No. 15-16380

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

JEFFREY CAMPIE and SHERILYN CAMPIE

Relator-Appellants; ex rel. United States of America

and

UNITED STATES OF AMERICA,

Plaintiff

v.

GILEAD SCIENCES, INC.

Defendant-Appellee

Appeal from United States District Court for the Northern District of California
Civil Case No. 11-cv-941 EMC (Honorable Edward M. Chen)

RELATOR-APPELLANTS' REPLY BRIEF

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REPLY BRIEF

The complaints allege that Gilead knowingly produced multiple important drugs by sourcing the active ingredient from a cut-rate facility in China that had not been approved by the Food and Drug Administration (FDA) and was incapable of producing ingredients conforming to the required specifications. Gilead then distributed pills containing that noncompliant ingredient—many of which were badly contaminated—by concealing the unapproved source. Gilead later attempted to legitimize the Chinese facility by amending its New Drug Applications (NDA) to permit the use of that facility. But the product sourced from China was far too tainted to gain approval, so Gilead falsified critical test results to deceive the FDA into approving the amendments. All told, Gilead received billions of dollars in public funds for nonconforming drugs through direct sales and health insurance reimbursements.

Based on these allegations, we advanced four theories of False Claims Act (FCA) liability. First, Gilead violated the FCA by knowingly seeking government payments for knock-off drugs that mimicked Gilead's approved drugs, but were not produced in the manufacturing facilities or in the manner required by the FDA-approved NDAs. Second, Gilead committed promissory fraud when it later deceived the FDA into approving amendments to the NDAs, knowing that this approval was absolutely necessary for it to continue to receive government

payments. Third, Gilead knowingly sought government payments for drugs that were illegal to distribute in interstate commerce because they were adulterated and misbranded in ways that would have been important to the government's payment decisions. Finally, Gilead independently violated the FCA by retaliating against appellant Jeffrey Campie, terminating him over the matter.

In response, Gilead principally argues that the one and only condition it had to satisfy was securing FDA approval of the NDAs for its drugs. Once Gilead had that, it argues, the government became obligated to pay for whatever substance Gilead delivered—even if the pills were not produced in conformity with the NDAs, and even if it obtained necessary amendments to the NDAs by fraud. According to Gilead, unless and until the FDA revoked the NDAs altogether, its sale of knock-off drugs could not have been "false" under the FCA. Indeed, Gilead's counsel conceded below that under its theory the government would have no FCA recourse even in the "extreme" case that Gilead "substituted a placebo" or a "fake" pill for an approved drug. E.R. 294.

Conceptually, the flaw with Gilead's argument is that it refuses to acknowledge that the FCA applies when a private party dupes the government into overpaying for inferior goods, *i.e.*, the "archetypal qui tam False Claims action." *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1170 (9th Cir. 2006). Indeed, the contrary proposition is a recurring theme in Gilead's brief. Time

and again, it treats the FCA as an all-or-nothing statute—*e.g.*, unless the FDA withdraws NDA approval altogether, there is no false claim; unless the drugs are completely worthless, there is no false claim; unless a contract expressly conditions payment on compliance with a particular law, there is no false claim. But such rigid, categorical rules are roadmaps for fraud because they are so easy to circumvent. If this Court accepts Gilead's argument, its ruling would immunize a broad range of pharmaceutical frauds, imperiling both the public fisc and public health.

Fortunately, the FCA is not so easily thwarted. It reaches "all types of fraud, without qualification, that might result in financial loss to the Government." *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968). To be sure, Gilead can argue to a jury that its falsehoods were not material or that it lacked scienter, so that it is guilty only of a series of regulatory violations instead of fraud. However, the complaints allege otherwise, and Gilead therefore cannot win these arguments as a matter of law. This Court should reverse the decision below.

I. The False Claims Act Prohibits Gilead From Seeking Government Payments For Unapproved Variants Of Approved Drugs.

1. Gilead knowingly deviated from the terms of its NDAs by distributing drugs containing FTC from Synthetics China before the NDAs were amended to permit the use of that manufacturer. The NDA regulation expressly requires NDAs to list the manufacturers of all ingredients. *See* 21 C.F.R. § 314.50(d)(1). Gilead's

NDAs did not list Synthetics China, and Gilead actively concealed its use of that facility. Gilead's liability under this theory is *not* premised on allegations that the drugs in question are adulterated or misbranded, or that Gilead violated the good manufacturing practice (GMP) regulations. Instead, FCA recourse is appropriate because Gilead's pills containing FTC from Synthetics China were outside the scope of the NDAs altogether. Gilead does not dispute that if this theory is valid, it applies to all drugs containing FTC sourced from Synthetics China Plant 202 prior to the NDA amendments, and from Plant 203 regardless of date.

Gilead's response rests on the false premise that the pills it sold were FDA-approved. It states, for example, that "[e]ven taking as true Relators' allegations that Gilead used active ingredients from Synthetics China before the facility was approved by the FDA, or that the *pills* contained contaminants, the *medicines* were FDA-approved during the entire period of time at issue." Br. 18 (emphasis added). Gilead thus equates the nonconforming "pills" with the approved "medicines." But it is precisely that equivalence that the complaints challenge as false: because the pills for which Gilead sought payment were not produced in the manner permitted by its NDAs, its assertion that the pills were FDA-approved is false.

Gilead's nonconforming pills cannot be regarded as approved. Prior to 1962, the general rule was that companies could bring drugs to market unless the FDA determined that they were dangerous. *See Wyeth v. Levine*, 555 U.S. 555, 566

(2009). The FDA had sixty days to deny an NDA; otherwise, the application would be approved by default. The 1962 amendments to the Food, Drug, and Cosmetics Act (FDCA) inverted that regime: from that point forward, no manufacturer may distribute a drug without first obtaining FDA permission in the form of NDA approval. *See id*. at 567. Thus, no mass-produced drugs are lawful to distribute absent specific FDA approval.

To obtain the required approval, manufacturers must submit detailed information to the FDA about the efficacy and the safety of the drug, which the FDA must weigh in deciding whether to approve the NDA. Manufacturers must specify not only the proposed chemical composition of the drug, but also how they plan to manufacture it—including the name and address of the manufacturer of every ingredient. *See* 21 C.F.R. § 314.50(d)(1).

Once the NDA is approved, the manufacturer may only market drugs that conform precisely to the NDA—not unapproved variants. If the manufacturer wishes to change any aspect of the NDA, it must notify the FDA. *Id*. § 314.70(a); FDA, Guidance for Industry: Changes to an Approved NDA or ANDA 4 (2004), *available at* http://tinyurl.com/ChangestoNDAs ("Other than for editorial changes in previously submitted information (*e.g.*, correction of spelling or typographical errors, reformatting of batch records), an applicant must notify FDA about each change in each condition established in an approved application beyond the

variations already provided for in the application."). For major manufacturing changes, including the use of a new facility that has not previously produced the drug in question, the manufacturer must obtain FDA approval to amend the NDA *before* distributing a drug pursuant to the change. *Id*. at 31; 21 U.S.C. § 356a(c)(2) (emphasis added).

A manufacturer that knowingly seeks government payments for pills that deviate from the terms of an NDA is liable under the FCA because the manufacturer seeks payment for goods that are not what they are claimed to be. We illustrated this point in our opening brief (at 37-38) by noting that if Gilead claimed that certain pills were Atripla, but the pills were in fact a different, cheaper medicine (*e.g.*, Emtriva), that would be obvious fraud. We extended the hypothetical to illustrate that the same would be true if Gilead sold a drug containing all the active ingredients of Atripla but different inactive ingredients (*e.g.*, an unapproved liquid Atripla equivalent) because there, too, Gilead would have falsely certified that the drugs it was delivering embody the NDA, when the drugs in fact deviate materially from the NDA. We then explained that the same is true of unapproved alterations to the manufacturing process described in the NDA—even if the alterations result in a perfect copy of the approved drug and especially when, as here, they produce a contaminated substitute. Opening Br. 38-39.

2. Gilead's answer to this argument is unclear. Specifically, Gilead does not explain how NDA approval could possibly constitute approval of a facility that was not listed in the NDA. As best as we can tell, Gilead might be arguing three things.

a. First, Gilead might be arguing that federal payers, *e.g.*, the Centers for Medicare and Medicaid Services (CMS), are indifferent about whether the pills Gilead sells actually conform to the terms of the relevant NDAs. *See* Gilead Br. 9 ("The statutes condition payment only on an approved NDA."); *id.* at 17 (arguing that there is no "material condition of payment" to use certain chemicals or facilities in producing a drug). In other words, Gilead suggests that any deviation from NDA approval is immaterial to the government payer agencies as a matter of law. But the government disagrees: it explains that when it pays for a particular drug by name—whether in a purchase or by reimbursement—it necessarily means to pay for drugs that have the attributes of the approved NDA, and not cheap copies. *See* U.S. Br. 16-17. That makes sense: when Gilead says, "this medicine is Atripla," or causes another to seek reimbursement for "Atripla," the government necessarily interprets those statements to refer to FDA-approved Atripla, and not something else—even if that "something else" is very similar to FDA-approved Atripla. The statutes Gilead cites do not suggest otherwise. On the contrary, by

conditioning payment on FDA approval, the statutes make it clear that only pills that conform to their approvals are eligible for payment.

Moreover, Gilead's claim that FDA approval is the *only* condition for payment is demonstrably false. Some programs, including Medicare, include additional express payment conditions, *e.g.*, that the drug must be "reasonable and necessary" for the patient population. *See* Opening Br. 13 (citing 68 Fed. Reg. 55634, 55636 (Sept. 26, 2003); 42 U.S.C. §§ 1395w-102(e)(3), 1395y(a)(1)); Opening Br. 53. Gilead does not attempt to argue that its contaminated knock-offs meet this additional condition—let alone with sufficient certainty that it is entitled to judgment as a matter of law.

b. Second, Gilead might be arguing that because the FDA never withdrew NDA approvals for the drugs at issue here, despite being informed of the nonconformity, the agency implicitly determined that the pills did, in fact, conform to the NDAs. *See* Gilead Br. 17, 20-21. That's wrong because it reads too much into agency inaction. Although the FDA is sometimes required to withdraw approval, it is not required to do so in response to manufacturing nonconformity (although it may). *See* 21 U.S.C. § 355(e). There are any number of reasons why the FDA might not have withdrawn approval for Gilead's drugs even if many of Gilead's pills did not conform to the NDAs. The agency might have decided that the material number of nonconforming pills did not provide a reason to withdraw

approval for conforming ones. It might have acknowledged that Gilead eventually stopped sourcing ingredients from Synthetics China. It might have relied on Gilead's subsequent voluntary recall of some (but not all) batches of the contaminated drugs. Or it might have been deceived by Gilead into maintaining the approval. Ultimately, the reason that the FDA decided not to withdraw the NDA is irrelevant. The key point is that merely maintaining the approval for conforming drugs does not suggest that the pills in this case were conforming, or that the government determined otherwise.

In any event, the point of the FCA, and of our complaints under it, is not to force the FDA to withdraw drug approvals; it is to protect the government from fraud. Just as Gilead defrauds the government by overcharging for FDA-approved drugs, it defrauds the government by selling full-priced nonconforming knock-offs as if they are approved. As long as Gilead knowingly misrepresents an important characteristic of the pills for which it seeks government payments, it can be liable under the FCA, even if sale of conforming pills remains approved.

c. Third, Gilead might be arguing that its pills substantially conformed to the NDAs, except for minor violations of GMP regulations, and therefore should be treated as approved drugs. This argument impermissibly disregards the severity of the defects alleged in the complaints, and mischaracterizes our theory of liability. While Gilead is correct that "FDA-approved medicines do not become unapproved

or ineligible for reimbursement merely because a GMP violation occurred," Gilead Br. 19, that is irrelevant because we are not arguing that the NDA approvals for Gilead's drugs were rendered void. We are arguing that the pills Gilead actually distributed were *always* outside the scope of those approvals and as such ought not to have been billed to the government as FDA-approved. Moreover, for purposes of this first theory of FCA liability, we are not arguing that every GMP violation renders a pill ineligible for payment. For example, if Gilead produced pills using the ingredient suppliers that had been approved in the NDA, and one of those approved suppliers had a GMP problem, this theory of liability would fail. Here, however, Gilead brazenly disregarded the terms of the NDA itself by sourcing a key active ingredient from a Chinese company that was not listed in the NDA at all. It is that intentional decision to deviate from the NDA, and not some downstream GMP problem, that puts Gilead's drugs outside the scope of approval.

This point distinguishes this case from *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694 (4th Cir. 2014). In *Omnicare*, there was no allegation that the manufacturer intentionally deviated from the terms of its NDAs; the only allegation was GMP noncompliance.

3. Gilead also argues that the complaints are insufficient under Rule 9(b) because they do not "allege any material nonconformance with a contractual requirement or specification," or "any specific details about claims for payment."

Gilead Br. 21. It seeks to distinguish our principal cases because in each of those: (1) there was an allegation that the product delivered differed from a specific material contract term; and (2) the government agency itself noted the problem. *Id*. 22-23.

The complaints satisfy Rule 9(b), which requires them to allege only "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998-99 (9th Cir. 2010) (quotation marks omitted). Thus, the complaints allege that Gilead knowingly and covertly distributed drugs containing FTC from Synthetics China Plant 202 before it obtained FDA approval to use that site, and later knowingly distributed drugs containing FTC from Synthetics China Plant 203 even though it *never* obtained FDA approval to use that site. They further allege that Gilead sought public funds for these drugs through both direct sales and reimbursements. There are ample "reliable indicia" that these sales and reimbursements occurred: Gilead's own securities filings establish that it receives billions of taxpayer dollars for antiretroviral drugs in exactly this manner. Those claims for payment were false because the drugs Gilead delivered were outside the scope of its NDA approvals, but Gilead led the government to believe otherwise.

Gilead's argument therefore boils down to the assertion that we have not identified specific individual claims for payment. But "representative examples" are not required if the complaints plausibly allege that false claims were submitted. *Id.* at 998. In a purchase contract or reimbursement request for, *e.g.*, Atripla, the word "Atripla" (or the drug registration number for Atripla) means FDA-approved Atripla, and not Gilead's knock-off. Thus, payment under *each and every* such contract or claim constitutes an FCA violation. "It would stretch the imagination to believe that" Gilead went through the trouble of sourcing FTC from Synthetics China "only for the scheme to deviate . . . at the last moment such that [it] did not" then sell pills containing that ingredient. *United States v. Kaplan, Inc.*, No. 11-16651, 2013 WL 520418, at *2 (9th Cir. Feb. 13, 2013) (unpublished disposition). As for the formality of finding the actual contract documents and claims for reimbursement, even cursory discovery will reveal those.

Unsurprisingly, the Rule 9(b) cases Gilead cites bear no resemblance to this one. In *Bly-Magee v. California*, 236 F.3d 1014, 1018 (9th Cir. 2001), the relator alleged, in conclusory fashion and with no "particularized supporting detail," that one of the defendants "concealed the fraudulent submission of false claims . . . to avoid repayment of funds to the United States" and conspired with others to "defraud the United States by obtaining payment of fraudulent claims." In *United States ex rel. King v. Alcon Labs., Inc.*, 232 F.R.D. 568, 572 (N.D. Tex. 2005), the

relator "failed to allege any facts as to exactly how the fraud was committed." Instead, he stated "that the defendants 'operate[d] in a manner that d[id] not comply' with certain laws and regulations," and then proceeded "without any factual support, to list the alleged regulations that each defendant failed to comply with." *Id*. The court acknowledged, however, that "when the facts relating to the alleged fraud are peculiarly within the perpetrator's knowledge or control or where fraud occurred over an extended period of time and consists of numerous acts, the specificity requirements of Rule 9(b) are applied less stringently." *Id*. at 570. Here, by contrast, the complaints allege, in detail, exactly how Gilead's fraud worked and when, where, and how the illicit sales were made, easily meeting the standard this Court adopted in *Ebeid*.

Gilead's attempt to distinguish the cases upon which we rely also fails because none of those cases turned on the facts that Gilead highlights. Take, as an example, *United States v. National Wholesalers*, 236 F.2d 944 (9th Cir. 1956). There, the government sought bids for generator regulators for motor vehicles, and specified a manufacturer and a part number. The winning bidder could not procure the part, and so created knock-offs that performed just as well as the genuine regulators. The government's FCA claim nevertheless succeeded. The dispositive fact, however, was not that the contract was so explicit about the particular regulator—indeed, the Court held that if "this case involved only the manufacture

of a substitute article, without the misbranding, then it should go back for a finding as to whether the parties intended to file a false claim." *Id*. at 950. The case instead turned on the fact that the contractor had deliberately mislabeled the regulators, and had therefore "intend[ed] to pass off the regulators of its own manufacture as the genuine proprietary article (and be paid for it)." *Id*. It was that transparently fraudulent intent that brought the case within the ambit of the FCA.

Here, Gilead's intent was equally plain: it obtained FTC from an unapproved source and smuggled it into drugs sold to the American public and paid for by public funds. Gilead has identified no innocent explanation for its conduct, and so this case is on all fours with *National Wholesalers*.

Furthermore, even if Gilead is correct that *National Wholesalers* came out the way it did because the contract was very specific, the same is true here. As we have now said a few times—and as the government confirms (in its brief at 16)—when a contract or a claim for reimbursement identifies a specific drug by name or by some other unique identifier (*e.g.*, the registration number), it refers to products that have "certain attributes," *i.e.*, FDA approval. If the pills the manufacturer actually delivers do not exhibit those attributes because they do not conform to the NDA for the specifically identified drug, then they do not satisfy that contract term. Any claim for payment for such a nonconforming pill is false.

Gilead also points out that in *National Wholesalers* the government itself noted the nonconformity, while here the FDA has not withdrawn Gilead's drug approval and the United States has not intervened. That is a distinction without a difference. FCA claims do not founder if the government does not take corrective action of its own. While Gilead may at trial attempt to raise these facts if it chooses to dispute the materiality of its falsehoods, they do not go to whether its claims were false in the first instance. *See, e.g., United States ex rel. Chandler v. Cook Cty.*, 277 F.3d 969, 974 n. 5 (7th Cir. 2002) ("There is no reason to presume that a decision by the Justice Department not to assume control of the suit is a commentary on its merits. The Justice Department may have myriad reasons for permitting the private suit to go forward including limited prosecutorial resources and confidence in the relator's attorney."), *aff'd*, 538 U.S. 119 (2003); *Universal Health Servs., Inc. v. United States ex rel. Escobar*, No. 15-7, Oral Argument Tr., at 48 (Apr. 19, 2016) (Deputy Solicitor General explains that courts should not infer disapproval of the relator's legal theory from the government's decision not to intervene). Moreover, there have in fact been two recalls of Gilead's antiretroviral drugs, which Gilead publicly attributed to defects coming from a Chinese supplier. Opening Br. 20-21.

4. Gilead argues, at length, that the drugs it sold are not medically worthless. Br. 26-31. This entire argument misses the point. The only requirement for FCA

liability is that the supplier's misrepresentations be *material*, not that the goods be entirely worthless. The "worthless services" theory is merely an additional path to liability, available even when a drug manufacturer makes no false certifications. It is unnecessary here because Gilead falsely certified that its pills embodied their NDAs; it made further misrepresentations to the FDA while amending the NDAs (*see* Part II, *infra*); and it made the implied misrepresentation that the drugs were lawful to sell, when it knew otherwise (*see* Part III, *infra*).

II. The False Claims Act Prohibits Gilead From Obtaining Eligibility For Government Payments By Defrauding The FDA Into Approving Amendments To Its New Drug Applications.

1. If Gilead cannot seek government payments for unapproved pills on the pretense that those pills actually were approved drugs, it follows that Gilead cannot seek payment for pills if it fraudulently obtained FDA approval to market them. To hold otherwise would place fraudulent applications on par with legitimate ones.

When Gilead sought to amend its NDAs by belatedly asking the FDA to approve the use of Synthetics China, it knowingly lied to the FDA about the quality of Synthetics China's FTC and falsified critical test data. The FDA relied on these falsehoods to approve Gilead's amendments, and Gilead continued to seek government payments for products containing that FTC. This conduct is actionable under the theory of "promissory fraud" set forth in *Hendow*, which applies when

an "original fraud" used to secure eligibility for a government benefit taints "subsequent claims" that depend on that original fraud. 461 F.3d at 1173.

2. Gilead's principal response is that payments under Medicare and Medicaid are conditioned only on initial NDA approval, and not on amendments to the NDA using a Prior Approval Supplement (PAS) application. Therefore, Gilead argues (at 37), any fraud in a PAS application is not actionable—even if the drugs it sold did not fall within the scope of the original NDA and it was only because of the false PAS that Gilead could market them.

As we explained in our opening brief (at 42 n.19), this argument makes no sense. A PAS is not a different kind of approval than NDA approval, but is instead merely a request to amend an existing NDA. *See, e.g.*, 21 C.F.R. § 314.70 (entitled "Supplements and other changes to an approved application"). Thus, if Gilead would be liable for making false statements in its original NDA, there is no sound reason why false statements in the application to amend the NDA should be treated differently. Indeed, the FDA has withdrawn approval when manufacturers make false statements in PAS applications. Opening Br. 46. Moreover, when the FDA approves PAS applications, including to amend the NDA for Truvada (one of the drugs at issue in this case), it states that such applications are "submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act," which is the same provision that the Medicare and Medicaid statutes condition payment upon. *See* 42

U.S.C. § 1396r-8(k)(2)(A) (defining "covered outpatient drug" as a drug "approved for safety and effectiveness as a prescription drug under section 505" of the FDCA). The district court reached a contrary conclusion because the procedure for obtaining a PAS is set forth in Section 506 of the FDCA, but that holding ignores the relationship between PAS applications and NDAs and inappropriately privileges form over substance—particularly in light of Congress's admonition that "the scope of false or fraudulent claims should be broadly construed." *Hendow*, 461 F.3d at 1170 (citing S. Rep. No. 99-345, at 9 (1986)).

Gilead argues that this Court's decisions in *Hendow* and *Ebeid* support its position, but nothing could be further from the truth. Gilead contends (at 38) that in both of those cases, the Court found FCA liability *only* because the payment was expressly conditioned on compliance with a specific law. However, *Hendow* explained that "[a]n explicit statement . . . is not necessary to make a statutory requirement a condition of payment, and we have never held as much." 461 F.3d at 1177. *Ebeid* said: "We need not decide whether to adopt the . . . requirement in the Medicare context that the underlying statute expressly condition payment on compliance . . ." 616 F.3d at 998 n.3 (quotation marks omitted). To be sure, the Court held that the relevant condition must be a "sine qua non" of payment, *i.e.*, it must be necessary. *Id*. at 998. But that test is met here because without FDA

approval of the amendment, Gilead could not claim that drugs containing FTC from Synthetics China were covered by its NDA.

Gilead attempts to rationalize its proposed distinction between NDA and PAS approval by arguing that it is easy for courts to determine whether NDA approval has been granted, but more difficult to determine whether a PAS is required—such that courts should refrain from even attempting the latter inquiry, leaving it solely to the discretion of the FDA. *See* Gilead Br. 36, 42-44. But courts cannot ignore the law simply because a legal inquiry might be challenging.

In fact, courts make these sorts of inquiries all the time. For example, drug manufacturers facing state tort liability for defective drugs or drug labels frequently argue that it is impossible for them to comply with state law because they cannot deviate from their NDAs. *See Wyeth*, 555 U.S. at 568-69; *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470-71 (2013). Courts evaluate those preemption defenses by asking whether the manufacturer could change the label or drug unilaterally, or whether it would instead have to first obtain FDA approval by filing a PAS or similar application. *See Wyeth*, 555 U.S. at 571; *Bartlett*, 133 S. Ct. at 2479. That is precisely the inquiry that Gilead suggests courts cannot conduct. Similarly, in FCA cases, courts frequently determine whether claims for Medicare reimbursement are false by asking whether CMS would make the discretionary

determination that a given treatment was "reasonable and necessary" for a particular patient. Opening Br. 47-48.

Gilead's argument also fails on its own terms because it a PAS *obviously was required* before Gilead could market drugs using FTC from Synthetics China. The clearest evidence, of course, is the fact that Gilead submitted a PAS (albeit long after it was required to do so). Manufacturers do not take on regulatory burdens for no reason, so the Court can infer necessity from Gilead's own actions.

There is more. The FDCA provides that a PAS is required for "a major manufacturing change" to an NDA, which is any "change that is determined by the Secretary to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug." 21 U.S.C. § 356a(c)(2). The FDA's regulations expressly provide that this includes any change in the "production process . . . or facilities" with the potential to adversely affect the drug. 31 C.F.R. § 314.70(b). The FDA's guidance gives examples of major changes, including but not limited to the use of a new manufacturing site when "the new manufacturing site has never been inspected by FDA for the type of operation being moved," or "the new manufacturing site does not have a satisfactory current good manufacturing practice (CGMP) inspection for the type of operation being moved." Changes to an Approved NDA or ANDA, *supra*, at 31. The FDA further clarifies that it does not matter whether the manufacturer determines that a change

is unlikely to adversely affect drug quality because "[t]he recommended reporting category is based on the *potential* for the change to adversely affect" drug quality, and not on whether any particular change actually does so. FDA, Guidance for Industry: Changes to an Approved NDA or ANDA, Questions and Answers 2 (2001), *available at* http://tinyurl.com/ChangestoNDAsQandA. Under these rules, there is no straight-faced argument that an amendment to the NDA was not required before Gilead could use FTC from Synthetics China—a facility that had never before produced FTC for Gilead, and had not been inspected for its ability to do so. Indeed, Gilead does not even attempt to make such an argument, and its suggestion that the Court lacks the competence to work through this issue is meritless.

3. Gilead argues (at 45-48) that because the FDA did not revoke approval for the drugs in question, our theory that Gilead defrauded the FDA into approving the PAS is "implausible" as a matter of law. But as explained above, there are many reasons why the FDA might not have taken that course of action—including the fact that Gilead had stopped sourcing FTC from Synthetics China by the time the FDA learned of the violations. To the extent that the FDA's behavior is relevant to this case, it speaks to the question of materiality—which is a question of fact for the jury to decide later. But it is not "implausible" that if Gilead had told the truth about the quality of Synthetics China's FTC, the FDA would have refused to allow

Gilead to source the ingredient from there. Indeed, that is why Gilead took the incredible risk of lying about it. Nor is it "implausible" that payer agencies would have balked at paying for the nonconforming drugs had the truth been known to them.*

III. The False Claims Act Prohibits Gilead From Seeking Reimbursement For Drugs That Are Illegal To Distribute In Interstate Commerce.

Our third theory of liability is that Gilead violated the FCA by knowingly seeking government payments for drugs that it was not permitted to distribute in interstate commerce, *i.e.*, for passing off contraband as lawful wares. Under the FDCA, violations that render drugs adulterated or misbranded prohibit manufacturers from distributing them, and others from receiving them, whether for pay or otherwise. 21 U.S.C. § 331(a), (c). Violations are criminal. *Id*. § 333. If a drug cannot be distributed *at all*, then *a fortiori* it cannot be sold to the

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* Gilead's cases (at 46-47) distinguish themselves. In *Gonzalez v. Planned Parenthood of Los Angeles*, 759 F.3d 1112, 1115 (9th Cir. 2014), the relator "did not plausibly state a claim under the FCA because his assertion that Planned Parenthood knowingly submitted false claims for reimbursement is compellingly contradicted by a series of letters he attached to his complaint," which showed a lack of scienter. The continued payments were likewise evidence of the lack of scienter—not proof that the claim was not false. In *United States ex rel. Absher v. Momence Meadows Nursing Center, Inc.*, 764 F.3d 699, 710 (7th Cir. 2014), which Gilead describes as "particularly notable," the continued payments only disproved a claim for worthless services—because nobody would, if fully informed, continue to pay for such services. *See also* U.S. Br. 21 (distinguishing *Absher*).

government. And the government could not buy such drugs, because to do so would be a crime. It therefore also follows that if Gilead knowingly distributes drugs in interstate commerce, it is implicitly certifying that they are legal to distribute, and is therefore liable if that certification is false.

Gilead argues (at 49-50) that the Medicare and Medicaid reimbursement statutes do not condition payment on compliance with the adulteration and misbranding statute, or with GMP regulations, and so even if a drug is adulterated or misbranded because of GMP violations, it is still eligible for reimbursement under those programs. In support, it cites the Fourth Circuit's decision in *Omnicare*, the Northern District of Texas's decision in *Alcon Labs*, and, in a letter submitted under Rule 28(j), the Second Circuit's decision in *Bishop v. Wells Fargo & Co.*, No. 15-2449, 2016 WL 2587426 (2d Cir. May 5, 2016).

Gilead is correct that the Medicare and Medicaid statutes do not expressly condition reimbursement on compliance with these laws in the literal sense that the reimbursement statutes do not cite the adulteration and misbranding statute. However, it ignores critical points. First, our theory applies not only to reimbursements, but also to direct sales to the government, which are not governed by the Medicare and Medicaid statutes. Opening Br. 51. Gilead says nothing about those sales—which we allege are conditioned on the drugs being lawful to distribute. Second, Gilead ignores the fact that this Court has declined to adopt an

"express condition" requirement. *See* Opening Br. 52 (citing *Ebeid*, 616 F.3d at 998 n.3). While the relevant condition must still be the "sine qua non of payment," this Court has not required the payment statute to reference the condition by name. Instead, relators can prove the existence of a condition by other means. Here, applying the ordinary rule that federal laws should be read harmoniously, and the common-sense principle that we should not assume the federal government's willingness to aid and abet federal crimes, it makes sense to treat compliance with the government's own adulteration and misbranding statutes as a condition for government payments.

We recognize that this theory could have broad implications given the breadth of defects that are deemed by Congress to render drugs adulterated or misbranded. We also acknowledge that in some cases, as the government has suggested, it may be willing to reimburse for certain adulterated or misbranded drugs—and so the violations in those cases may not be material. But when, as here, the nature of the adulteration or misbranding affects the composition of the drug (*e.g.*, when there are credible allegations that drugs were contaminated during production), the implied certification doctrine supports FCA liability against a manufacturer that knowingly distributes the contaminated drugs. Moreover, the fact that the federal government is willing to reimburse a patient or an insurer does not prove that it is content to pay full price.

This point about contamination neatly distinguishes the three cases upon which Gilead relies. In *Omnicare*, the relator literally alleged only GMP violations relating to how drugs were packed—which did not go to the composition of the drugs themselves. Moreover, there were no allegations of false statements or scienter. *See* Opening Br. 54-55 & n.24 (quoting the *Omnicare* circuit and district court opinions). Similarly, in *Alcon Labs*, the only specific GMP violations that the relator pled were that the manufacturer was not engaging in required testing. 232 F.R.D. at 571 n.5. He apparently did not allege that the drugs had been contaminated with metal, glass, arsenic, and other dangerous substances, as we do here. And *Bishop*, cited in Gilead's 28(j) letter, is even farther afield because that case had nothing to do with drugs whatsoever. There, the relators attempted to use boilerplate contract language requiring banks to comply with essentially every applicable law or regulation in order to establish a condition for borrowing from the Federal Reserve's discount window. *Id*. at *7. The banks in question had allegedly misrepresented their solvency in order to obtain eligibility for federal loans, but the loan program in question did not require them to submit information regarding their solvency. *Id*. at *11. The Second Circuit held that the cited language was too general to create a condition for payment, extending the "express condition" rule that this Court declined to embrace. *Id*. at *11-*12. In contrast with all of these cases, Gilead's violations were far more grave, the payment conditions

that it violated are more precise, and the certifications relating to adulteration and misbranding are more germane to government payments.

Under Gilead's theory, even claims relating to the safety and efficacy of the drug would be beyond the reach of the FCA. But the government correctly explains that "[t]he knowing sale of materially defective products lies at the heart of the False Claims Act, and protecting the government from this type of fraud was a key reason the statute was first enacted during the Civil War." U.S. Br. 13. Thus, it is actually Gilead's rule—which would insulate every form of adulteration and misbranding from FCA liability regardless of materiality—that is inconsistent with the statute.

It also bears repeating that falsity is only one element of an FCA cause of action. A relator must also separately prove scienter and materiality. Thus, Gilead's position is effectively that even if a manufacturer knowingly distributes illegal tainted drugs to American patients, and even if the government would ordinarily refuse to reimburse for those drugs, Gilead should escape liability because the payment statutes do not explicitly require that the drugs be legally distributable as a condition of payment. Such a rule would threaten not only the public fisc, but public health as well, and this Court should reject it.

IV. Gilead's Retaliation Against Jeffrey Campie Violated The False Claims Act.

The final theory of FCA liability is that Gilead unlawfully retaliated against Jeffrey Campie, who discovered its violations, threatened to report them, and was denigrated and then fired as a result. Gilead argues: (1) that Campie was merely doing his job, and not conducting an independent fraud investigation; and (2) that Gilead was not on notice that Campie was investigating false claims.

1. Gilead repeatedly misstates Campie's responsibilities when it argues that his job was to investigate and report regulatory violations. *E.g.*, Gilead Br. 10, 53, 58, 59. In fact, Campie's job was not in regulatory affairs, which investigates such issues, but in quality assurance, which seeks principally to ensure that manufacturing processes produce high-quality drugs. E.R.112. Naturally, Campie's job required him to be intimately familiar with good manufacturing practices. But his job involved quality assurance of finished drug products, not their ingredients. E.R. 143. Thus, his investigations into the sources and contamination of FTC acquired by Gilead fell outside the scope of his duties. So too did his reporting outside of the corporate chain of command of the misconduct he discovered.

Gilead argues that Campie was not engaged in a protected investigation because he was only trying to get Gilead to comply with FDA regulations, and not recover money for the government. This argument fails on two levels. First, Campie's subjective motivations are irrelevant if the subject matter of his

investigation nevertheless covered matters that reasonably could have led to a viable FCA case. *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1269 (9th Cir. 1996). Campie's investigation was exactly that sort of inquiry. Gilead argues that for this to be true, the underlying FCA theory must be viable—but that is no problem here because similar investigations and claims have led to nine-figure settlements against other pharmaceutical manufacturers. Opening Br. 59. Second, Campie had more than one motivation: he was not only attempting to induce Gilead to follow the law, but *also* believed that the government was being defrauded, and *also* threatened to report the non-compliance to the government.

It is strange that Gilead attempts to draw such a firm line between investigations pertaining to FDA violations on the one hand, and investigations pertaining to FCA violations on the other, when it simultaneously argues that it has not violated the FCA *because* the FDA did not withdraw its NDAs. Clearly, since FDA approval is a prerequisite to government payments, even investigations that relate principally to FDA compliance reasonably can lead to viable FCA claims, and are therefore protected.

2. Regarding notice, Gilead papers over the fact that Campie threatened to report his findings to the government, which "clearly is one way to make an employer aware" of an investigation. *United States ex rel. Yesudian v. Howard Univ.*, 153 F.3d 731, 743 (D.C. Cir. 1998). Campie's discussions with company

officials outside the chain of command also put Gilead on notice that he was not merely doing his job. *See Moore v. Cal. Inst. Tech. Jet Propulsion Lab.*, 275 F.3d 838, 847 (9th Cir. 2002). And finally, given Gilead's overwhelming dependence on government payments, it was unquestionably on notice that any material non-compliance with the terms of its NDAs or other payment conditions would likely result in an FCA claim. Indeed, that is why Gilead included language in its proposed severance agreement asking Campie to waive his FCA claims. Gilead argues (at 59 n.27) that this provision is "boilerplate," but that is a terrible fact for Gilead: in any industry where FCA waivers are common in severance agreements, that is only because employers are on constant notice that fired employees may blow the whistle.

CONCLUSION

The judgment below should be reversed.

Respectfully submitted,

s/Tejinder Singh

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June 3, 2016

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 6995 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

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June 3, 2016

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 June 3, 2016.

I certify that counsel for Gilead and the United States are registered CM/ECF users and that service will be accomplished on them by the appellate CM/ECF system.

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