No. 15-16380

IN THE
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES

ex rel. JEFFREY CAMPIE and SHERILYN CAMPIE, et al.,
Relators-Appellants,

v.

GILEAD SCIENCES, INC.,
Defendant-Appellee.

Appeal from a Judgment of the United States District Court
for the Northern District of California, Case No. 3:11-cv-941 EMC
Honorable Edward M. Chen

DEFENDANT-APPELLEE'S PETITION FOR REHEARING OR REHEARING EN BANC

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RULE 35(b)(1) STATEMENT & INTRODUCTION

The Ninth Circuit is now a False Claims Act ("FCA") outlier. Splitting with the Supreme Court's decision in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), and six circuits, the panel held that a relator can litigate an FCA claim based on allegations of regulatory infractions, even though the Government and its agencies consider those allegations wrong or inconsequential.

Relators' complaint against Gilead Sciences, Inc. ("Gilead") boils down to an allegation that Gilead sold the Government drugs representing them as approved by the Food and Drug Administration ("FDA") even though, Relators claim, the drugs failed to meet certain manufacturing standards. But they *were* FDA-approved, and still are to this day. Even after multiple inspections, audits, and investigations, FDA has never withdrawn approval. The Government purchasers were also unfazed. Far from seeking refunds when the allegations came to light, the Government purchasers continued buying drugs from Gilead year after year. Nevertheless, Relators seek to claw back billions of dollars.

This is the paradigmatic FCA suit "motivated primarily by prospects of monetary reward rather than the public good." *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 949 (1997). It seeks to persuade a jury to override intricate regulatory judgments about the public good, including what

drugs should be approved and stay on the market and how FDA should enforce compliance with its own standards. Yet, the panel sustained the complaint in a ruling that invites similar suits against just about any contractor in all regulated industries.

This is not how the FCA is supposed to work. The Supreme Court has prescribed "rigorous" and "demanding" pleading requirements to stem a tide of FCA litigation premised on recasting any purported regulatory infraction as a fraudulent claim for payment. *Escobar*, 136 S. Ct. at 1996, 2002, 2003, 2004 n.6; *see* 31 U.S.C. § 3729(a)(1).

The panel's approach is flatly inconsistent with this direction and with opinions from six circuits—the most recent of which criticized the panel as "offer[ing] no rebuttal at all to [the] observation that six jurors should not be able to overrule the FDA." *United States ex rel. Nargol*, No. 16-1442, 2017 WL 3167622, at *5 (1st Cir. July 26, 2017). The panel here acknowledged that other circuits have "cautioned against" stretching the FCA to override regulatory regimes but was undeterred. Op. 25. Consequently, the Ninth Circuit is now the only court of appeals that permits a new breed of "fraud" where the purported victim was unharmed and unconcerned about the accused practice—and even affirmatively authorized it. The result is open season for enterprising lawyers to pore over regulations in search of trivial infractions and pour into the Ninth Circuit

seeking jackpots. These suits not only will burden businesses with litigation costs and exorbitant settlements, but also will override agencies' considered judgments as to what is (and is not) a violation and what consequence, if any, should follow.

The panel opinion cannot stand.

BACKGROUND

This case arises from Gilead's sale of life-saving HIV medicines. FDA approved them over a decade ago, Op. 4-5, and appears to want them to stay on the market. The Government is one of the biggest purchasers of these approved drugs. Government agencies, such as Centers for Medicare and Medicaid Services ("CMS"), also reimburse other buyers through federal healthcare programs. *E.g.*, 42 U.S.C. § 1395w-102(e).

Products like these present a gold mine to those wielding the FCA. "[T]he government spent over $5 billion" on the drugs at issue in a single two-year period. Op. 5. That is 5 billion reasons to scrutinize Gilead's every move in search of anything that can be distorted into a false claim for payment. Even when the Government is indifferent, lawyers and relators have massive incentives to scour the terms of the FDA approval and the web of FDA regulations—called "Good Manufacturing Practices" ("GMPs")—detailing standards for quality control, product testing, and other subjects. *See* 21 C.F.R. pt. 211.

Here, Relators claim that Gilead's sales were fraudulent because it used an active ingredient (called "FTC") manufactured by a company named Synthetics China. Specifically, they allege that the source was not originally FDA-approved, although it undisputedly is now. Op. 6-7. That practice, they allege, breached the GMPs, which means the resulting product was "adulterated." Op. 8. But "adulterated" is just a regulatory label that applies whenever a manufacturer departs—however trivially—from the GMPs, 21 U.S.C. § 351(a)(2)(B); "it does not mean that there is necessarily something wrong with the drug." FDA, *Facts About the Current Good Manufacturing Practices (CGMPs)* (Jan. 6, 2015) [hereinafter, FDA, *Facts*], http://tinyurl.com/muq4rs; *see United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 701-02 (4th Cir. 2014). Even when FDA finds a GMP violation, it "usually advises [patients] not to interrupt their drug therapy." FDA, *Facts*, *supra*. That is because "the risk that the drug is unsafe or ineffective could be minimal." *Id.* Only "[i]n rare cases" does FDA halt distribution of the product. *Id.*

This case epitomizes immateriality. As the panel acknowledged, for years, FDA and the Government purchasers have known all about Gilead's relationship with Synthetics China. Op. 6; 27-28. They had multiple iterations of Relators' complaint—dating back to 2010. FDA exercised extensive regulatory oversight of Gilead, including multiple inspections of Synthetics China. Op. 27-28. Separately,

FDA issued a notice that included an inspection observation "regarding product from Synthetics China." Op. 28. Through it all, FDA has never suggested that Gilead should stop distributing these medicines. FDA even authorized Gilead to use the very ingredient from the very manufacturer that is the basis of the fraud claim here. Op. 6-7. The actual Government customers, including CMS, consistently paid for the Gilead medicines, never sought a refund, and never complained about the challenged practice. Op. 25. And in 2013, DOJ declined to intervene in this case. ER299.

The district court dismissed Relators' claims. But a panel of this Court (Judges Reinhardt, Tashima, and Molloy (D. Mont.)) reversed. The panel sustained the complaint based on allegations that Gilead violated the FCA by seeking payment for medicines that departed from manufacturing standards. The panel also rejected Gilead's distinct argument for dismissal based on the FCA's demanding materiality requirement, ruling that the materiality arguments here are "matters of proof, not legal grounds to dismiss relators' complaint." Op. 29.

REASONS FOR GRANTING THE PETITION

I. The Panel's Opinion Conflicts With Supreme Court Precedent And Decisions Of Six Circuits.

The panel violated the Supreme Court's direction in *Escobar* and split with six circuits on what an FCA relator must demonstrate to litigate a claim.

A. A false claim is not material unless it has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). In its recent decision in *Escobar*, the Supreme Court explained that statutory and regulatory requirements are "not automatically material," and the FCA is not "a vehicle for punishing garden-variety breaches of contract or regulatory violations." 136 S. Ct. at 2001, 2003. The Court repeatedly emphasized that the FCA's pleading requirements are "rigorous" and "demanding." *Id.* at 1996, 2002, 2003, 2004 n.6. Specifically, *Escobar* announced: "Under any understanding of the concept, materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'" 136 S. Ct. at 2002 (quoting 26 Williston on Contracts § 69:12 (4th ed. 2003)).

The panel applied a rule that bears little similarity to *Escobar*'s: It sustained the complaint here because it alleges "more than the *mere possibility* that the government would be *entitled to* refuse payment if it were aware of the violations." Op. 29 (emphasis added). "More than merely possible" is not the standard; Government action must be "likely or actual." And the question is not whether the "government would be *entitled to* refuse payment"; indeed, *Escobar* rejected the notion that a regulatory violation is material whenever "the Government would be entitled to refuse payment were it aware of the violation." 136 S. Ct. at 2004.

Rather, the question is whether the Government *likely would* refuse payment had it known of the regulatory infractions—or *actually* did when it found out. With the "benefit of hindsight," courts must consider "what actually occurred." *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1034 (D.C. Cir. 2017).

Had the panel asked the right question, this complaint could not have survived. We know what the Government likely would have done because the complaint establishes what the Government *did* do when it investigated the allegations: practically nothing. As explained, FDA never withdrew approval; the Government kept buying the drugs; CMS kept paying for them; and DOJ took no action—and declined to intervene here. Plus, as if to declare, "This is not material," FDA authorized Gilead to use the ingredient from Synthetics China that is the basis of Relators' claim. Op. 7 (noting that "the Synthetics China facility was registered in 2010").

More broadly, the panel ignored an obvious obstacle to Relators' allegations: Although agencies pay claims for FDA-approved drugs, ER116-17, "[p]ayment under government health programs is not generally conditioned on a manufacturer's compliance with various FDA procedures," U.S. Amicus Br. 25-26; *see Omnicare*, 745 F.3d at 702. The panel's focus on Relators' allegations that Gilead's medicines were "adulterated" and "misbranded," Op. 8, was particularly misguided because those are simply regulatory labels that apply to even the most

trivial departures from the guidelines, *see* 21 C.F.R. § 210.1. Nothing in the complaint offers any indication as to why this would have been one of the extraordinary circumstances in which the Government would have stopped paying for Gilead's medicines on the basis of the alleged infractions.

Given both the facts alleged and the regulatory context, that omission should have doomed the complaint. As the Supreme Court explained in *Escobar*: "[I]f the Government pays a particular claim in full"—here, for medicines that remain FDA-approved notwithstanding alleged manufacturing infractions—"despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material." 136 S. Ct. at 2003. The panel could not overcome the inference by kicking the can down the road to the jury with the assertion that the materiality issue raises "matters of proof." Op. 29. *Escobar* held the opposite: Materiality is *not* "too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss or at summary judgment." *Escobar*, 136 S. Ct. at 2004, n.6.

The panel was thus wrong to reason that, "[a]lthough it may be that the government regularly pays this particular type of claim in full despite actual knowledge that certain requirements were violated, such evidence is not before us." Op. 29. That flips the pleading standard on its head. *Relators* must "plead their claims with plausibility and particularity." *Escobar*, 136 S. Ct. at 2004 n.6.

Thus, *Relators* had to allege that the Government does *not* ordinarily pay these types of claims once it learns of the purported infractions and explain how the infractions could possibly be material to payment when the Government kept paying and even ratified the challenged conduct by approving Synthetics China.

B. Five circuits have rejected FCA claims as immaterial based on similar Government reactions to alleged infractions, two in the FDA context.

The First Circuit rejected a claim that a defendant failed to provide the training it had promised in seeking approval for a medical device, and therefore made "fraudulent representations to the FDA." *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016). The court held that "FDA's failure actually to withdraw its approval of [the medical device] in the face of [the relator's] allegations precludes [the relator] from resting his claims on a contention that the FDA's approval was fraudulently obtained." *Id.* at 8. The panel here did not even try to distinguish *D'Agostino*. It just summarily rejected the First Circuit's analysis, asserting that "[m]ere FDA approval cannot preclude False Claims Act liability." Op. 26 & n.7.

Punctuating the split, the First Circuit reaffirmed *D'Agostino* and criticized the panel's opinion within three weeks of its issuance. The complaint in *Nargol* revolved around certain defects in medical devices used for hip replacements. 2017 WL 3167622, at *2. The manufacturer allegedly had made misrepresentations to FDA, which the relators claimed could have led FDA to

withdraw its approval. *Id.* The problem, as here, was that FDA never withdrew approval, despite being "told what Relators have to say." *Id.* at *3. FDA never "employ[ed] [its] tools in the wake of Relators' allegations so as to withdraw or even suspend its approval of the … device[s]," and because "government reimbursement rules" rely on FDA approval, the alleged infractions were immaterial as a matter of law. *Id.* That "render[ed] a claim of materiality implausible." *Id.* The First Circuit explicitly disagreed with the opinion here, explaining that "*Campie* offers no rebuttal at all to *D'Agostino*'s observation that six jurors should not be able to overrule the FDA." *Id.* at *5.[1]

The Third Circuit agrees. In *United States ex rel. Petratos v. Genentech Inc.*, the relator alleged that a drug company suppressed data that, if known, would have precluded CMS from paying claims. 855 F.3d 481, 485-87 (3d Cir. 2017) (citing 42 U.S.C. § 1395y(a)(1)(A)). The Third Circuit dismissed the relator's complaint, because it "fail[ed] to plead that CMS 'consistently refuses to pay' claims like those alleged." *Id.* at 490. The court noted that even after the relator disclosed the violation, FDA "continued its approval of" the drug and opted not to

[1] The First Circuit appears to have misunderstood the record in this case when it distinguished *Nargol* on the ground that it presents "a situation in which the FDA was not alleged to have ever withdrawn its approval, even long after it acquired full knowledge of Relators' claims." *Nargol*, 2017 WL 3167622, at *5. That is exactly what we have here: "[A]t all times relevant, the drugs at issue were FDA-approved," Op. 25, even though Relators alerted the Government to their allegations seven years ago.

initiate any proceedings, while DOJ declined to intervene. *Id*. Under *Escobar*'s "heightened materiality standard," the Government's inaction established that the false claims did not "affect[] CMS's payment decision." *Id*. at 492.

The panel here rejected that analysis: "[R]ead[ing] too much into the FDA's continued approval" would allow defendants to use "fraudulently-obtained FDA approval as a shield against liability for fraud." Op. 28. But the Supreme Court has admonished that the FCA "is not an all-purpose antifraud statute." *Escobar*, 136 S. Ct. at 2003 (internal quotation marks omitted). The panel also noted that "there are many reasons the FDA may choose not to withdraw a drug approval, unrelated to the concern that the government paid out billions of dollars for nonconforming and adulterated drugs." Op. 28. That is a non sequitur. Continued approval and reimbursement necessarily make the alleged falsity immaterial to the Government's payment decision, whatever the reasons behind the Government's actions.

The panel also attempted to distinguish the Third Circuit's decision by insisting FDA did not have as much knowledge here. Op. 28-29. But the question is whether FDA knew enough about the alleged infractions to take action, and the opinion itself demonstrates that FDA had enough knowledge to do just that. Op. 27-28. And FDA *did* take action, inspecting Gilead repeatedly. *Id.*; ER152. The Government thus knew enough to decide whether to withdraw approval or seek a

refund but did neither, which is fatal under the Third Circuit's analysis. *See Petratos*, 855 F.3d at 490.[2]

The panel opinion also conflicts with decisions of three more circuits outside the FDA context, all disposing of FCA cases on summary judgment. In a case involving helicopter parts, the Seventh Circuit ruled against the relators because "the government's actual conduct" in continuing to make payments after learning of concerns "suggests that the allegedly false statements were immaterial." *United States ex rel. Marshall v. Woodward, Inc.*, 812 F.3d 556, 563 (7th Cir. 2015), *cert. denied*, 136 S. Ct. 2510 (2016). The Tenth Circuit likewise rejected a claim involving a power project, emphasizing that the government agency "did not withhold payment after learning of Relators' allegations." *United States ex rel. Thomas v. Black & Veatch Special Projects Corp.*, 820 F.3d 1162, 1172 (10th Cir. 2016). And the Fifth Circuit found no dispute as to materiality where the Government allowed an oil facility "to continue drilling after a substantial

[2] The panel suggested that continued approval and reimbursement "does not have the same significance" here because Gilead "stopped using Synthetics China as a supplier in October 2011." Op. 7, 28. That is wrong on the law: Relators cannot satisfy the materiality requirement when the Government is "told what [they] have to say" and takes no action. *Nargol*, 2017 WL 3167622, at *3. It is also wrong on the alleged facts. The panel noted FDA's concerns "regarding product from Synthetics China" in *2012*, Op. 28, and the complaint alleged in *2015* that Gilead "continues to incorporate Synthetics China-made API into its finished drug products," ER152. If these allegations amounted to material infractions, the Government would have acted by now.

investigation into Plaintiffs' allegations." *Abbott v. BP Exploration & Prod., Inc.*, 851 F.3d 384, 388 (5th Cir. 2017).

These five circuits all recognize that the Government's continued payment after learning of alleged regulatory violations can demonstrate immateriality as a matter of law. When the Government's knowledge is already established, materiality is not a "matter[] of proof" to be resolved later. Op. 29.

C. The Fourth Circuit has joined the First and Third Circuits in "caution[ing] against allowing claims under the False Claims Act to wade into the FDA's regulatory regime." Op. 25. In *Omnicare*, as here, the Fourth Circuit confronted allegations that the defendant failed to comply with GMPs and thus distributed "adulterated" drugs that were "ineligible for reimbursement by Medicare and Medicaid." 745 F.3d at 700. The Fourth Circuit rejected the theory, in part "because compliance with the CGMPs is not required for payment by Medicare and Medicaid." *Id.* at 702.

While the Fourth Circuit assessed the deficiency in the complaint through the lens of falsity rather than materiality, the court applied the same principles as the circuits recounted above, but rejected by the panel here. The court considered FDA approval critical: "[O]nce a new drug has been approved by the FDA and thus qualifies for reimbursement," a claim for reimbursement "cannot constitute a 'false' claim … on the sole basis that the drug has been adulterated as a result of

having been processed in violation of FDA safety regulations." *Id.* at 701-02. Thus, in the Fourth Circuit, "allegations of regulatory violations fail to support FCA liability." *Id.* at 702. The panel's ruling here is in direct conflict.

The Government, too, rejects the panel's position on this point. In its amicus brief in this case, the Government disagreed that "a 'false' claim is submitted every time a finished drug has an imperfection of any kind." U.S. Br. 17. The Government explained that to form the basis of an FCA claim, the defect must be so severe that what was provided was "understood to be different" from the approved product. U.S. Br. 16-17. The First Circuit embraced a similar "palming off" theory in *Nargol*, but the panel did not rely on that theory in this case. In any event that theory requires that any alleged deficiencies caused the product to "materially differ[] from the [product] the FDA approved," which is not the case here. 2017 WL 3167622, at *5. To the contrary, it is undisputed that manufacturing infractions do "not mean that there is necessarily something wrong with the drug." FDA, *Facts*, *supra*. Any suggestion that the alleged infractions here were material is untenable in light of the Government's continued approval of, and payment for, Gilead's medicines.

II. The Panel's Decision Invites A Litigation Deluge That Overrides Intricate Regulatory Judgments.

This case comes down to the question of who should enforce compliance with Government regulations. Should it be the expert agencies vested by Congress

with a range of remedial powers and the responsibility to weigh the costs and benefits of intervention? Or should it be private citizens seeking a windfall in the form of refunds the Government never sought? The FCA is not "a sweeping mechanism to promote regulatory compliance," especially "[w]hen an agency has broad powers to enforce its own regulations, as the FDA does in this case." *Omnicare*, 745 F.3d at 702. Nevertheless, the panel decision authorizes exorbitant rewards even when an expert agency decides against taking action. The opinion turns every minor regulatory misstep into a potential FCA case, despite *Escobar*'s admonition that the FCA "is not a means of imposing treble damages and other penalties for insignificant regulatory or contractual violations." 136 S. Ct. at 2004.

The Supreme Court expected its pleading standard to stem a tide of FCA litigation. The panel has steered the tidal wave to this Circuit. Consider the volume of activity just in FDA's realm. In 2016, the agency issued 649 general warning letters—255 citing GMP violations alone.[3] In a recent one-year period, it issued over 4,500 notifications of possible statutory violations, 691 for drug products.[4] The panel's approach creates the prospect of countless FCA cases over

[3] FDA, *2016 Warning Letters* (Aug. 16, 2017), https://tinyurl.com/y96yrzek.

[4] FDA, *FDA Form 483 Frequently Asked Questions* (July 24, 2017), http://tinyurl.com/y6udmwox; FDA, *FY 2016 Inspectional Observation Summaries* (Dec. 14, 2016), https://tinyurl.com/y9usftmq.

manufacturing and other infractions that raise no significant safety risks, targeting drugs that FDA wants to keep on the market.

That just scratches the surface. The Federal Government procures hundreds of billions of dollars a year in goods and services, all governed by a web of procurement regulations. The panel's ruling applies to *every* industry—not just pharmaceuticals—and all of the millions of payment claims presented to federal agencies. As DOJ recently effused, the FCA extends to "such varied areas as health care, defense and national security, food safety and inspection, federally insured loans and mortgages, highway funds, small business contracts, agricultural subsidies, disaster assistance, and import tariffs." DOJ, *Justice Department Recovers Over $4.7 Billion From False Claims Act Cases in Fiscal Year 2016* (Dec. 14, 2016), http://tinyurl.com/j3jobgb. All are targets now.

The Supreme Court expected that the stringent pleading standards it prescribed would ensure that expert agencies maintain control of policy decisions. This case illustrates why that control is crucial. The HIV drugs at issue save lives. So far as it appears from its behavior, FDA *wants* Gilead to sell them, despite the purported manufacturing infractions. Congress has entrusted expert agencies like FDA with the task of deciding whether an infraction is serious enough to preclude distribution or cancel payment—or to warrant any number of other regulatory enforcement actions. Private relators overriding that judgment with the blunt

instrument of the FCA can deprive the public of life-saving drugs. Left unchecked, this bounty-seeking litigation threatens to wreak havoc in every arena of federal contracting.

As the Supreme Court and other circuits have recognized, mere failure to satisfy any provision of a contract or comply with any regulation does not justify an FCA claim. If the panel's opinion stands, the Ninth Circuit will become a magnet for FCA claims that could not survive anywhere else.

CONCLUSION

For the foregoing reasons, the petition for rehearing or rehearing en banc should be granted.

August 21, 2017

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This petition complies with the type-volume limitation of Ninth Circuit R. 40-1(a) because this petition contains 3,892 words, excluding the parts of the petition exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

This petition complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this petition has been prepared in a proportionally spaced typeface using Microsoft Word 2013 in Times New Roman 14-point font.

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on August 21, 2017.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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ADDENDUM

FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA EX REL. JEFFREY CAMPIE and SHERILYN CAMPIE, *Plaintiffs-Appellants*, v. GILEAD SCIENCES, INC., *Defendant-Appellee.*	No. 15-16380 D.C. No. 3:11-cv-00941-EMC OPINION

Appeal from the United States District Court
for the Northern District of California
Edward M. Chen, District Judge, Presiding

Argued and Submitted April 19, 2017
San Francisco, California

Filed July 7, 2017

Before: Stephen Reinhardt and A. Wallace Tashima, Circuit Judges and Donald W. Molloy,* District Judge.

Opinion by Judge Molloy

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* The Honorable Donald W. Molloy, District Judge for the U.S. District Court for the District of Montana, sitting by designation.

SUMMARY**

False Claims Act

The panel reversed the district court's Fed. R. Civ. P. 12(b)(6) dismissal of claims under the False Claims Act by relators Jeff and Sherilyn Campie alleging that their former employer, Gilead Sciences, Inc., made false statements about its compliance with Food and Drug Administration regulations regarding certain HIV drugs, resulting in the receipt of billions of dollars from the government; and alleging retaliation against relator Jeff Campie.

The panel held that the relators stated a plausible claim that Gilead's claims seeking payment for noncompliant drugs were a basis for liability under the False Claims Act. Considering the four elements of False Claims Act liability, first, the panel held that relators alleged a "false claim" under theories of factually false certification, implied false certification, and promissory fraud. Second, relators adequately pled "scienter." Third, the relators sufficiently pled "materiality" at this stage of the case where they alleged more than the mere possibility that the government would be entitled to refuse payment if it were aware of the violations. Fourth, the relators sufficiently alleged that Gilead submitted false claims in a number of ways.

The panel held that the relators adequately pled a claim for retaliation in violation of the False Claims Act. Specifically, the panel held that the second amended

** This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

complaint sufficiently alleged facts showing that Jeff Campie had an objectively reasonable, good faith belief that Gilead was possibly committing fraud against the government; that Gilead knew Campie was engaged in protected activity: and that Gilead discriminated against Campie because he engaged in protected activity.

The panel declined to decide in the first instance the question of whether relators' claims pursuant to 31 U.S.C. § 3729(a)(1)(A), (B) met the heightened pleading standard under Fed. R. Civ. P. 9(b).

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OPINION

MOLLOY, District Judge:

This case involves allegations under the False Claims Act, 31 U.S.C. §§ 3729–33, that Defendant-Appellee Gilead Sciences, Inc. (Gilead) made false statements about its compliance with Food and Drug Administration (FDA) regulations regarding certain HIV drugs, resulting in the receipt of billions of dollars from the government. Relators Jeff and Sherilyn Campie (relators), two former Gilead employees, allege that these noncompliant drugs were not eligible to receive payment or reimbursement and, therefore, any claims presented to the government for payment were false under the False Claims Act. Relators further allege that Gilead violated the False Claims Act when it fired relator Jeff Campie, who discovered and ultimately reported the violations. *See* 31 U.S.C. § 3730(h). The district court dismissed relators' claims under Federal Rule of Civil Procedure 12(b)(6). It did so before the Supreme Court decided *Universal Health Servs., Inc. v. United States (Escobar)*, ___ U.S. ___, 136 S. Ct. 1989 (2016). We reverse.

I.

Gilead is a large drug producer, with a majority of its prescription drug product sales occurring in the United States. Relevant here, Gilead produces anti-HIV drug therapies,

including the drugs Atripla, Truvada, and Emtriva. In 2008 and 2009 alone, the government spent over $5 billion on these anti-retrovirals. Relators claim that in its sale of these drugs to the government, Gilead concealed violations of FDA regulations and knowingly made false statements regarding its regulatory compliance. The facts recited in the relators' complaints, which are taken as true at this stage, *Escobar*, 136 S. Ct. at 1997, are as follows.

When a drug manufacturer wishes to get a drug approved for manufacture and sale in the United States, it must submit a "new drug application" (NDA) to the FDA, in which it states the chemical composition of a drug and specifies the facilities where it will be manufactured, as well as methods and controls used in the manufacturing process. 21 U.S.C. § 355(a), (b)(1); 21 C.F.R. § 314.50(d)(1). Acceptable facilities must meet federal standards, known as "good manufacturing practices." *See* 21 C.F.R. Parts 210, 211. The FDA may refuse an application or withdraw a previously approved application if the methods or facilities "are inadequate to preserve [the drug's] identity, strength, quality, and purity." 21 U.S.C. § 355(d), (e). Once approved, the manufacturer must obtain FDA approval to make major changes to the manufacturing process "before the distribution of the drug" by submitting an application called a Prior Approval Supplement, or PAS. 21 U.S.C. § 356a(c)(2); 21 C.F.R. § 314.70(b)(3). Both an NDA and PAS require the applicant to certify that all statements in the application are true and agree to comply with all applicable laws and regulations. *See* Form 356h.

In the mid-2000s, Gilead submitted NDAs and received FDA approval for Emtriva, Truvada, and Atripla. These

drugs contain the active ingredient[1] emtricitabine (commonly known as FTC).[2] In its NDA applications, Gilead represented to the FDA that it would source the FTC from specific registered facilities in Canada, Germany, the United States, and South Korea. But, relators allege that as early as 2006, Gilead contracted with Synthetics China to manufacture unapproved FTC at unregistered facilities. For a period of sixteen months beginning in December 2007, Gilead brought illicit FTC from a Synthetics China facility into the United States to use in its commercial drugs, claiming that the FTC had come from its approved South Korean manufacturer. Gilead allegedly began using Synthetics China to save money and trigger price reduction clauses in contracts with other FTC suppliers.

Gilead ultimately sought approval from the FDA to use Synthetics China's FTC in October 2008, but according to relators, Gilead had been including products from Synthetics China in its finished drug products for at least two years before this approval was obtained in 2010. Relators also allege that Gilead falsified or concealed data in support of its application to get Synthetics China approved by the FDA. For example, Gilead claims in its application that it had received three full-commercial-scale batches of FTC from Synthetics China that passed testing and were consistent with

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[1] The term "active ingredient" refers to the biologically active component of a drug, i.e., any "component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure of any function of the body." 21 C.F.R. § 210.3(b)(7).

[2] In addition to using the term FTC, relators use the term "API" to refer to "active pharmaceutical products" throughout their complaints. To avoid confusion, this opinion uses only the term FTC.

or equivalent to FTC batches made from existing, approved manufacturers. Relators contend that this representation was false as two of three batches had failed internal testing. One of the batches purportedly contained "residual solvent levels in excess of established limits" and other impurities. A second batch had "microbial contamination" and showed the presence of arsenic, chromium and nickel contaminants. Gilead did not report this to the FDA, but rather secured two new batches from the unapproved Chinese site and amended its PAS on April 24, 2009, to include the substitute data. The FDA approved the amended PAS in May 2009 and the Synthetics China facility was registered in 2010. Gilead also began using FTC from another, unapproved Synthetics China facility, but ultimately stopped using Synthetics China as a supplier in October 2011, following continued contamination issues. Two recalls of contaminated products occurred in 2014.

Gilead never acknowledged or notified the FDA about the bad test results or the contamination and adulteration problems. Despite being aware of manufacturing problems with Synthetics China, Gilead allegedly released 77 lots of FTC produced by Synthetics China to its contract manufacturers before the FDA approval of the Synthetics China facility. Relators allege that the drug products made with FTC affecting the quality and purity of the drug and produced at a different, uninspected manufacturing site are not FDA-approved. And, according to relators, had the FDA been aware of these issues, it would not have approved the use of the Synthetics China manufacturing facility. Relators make a similar argument for the use of unapproved sites in Alberta, Canada to produce ambrisentan, the active ingredient in Letairis, and contamination of tenofovir disoproxil fumarate (a.k.a. Viread), another active ingredient.

Relators insist that Gilead actively concealed its use of illicit FTC products by Synthetics China in a number of ways. First, Gilead imported the FTC through its Canadian facilities and used fraudulent labeling. Second, the labels and paperwork for the FTC were obscured or augmented to conceal where the FTC was actually produced. Third, Gilead credited its approved FTC manufacturers with the production of the Synthetics China FTC. Relators allege Gilead's false statements and fraudulent conduct resulted in government payments both directly, through programs such as the Department of Defense, Department of Veterans Affairs, Federal Bureau of Prisons, USAID, and the Public Health Service, and through reimbursement programs, such as Medicare, Medicaid, TRICARE, FEHBP, and the Ryan White Program. Payment for drugs under these programs is contingent upon FDA approval. *See, e.g.*, 48 C.F.R. § 46.408 (direct payment); 42 U.S.C. § 1396r-8(k)(2)(A)(i) (Medicaid); 42 U.S.C. § 1395w-102(e) (Medicare Part D). Relators allege that because the drugs paid for by the government contained FTC sourced at unregistered facilities, they were not FDA approved and therefore not eligible for payment under the government programs.

Relators further claim that these drugs were "adulterated" or "misbranded" in violation of the law. Congress expressly prohibits any person from introducing or receiving any "adulterated" or "misbranded" drugs in interstate commerce. 21 U.S.C. § 331(a), (c). A drug is "adulterated" if "the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice," or if "any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part

therefor." 21 U.S.C. § 351(a)(2)(B), (d). A drug is "misbranded" if, *inter alia*, "it is an imitation of another drug," or "it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered" under the Food, Drug, and Cosmetic Act. 21 U.S.C. § 352(i)(2), (o). Violations of that restriction are crimes and adulterated or misbranded drugs can be seized. 21 U.S.C. §§ 333(a), 334.

Relators finally raise a retaliation claim regarding the termination of Relator Jeff Campie. *See* 31 U.S.C. § 3730(h). Mr. Campie worked at Gilead as its Senior Director of Global Quality Assurance from July 2006 to July 2009. His "regular job duties focused on commercial drug product quality assurance/control issues[, but] he was (based on job requirements) expected to review [active ingredient] submissions as well." While employed with Gilead, Campie had quality control oversight of (1) all commercially released drug products by Gilead; (2) Gilead's policies, practices, and good manufacturing practice compliance; and (3) the development of quality systems. It appears that Campie raised concerns about "the integrity of the data being generated to support the release of Gilead drugs" as early as July 2007. In 2008, Campie became worried about Gilead's use of FTC manufactured by Synthetics China, and in January 2009, convened a meeting to caution Gilead management that FTC could not be shipped from an unapproved manufacturing site. Through the remainder of his employment, "Mr. Campie continued to voice strenuous objections to the false representations and omissions being made to the Government concerning the source and lack of purity of the [active ingredients] from Synthetics China and that [sic] lack of a truthful, valid and approved PAS." "Although Mr. Campie was supposed to be responsible for commercial quality input

on regulatory filings implicating quality or supply issues, Gilead began to selectively circumvent Mr. Campie's review and effectively removed or excluded him from Gilead's regulatory review process." In a March 2009 meeting, "Mr. Campie made clear that he expected Gilead to stop its deceptive practices and threatened to inform the FDA if Gilead continued its fraudulent conduct." In April 2009, Campie initiated a quarantine to prevent non-approved Letairis from entering the supply chain. That quarantine was lifted and Campie was chastised by management. During this time, Campie continued to voice his concerns.

On June 20, 2009, Campie was informed he would be terminated effective July 2009. He was told that his "heart wasn't in the job anymore." Campie maintains, however, that he was terminated because he "discovered, investigated, and raised concerns over Gilead's release and distribution . . . of tons of contaminated and adulterated [active ingredients] that had been manufactured at unregistered and uninspected" facilities and thus "were not eligible for payment under the Government Payment Programs, causing the submission of false claims paid by the [federal] Government and the States." Upon termination, Campie was asked to sign a severance agreement agreeing not to initiate any claims under the False Claims Act. He refused.

The district court dismissed relators' first amended complaint on January 7, 2015, under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim, but gave relators an opportunity to amend. On June 12, 2015, the district court dismissed relators' second amended complaint with prejudice, holding that it also failed to state a claim

under the False Claims Act.[3] Relators timely appealed. Although it declined to intervene in the case below, the United States Department of Justice submitted a brief as amicus curiae supporting reversal of the district court.

II.

We have jurisdiction pursuant to 28 U.S.C. § 1291. We review the dismissal of claims under the False Claims Act de novo. *United States ex rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166, 1170 (9th Cir. 2006). We assume the facts as alleged are true and examine only whether relators' allegations support a cause of action under the False Claims Act under the theories presented. *Id.* A Rule 12(b)(6) dismissal "can be based on a lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1990). A complaint must plead "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim under the False Claims Act must not only be plausible, Fed. R. Civ. P. 8(a), but pled with particularity under Rule 9(b), *Cafassao ex rel. United States v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1054–55 (9th Cir. 2011). The district court based its dismissal on Rule 12(b)(6) and did not address whether the relators' complaints met Rule 9(b)'s heightened pleading standard.

[3] The parallel state claims were dismissed without prejudice.

III.

The False Claims Act makes liable anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A), (B). A "claim" includes direct requests for government payment as well as reimbursement requests made to the recipients of federal funds under a federal benefits program. 31 U.S.C. § 3729(b)(2)(A); *Escobar*,136 S. Ct. at 1996. A claim under the False Claims Act requires a showing of "(1) a false statement or fraudulent course of conduct, (2) made with the scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *Hendow*, 461 F.3d at 1174. It is not enough to allege regulatory violations, *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996); rather, the false claim or statement must be the "*sine qua non* of receipt of state funding," *Ebied ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010). We construe the Act broadly, as it is "intended to reach all types of fraud, without qualification, that might result in financial loss to the Government." *Hendow*, 461 F.3d at 1170 (quoting *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968)).[4] Such broad

[4] Although the Supreme Court admonished in *Escobar* that "[t]he False Claims Act is not 'an all-purpose antifraud statute,' or a vehicle for punishing garden variety breaches of contract or regulatory violations," 136 S. Ct. at 2003 (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 555 U.S. 662, 672 (2008) (citation omitted)), this instruction related only to the "demanding" materiality requirement of a False Claims Act claim, *see id.*, and therefore did not displace this court's obligation to construe broadly any theory of liability in which materiality can be proven.

construction has thus given rise to a number of doctrines "that attach potential False Claims Act liability to claims for payment that are not explicitly and/or independently false." *Hendow*, 461 F.3d at 1171.

Relators insist that Gilead's claims seeking payment for noncompliant drugs are a basis for liability under the False Claims Act for three reasons. First, Gilead charged the government for approved drugs, knowing that it had delivered unapproved "knock-offs" (factually false certification). Second, by selling its drugs to the government and causing others to seek reimbursement for them, Gilead implicitly certified that the drugs were approved for distribution when it knew otherwise (implied false certification). Third, Gilead lied to the FDA to secure approval of Chinese facilities, making them eligible for government payments (promissory fraud). The district court below rejected all three of relators' theories for recovery under the False Claims Act. First, the district court rejected relators' formulation of a factually false theory based on the provision of nonconforming goods. As to relators' second and third arguments, the district court recognized claims brought under either an implied false certification or promissory fraud theory could be viable, but concluded that relators failed to state a claim under either one because they failed to allege Gilead made a false statement related to a material precondition for payment. The United States, while not taking a position on the merits of relators' claims, identifies in its amicus briefing two rulings by the district court as particularly significant to the government. First, it argues that the district court's dismissal of relators' nonconforming goods theory improperly limits liability under the False Claims Act. Second, it argues that the district court improperly rejected a promissory fraud theory where the fraud was initially directed at a non-payor agency. We

address each of the relevant theories for recovery under the False Claims Act and conclude that relators state a plausible claim.

A. Factually False Certification

Relators insist that Gilead's HIV drugs were not manufactured at an approved facility and thus were not approved by the FDA, and therefore Gilead's sale of those medicines, and attendant receipt of government payments, constituted a material false statement. Although the district court analyzed this claim in part as a failed claim for worthless services, *United States ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1053 (9th Cir. 2001), the claim is one of nonconforming goods, *United States v. Nat'l Wholesalers*, 236 F.2d 944, 950 (9th 1956); *see United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 305 (3d Cir. 2011) ("A claim is factually false when the claimant misrepresents what goods or services that it provided to the Government . . . ."). The value of the goods at issue is dispositive under the first characterization, *Lee*, 245 F.3d at 1053–54, and immaterial to the latter, *Nat'l Wholesalers*, 236 F.2d at 949–51 (finding a violation of the False Claims Act despite substitute goods of "equal" performance); *United States v. Aerodex, Inc.*, 469 F.2d 1003, 1007–08 (5th Cir. 1972) ("The mere fact that the item supplied under contract is as good as the one contracted for does not relieve defendants of liability if it can be shown that they attempted to deceive the government agency."). Although relators failed to allege that the drugs paid for by the government were "worthless," that failure does not affect relators' claim for nonconforming goods.

In *National Wholesalers*, a wholesaler contracted with the United States to furnish proprietary engine regulators but instead delivered regulators manufactured by the wholesaler bearing spurious proprietary labels. 236 F.2d at 945–47. Even though the substitute regulators functioned equally to those contracted for, we found liability under the False Claims Act because the wholesaler "misbrand[ed]" the substitutes to make them appear to be the genuine article. *Id.* at 950. The Fifth Circuit reached a similar conclusion in *Aerodex*, where the defendants sold the United States Navy engine bearings different from the ones contracted for, admitting that they both reworked and renumbered the bearings to appear compliant with their contract. 469 F.2d at 1007. Despite the fact that the bearings provided were also approved for use in the engines at issue, the Fifth Circuit found liability under the False Claims Act due to the defendant's deliberate mislabeling. *Id.* at 1007–08.

Contrary to the position taken by Gilead, a claim for nonconforming goods is not limited to situations where there is an express specification in a payment contract between a supplier and the government regarding the disputed aspect of the product to be supplied. Such a circumscribed view of False Claims Act liability was expressly rejected by the Supreme Court in *Escobar*, 136 S. Ct. at 2001, a case decided after the district court had ruled in this case. Additionally, as we have previously explained, the False Claims Act "was enacted during the Civil War with the purpose of forfending widespread fraud by government contractors who were submitting inflated invoices and shipping faulty goods to the government." *Hopper*, 91 F.3d at 1265–66. That core purpose would not be served if a defendant could escape liability for delivering nonconforming goods merely because the goods retained some value or in the absence of a bilateral

contract. It is fraudulent conduct that gives rise to liability, regardless of whether the underlying relationship is based in contract, regulation, or statute. *Nat'l Wholesalers*, 236 F.2d at 950.

As we have previously held, the provision of nonconforming goods can be a basis of liability under the False Claims Act. *See Hopper*, 91 F.3d at 1266 (citing *Aerodex* for proposition that "[False Claims Act] actions have also been sustained under theories of supplying substandard products or services"). But, unlike the situation in *Lee*, where a claim for medically "worthless" drugs does not require a showing of "false certification," 245 F.3d at 1053, a claim for nonconforming goods must include an intentionally false statement or fraudulent course of conduct that was material to the government's decision to pay, *Nat'l Wholesalers*, 236 F.2d at 950.

B. Implied False Certification

Claims under an implied false certification theory can also be viable under the False Claims Act. *Escobar*, 136 S. Ct. at 1999. Under such a theory, "when a defendant submits a claim, it impliedly certifies compliance with all conditions of payment. But if the claim fails to disclose the defendant's violation of a material statutory, regulatory, or contractual requirement . . . the defendant has made a misrepresentation that renders the claim 'false or fraudulent' under § 3729(a)(1)(A)." *Id.* at 1995. In *Escobar*, the Supreme Court recently "clarif[ied] some of the circumstances in which the False Claims Act imposes liability" under this theory. *Id.* As pointed out above, the district court did not have the benefit of *Escobar* in making its decision.

In *Escobar*, parents brought suit following the death of their daughter after she was treated at a mental health clinic by various unlicensed and unsupervised staff in violation of state Medicaid regulations. *Id.* at 1997. The operative complaint asserted that the healthcare provider "submitted reimbursement claims that made representations about the specific services provided by specific types of professionals, but that failed to disclose serious violations of regulations pertaining to staff qualifications and licensing requirements for those services." *Id.* at 1997–98 (footnote omitted). The state Medicaid program, "unaware of these deficiencies, paid the claims." *Id.* at 1998. The Court concluded that "by submitting claims for payment using payment codes that corresponded to specific counseling services, [the healthcare provider] represented that it had provided individual therapy, family therapy, preventive medication counseling, and other types of treatment." *Id.* at 2000. Moreover, staff members "submitt[ed] Medicaid reimbursement claims by using National Provider Identification numbers corresponding to specific job titles. And these representations were clearly misleading in context." *Id.*

The Supreme Court held that although the implied certification theory can be a basis for liability, two conditions must be satisfied. *Id.* at 2000. First, the claim must not merely request payment, but also make specific representations about the goods or services provided. *Id.* Second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements must "make[] those representations misleading half-truths." *Id.* at 2001 (footnote omitted). The violation need not be of a contractual, statutory, or regulatory provision that the Government expressly designated as a condition of payment. *Id.* However, the misrepresentation must be

"material to the Government's payment decision." *Id.* at 2002. Although *Escobar* clarifies the conditions upon which an implied false certification claim can be made, the four essential elements identified above remain the same. *See Hendow*, 461 F.3d at 1174; *see also United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 332–33 (9th Cir. 2017) (applying *Escobar* to former employee of a defense contractor alleging that his employer's submission of vouchers constituted a false certification of work performed under a contract).

C. Promissory Fraud

Another approach to finding liability under the False Claims Act in the absence of an explicitly false claim is the "promissory fraud" or "fraud-in-the-inducement" theory. *Hendow*, 461 F.3d at 1173. Under this theory, "liability will attach to each claim submitted to the government under a contract, when the contract or extension of the government benefit was originally obtained through false statements or fraudulent conduct." *Id.* "In other words, subsequent claims are false because of an *original fraud* (whether a certification or otherwise)." *Id.* The elements of a claim for promissory fraud are very similar to those necessary for an implied false certification claim, requiring a false claim wherein the falsity is knowingly perpetrated and the underlying fraud is material to the government's decision to pay. *Id.* at 1174.

D. Elements

Under all three theories the essential elements of False Claims Act liability are: (1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or

forfeit moneys due. *Escobar*, 136 S. Ct. at 2000–02; *Nat'l Wholesalers*, 236 F.2d at 950; *Hendow*, 461 F.3d at 1174. Here, the dispute focuses primarily on the first and third elements, falsity and materiality. The district court rejected relators' claims for a number of reasons, including that the fraud was directed at the FDA, not the payor agency; payment was not conditioned on compliance with FDA regulations, but merely FDA approval; and the False Claims Act was not meant to intrude on the FDA's complex regulatory regime.

1. Falsity

The first requirement of a False Claims Act claim is a false claim. *Hendow*, 461 F.3d at 1171; *Hopper*, 91 F.3d at 1266 ("Violations of laws, rules, or regulations alone do not create a cause of action. It is the false *certification* of compliance which creates liability when certification is a prerequisite to obtaining a government benefit."). Relators allege a false claim here.

a. Factually false certification

Relators have adequately satisfied the falsity requirement under a theory of factually false certification. As in *National Wholesalers*, Gilead committed factually false certification by supplying "misbrand[ed]" goods. 236 F.2d at 950. Specifically, Gilead represented to the FDA that its active ingredients had been manufactured in approved facilities that had been registered therewith.

b. Implied false certification

Relators have also adequately satisfied the falsity requirement under a theory of implied false certification. To succeed on such a claim, pursuant to *National Wholesalers* and *Escobar*, Gilead must not merely request payment, but also make specific representations about the goods or services provided. *Escobar*, 136 S. Ct. at 2000; *Nat'l Wholesalers*, 236 F.2d at 950. Here, relators allege that by submitting claims for payment or reimbursement for Truvada, Emtriva, and Atripla, Gilead represented that it provided medications approved by the FDA that were manufactured at approved facilities and were not adulterated or misbranded. Just as payment codes correspond to specific health services, *Escobar*, 136 S. Ct. at 2000, and proprietary labels indicate that engine regulators are a proprietary design, *Nat'l Wholesalers*, 236 F.2d at 950, these drug names necessarily refer to specific drugs under the FDA's regulatory regime. *Escobar* further requires that Gilead's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements must "make[] those representations misleading half-truths." 136 S. Ct. at 2000 (footnote omitted). Setting aside the question of materiality, relators allege Gilead's representations were misleading in this context because Gilead acquired unapproved FTC from a Chinese supplier, re-labeled it to conceal its true nature, falsified test results that showed it was contaminated, and then used that unapproved and contaminated FTC in drugs for which payment was requested and received. Although the drugs at issue were at all times ostensibly "FDA approved," relators allege Gilead requested payment for drugs that fell outside of that approval and omitted critical information regarding compliance with FDA standards.

The district court rejected relators' claims in part because the alleged fraud was directed at the FDA, not the payor agency. That concern is factually assuaged to some degree for the purposes of this case in that both the FDA and the Center for Medicare & Medicaid Services (CMS) (the primary payor agency for reimbursement claims) are overseen by the Secretary of Health and Human Services. Therefore, the fraud was, at all times, committed against the Department of Health and Human Services. But more importantly, the False Claims Act imposes no such limitation. *See* 31 U.S.C. § 3729(a)(1)(B) (extending liability to those who cause false statements to be used). It is not the distinction between the agencies that matters, but rather the connection between the regulatory omissions and the claim for payment. *See United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 492 (3d Cir. 2017) ("[O]ur focus here should not be whether the alleged fraud deceived the prescribing physicians, but rather whether it affected CMS's payment decision."). As we stated in *Hendow*, "if a false statement is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork." 461 F.3d at 1174. *Hendow* itself involved false statements submitted to the Department of Education where claims were submitted to private lenders. *Id.* at 1169–80; *see also, e.g.*, *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 12, 29–30 (1st Cir. 2009) (alleging defendant's fraud caused medical providers to submit false claims); *Hutchenson*, 647 F.3d at 378 (similar). Moreover, relators allege that in addition to making a number of false and fraudulent statements to the FDA, Gilead's submission of alleged unapproved and noncompliant drugs to the payor agencies was itself an alleged false certification. *Escobar*, 136 S. Ct. at 2000.

The district court also rejected relators' claims because payment was not "conditioned on the falsity." As made clear in *Escobar*, "'[I]nstead of adopting a circumscribed view of what it means for a claim to be false or fraudulent,' concerns about fair notice and open-ended liability 'can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements.'" 136 S. Ct. at 2002 (quoting *United States v. Science Applications Int'l Corp.*, 626 F.3d 1257, 1270 (D.C. Cir. 2010)). We therefore address the district court's concern in the context of materiality.

Gilead insists its certification was not "false" pursuant to *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 701–02 (4th Cir. 2014). In *Omnicare*, the Fourth Circuit concluded that

> once a new drug has been approved by the FDA and thus qualifies for reimbursement under the Medicare and Medicaid statutes, the submission of a reimbursement request for that drug cannot constitute a "false" claim under the [False Claims Act] on the sole basis that the drug has been adulterated as a result of having been processed in violation of FDA safety regulations.

745 F.3d at 701–02. In *Omnicare*, the relator alleged only regulatory violations, not a false claim. *Id.* Although we rejected a regulatory violation claim in *Hopper*, 91 F.3d at 1265–67, we have since clarified that the "fatal defect" in that case "was not that the claimed infraction was a regulatory violation, but that there was a 'lack of a false claim,'" *Hendow*, 461 F.3d at 1171; *see also Kelly*, 846 F.3d at 333 (finding no evidence of a "false claim" where dispute was

over *format* of cost reports). Here, relators allege false statements permeating the regulatory process. They allege Gilead mislabeled and misbranded nonconforming drugs and misrepresented its compliance with FDA regulations by omitting critical information. They allege that Gilead established policies and practices to violate the FDA's regulatory requirements and allege specific instances of such violations, such as altering inventory codes, and mislabeling or altering shipping and tracking information. All the while, Gilead was submitting claims for payment for "FDA approved" drugs. Moreover, they allege that Gilead made false statements regarding test results in order to get FDA approval and thus become eligible for government funds. As was the case in *Escobar*, "[t]he claims in this case do more than merely demand payment. They fall squarely within the rule that half-truths—representations that state the truth only so far as it goes, while omitting critical qualifying information—can be actionable misrepresentations." 136 S. Ct. at 2000 (footnote omitted). Relators adequately plead falsity under the False Claims Act. To hold otherwise would reduce FDA regulations akin to approval of the curate's egg.

c. Promissory fraud

Finally, relators have adequately satisfied the falsity requirement under a theory of promissory fraud. Because Gilead committed either factually false or impliedly false certification through its representations to the FDA and labeling of its products, *see supra*, each claim was fraudulent even if false representations were not made therein. *See Hendow*, 461 F.3d at 1173.

2. Scienter

Had Gilead accidentally produced adulterated pills and unwittingly shipped them and requested payment from the government, the intent requirement under the False Claims Act would not be met. That is not the case. Relators allege a false statement or course of conduct made knowingly and intentionally. *See* 31 U.S.C. § 3729(b)(1). They allege Gilead took internal actions perpetuating its fraud: altering test results, batch numbers, and Inventory Control Numbers, and representing that nonapproved FTC came from approved facilities. They also allege Gilead established practices to deceive the government, and repeatedly took actions to hide its fraud. In other words, relators allege Gilead provided statements to the government that were "intentional, palpable lie[s]," made with "knowledge of the falsity and with intent to deceive." *Hopper*, 91 F.3d at 1265, 1267. The scienter element is adequately pled.

3. Materiality

Under the False Claims Act, a falsehood is material if it has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). In *Escobar*, the Supreme Court clarified that "[t]he materiality standard is demanding." 136 S. Ct. at 2003. "A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance." *Id.* Materiality also "cannot be found where noncompliance is minor or insubstantial." *Id.* Proof

of materiality can include whether "the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated." *Id.*

FDA approval is the "the *sine qua non*" of federal funding here. *Hendow*, 461 F.3d at 1176. Eligibility for federal funding and reimbursement is conditioned on FDA approval under Medicaid, 42 U.S.C. § 1396r-8 (limited to "covered outpatient drug," which is defined as "approved for safety and effectiveness as a prescription drug" by the FDA), Medicare, 42 U.S.C. § 1395w-102e (similar), and the direct payment programs identified by relators, 48 C.F.R. § 46.408 (assigning FDA responsibility for ensuring quality of drugs purchased by agencies). All of these payment programs look to FDA-approval as a determination of the "safety and effectiveness" of the drugs at issue.[5] It is undisputed that at all times relevant, the drugs at issue were FDA-approved,[6] and that the government continues to make direct payments and provide reimbursements for the sale of the three drugs. Relators thus face an uphill battle in alleging materiality sufficient to maintain their claims.

We note that other courts have cautioned against allowing claims under the False Claims Act to wade into the FDA's regulatory regime. *See Omnicare*, 745 F.3d at 702–03;

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[5] Payment can also be conditioned on other aspects of the drug not regulated by the FDA, such as whether the product is "reasonable and necessary" under Medicare. *See* 42 U.S.C. § 1395y(a)(1)(A).

[6] The district court focused extensively on the difference between NDA-approval and PAS-approval, ultimately concluding NDA-approval was the sole condition of payment. That distinction is not persuasive post-*Escobar*. *See* 136 S. Ct. at 1999.

D'Agostino v. ev3, Inc., 845 F.3d 1, 9 (1st Cir. 2016);[7] *Petratos*, 855 F.3d at 490. However, just as it is not the purpose of the False Claims Act to ensure regulatory compliance, it is not the FDA's purpose to prevent fraud on the government's fisc. Mere FDA approval cannot preclude False Claims Act liability, especially where, as here, the alleged false claims procured certain approvals in the first instance.[8] A conclusion to the contrary would not be consistent with *Escobar*:

> By punishing defendants who submit "false or fraudulent claims," the False Claims Act encompasses claims that make fraudulent misrepresentations, which include certain misleading omissions. When, as here, a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided.

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[7] In *D'Agostino*, the First Circuit went as far as to conclude that "[t]he FDA's failure actually to withdraw its approval of [a medical device]. . . precludes [the relator] from resting his claims on a contention that the FDA's approval was fraudulently obtained" and that "the absence of some official agency action confirming its position and judgment in accordance with the law renders [a relator]'s fraud-on-the-FDA theory futile." 845 F.3d at 9.

[8] Take the hypothetical posed by relators: if a reimbursement request was submitted for 10 pills of Atripla, but Gilead actually provided 10 pills of Tylenol, that request for payment would be undeniably false. Even though Tylenol is FDA approved, it is not what the government paid for.

136 S. Ct. at 1999. The dispositive question is rather one of materiality, which turns on a number of factors:

> when evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Id. at 2003–04.

Here, Gilead insists that because the government continued to pay for the medications after it knew of the FDA violations, those violations were not material to its payment decision. Relators outline a variety of facts that speak to the government's knowledge, such as a September 2010 warning letter regarding impurities in the form of black specks and

spots, a June/July 2012 inspection and noncompliance letter regarding product from Synthetics China, December 2012 and July 2013 inspections of a specific facility, and two recalls that took place in 2014. Gilead's argument is premised on the continued FDA approval of the drugs even after the agency became aware of certain noncompliance.

Relators and the United States persuasively argue, however, that to read too much into the FDA's continued approval—and its effect on the government's payment decision—would be a mistake. First, to do so would allow Gilead to use the allegedly fraudulently-obtained FDA approval as a shield against liability for fraud. Second, as argued by Gilead itself, there are many reasons the FDA may choose not to withdraw a drug approval, unrelated to the concern that the government paid out billions of dollars for nonconforming and adulterated drugs. Third, unlike *Kelly*, where the government continued to accept noncompliant vouchers, 846 F.3d at 334, Gilead ultimately stopped using FTC from Synthetics China. Once the unapproved and contaminated drugs were no longer being used, the government's decision to keep paying for compliant drugs does not have the same significance as if the government continued to pay despite continued noncompliance. In making its argument, Gilead specifically cites to *Petratos*, where the Third Circuit concluded the materiality standard was not met where the relator did "not dispute that CMS would reimburse these claims even with full knowledge of the alleged reporting deficiencies." 855 F.3d at 490. Beside the fact that the relator in *Petratos* did not allege regulatory or statutory violations, *id.* ("Petratos does not claim that [the defendant]'s safety-related reporting violated any statute or regulation."), no such concession is made here. Rather, the parties dispute exactly what the government knew and when,

calling into question its "actual knowledge." Although it may be that the government regularly pays this particular type of claim in full despite actual knowledge that certain requirements were violated, such evidence is not before us.

The issues raised by the parties here are matters of proof, not legal grounds to dismiss relators' complaint.[9] *See Kelly*, 846 F.3d at 334 (concluding relator "failed to establish a genuine issue of material fact regarding [] materiality"). And, other statutes regulating "adulterated" and "misbranded" drugs reinforce the idea that violations of the FDA regulatory regime have ramifications beyond FDA enforcement actions. *See* 21 U.S.C. § 331; *see, e.g.*, *United States v. Marcus*, 82 F.3d 606, 610 (4th Cir. 1996) (upholding criminal liability for manufacturer's undisclosed addition of two inactive pharmaceutical ingredients not included in FDA-approved NDA given their unknown effect on safety and efficacy of the drug product).

In sum, relators allege more than the mere possibility that the government would be entitled to refuse payment if it were aware of the violations, *Kelly*, 846 F.3d at 334, sufficiently pleading materiality at this stage of the case.

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[9] In *D'Agostino*, the First Circuit highlighted the "[p]ractical problems of proof" in how a relator would show that the FDA would not have granted approval but for the fraudulent representations. 845 F.3d at 9. That concern is exactly that: a problem of proof. At the pleading stage we assume the facts alleged by the relators to be true. *Hendow*, 461 F.3d at 1170.

4. Claim

Relators allege Gilead submitted false claims in a number of ways, including submitting direct requests for payment from government agencies, as well as submitting requests for reimbursement. Those allegations are sufficient under the False Claims Act. *Hendow*, 461 F.3d at 1177.

Ultimately, relators have alleged sufficient facts under the False Claims Act to state a claim for relief that is plausible on its face. Fed. R. Civ. P. 8(a); *Ashcroft*, 556 U.S. at 678. We do not reach whether that claim is alleged with sufficient particularity to meet the requirements of Rule 9(b), as that question was not addressed by the district court.

IV.

Relator Jeff Campie also alleges Gilead retaliated against him in violation of the False Claims Act. 31 U.S.C. § 3730(h). To state a claim for retaliation, a plaintiff must demonstrate that: (1) he "engaged in activity protected under the statute"; (2) the employer knew the plaintiff engaged in a protected activity; and (3) the employer discriminated against the plaintiff "because he . . . engaged in protected activity." *Mendiondo v. Centinela Hosp. Med. Ctr.*, 521 F.3d 1097, 1103 (9th Cir. 2008) (holding that the heightened pleading requirements of Rule 9(b) do not apply). The district court dismissed Campie's retaliation claim, holding that he failed to show either that he was engaged in a protected activity or that Gilead had notice of such activities. We reverse.

A. Protected Activity

An employee engages in a protected activity by "'investigating matters which are calculated or reasonably could lead to a viable [False Claims Act] action.'" *Moore v. Cal. Inst. of Tech. Jet Propulsion Lab.*, 275 F.3d 838, 845 (9th Cir. 2002) (quoting *Hopper*, 91 F.3d at 1269). The district court relied extensively on *Hopper* to conclude that because Campie's allegations are consistent with an investigation into regulatory noncompliance—as opposed to an effort to uncover fraud against the government—he failed to show he engaged in a protected activity. *See* 91 F.3d at 1263–65. However, in *Moore* we subsequently clarified "that an employee engages in protected activity where (1) the employee in good faith believes, and (2) a reasonable employee in the same or similar circumstances might believe, that the employer is possibly committing fraud against the government." 275 F.3d at 845–46 (footnote omitted). The Second Amended Complaint sufficiently alleges facts showing that Campie had an objectively reasonable, good faith belief that Gilead was possibly committing fraud against the government.

B. Notice

It is not enough for relators to allege that Jeff Campie was engaged in a protected activity; they must also show that Gilead knew Campie was engaged in such activity. *Mendiondo*, 521 F.3d at 1103; *Hopper*, 91 F.3d at 1269. As made clear in *Mendiondo*, an allegation of knowledge is not a high bar:

> For the second element of her . . . retaliation claims, Mendiondo alleges she complained to

> [the defendant]'s CEO . . . about possible "civil and criminal violations." Although vague, the reference to "civil violations" can be construed to include the suspected Medicare fraud described above. Because Mendiondo complained to [the CEO] about the suspected civil violations, [the defendant] was informed of Mendiondo's protected activity.

521 F.3d at 1104. Here, the Second Amended Complaint alleges Campie was told it was "none of his concern" when he discussed contamination and adulteration problems on multiple occasions, and he was asked to sign a severance agreement stating he would not bring a False Claims Act claim. Further, "Mr. Campie explicitly complained that Gilead was violating FDA regulations in order to sell its drugs to the Government and States notwithstanding their lack of compliance with [regulatory requirements] . . . ." These allegations are sufficient under *Mendiondo.*

That said, as noted by the district court, the monitoring and reporting activities outlined by relators are by-and-large the types of activities Campie was required to undertake as part of his job. Courts have held that when an employee is tasked with such investigations, it takes more than an employer's knowledge of that activity to show that an employer was on notice of a potential *qui tam* suit. *See United States ex rel. Ramseyer v. Century Healthcare Corp.*, 90 F.3d 1514, 1523 (10th Cir. 1996) (holding retaliation allegation insufficient where plaintiff's job duties entailed the monitoring and reporting activities at issue); *see also Robertson v. Bell Helicopter Textron, Inc.*, 32 F.3d 948, 952

(5th Cir. 1994) (concluding that relator failed to rebut defendant's *trial testimony* regarding lack of knowledge).

Although *Ramseyer* is instructive, it is distinct from this case. First, the plaintiff in *Ramseyer* "gave no suggestion that she was going to report [the] noncompliance to government officials." 90 F.3d at 1523. Here, the Second Amended Complaint alleges that "Mr. Campie made clear that he expected Gilead to stop its deceptive practices and threatened to inform the FDA if Gilead continued its fraudulent conduct." Second, Campie alleges he was "selectively circumvent[ed]" and "exclud[ed]" from the regulatory review process in which he was meant to take part, was told certain regulatory compliance actions, such as issuing a quarantine, were "not in his job description," and had conversations outside of his chain of command regarding his concerns. The Second Amended Complaint alleges sufficient facts to show Gilead knew of Campie's protected activity.

C. Causation

Finally, relators' pleading must show that Gilead discriminated against Mr. Campie "because he [] engaged in protected activity." *Mendiondo*, 521 F.3d at 1104. It is sufficient at the pleading stage for the plaintiff "to simply give notice that []he believes [the defendant] terminated h[im] because of h[is] investigation into the practices [] specified in the complaint." *Id.* Although the district court did not address this requirement because it found the operative complaint insufficient under the first two requirements, such a showing has been made here.

Based on the forgoing, the retaliation claim included in the Second Amended Complaint contains sufficient facts to survive dismissal under Rule 12(b)(6).

V.

Relators plead sufficient factual allegations to state a claim under the False Claims Act. Because the district court did not address whether relators' claims pursuant to 31 U.S.C. § 3729(a)(1)(A), (B) meet the heightened pleadings standard under Rule 9(b), we decline to decide that question in the first instance.

REVERSED AND REMANDED.