22-107-cv
United States ex rel. Yu v. Grifols USA, LLC

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

SUMMARY ORDER

RULINGS BY SUMMARY ORDER DO NOT HAVE PRECEDENTIAL EFFECT. CITATION TO A SUMMARY ORDER FILED ON OR AFTER JANUARY 1, 2007, IS PERMITTED AND IS GOVERNED BY FEDERAL RULE OF APPELLATE PROCEDURE 32.1 AND THIS COURT'S LOCAL RULE 32.1.1. WHEN CITING A SUMMARY ORDER IN A DOCUMENT FILED WITH THIS COURT, A PARTY MUST CITE EITHER THE FEDERAL APPENDIX OR AN ELECTRONIC DATABASE (WITH THE NOTATION "SUMMARY ORDER"). A PARTY CITING TO A SUMMARY ORDER MUST SERVE A COPY OF IT ON ANY PARTY NOT REPRESENTED BY COUNSEL.

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 14th day of October, two thousand twenty-two.

PRESENT:

DENNY CHIN,
SUSAN L. CARNEY,
BETH ROBINSON,
Circuit Judges.

UNITED STATES *EX REL.* ALLEN TIMOTHY YU,

Plaintiff-Appellant,

ABC,

Plaintiff,

v. No. 22-107

GRIFOLS USA, LLC, GRIFOLS SHARED SERVICES NORTH AMERICA, INC., GRIFOLS, S.A., AND GRIFOLS BIOLOGICALS, INC.,

Defendants-Appellees,

DEF, GRIFOLS, INC., GRIFOLS BIOLOGICALS, INC.,

Defendants.

FOR APPELLANT: MONIQUE OLIVIER, Olivier Schreiber & Chao LLP, San Francisco, CA; Anna K. D'Agostino, Miller Shah, LLP, New York, NY (Laurie Rubinow, Heidi A. Wendel, Miller Shah LLP, New York, NY; James E. Miller, Miller Shah LLP, Chester, CT; Natalie Finkelman Bennett, James C. Shah, Bruce D. Parke, Eric L. Young, Miller Shah LLP, Philadelphia, PA; Nathan Zipperian, Miller Shah LLP, Fort Lauderdale, FL; David J. Caputo, Youman & Caputo, LLC, Philadelphia, PA, *on the brief*)

FOR APPELLEES: TOBIAS S. LOSS-EATON, Sidley Austin LLP, Washington, D.C.

Appeal from a judgment of the United States District Court for the Southern District of New York (Woods, *J.*).

UPON DUE CONSIDERATION WHEREOF, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the order appealed from entered on January 5, 2022, is **AFFIRMED**.

Allen Timothy Yu ("Yu"), serving as *qui tam* relator,[1] appeals from the judgment of the District Court (Woods, *J.*), dismissing the amended complaint in his False Claims Act ("FCA") suit against Grifols USA, Grifols Biologicals, Grifols, S.A., and Grifols Shared Services as defendants (collectively, "Grifols") for failure to plausibly allege a violation of the FCA.

Grifols is a manufacturer of pharmaceutical products. In 2011, Grifols converted a manufacturing facility in Los Angeles (the "Los Angeles Plant") in order to produce Gamunex—an intravenous immunoglobulin ("IVIG") pharmaceutical used for treating various autoimmune disorders. In order to manufacture Gamunex, Grifols needed the Food and Drug Administration ("FDA") to approve its manufacturing method through a Prior Approval Supplement ("PAS"). The PAS approval process required the FDA to conduct a Pre-Approval Inspection audit of the facility and its equipment, and to review Grifols' manufacturing validation records for IVIG products. Grifols hired Yu in 2011 to serve as a quality assurance project manager during the Los Angeles

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[1] The False Claims Act ("FCA") provides that a person may bring a civil action for violating the FCA on behalf of that person and the United States Government. 31 U.S.C. § 3730(b)(1). The action is brought in the name of the government, and the government may either intervene and prosecute the action, or, as here, allow the original plaintiff, known as the *qui tam* relator, to proceed with the suit. *See U.S. ex rel. Kreindler & Kreindler v. United Technologies Corp.*, 985 F.2d 1148, 1153 (2d Cir. 1993).

Plant approval process. His job was to perform routine and *ad hoc* quality assurance review of qualifications, investigations, documentation, audits, protocols, and final reports for the Los Angeles Plant. This suit arises from the actions that Yu alleged that he witnessed while working for Grifols.

Yu's amended complaint includes three counts under the FCA. Yu contends as follows: first, Yu alleges that Grifols presented false or fraudulent claims to the government for payment from various "Government Healthcare Programs" [2] in violation of 31 U.S.C. § 3729(a)(1)(A)-(B). Yu contends that the claims were false or fraudulent because Grifols knowingly and/or recklessly secured FDA approval to sell the drugs on the basis of false representations to the FDA, and then manufactured drugs in violation of current Good Manufacturing Practices ("cGMPs"), compliance with which is required by FDA regulations.[3] Second, Yu alleges that as a result of its false claims, Grifols received overpayments from the Centers for Medicare and Medicaid Services ("CMS") and failed to report and return the overpayments as required by law.

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[2] Yu specifically identifies the Veterans Administration (the "VA"), TRICARE (the health care program for uniformed service members, retirees, and their families), and the Centers for Medicare and Medicaid Services ("CMS") as affected government payers.

[3] FDA regulations under the Food, Drug, and Cosmetic Act (the "FDCA") provide that failure of a drug to comply with cGMP regulations "shall render such drug to be adulterated." 21 C.F.R. § 210.1. The FDCA prohibits the sale or manufacture of any drug that is "adulterated." 21 U.S.C. § 331(a).

See 42 U.S.C. § 1320a-7k. Yu contends that, because Grifols knowingly used false records and statements to conceal its obligation to return the monies improperly obtained, its conduct violated the FCA as well as requirements in the Social Security Act. *See* 31 U.S.C. § 3729(a)(1)(A)–(B) and 31 U.S.C. § 3729(a)(1)(G). Finally, Yu alleges that to obtain FDA approval for the Los Angeles Plant, Grifols submitted fraudulent statements and submissions to the FDA; the FDA was induced by Grifols' fraud to approve the Los Angeles Plant's request for authority to manufacture Gamunex;[4] and the Government Healthcare Programs were, in turn, induced to enter into contracts with Grifols relating to the supply and sale of Gamunex.

The district court dismissed the amended complaint, concluding primarily that Yu had failed to sufficiently allege that Grifols' claims to the Government Healthcare Programs contained records or statements *material* to a fraudulent claim. The court granted Yu leave to replead the dismissed claims. *United States ex rel. Yu v. Grifols USA, LLC*, No. 1:17-CV-2226-GHW, 2021 WL 5827047

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[4] Under the FDCA, the FDA "shall issue an order refusing to approve the application" 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 to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." 21 U.S.C. §§ 351(a), 355(d).

(S.D.N.Y. Dec. 8, 2021). Yu did not further amend his complaint and instead filed a timely Motion for Entry of Judgment. The district court entered judgment and Yu appealed. We assume the parties' familiarity with the underlying facts, procedural history, and arguments on appeal, to which we refer only as necessary to explain our decision to affirm.

We review de novo the dismissal of the amended complaint pursuant to Federal Rule of Civil Procedure 12(b)(6), accepting all factual allegations in the amended complaint as true and drawing all reasonable inferences in Yu's favor. *Biro v. Conde Nast*, 807 F.3d 541, 544 (2d Cir. 2015). However, the requirement to accept all factual allegations as true does not extend to allegations that are "naked assertions" or "conclusory statements." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).[5]

To survive a Rule 12(b)(6) motion to dismiss for failure to state a claim, the complaint must plead enough facts to "state a claim to relief that is plausible on its face." *Id.* (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). In addition, when alleging fraud, a plaintiff must meet both the plausibility standard of Rule 8 and satisfy the heightened pleading standard of Rule 9(b),

[5] Unless otherwise noted, in quoting caselaw this Order omits all alterations, citations, footnotes, and internal quotation marks.

which requires the complaint to state with "particularity the circumstances constituting fraud." *United States ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 25 (2d Cir. 2016) (quoting Fed. R. Civ. P. 9(b)).

The FCA imposes civil liability on "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). The United States Supreme Court has held that in some circumstances, "implied false certification" can amount to a false or fraudulent claim. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 186 (2016). In particular, at least where a claim for payment makes specific representations about the goods or services provided, but then fails to disclose noncompliance with material statutory, regulatory, or contractual requirements, the omission may render the representations "misleading half-truths." *Id.* at 190.

However, "a misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act." *Id.* at 192. In addition to alleging a particular misrepresentation (including a potentially actionable omission), a plaintiff must therefore plead sufficient facts to plausibly allege that the misrepresentation is *material*. *United States ex rel.*

Foreman v. AECOM, 19 F.4th 85, 109 (2d Cir. 2021). The FCA defines materiality as "having 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 assessing materiality, "we look[ ] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation . . . rather than superficial designations." *Foreman*, 19 F.4th at 109.

In *Escobar*, the Supreme Court identified three factors relevant to the materiality assessment: "(1) whether the government expressly designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment; (2) the government's response to noncompliance with the relevant contractual, statutory, or regulatory provision; and (3) whether the defendants' alleged noncompliance was 'minor or insubstantial.'" *Id.* at 110. These factors are considered holistically as "[n]o one factor is dispositive." *Id.* We conclude based on an application of these factors that Yu has failed to allege a material misrepresentation sufficient to support an FCA claim.

1. Express Condition of Payment

The first *Escobar* factor for materiality is whether the government "expressly identif[ied] a provision as a condition of payment." *United States v. Strock*, 982 F.3d 51, 62 (2d Cir. 2020) (quoting *Escobar*, 579 U.S. at 190). Yu argues

that the Government Healthcare Programs require that drugs not be "adulterated," which Yu contends means that Grifols' manufacturing processes must comply with all applicable cGMPs. In addition, Yu makes a more attenuated argument that Grifols submitted its claims pursuant to contracts with Government Healthcare Programs; Grifols' eligibility for those contracts is conditioned on FDA approval of Gamunex under the FDCA; FDA approval is, in turn, conditioned on compliance with cGMPs, 21 C.F.R. § 210.1, 21 U.S.C. § 331(a); so Grifols' contracts with the Government Healthcare Programs thus incorporate by reference and require compliance with cGMP standards.

With respect to either argument—even assuming that an incorporation-by-reference theory this attenuated could support an FCA claim—a contract that merely incorporates by reference and lacks a provision that "specifically identifies any of the contractual or regulatory requirements" that Grifols allegedly violated as an express condition of payment, "at most, weighs neutrally in the materiality analysis" for this factor. *Foreman*, 19 F.4th at 110. As the *Escobar* Court noted, "if the government were to designat[e] every legal requirement an express condition of payment, it would make it difficult for would-be defendants [to] anticipate and prioritize compliance obligations

because billing parties are often subject to thousands of complex statutory and regulatory provisions." *Id.* at 111 (quoting *Escobar*, 579 U.S. at 192).

Yu has identified no provisions in the contracts that expressly condition payment by the Government Healthcare Programs on Grifols' compliance with any specific cGMPs Grifols is alleged to have violated. To the extent that Yu argues that Grifols' agreements with Government Healthcare Programs, in tandem with applicable federal regulations, incorporate all cGMPs by requiring that the drugs not be legally considered "adulterated," the argument proves too much. Grifols itself acknowledges that not every violation of a cGMP would be "material" for purposes of a FCA claim. For these reasons, this factor does not support a conclusion that the alleged misrepresentations are material.

2. *The Government's Response to Noncompliance*

The second materiality factor "concerns the government's response to noncompliance with the relevant contractual, statutory, or regulatory provision," looking at noncompliance both in other cases generally, and as it applies to this particular case. *Strock*, 982 F.3d at 62. As the Supreme Court has explained, evidence 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" at issue can prove materiality. *Escobar*, 579 U.S. at 195.

On the other hand, "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." *Id.*

Yu asserts that if the United States had been aware of the Defendants' fraudulent statements and submissions, it would not have approved the Los Angeles Plant's application and, presumably, the Government Healthcare Programs would have declined to pay Grifols' claims. But he has failed to support this assertion with any non-conclusory factual assertions plausibly alleging that in other cases with comparable cGMP violations the Government Healthcare Programs declined to pay claims for payment, or that in cases with comparable cGMP violations the FDA declined to approve, or withdrew approval of, the manufacture of a drug.

With respect to the government's response to the alleged violations in *this* case, we decide that the factor is inconclusive. Grifols assigns great weight to the fact that the Government Healthcare Programs have continued to pay its claims, and the FDA has not withdrawn its approval, notwithstanding Yu's allegations concerning Grifols' manufacturing practices and representations to the Government. However, FDA approval and the Government Healthcare Programs' continued payment of Grifols' claims are relevant only if the agencies

had *actual knowledge* of the asserted violations and misrepresentations. *Escobar*, 579 U.S. at 195. Neither Yu's factual assertions nor matters of which we can take judicial notice plausibly allege that the FDA or any of the Government Healthcare Programs has actual knowledge of the specific misrepresentations or departures from cGMPs that Yu alleges.[6] Yu has alleged that the FDA might not be aware of the violations because Grifols managed to hide them both during the application process and the subsequent audit. *See* Jt. App'x 52. Grifols argues that the FDA must be aware of Yu's claims because "regulations require DOJ lawyers in 'any False Claims Act matter' to 'confer with the relevant agency during the investigati[on].'" Appellees' Br. at 41. And in ascribing significance to the FDA's failure to withdraw its approval of Grifols' manufacture of Gamunex and to the Government Healthcare Programs' continued payments to Grifols, the district court relied heavily on this factor, assuming that the FDA must have notice because this litigation has been pending for over four years. *Yu*, 2021 WL 5827047, at *9. While Grifols' arguments may contradict the

[6] Grifols attached Exhibit A to its Motion to Dismiss, which it identifies as a portion of the PAS that it submitted to the FDA during the approval process for the Los Angeles Plant. Yu moved to strike the Exhibit from the record, disputing its authenticity and accuracy. We agree with the district court's reasoning that Exhibit A is neither integral to the Amended Complaint, nor is its authenticity undisputed, so it cannot be considered in determining this appeal. *See Foreman*, 19 F.4th at 106 ("[I]t must be clear on the record that no dispute exists regarding the authenticity or accuracy of the document.").

allegations in the amended complaint, Yu has not alleged that the FDA has withdrawn approval or that the Government Health Programs have discontinued payment. Without evidence that the FDA knew of the cGMP violations, this factor does not carry much weight.

3. *The Substantiality Factor*

This factor looks at the "contracts' purpose and whether the defendants' noncompliance deprived the government of the intended benefits of the contract." *Foreman*, 19 F.4th at 116. In short, the analysis focuses on the substantiality of the noncompliance and its impact on the goals of the contract.

Accepting Yu's contention that the benefit of the Government Healthcare Programs' bargain is that they receive safe and effective Gamunex, his allegations fail to plausibly allege in other than speculative or conclusory terms that the violations he observed, and the misrepresentations that he alleges, substantially compromised this goal. The district court correctly noted that Yu alleges only that the various violations "may" or "could" cause negative consequences. *Yu*, 2021 WL 5827047, at *10. Despite the length of Yu's complaint, it is difficult to discern what actual misrepresentations or cGMP violations Yu alleges persisted through and beyond the FDA approval process. Yu gives examples of some of the cGMP violations that he allegedly observed

during his work for Grifols, nearly all of which relate to errors in documentation. For example, Yu asserts that in January 2014, prior to the FDA's approval, he found over 100 discrepancies in Installation Qualification reports relating to all thirteen Clean-In-Place ("CIP") systems. He does not identify which of these discrepancies persisted after his reports to and remedial action by Grifols prior to preparation of the Final Validation Reports made available to the FDA.

In any event, even assuming that all of the documentation discrepancies and cGMP violations that Yu allegedly observed in January 2014 persisted at the time of the FDA's review of Grifols' application, Yu's complaint fails to identify the particular violations that led to any adverse impact on Gamunex's quality with enough specificity to enable us to evaluate their impact on the goals of Grifols' contracts. Without knowing more clearly what the alleged violations are, we are unable to effectively evaluate materiality.

Yu suggests that two recalls of Gamunex in 2019 were due to cGMP violations (although he does not tie them to the specific cGMP violations he alleged based on his own observations). Specifically, Yu states that Confidential Witness Six ("CW6")—a manufacturing technician at the Los Angles Plant from 2009 to 2017—"assumed the conditions that led to the recalls were from cross-contamination, resulting in bacteria being introduced into the Gamunex, based

upon the cGMP violations [CW6] regularly observed." Jt. App'x 51. But a confidential witness's bare assumption that unspecified cGMP violations caused contamination leading to a recall is insufficient to plausibly allege that any of the misrepresentations or cGMP violations alleged by Yu were material.

In short, because Yu does not point to anything to suggest that Grifols' alleged violations have resulted in "significant financial cost to the government," or demonstrate that the violations go to the "heart of the bargain," this factor weighs against a finding of materiality. *Foreman*, 19 F.4th at 117.

4. Conclusion

After weighing all of the above factors, we conclude that Yu does not plausibly allege that any misrepresentation by Grifols materially impacted the Government Healthcare Programs' payment determination. For that reason, the district court did not err in dismissing his FCA claims.[7]

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[7] Yu also brings claims under 31 U.S.C. §§ 3729(a)(1)(B) and (a)(1)(G), both of which contain materiality requirements. Claims brought under these sections fail for the same lack of materiality.

We have considered Yu's remaining arguments and conclude that they are without merit. For the foregoing reasons, the District Court's order is **AFFIRMED.**

FOR THE COURT:
Catherine O'Hagan Wolfe, Clerk of Court