**PRECEDENTIAL**

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 25-1480

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PAUL LISENBY,
Appellant

v.

OLYMPUS CORP. OF THE AMERICAS; OLYMPUS AMERICA INC.; GYRUS ACMI, INC.

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On Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D.C. No. 5:24-cv-01803)
District Judge: Honorable Jeffrey L. Schmehl

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Submitted Pursuant to Third Circuit L.A.R. 34.1(a)
February 9, 2026

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Before: CHAGARES, Chief Judge, SCIRICA* and RENDELL, Circuit Judges

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* The Honorable Anthony J. Scirica was unavailable to participate in the decision in this case after submission to the

(Opinion Filed: August 4, 2026)

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OPINION OF THE COURT

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CHAGARES, Chief Judge.

Paul Lisenby worked as the Global Head of Product Development for the defendants-appellees Gyrus ACMI, Inc., Olympus Corporation of the Americas, and Olympus America, Inc. (together, "Olympus"),[1] which are United States subsidiaries of a Japanese medical device company. Olympus sells medical devices to the United States government and receives millions of dollars in federal awards every year. Over a two-week period, Lisenby raised concerns that Olympus had violated U.S. Food and Drug Administration ("FDA") regulations with respect to design quality and product testing. Olympus eliminated Lisenby's position shortly thereafter. Lisenby filed suit against Olympus, alleging, as relevant here, that Olympus had retaliated against him in violation of the False Claims Act ("FCA" or "Act"), 31 U.S.C. § 3730(h).

The District Court granted Olympus's motion to dismiss the Amended Complaint. The court noted that the allegations

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merits panel. This opinion is filed by a quorum of the panel pursuant to 28 U.S.C. § 46(d) and 3d Cir. I.O.P. 12.1(b).

[1] The defendants-appellees are wholly-owned subsidiaries of Olympus Corporation, all of which are part of a single enterprise. For ease of reference, we will refer to the defendants-appellees collectively as "Olympus."

in the Amended Complaint did not connect Lisenby's concerns about FDA regulatory violations to the submission of false claims for payment to the federal government. The District Court thus concluded that Lisenby failed to allege that he had engaged in protected conduct under the "other efforts" prong of the FCA's anti-retaliation provision.

We have held that Congress's 2009–2010 amendments to the FCA expanded the scope of the FCA's anti-retaliation provision to include "other efforts" to stop violations of the Act. United States ex rel. Ascolese v. Shoemaker Constr. Co., 55 F.4th 188, 194–95 (3d Cir. 2022). But we have not yet considered what constitutes protected conduct under the "other efforts" prong of the FCA's anti-retaliation provision, 31 U.S.C. § 3730(h)(1). As explained below, we hold that a plaintiff's actions constitute protected conduct under the "other efforts" prong of § 3730(h)(1) when they are motivated by an objectively reasonable belief that the employer has submitted, or will submit, false or fraudulent claims for payment to the federal government. The Amended Complaint at issue here lacks allegations of any such belief. We will therefore affirm the District Court's order.

I.[2]

[2] We take these facts from the Amended Complaint. At the motion to dismiss stage, we accept all factual allegations as true and construe them in the light most favorable to the plaintiff. Newark Cab Ass'n v. City of Newark, 901 F.3d 146, 151 (3d Cir. 2018).

Olympus sells medical devices to the federal government, including the Department of Veteran Affairs ("VA"). The VA is Olympus's largest customer in the United States, and Olympus America, Inc. receives more than $85 million in federal awards each year. Olympus also sells its products to hospitals and other entities that receive Medicare and Medicaid reimbursements. Lisenby worked as Olympus's Global Head of Product Development between May 2022 and March 2024. In this position, Lisenby was not responsible for investigating fraud or compliance issues. He was, however, knowledgeable about the requirements for FDA approval of medical devices.

During an approximately two-week period in early 2024, Lisenby complained to other Olympus employees that Olympus was violating FDA regulations.[3] Lisenby's concerns stemmed from his investigation of the failure of an Olympus product called the Quick-Clip Pro 2 ("QCP2"). Lisenby discovered systemic issues in Olympus's "design approach and quality management system related to already-sold products," including "inadequate sample test sizes, insufficient design validations, inadequate supplier controls, [and] a lack of test method validations." Joint Appendix ("App.") 7. Lisenby also found a lack of quality management controls and testing to ensure that the product was safe for clinical use in patients.

[3] The Amended Complaint alleges that Lisenby raised other concerns during his tenure at Olympus. On appeal, Lisenby "limits the issue of protected activity to his efforts to stop systemic FDA violations in the weeks leading up to his termination." Lisenby Br. 5 n.2. We will therefore consider only the allegations with respect to Lisenby's actions between January 21, 2024, and February 13, 2024.

Lisenby's concerns thus focused on "design quality and non-compliant product testing issues required by FDA regulations." App. 6. Given these issues, Lisenby "believed that if Olympus were to sell QCP2 in its current state, it would be misrepresenting data to the FDA to obtain approval, as it had done in the past." App. 7.

Lisenby first began sharing his concerns in late January 2024. These communications were made outside of his chain of command. Lisenby first met with Gabriela Kaynor, the Global Head of Olympus's Therapeutic Solutions Division at that time. He told Kaynor about Olympus's "systemic failures to comply with FDA testing and regulatory standards in its product development process [and] inadequate training of engineers to follow FDA regulatory and testing standards." App. 7. He also shared his "serious concerns" about "Olympus'[s] medical devices that had already been launched in the market that did not comply [with] FDA regulatory standards and had been shown to cause patient harm." App. 7–8. A few days later, Lisenby discussed the same concerns in a meeting with Mike Callaghan, the Vice President and General Manager of the GI Endo-Therapy Business Unit. Callaghan told Lisenby that selling non-compliant products was "not his call" because the responsibility rested with a quality control department in Japan. App. 8.

Lisenby then emailed Andre Roggan, his direct supervisor, and Tomohisa Sakurai, Olympus's Deputy Chief Technology Officer ("CTO"), about a design methodology called Design for Six Sigma ("DFSS"). He noted that quality and compliance issues existed in Japan, Europe, and the United States. Lisenby suggested that Olympus could use DFSS to address these systemic issues in product design procedure,

comply with FDA requirements, and manage patient safety risks. Lisenby further stated that he "believe[d] DFSS would ultimately address the major sticking points [Olympus was] having with the FDA." App. 9.

Lisenby also shared his concerns at the CTO Management Committee meetings between January 29, 2024, and February 2, 2024. He added a session about DFSS to the agenda, during which he proposed DFSS as a possible solution to the systemic issues that he had observed. He explained how DFSS was "a way to eliminate [Olympus's] systemic FDA compliance failures and ensure products were designed to address patient safety risks." App. 9–10. The other meeting attendees acknowledged Lisenby's findings but informed him that he needed Roggan's approval to implement his proposed changes. Roggan later told Lisenby that a research and development committee should pre-screen DFSS.

A little over a week after the CTO meetings, Lisenby met with Eric Rainis, the Global Vice President of Quality Design and Assurance. Lisenby told Rainis about Olympus's "inadequate complaint handling system" and how Olympus lacked adequate product testing to ensure patient safety. App. 10. He also discussed his concern that Olympus did not have a quality assurance entity in Japan to ensure compliance with FDA regulatory standards. Rainis agreed with Lisenby's concerns but explained that procedural issues in Japan were not within the scope of his responsibilities. The next day, Lisenby met with Todd Brill, the Senior Vice President of Regulatory Affairs. Lisenby discussed his concerns about Olympus's "failure to comply with FDA standards" that, in turn, "impacted patient safety and caused patient harm." App. 11. He again proposed using DFSS as a possible solution.

The day after Lisenby met with Brill, Roggan told Lisenby that his position had been eliminated. Olympus did not eliminate any other positions during this time. Lisenby subsequently filed a lawsuit against Olympus, asserting a retaliation claim under the False Claims Act as well as claims under the Pennsylvania Whistleblower Law and Florida Private Whistleblowers Act. Olympus moved to dismiss the Complaint for failure to state a claim, and Lisenby amended the Complaint. Olympus then filed another motion to dismiss under Federal Rule of Civil Procedure 12(b)(6).

The District Court granted Olympus's motion, dismissing both the FCA retaliation claim and the state law claims.[4] The District Court noted that this Court has not yet considered what constitutes protected conduct under the "other efforts" prong of the FCA's anti-retaliation provision. The court thus concluded that a plaintiff "must demonstrate a nexus between his actions and that his employer knowingly submitted or planned to submit a false or fraudulent claim to the government for payment." App. 107. Because Lisenby did not connect his internal warnings about Olympus's alleged FDA regulatory violations to a specific FCA violation, the District Court held that Lisenby had not sufficiently alleged protected conduct. The District Court therefore dismissed Lisenby's retaliation claim with prejudice.[5] Lisenby timely

[4] Lisenby does not challenge on appeal the District Court's dismissal of the state law claims.

[5] The District Court did not explain why dismissal with prejudice was warranted. But on appeal, Lisenby does not challenge the District Court's analysis — or lack thereof — as to why the FCA retaliation claim was dismissed with prejudice.

appealed.

## II.[6]

On appeal, Lisenby challenges the District Court's dismissal of his retaliation claim under the False Claims Act. We first describe the relevant parts of that statute. Next, we consider two questions of first impression for this Court: whether a retaliation claim under the False Claims Act, 31

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Nor does he contend, in the alternative, that he should be given leave to further amend the Amended Complaint. Even if Lisenby had raised such an argument before us, that argument would fail because he did not move for leave to file a Second Amended Complaint before the District Court. See Fletcher-Harlee Corp. v. Pote Concrete Contractors, Inc., 482 F.3d 247, 253 (3d Cir. 2007) ("[I]n ordinary civil litigation it is hardly error for a district court to enter final judgment after granting a Rule 12(b)(6) motion to dismiss when the plaintiff has not properly requested leave to amend its complaint.").

[6] The District Court had jurisdiction over Lisenby's FCA claim pursuant to 28 U.S.C. § 1331, and we have jurisdiction under 28 U.S.C. § 1291. We exercise plenary review of a district court's grant of a motion to dismiss under Rule 12(b)(6). Bah v. United States, 91 F.4th 116, 119 (3d Cir. 2024). To survive a motion to dismiss under Rule 12(b)(6), a plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

U.S.C. § 3730(h), is subject to the particularity requirement of Federal Rule of Civil Procedure 9(b); and what constitutes protected conduct under the "other efforts" prong of a False Claims Act retaliation claim. We hold that a False Claims Act retaliation claim is not subject to the Rule 9(b) particularity requirement. We also hold that to engage in protected "other efforts" conduct under § 3730(h)(1), the plaintiff must have held an objectively reasonable belief that his or her employer was violating or was about to violate the FCA. Applying the proper standard here, the Amended Complaint fails to allege that Lisenby engaged in conduct protected by the "other efforts" prong of § 3730(h)(1). We will therefore affirm the District Court's order dismissing Lisenby's FCA retaliation claim.

A.

The False Claims Act imposes liability on any person who "knowingly presents, or causes to be presented, [to the federal government] a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). The FCA provides two ways of initiating an action. Hutchins v. Wilentz, Goldman & Spitzer, 253 F.3d 176, 181–82 (3d Cir. 2001). The government may file suit to recover damages stemming from fraudulent claims. 31 U.S.C. § 3730(a); Hutchins, 253 F.3d at 181. A private plaintiff may also file a qui tam suit on the government's behalf and, if successful, retain up to thirty percent of the funds recovered. 31 U.S.C. §§ 3730(b)(1), (d)(2); Hutchins, 253 F.3d at 181–82.

The FCA contains an anti-retaliation provision that shields employee whistleblowers from retaliation "because of" conduct protected by the Act. 31 U.S.C. § 3730(h)(1). To state

a retaliation claim under the FCA, a plaintiff must allege that he (1) engaged in protected conduct, and (2) was discriminated against because of his protected conduct. DiFiore v. CSL Behring, LLC, 879 F.3d 71, 76 (3d Cir. 2018) (citing Hutchins, 253 F.3d at 186). A plaintiff must also show that his employer was on notice that he was engaged in protected conduct, United States ex rel. Ascolese v. Shoemaker Constr. Co., 55 F.4th 188, 194–95 (3d Cir. 2022), and that the protected conduct was the "but-for" cause of the employer's retaliation, DiFiore, 879 F.3d at 78. The FCA's anti-retaliation provision identifies two categories of protected conduct. See 31 U.S.C. § 3730(h)(1). Section 3730(h)(1) protects employees from retaliation for "lawful acts done . . . in furtherance of" either "an action [under the FCA]" or "other efforts to stop 1 or more violations of" the FCA. Id. This appeal involves only the "other efforts" prong.

Before considering the merits, we must first determine what pleading standard governs an FCA retaliation claim. Federal Rule of Civil Procedure 8(a) requires only "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Federal Rule of Civil Procedure 9(b), by contrast, requires claims involving allegations of fraud to be pled with particularity. Fed. R. Civ. P. 9(b).

A person is liable under the FCA for, among other things, "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval" to the federal government. 31 U.S.C. § 3729(a)(1)(A). FCA claims are thus subject to Rule 9(b)'s heightened pleading standard. See Foglia v. Renal Ventures Mgmt., LLC, 754 F.3d 153, 155, 157–58 (3d Cir. 2014) (determining whether the plaintiff's allegations with respect to his FCA claim satisfy the Rule 9(b)

standard). Retaliation claims under the FCA do not, however, involve allegations of fraud. See 31 U.S.C. § 3730(h)(1) (imposing liability on employers that "discriminate[] against" an employee "because of lawful acts done . . . in furtherance of an action under [the FCA] or other efforts to stop 1 or more violations" of the FCA). Accordingly, we hold that allegations with respect to an FCA retaliation claim need only satisfy Rule 8(a)'s notice pleading standard.[7]

We turn now to the question of what constitutes protected conduct under the "other efforts" prong of § 3730(h)(1). This Court's decision in Ascolese recognized that Congress's 2009–2010 amendments to the FCA expanded the anti-retaliation provision to include "other efforts to stop 1 or more violations of" the Act. 55 F.4th at 195 (quoting 31 U.S.C. § 3730(h)(1)). But this Court has not yet had an opportunity to determine the legal standard for protected conduct under the "other efforts" prong of the FCA's anti-retaliation provision. We will do so here.

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[7] This conclusion is consistent with the decision of every other Court of Appeals to have addressed this issue. See United States ex rel. Sibley v. Univ. of Chi. Med. Ctr., 44 F.4th 646, 661–62 (7th Cir. 2022); United States ex rel. Chorches v. Am. Med. Response, Inc., 865 F.3d 71, 95 (2d Cir. 2017); Smith v. Clark/Smoot/Russell, 796 F.3d 424, 433 (4th Cir. 2015); Mendiondo v. Centinela Hosp. Med. Ctr., 521 F.3d 1097, 1103 (9th Cir. 2008); United States ex rel. Williams v. Martin-Baker Aircraft Co., 389 F.3d 1251, 1259 (D.C. Cir. 2004); United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 238 n.23 (1st Cir. 2004), abrogated on other grounds by Allison Engine Co. v. United States ex rel. Sanders, 553 U.S. 662 (2008).

We first conclude that to state a retaliation claim under the "other efforts" prong of § 3730(h)(1), a plaintiff's actions must be connected to a violation of the FCA. That is, a plaintiff's conduct must be related to the submission of a false or fraudulent claim to the federal government for payment or approval. The text of the FCA plainly requires this nexus. Section 3730(h)(1) protects employees from retaliation for "lawful acts done . . . in furtherance of . . . other efforts to stop 1 or more violations of this subchapter." 31 U.S.C. § 3730(h)(1) (emphasis added). Because the text of the statute is clear, we need not look any further. See Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A., 530 U.S. 1, 6 (2000).

This conclusion is in accord with the decisions of several of our sister Courts of Appeals. See, e.g., Hickman v. Spirit of Athens, Ala., Inc., 985 F.3d 1284, 1289 (11th Cir. 2021) (noting that plaintiffs "are, at a minimum, required to show that the activity they were fired over had *something* to do with the False Claims Act—or at least that a reasonable person might have thought so"); Singletary v. Howard Univ., 939 F.3d 287, 296 (D.C. Cir. 2019) ("[T]he ["other efforts"] prong . . . requires that the employee's efforts pertain to fraud in connection with the submission of a claim for federal government funds."); United States ex rel. Reed v. KeyPoint Gov't Sols., 923 F.3d 729, 767 (10th Cir. 2019) (explaining that a plaintiff's actions must be connected to the FCA); United States ex rel. Grant v. United Airlines, Inc., 912 F.3d 190, 202 (4th Cir. 2018) ("[W]hile the plaintiff's actions need not lead to a viable FCA action[,] . . . they must still have a nexus to an FCA violation." (citation and quotation marks omitted)). Accordingly, a plaintiff has not engaged in protected conduct under the "other efforts" prong if his actions pertain only to

reporting statutory or regulatory noncompliance without some additional connection to an FCA violation.

We also hold that to engage in conduct protected by the "other efforts" prong of § 3730(h)(1), a plaintiff must, in good faith, have held an objectively reasonable belief that his employer was violating, or would violate, the FCA.[8] This standard sets a relatively low bar that coheres with Congress's intent to expand the scope of the FCA's anti-retaliation provision to protect employees' "'efforts to stop' violations of the statute *before* they happen or recur." Ascolese, 55 F.4th at 194 (quoting Singletary, 939 F.3d at 296); see also Singletary, 939 F.3d at 296 (noting that the "other efforts" prong is "preventative").[9] This holding is consistent with the decisions

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[8] The parties agree that this Court should adopt an objectively reasonable belief standard for retaliation claims under the FCA.

[9] The objective reasonableness standard also comports with how this Court has interpreted anti-retaliation provisions in other statutes. The FCA is one of several federal statutes that protect whistleblowers from retaliation. See, e.g., Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e-3(a); Americans with Disabilities Act ("ADA"), 42 U.S.C. § 12203(a); Age Discrimination in Employment Act ("ADEA"), 29 U.S.C. § 623(d); Emergency Medical Treatment and Labor Act ("EMTALA"), 42 U.S.C. § 1395dd(i). This Court has applied an objectively reasonable belief standard to retaliation claims under each of those statutes. See Moore v. City of Philadelphia, 461 F.3d 331, 341 (3d Cir. 2006) (holding that to state a Title VII retaliation claim, an "employee must hold an objectively reasonable

of several other Courts of Appeals, each of which have adopted an objective reasonableness standard for retaliation claims under the "other efforts" prong of the FCA's anti-retaliation provision. See, e.g., Mooney v. Fife, 118 F.4th 1081, 1092 (9th Cir. 2024); Singletary, 939 F.3d at 296; United States ex rel. Strubbe v. Crawford Cnty. Mem'l Hosp., 915 F.3d 1158, 1167 (8th Cir. 2019); Grant, 912 F.3d at 201–02; United States ex rel. Uhlig v. Fluor Corp., 839 F.3d 628, 635 (7th Cir. 2016). This standard consists of both a subjective component and an objective component. The subjective component requires the employee to believe, in good faith, that his employer is violating, or will soon violate, the FCA. The objective component asks whether a reasonable employee in the same or similar circumstances would believe that the employer is submitting, or will submit, false claims for payment to the

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belief, in good faith, that the activity they oppose is unlawful under Title VII"); Williams v. Phila. Hous. Auth. Police Dep't, 380 F.3d 751, 759 n.2 (3d Cir. 2004) (noting that an ADA retaliation claim requires the plaintiff to have a "reasonable, good faith belief that she was entitled to request the reasonable accommodation she requested"), superseded by statute on other grounds, ADA Amendments Act of 2008, Pub. L. No. 110-325, 122 Stat. 3553, as recognized in Robinson v. First State Cmty. Action Agency, 920 F.3d 182, 188 n.30 (3d Cir. 2019); Daniels v. Sch. Dist. of Phila., 776 F.3d 181, 192–94 (3d Cir. 2015) (applying the "objectively reasonable belief" standard to retaliation claims under the ADEA); Gillispie v. RegionalCare Hosp. Partners, Inc., 892 F.3d 585, 593 (3d Cir. 2018) (holding that to engage in protected conduct under the EMTALA, a plaintiff "need only establish that [s]he was acting under a good faith, reasonable belief that a[n] [EMTALA] violation existed" (citation and quotation marks omitted)).

government. By ensuring that the employee not only believes, but reasonably believes, that his employer is violating the FCA, the objectively reasonable belief standard balances the two aims of the FCA: "preventing opportunistic suits" and "encouraging citizens to act as whistleblowers." See United States ex rel. LaCorte v. SmithKline Beecham Clinical Lab'ys, Inc., 149 F.3d 227, 233 (3d Cir. 1998) (explaining how § 3730 "attempts to reconcile two conflicting goals"). We therefore conclude that protected conduct under the "other efforts" prong requires a plaintiff to hold, in good faith, an objectively reasonable belief that his or her employer is violating, or will violate, the FCA.

B.

We turn now to the allegations in the Amended Complaint. At the motion to dismiss stage, Lisenby must allege facts that, when viewed in his favor, support an inference that he believed, and it was objectively reasonable for him to believe, that Olympus was violating the FCA. The Amended Complaint fails to allege that Lisenby believed that Olympus had submitted, or was submitting, false claims for payment to the federal government. Accordingly, we will affirm the District Court's order.

The Amended Complaint does not contain any allegations from which we may infer that Lisenby believed that Olympus was violating, or would soon violate, the FCA. Instead, the Amended Complaint alleges that Lisenby was concerned about Olympus violating FDA regulations. Lisenby points to several facts alleged in the Amended Complaint that he contends demonstrate his belief that Olympus had committed, or would commit, fraud on the government. These

facts include that Olympus is a federal contractor; Olympus sells its medical devices to hospitals for use in medical procedures covered by Medicare and Medicaid; Lisenby discovered systemic deficiencies in Olympus's design approach and quality management system that resulted in violations of FDA regulations; Olympus had already sold noncompliant products; and Lisenby reported his concerns to others, providing examples of already-sold products that did not conform to FDA regulations.

Yet these allegations suggest only that Lisenby was concerned about Olympus's alleged FDA regulatory violations and the attendant risks to patient safety, not fraud committed against the government. For example, the Amended Complaint alleges that Lisenby "raised concerns regarding design quality and non-compliant product testing issues required by FDA regulations" during the CTO meetings. App. 6. His concerns focused on "a lack of product safety," "FDA compliance issues," and "patient safety risks." App. 7–8. At no point does the Amended Complaint connect Lisenby's concerns about FDA regulatory violations and safety risks to a belief that Olympus was submitting false claims for payment to the federal government.

Lisenby's other arguments are unavailing. He first contends that "it was objectively reasonable for Lisenby to believe that Olympus violated the FCA" because the implied false certification theory provides a basis for FCA liability. Lisenby Br. 22. The Supreme Court has held that, in some circumstances, the implied false certification theory can provide a basis for liability under the False Claims Act. Universal Health Servs., Inc. v. United States ex rel. Escobar, 579 U.S. 176, 181 (2016). Liability can arise under this theory

when a defendant submits a claim for payment and "knowingly fails to disclose [its] noncompliance with a statutory, regulatory, or contractual requirement," rendering its specific representations about the goods or services misleading. Id. A claim premised on this theory is actionable under the FCA only if "[a] misrepresentation about compliance with a statutory, regulatory, or contractual requirement [is] material to the Government's payment decision." Id. The Supreme Court's decision in Universal Health was limited to the FCA's qui tam provision and did not address its anti-retaliation provision. See id. at 184–87 (concluding that the implied false certification theory can provide a basis for a qui tam suit). See also Guilfoile v. Shields, 913 F.3d 178, 188 (1st Cir. 2019) (distinguishing between the standards for a qui tam claim under 31 U.S.C. § 3730(b) and a retaliation claim under 31 U.S.C. § 3730(h)); Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson, 545 U.S. 409, 416 n.1 (2005) (noting that "proving a violation of § 3729 is not an element of a § 3730(h) [retaliation] cause of action").

Here, Lisenby contends that Olympus defrauded the government by falsely certifying that it had satisfied FDA regulations, compliance with which is allegedly a material condition of payment by the federal government. According to Lisenby, "misrepresenting data to the FDA can lead to a violation of the FCA's *qui tam* provision, [so] an employee's observation that this type of misconduct was occurring easily satisfies the lower standard of a reasonable belief." Lisenby Br. 25. Yet Lisenby appears to misapprehend the relevant legal standard. As explained above, a retaliation claim under the "other efforts" prong requires a plaintiff to reasonably believe that his employer was committing fraud against the federal government. That inquiry is distinct from the test for

substantive liability under the FCA. See Guilfoile, 913 F.3d at 188 (noting how the standards for a qui tam claim and retaliation claim under the FCA differ). At issue on appeal is an FCA retaliation claim, not a qui tam claim. Even if we assume that Olympus would be liable under the implied false certification theory, Lisenby has not alleged that he believed that Olympus was committing fraud against the federal government — a necessary element of an FCA retaliation claim. Lisenby's reliance on the implied false certification theory thus cannot fill the gaps in the Amended Complaint.

Lisenby also relies on the Court of Appeals for the District of Columbia Circuit's opinion in Singletary for the proposition that "a regulatory violation can give rise to a reasonable belief of an FCA violation." Lisenby Br. 25–26. Yet the facts of the Singletary decision are distinguishable. The plaintiff in Singletary worked as a veterinarian in a university's research laboratory that received federal funding. 939 F.3d at 291, 293. According to the complaint, the university made annual certifications to the National Institutes of Health ("NIH") and other federal agencies that the laboratory animals were cared for in accordance with federal regulations. Id. at 298. The plaintiff alleged that those certifications "were necessary for [the University] to receive and retain the grant monies that [it] in fact received from the United States." Id. The plaintiff repeatedly informed her supervisor that the laboratory was not complying with NIH standards and that its noncompliance "constituted violations of the terms and conditions under which [the University] received grant money from NIH and the federal government." Id. at 297. The court concluded that these allegations were sufficient to allege protected activity under the "other efforts" prong of § 3730(h)(1). Id. at 297–99. The court noted that the

plaintiff's concerns, as alleged in the complaint, "did not accuse the University of fraud in terms." Id. at 298. The court nevertheless concluded that the plaintiff "had an objectively reasonable belief that the University was or would soon be submitting false certifications of its compliance with animal welfare requirements in connection with funding claims." Id.

Lisenby correctly notes that "magic words" are not required to state an FCA retaliation claim. Lisenby Br. 36. Yet he acknowledges that "[t]he facts alleged in the Amended Complaint demonstrate that Lisenby reported his concerns about Olympus'[s] systemic failures to comply with FDA standards." Lisenby Br. 38. And here, unlike the plaintiff in Singletary, the Amended Complaint lacks any allegations connecting Lisenby's concerns about FDA regulatory violations to a belief that Olympus was committing fraud against the government. Absent allegations supporting such a nexus, Lisenby has failed to state a retaliation claim under the "other efforts" prong.

Lisenby further contends that the District Court "improper[ly] narrow[ed]" his allegations of protected activity in the Amended Complaint. Lisenby Br. 27. He asserts that the District Court failed to acknowledge his allegations that "Olympus was already selling products to the government that failed to comply with FDA regulations." Lisenby Br. 28. But even if we assume that those allegations are true, nothing in the Amended Complaint suggests that Lisenby believed that Olympus had made, or would make, false claims for payment with respect to those products. The Amended Complaint focuses on concerns about regulatory violations and patient safety, not false claims for payment. Lisenby has thus failed to state a retaliation claim under the "other efforts" prong of

§ 3730(h)(1).[10] We will therefore affirm the District Court's order.

## III.

For the foregoing reasons, we will affirm the District Court's order dismissing the FCA retaliation claim.

[10] As explained above, Lisenby has not sufficiently alleged that he believed that Olympus was submitting false or fraudulent claims to the government for payment. Accordingly, we need not consider whether any such belief was objectively reasonable or whether his actions put Olympus on notice of conduct protected under the FCA.