district court did not abuse its discretion in denying Relator's motion for leave to file a fourth amended complaint.

II.

We review de novo the district court's dismissal of a complaint for failure to state a claim under Fed. R. Civ. P. 12(b)(6). *Harrison*, 176 F.3d at 783. To survive a Rule

[5]Because Relator does not appeal the district court's decision declining to exercise supplemental jurisdiction over Relator's state law claims, we do not address those claims here.

12(b)(6) motion to dismiss, a complaint must "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). Facts that are "merely consistent with" liability do not establish a plausible claim to relief. *Id.* (citation omitted). In addition, although we must view the facts alleged in the light most favorable to the plaintiff, we will not accept "legal conclusions couched as facts or unwarranted inferences, unreasonable conclusions, or arguments." *Wag More Dogs, LLC v. Cozart*, 680 F.3d 359, 365 (4th Cir. 2012) (citation and internal quotation marks omitted).

Before addressing the substantive allegations in the amended complaint, we first state the pleading requirements for fraud-based claims brought under the Act. In addition to meeting the plausibility standard of *Iqbal*, fraud claims under the Act must be pleaded with particularity pursuant to Rule 9(b) of the Federal Rules of Civil Procedure. *Harrison*, 176 F.3d at 783-85. Rule 9(b) provides:

> In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally.

To satisfy Rule 9(b), a plaintiff asserting a claim under the Act "must, at a minimum, describe the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008) (citation and internal quotation marks omitted).

The parties dispute the proper application of Rule 9(b) in this case. In Relator's view, to meet the requirements for pleading a fraud claim under the Act, a relator need only allege the existence of a fraudulent scheme that supports the inference that false claims were presented to the government

for payment. In contrast, Takeda argues that Rule 9(b) requires that a relator plead facts plausibly alleging that particular, identifiable false claims actually were presented to the government for payment.

In view of the rationale underlying Rule 9(b), we decline to adopt Relator's argument for a more lenient application of the Rule. We have adhered firmly to the strictures of Rule 9(b) in applying its terms to cases brought under the Act. *See, e.g.*, *Wilson*, 525 F.3d at 379-80 (explaining the requirements of Rule 9(b) and affirming dismissal for failing to comply); *Harrison*, 176 F.3d at 784, 789-90 (same). The multiple purposes of Rule 9(b), namely, of providing notice to a defendant of its alleged misconduct, of preventing frivolous suits, of "eliminat[ing] fraud actions in which all the facts are learned after discovery," and of "protect[ing] defendants from harm to their goodwill and reputation," *Harrison*, 176 F.3d at 784 (citation omitted), are as applicable in cases brought under the Act as they are in other fraud cases. Indeed, such purposes may apply with particular force in the context of the Act, given the potential consequences flowing from allegations of fraud by companies who transact business with the government. Moreover, we have emphasized that a claim brought under the Act that "rest[s] primarily on facts learned through the costly process of discovery . . . is precisely what Rule 9(b) seeks to prevent." *Wilson*, 525 F.3d at 380; *see also Harrison*, 176 F.3d at 789. For these reasons, nothing in the Act or in our customary application of Rule 9(b) suggests that a more relaxed pleading standard is appropriate in this case.

Neither are we persuaded by Relator's contention that allegations of a fraudulent scheme, in the absence of an assertion that a specific false claim was presented to the government for payment, is a sufficient basis on which to plead a claim under the Act in compliance with Rule 9(b). As the Supreme Court has cautioned, the Act "was not designed to punish every type of fraud committed upon the government." *Harrison*, 176 F.3d at 785 (citing *United States v. McNinch*, 356 U.S. 595,

599 (1958)). Instead, the critical question is whether the defendant caused a false claim to be presented to the government, because liability under the Act attaches only to a claim actually presented to the government for payment, not to the underlying fraudulent scheme. *Id.* (citing *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995)). Therefore, when a relator fails to plead plausible allegations of presentment, the relator has not alleged all the elements of a claim under the Act. *See United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1313 (11th Cir. 2002) ("[W]e cannot be left wondering whether a plaintiff has offered mere conjecture or a specifically pleaded allegation on an essential element of the lawsuit.").

We agree with the Eleventh Circuit's observation that the particularity requirement of Rule 9(b) "does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government." *Id.* at 1311. Rather, Rule 9(b) requires that "some indicia of reliability" must be provided in the complaint to support the allegation that an actual false claim was presented to the government. *Id.* Indeed, without such plausible allegations of presentment, a relator not only fails to meet the particularity requirement of Rule 9(b), but also does not satisfy the general plausibility standard of *Iqbal*. *See Clausen*, 290 F.3d at 1313 ("If Rule 9(b) is to carry any water, it must mean that an essential allegation and circumstance of fraudulent conduct cannot be alleged in such conclusory fashion."); *cf. United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 557 (8th Cir. 2006) (requiring relator to "provide some representative examples of [the defendants'] alleged fraudulent conduct").

Our conclusion is not altered by the cases cited by Relator, in which courts have held that the requirements of Rule 9(b) can be satisfied in the absence of particularized allegations of

specific false claims. Based on the nature of the schemes alleged in many of those cases, specific allegations of the defendant's fraudulent conduct necessarily led to the plausible inference that false claims were presented to the government.

For example, in *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180 (5th Cir. 2009), the relator alleged a conspiracy by doctors to seek reimbursement from governmental health programs for services that never were performed. The court concluded that, because the complaint included the dates of specific services that were recorded by the physicians but never were provided, such allegations constituted "more than probable, nigh likely, circumstantial evidence that the doctors' fraudulent records caused the hospital's billing system in due course to present fraudulent claims to the Government." *Id.* at 192. Accordingly, the court further concluded that it would "stretch the imagination" for the doctors to continually record services that were not provided, but "to deviate from the regular billing track at the last moment so that the recorded, but unprovided, services never get billed." *Id.*; *see also United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 30 (1st Cir. 2009) (holding that, in scheme alleging kickbacks to health care providers, allegations regarding "the dates and amounts of the false claims filed by these providers with the Medicare program" met the standard imposed by Rule 9(b)).[6]

Applying these principles, we hold that when a defendant's actions, as alleged and as reasonably inferred from the allega-

[6]In another case cited by Relator, the Tenth Circuit held that "claims under the [False Claims Act] need only show the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme." *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (10th Cir. 2010). In *Lemmon*, however, it was clear that the relator had pleaded specific details of false claims, including the dates of the alleged violations, the dates payment requests were submitted, details of the purported violations, and the allegedly false certification language.

tions, *could* have led, but *need not necessarily* have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment. To the extent that other cases apply a more relaxed construction of Rule 9(b) in such circumstances, we disagree with that approach.

In reaching this conclusion, we acknowledge the practical challenges that a relator may face in cases such as the present one, in which a relator may not have independent access to records such as prescription invoices, and where privacy laws may pose a barrier to obtaining such information without court involvement. Nevertheless, our pleading requirements do not permit a relator to bring an action without pleading facts that support all the elements of a claim. *See Dickson v. Microsoft Corp.*, 309 F.3d 193, 213 (4th Cir. 2002) (noting "the basic pleading requirement that a plaintiff set forth facts sufficient to allege each element of his claim"). We further emphasize, however, that the standard we articulate today does not foreclose claims under the Act when a relator plausibly pleads that specific, identifiable claims actually were presented to the government for payment. Of course, whether such factual allegations in a given case meet the required standard must be evaluated on a case-specific basis.

III.

Employing the above pleading standard, we turn to consider the sufficiency of the amended complaint in this case. Relator relies on four categories of allegations in the amended complaint, which he contends state with particularity that Takeda caused false claims to be presented to the government for payment. We address each set of allegations in turn, and conclude that, individually as well as collectively, Relator's allegations fail to allege an essential element of a claim under the Act.

First, Relator alleges in the amended complaint that Takeda promoted Kapidex to rheumatologists, who do not treat the conditions for which Kapidex has been approved.[7] According to Relator, when promoting Kapidex to rheumatologists, Takeda sales representatives equated Kapidex with Prevacid, even though Kapidex was not approved for 10 of the 13 indications for which Prevacid was approved, including the gastric conditions commonly suffered by rheumatology patients. Relator further alleges that Takeda sales representatives were instructed to promote Kapidex to rheumatologists without disclosing that the drug is not approved for the gastric condition often experienced by rheumatology patients.

These allegations concerning the promotion of Kapidex to rheumatologists fall far short of the pleading standards set forth in Rule 9(b) and in *Iqbal*. Fatal to the claim, Relator does not allege in the amended complaint that the targeted rheumatologists wrote any off-label prescriptions that were submitted to the government for payment, a critical omission in a case brought under the Act.[8] *See United States ex rel.*

[7]According to Relator, rheumatologists do not treat GERD or EE, the two indications for which Kapidex is approved. Rheumatology patients may use Prevacid for gastric protection, a need associated with long-term ingestion of anti-inflammatory drugs such as Advil. However, as discussed above, Kapidex is not approved for gastric protection.

[8]After filing the amended complaint, Relator submitted to the district court a supplemental affidavit with attachments, which allegedly showed that two rheumatologists in Relator's sales territory wrote Kapidex prescriptions during a particular month. However, Relator cannot cure pleading deficiencies in the amended complaint with later-filed supporting documentation. *See E.I. du Pont de Nemours & Co. v. Kolon Indus.*, 637 F.3d 435, 448-49 (4th Cir. 2011) (explaining that "matters beyond the pleadings . . . cannot be considered on a Rule 12(b)(6) motion"); *Sec'y of State for Defence v. Trimble Navigation Ltd.*, 484 F.3d 700, 705 (4th Cir. 2007) (stating the documents that may be considered in evaluating a Rule 12(b)(6) motion). Moreover, we agree with the district court's observation that, even if these allegations had been included in the amended complaint, "there is nothing that prevents a rheumatologist from prescribing Kapidex for an approved condition at an approved dosage," and there was no indication in the record of the prescriptions' dosage, the conditions for which they were written, or that the prescriptions were submitted to the government for reimbursement.

Rost v. Pfizer, Inc., 507 F.3d 720, 733 (1st Cir. 2007) (holding that a complaint does not meet the requirements of Rule 9 when the complaint did not "give notice to [the defendant] of false claims submitted by others for federal reimbursement of off-label uses, only of illegal practices in promotion of the drug"), *overruled on other grounds by Allison Engine Co. v. United ex rel. Sanders*, 553 U.S. 662 (2008). Accordingly, Relator has not plausibly alleged that Takeda caused rheumatologists to write Kapidex prescriptions for off-label uses that actually were presented to the government for payment.

Second, in the amended complaint, Relator identifies 16 primary care physicians (PCPs) who received 60 mg samples of Kapidex from Takeda and collectively wrote 98 prescriptions for the drug that were submitted to the government for reimbursement. Although Relator alleges that these claims were presented to the government for payment, Relator does not plausibly allege that the prescriptions were written for off-label uses.

Rather, Relator alleges in the amended complaint that because PCPs generally do not treat active cases of EE, the only condition for which a 60 mg dose is indicated, any 60 mg prescriptions written by PCPs necessarily were for off-label uses. Notably, however, Relator does not allege facts that specifically address the dosage level of any of the 98 prescriptions. Instead, Relator relies on speculative contentions regarding the 98 prescriptions he has identified. Relator alleges that physicians tend to prescribe drugs in the same dose as the sample the patient has received and that, therefore, the identified PCPs must have prescribed 60 mg doses because they received only 60 mg samples. The allegations in the amended complaint contain the additional speculative assertion that at least 90 percent of the 98 prescriptions must have been written at the 60 mg level, because 93 percent of the overall sales of Kapidex are for dosages of 60 mg.

As the district court observed, Relator fails to state any plausible allegation connecting these general statistics to the

98 prescriptions identified or to prescriptions written by PCPs generally. To the contrary, drawing on the language in the amended complaint, it is logical to assume that a much lower-than-average percentage of the 98 prescriptions were written for 60 mg doses, given that PCPs purportedly do not treat the condition for which the higher 60 mg dose is indicated. Relator also fails to allege directly that any of the identified prescriptions were for off-label uses, instead requiring that a court draw an implausible inference linking general statistics to the 98 prescriptions for Kapidex. *Cf. United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997) (upholding dismissal of False Claims Act claim for lack of particularity because statistical studies cited by the relator did not "directly implicate defendants").

Moreover, even if Relator had pleaded adequately that the 98 prescriptions were written at the 60 mg dosage level, the existence of a 60 mg prescription written by a PCP would not itself constitute a plausible allegation that the prescription was for an off-label use. PCPs can still prescribe a 60 mg dose for an approved use, even though such physicians allegedly do not typically treat the approved condition. This possibility highlights the weakness in the amended complaint, namely, Relator's attempt to draw inferences from general facts, such as that PCPs generally do not treat active cases of EE and that Kapidex generally is prescribed in 60 mg doses, to reach the conclusion that the 98 prescriptions identified in the amended complaint were for off-label uses. We conclude that such inferences are implausible and unsupported by the stated facts and, thus, that the allegations relating to the PCPs do not state with particularity that any false claims were submitted to the government for payment.

Third, Relator alleges in the amended complaint that about 9,000 Kapidex prescriptions were submitted to the government for reimbursement in two of Takeda's sales districts during certain one-year periods. Again, Relator does not allege the dosages of these prescriptions, nor, as the district court

observed, do these generalized statistics "identify the types of doctors issuing the prescriptions, the types of illnesses for which they issued the prescriptions at issue, or whether the doctors were subjected to Takeda's sample distribution practices." Thus, the references in the amended complaint to these 9,000 prescriptions do not constitute plausible allegations that Takeda caused presentment of a false claim to the government.

Fourth, in the amended complaint, Relator relies on allegations that are based on the affidavits of two gastroenterologists and one PCP, who averred that they prescribed 60 mg dosages of Kapidex to treat GERD in Medicare patients and were unaware that the drug was available in a 30 mg dosage due to Takeda's sampling practices. However, the amended complaint does not include any details about the particular prescriptions these physicians wrote for Medicare patients, such as approximate dates or patient information, nor does the amended complaint contain allegations that the Medicare patients ever "filled" these prescriptions or that corresponding claims for reimbursement ever were submitted to the government.[9]

As previously discussed, liability under the Act attaches only to false claims actually submitted to the government for reimbursement. General allegations such as those made here, that unidentified Medicare patients received prescriptions for off-label uses, do not identify with particularity any claims that would trigger liability under the Act. In the absence of the required specific allegations, a court is unable to infer that a Medicare patient who has received a prescription for an off-

[9]In a supplemental affidavit, Dr. Michael Yaffe, the PCP, averred that he had personal knowledge that some of his Medicare patients filled the off-label Kapidex prescriptions because the patients contacted his office to seek prescription refills. Once again, it is improper for Relator to attempt to buttress his faulty complaint with supplemental affidavits submitted later in the litigation, in this case, in opposition to Takeda's motion to dismiss.

label use actually filled the prescription and sought reimbursement from the government. Indeed, "[i]t may be that physicians prescribed [the drug] for off-label uses only where the patients paid for it themselves or when the patients' private insurers paid for it." *Rost*, 507 F.3d at 733. We therefore disagree with Relator's assertion that, if a patient is insured under a government program, we reasonably may infer that any prescription the patient received for an off-label use was filled and that a claim was presented to the government. For these reasons, we conclude that Relator's allegations in the amended complaint relating to the three physician affidavits do not adequately state that any false claims were presented to the government for payment.

Based on our consideration of the facts stated in the amended complaint, we observe that Relator essentially has alleged that some claims must have been presented to the government for payment, because prescriptions of this kind frequently and routinely are obtained by persons who participate in health care programs sponsored by the federal government, or because federally insured patients received off-label prescriptions. As we have explained, allegations of this type are insufficient because they are inherently speculative in nature. In contrast to cases such as *Grubbs*, 565 F.3d 180, Relator's claim does not involve an integrated scheme in which presentment of a claim for payment was a necessary result. We therefore hold that Relator has failed to plead with particularity a plausible claim that any off-label prescriptions were presented to the government for payment.

IV.

Finally, Relator challenges the district court's denial of his motion for leave to amend his complaint for a fourth time. We review the district court's denial of this motion for abuse of discretion. *Wilson*, 525 F.3d at 376. Federal Rule of Civil Procedure 15(a)(2) provides that a court "should freely give leave" to amend a complaint "when justice so requires."

Despite this general rule liberally allowing amendments, we have held that a district court may deny leave to amend if the amendment "would be prejudicial to the opposing party, there has been bad faith on the part of the moving party, or the amendment would have been futile." *Laber v. Harvey*, 438 F.3d 404, 426 (4th Cir. 2006) (en banc) (quoting *Johnson v. Oroweat Foods Co.*, 785 F.2d 503, 509 (4th Cir. 1986)).

Relator has amended his complaint three times. A decision granting him leave to amend yet again would have resulted in a fifth complaint filed in this case. We also observe that two years have elapsed between the filing of the original complaint and the district court's dismissal of the amended complaint currently before us in this appeal. The granting of leave to file another amended complaint, when Relator was on notice of the deficiencies before filing the most recent amended complaint,[10] would undermine the substantial interest of finality in litigation and unduly subject Takeda to the continued time and expense occasioned by Relator's pleading failures. In view of the multiple opportunities Relator has been afforded to correct his pleading deficiencies and the deference due to the district court's decision, we conclude that the district court did not abuse its discretion in denying him leave to file a fourth amended complaint.

V.

For these reasons, we hold that the district court properly dismissed the amended complaint under Rule 12(b)(6) for

[10]In May 2011, the district court dismissed Relator's second amended complaint for failure to state a claim, but granted leave to amend. In its order, the district court noted the lack of specific allegations regarding actual presentation of false claims to the government. Although the amended complaint before us includes considerably more detail, this fundamental defect was not addressed adequately by the last amendment. The district court also cautioned Relator that any evidence provided outside the amended complaint could not be considered in an attempt to avoid dismissal under Rule 12(b)(6).

failure to state a claim, and did not abuse its discretion in denying Relator leave to file a fourth amended complaint.

AFFIRMED