UNPUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 19-2042

LIUBOV SKIBO, as relator on behalf of the United States of America; EDWARD PATT, as relator on behalf of the United States of America,

Plaintiffs - Appellants,

v.

GREER LABORATORIES, INCORPORATED,

Defendant - Appellee.

Appeal from the United States District Court for the Western District of North Carolina, at Statesville. Kenneth D. Bell, District Judge. (5:13-cv-00110-KDB-DSC)

Argued: October 28, 2020 Decided: January 8, 2021

Before AGEE, FLOYD, and THACKER, Circuit Judges.

Affirmed by unpublished per curiam opinion.

ARGUED: Louis M. Bograd, MOTLEY RICE, LLC, Washington, D.C., for Appellants. Michael Thomas Gass, CHOATE, HALL & STEWART LLP, Boston, Massachusetts, for Appellee. **ON BRIEF:** Charles H. Rabon, Jr., RABON LAW FIRM, PLLC, Charlotte, North Carolina; William S. Norton, Joshua C. Littlejohn, Christopher F. Moriarty, Erin C. Williams, MOTLEY RICE LLC, Mount Pleasant, South Carolina, for Appellants. Melissa Bayer Tearney, Kristen L. Dooley, CHOATE, HALL & STEWART LLP, Boston, Massachusetts; Eric H. Cottrell, PARKER POE ADAMS & BERNSTEIN LLP, Charlotte,

North Carolina, for Appellee.

Unpublished opinions are not binding precedent in this circuit.

PER CURIAM:

Relators Liubov Skibo and Edward Patt (collectively, "Appellants") appeal the district court's grant of summary judgment on their False Claims Act ("FCA") and employment retaliation claims against Greer Laboratories, Inc. ("Appellee").

As explained below, we agree with the district court that Appellants failed to demonstrate a material issue of fact that Appellee acted with the requisite scienter to be liable for a violation of the FCA. Further, we agree with the district court that Appellants failed to establish an issue of material fact that they engaged in a "protected activity" sufficient to support their retaliation claim. Therefore, we affirm the holding of the district court.

I.

A.

Appellee manufactures allergenic extracts which a physician injects into a patient in order to increase tolerance to allergens. Manufacturers of allergenic extracts must obtain a Food and Drug Administration ("FDA") approved Biologics License Application ("BLA") in order to ensure their products are safe for consumption. At all relevant times, Appellee possessed a BLA.

Appellant Skibo was Appellee's Director of New Products and Business Development from November 2008 until October 2009 and was Appellee's Senior Director and Head of Regulatory from October 2009 until May 2012, when Appellee terminated her employment. Appellant Patt was Appellee's Director of Compliance from July 2008 until May 2012, when Appellee terminated his employment.

At issue in this case is Appellee's production of "custom mixes" of its licensed allergens. Custom mixes are mixes of individual extracts for general use by a physician rather than those that are made pursuant to a specific patient prescription. Appellee did not seek separate licenses for each of its custom mixes because it believed that the custom mixes fell under its general BLA license.

At the time Appellee was granted its BLA in 1968, the FDA defined a "product" by the category of biologic -- for example, "allergenic extract" -- and issued a license to Appellee for all of its allergenic extracts. The FDA enacted the regulation at issue in this case in 1974. That regulation provides, "Licensed products may not be combined with other licensed products either therapeutic, prophylactic or diagnostic, except as a license is obtained for the combined product." 21 C.F.R. § 610.17. In February 2015, 40 years after the regulation was enacted, the FDA released a draft guidance document titled "Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application: Guidance for Industry." 80 Fed. Reg. 8881 (Feb. 19, 2015) (hereinafter, "2015 Guidance"). The 2015 Guidance stated, "[M]ixes of allergenic extracts that are not prescription sets must be the subject of an approved BLA." 2015 Guidance at 12 n.22. Once the FDA issued this guidance, Appellee stopped manufacturing its custom mixes.

Appellants argue that because Appellee's custom mix allergenic extracts were not licensed by the FDA or prepared for individual patients via physician prescriptions, Appellee violated the FCA. Specifically, Appellants allege that Appellee effectively caused its customers -- i.e., physicians administering these custom mix allergenic extracts

to their patients -- to submit false claims to the government for reimbursement of the custom mix allergenic extracts, contending those claims were false because government payors (including Medicare and Medicaid) will not provide such reimbursement for unlicensed drugs. Appellee responds that it advertised its service of preparing custom mixes in a way that made it clear such service was distinct from specific patient prescriptions. That is, Appellee's product catalogue -- which it provided to the FDA -- identified its mixes as "custom mixes, stock mixes, . . . and named-patient prescriptions." Appellee's Br. 7–8. In her role as the head of Appellee's regulatory group, Appellant Skibo approved the language advertising the custom mixes in Appellee's product catalogue.

Appellee claims that in the nearly five decades between receiving its BLA in 1968, and 2015 when Appellee stopped selling custom mixes, it was inspected and approved by the FDA numerous times; it was clear to the FDA that Appellee was making the custom mixes; and the FDA never took action against Appellee for doing so.

During the FDA's inspection in 2013, an inspector issued a warning to Appellee suggesting that each separate custom mix required a license from the FDA. And in February 2014, the FDA issued a formal warning letter to Appellee informing it that a separate BLA license was needed for each of its custom mixes. Appellee then corresponded with the FDA to request clarification on the issue of licensing for custom mixes, but the FDA declined to respond, stating that custom mixes were "an issue that is a focus industry wide and that the other manufacturers would be notified as well." J.A.

1455–56.[1] Appellee met with the FDA to discuss the issue again in June 2014, and the FDA again stated that it was not in a position to discuss the issue.

In the meantime, in April 2014, the Allergen Product Manufacturers' Association ("APMA") sent a letter to the FDA requesting guidance on the manufacturing of custom mixes, stating:

> It has become apparent to the representative companies of the APMA that a focus during recent FDA inspections is the historical practice of manufacturing "Custom Mixes" . . . and whether or not this activity is within the scope of the manufacturer's licenses . . . . This practice of manufacturing Custom Mixes by each APMA member company has been documented in various correspondences with [the] FDA, and includes recognition and acknowledgement of this practice, without objection, during facility inspections over the years.

J.A. 1456.

When the FDA ultimately issued its 2015 Guidance clarifying that separate licenses were required for each custom mix, physicians and trade groups responded, emphasizing that the use of custom mixes was a longstanding practice and the guidance should be reversed to allow such practice to continue.

B.

As noted, Appellants were each terminated by Appellee in May 2012. Appellee argues their termination was due to "longstanding performance and interpersonal issues." Appellee's Br. 19. But Appellants claim they were fired by Appellee for raising concerns about Appellee's custom mixes not complying with FDA regulations. Appellant Skibo

[1] Citations to the "J.A." refer to the Joint Appendix filed by the parties in this appeal.

claims that she raised the issue of non-compliance to an Appellee executive, John Roby, several times, only to be dismissed by him.

In August 2013, Appellants filed an FCA claim against Appellee for selling unlicensed allergenic extracts and an employment retaliation claim against Appellee for firing Appellants for engaging in protected activity. In July 2019, the district court held a hearing on Appellee's motion for summary judgment. At the summary judgment hearing, Appellee argued that Appellants could not demonstrate the scienter element of their FCA claim because Appellee reasonably believed that custom mixes were covered under their FDA license, and Appellee was not required to have separate licenses to manufacture and sell custom mixes, as supported by industry-wide practice. Further, Appellee argued there was no nexus between Appellants' dismissals and any protected activity. In response, Appellants asserted that Appellee's practice of making custom mixes was in clear violation of the FDA regulation and ran contrary to industry practice. Appellants also argued that Appellee fired them for raising regulatory concerns about custom mixes.

C.

On August 22, 2019, the district court granted summary judgment to Appellee on both the FCA and adverse employment retaliation claims. The district court held that Appellants did not specify any evidence that Appellee had "actual knowledge" that the custom mixes were required to be separately licensed, and the allegations of Appellant Skibo alone that she made complaints to Appellee -- which were never committed to writing -- were not enough to establish that Appellee had "actual knowledge." Additionally, the district court rejected Appellant's argument that the relevant FDA

regulation was clear and that Appellee violated it. The district court cited to the following facts: it took a year after the APMA requested guidance for the FDA to implement the 2015 Guidance banning custom mixes without a license; and there was a strong response from trade groups and physicians when the 2015 Guidance came out. The district court further held that there was no genuine issue of material fact that Appellee acted with "actual knowledge" or with "deliberate ignorance, or reckless[] disregard[] that a separate license was required when it mixed its individually licensed allergenic extracts in response to orders submitted by physicians for 'custom mixes.'" J.A. 1465–66.

The district court also granted summary judgment for Appellee on Appellants' claim that it terminated Appellants in retaliation for protected activity under the FCA. The court held that Appellants could not demonstrate that they engaged in protected activity because they were fired long before this FCA action was filed, and there was no evidence that Appellants were pursuing an FCA action prior to their termination. Appellants were fired in May 2012, but they did not file their lawsuit until over one year later in August 2013. Thus, the district court held they were not acting in furtherance of an FCA action. The district court also held that Appellants failed to demonstrate that they attempted to stop an FCA violation. Rather, the court concluded Appellants merely tried to keep Appellee in regulatory compliance, which was a part of their job descriptions. Thus, the district court held Appellants failed to show that they engaged in protected activity under the FCA and, therefore, summary judgment for Appellee was appropriate on Appellants' retaliation claim.

II.

We review a district court's decision to grant summary judgment de novo, applying the same legal standards as the district court and viewing all facts and reasonable inferences in the light most favorable to the nonmoving party. *See Smith v. Collins*, 964 F.3d 266, 274 (4th Cir. 2020).

III.

A.

False Claims Act Claim

1.

The FCA prohibits an individual from:

> "knowingly" presenting or making a false statement in connection with a claim seeking payments from the government. The FCA defines "knowingly" to mean[] that a person, with respect to information—(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

United States ex rel. Harrison v. Westinghouse Savannah River Co., 352 F.3d 908, 917–18 (4th Cir. 2003) (citing 31 U.S.C. § 3729). However, "the statute is not intended to punish honest mistakes or incorrect claims submitted through mere negligence." *United States ex rel. Ubl v. IIF Data Sols.*, 650 F.3d 445, 452 (4th Cir. 2011) (internal citations and quotation marks omitted). "Evidence that the government knew about the facts underlying an allegedly false claim can serve to distinguish between the knowing submission of a false claim, which generally is actionable under the FCA, and the

submission of a claim that turned out to be incorrect, which generally is not actionable under the FCA." *Id.*

Moreover, "[a]t summary judgment, although the court must draw all justifiable inferences in favor of the nonmoving party, the nonmoving party must rely on more than conclusory allegations, mere speculation, the building of one inference upon another, or the mere existence of a scintilla of evidence." *Sandlands C&D LLC v. Cnty. of Horry*, 737 F.3d 45, 54 (4th Cir. 2013) (internal quotation marks and citations omitted).

2.

At the outset, Appellants argue summary judgment is inappropriate on an element of a claim relating to a party's mental state. In fact, this court has held: "Summary judgment is seldom appropriate in cases in which particular states of mind are decisive elements of claim or defense, because state of mind is so often proved by inferences from circumstantial evidence and by self-serving direct evidence." *Magill v. Gulf & W. Indus.*, 736 F.2d 976, 979 (4th Cir. 1984). "[K]nowledge is such a state of mind." *Id.* Moreover, "the issue of fraudulent intention is generally not amenable to resolution on summary judgment. . . . [W]hen evidence of intention is ambiguous, summary judgment simply cannot be awarded." *United States ex rel. Bunk v. Gov't Logistics N.V.*, 842 F.3d 261, 276–77 (4th Cir. 2016) (internal citations omitted).

However, this proposition does not mean that summary judgment is never appropriate on the element of knowledge. *See, e.g.*, *Dalton v. Cap. Assoc. Indus.*, 257 F.3d 409, 418 (4th Cir. 2001) (summary judgment upheld where, "[e]ven though summary judgment is 'seldom appropriate' on whether a party possessed a particular state of mind,

evidence that [defendant] acted willfully [was] wholly lacking"). Therefore, in order for summary judgment to be appropriate, it must be clear that there is no issue of material fact as to whether Appellee acted with the requisite mental state -- here, scienter. Appellants argue there is a genuine issue of material fact on the scienter element. They assert that Appellee misled the FDA and hid its custom mix practices, and the FDA regulation was clear that Appellee's actions were impermissible.

a.

In attempt to support their scienter argument, Appellants first argue that Appellee mischaracterized the custom mixes as prescriptions by labeling the custom mixes "Rx." Appellants claim that the use of the "Rx" label was Appellee's effort at misleading the FDA into believing Appellee was making individual prescriptions. Appellee counters that the labels do not include a patient name, making it clear that they were not intended for specific patients. For its part, Appellee explains that the use of "Rx" or "Rx Only" on its labeling "simply denotes that the product is not available over the counter." Appellee's Br. 36; *see* J.A. 379 (requiring that a physician license be on file to order allergenic extracts).

Next, Appellants claim that a single, isolated letter Appellee sent to the FDA in 1982 outlining its labeling process demonstrates that Appellee misleadingly used "prescription" to refer to custom mixes.[2] Appellants assert that by way of this 1982 letter, Appellee

[2] Notably, Appellants did not enter the entire letter into the J.A., but rather referred only to snippets of the letter which were contained in a PowerPoint slide without context.

submitted to the FDA a "label for prescription mixtures" which made it seem as though Appellee's custom mixes were produced according to individual patient prescriptions because the letter included a sample label ("Exhibit 1, Rx #X5480") that specified the mixture was for a specified patient and was "prescribed by Dr. Baker." J.A. 1510–12. Of note, however, in this same document, Appellee referred to custom mixes and named patient-prescriptions as distinct. *Id.* ("Many prescribing physicians have *special mixes* (which we refer to as 'PO' mixes) which they frequently use in their *prescriptions* they order for their patients. (Refer to Exhibit #1, prescription #X5480, as an example)." (emphasis supplied)). Because this isolated letter did, in fact, differentiate between custom mixes and prescription mixes and specifically identified Exhibit #1, #Rx5480 as a prescription, we cannot see how this letter was misleading to the FDA.

Thus, we agree with Appellee and the district court that neither Appellee's use of the label "Rx," nor the 1982 letter, creates a genuine issue of material fact that Appellee acted with the requisite scienter.

b.

In another attempt to demonstrate issues of material fact on the scienter element, Appellants argue that Appellee continuously concealed its custom mix practice from the FDA. Specifically, Appellants assert that during a 1994 inspection by the FDA, Appellee provided the FDA a list of the different product types it manufactured and referred to "individual prescription mixtures" rather than specifically mentioning their practice of making custom mixes. However, as the primary licensing agency of Appellee, the FDA conducted regular inspections of Appellee, including inspecting Appellee's product

catalogues in which Appellee openly advertised its custom mix practice. In fact, the FDA inspected Appellee at least 57 times in the 45 years between granting its license in 1968 and 2013. It was not until 2013 that the FDA raised an issue with Appellee's custom mix practice. Thus, Appellants' claim that Appellee misled the FDA is not supported by the record.

c.

Finally, Appellants argue that the plain language of 21 C.F.R. § 610.17 made it clear that custom mixes required independent licenses from the FDA. Appellants argue that if there was ambiguity, Appellee could have and should have sought clarity from the FDA. For its part, Appellee asserts the regulation was clear that it allowed for custom mixes prior to the 2015 Guidance. Appellee first cites to its license issued by the FDA to sell "allergenic extracts" as the "product." J.A. 376. Thus, Appellee asserts combining multiple allergenic extracts -- as Appellee did in its custom mixes -- was not combining two "products," as all allergenic extracts were covered under the same product license. Instead, the plain language of Section 610.17 and the understanding of the term "product" made it clear that custom mixes did not require independent licenses.

Additionally, the actions of other similarly situated companies in the industry supports the finding that it was not previously settled prior to the issuance of the 2015 Guidance that Section 610.17 required separate licenses for custom mixes. Indeed, prior to 2015, nearly the entire industry manufactured custom mixes without acquiring separate licenses for each individual mix. As the district court notes and Appellee points out, several trade groups and physicians responded to the 2015 Guidance with opposition to the change

in practice. *See* J.A. 1462–63. For example, the Regional Chief of Allergy & Immunology for Southern California Permanente Medical Group wrote, "Mixtures of allergen extracts prepared for diagnosis and treatment of multiple patients, *called custom bulk extracts, have been used safely and effectively for approximately 100 years.*" Appellee's Br. 18 (emphasis in original). And, the American College of Allergy, Asthma & Immunology wrote, "We are concerned that under the draft guidance, *extract manufacturers will no longer be able to prepare these special mixes* because they would not be prepared for an individual patient . . . *We believe the draft guidance should permit this longstanding practice to continue*." *Id.* at 19 (emphases in original).

In the face of this strong evidence of industry practice, Appellants point to screenshots of competitor websites, some of which advertise individual prescription mixes. *See, e.g.*, J.A. 874 (screenshot of Hollister website advertising individual prescription mixes); J.A. 1243 (screenshot of Antigen website advertising individual prescription mixes). Appellants claim the district court erred by failing to consider this evidence and that such evidence demonstrates an issue of material fact with regard to the industry standard. However, these screenshots are insufficient to prove the negative; that is, evidence that some companies in the industry advertised and sold individual prescription mixes alone is not enough to prove that it was not industry practice to prepare custom mixes without a separate license, especially in light of the recognition of the widespread practice by trade groups and physicians in the industry.

In order to defeat a motion for summary judgment, Appellants were required to provide more than a "scintilla of evidence" to support their claim. *Sandlands*, 737 F.3d at

54. Here, however, the bulk of the record undercuts Appellants' claim. The record amply demonstrates that the common understanding of Section 610.17 in the industry was to allow the use of custom mixes. Appellee openly acted according to that understanding. Consequently, there is no issue of material fact as to whether Appellee acted with the requisite scienter. We affirm the district court's grant of summary judgment.

B.

Retaliation Claim

1.

To establish a claim of retaliation under the FCA, Appellants must establish "(1) [they] engaged in [a] protected activity; (2) [their] employer knew about the protected activity; and (3) [their] employer took adverse action against [them] as a result." *United States ex rel. Grant v. United Airlines Inc.*, 912 F.3d 190, 200 (4th Cir. 2018). The first element -- protected activity -- requires either (1) acts in furtherance of an FCA action; or (2) other efforts to stop one or more FCA violations. 31 U.S.C. § 3730(h)(1); *see id.* "In interpreting [the first prong], we appl[y] the 'distinct possibility' standard: employees engage[] in protected activity when 'litigation is a distinct possibility, when the conduct reasonably could lead to a viable FCA action, or when . . . litigation is a reasonable possibility.'" *Grant*, 912 F.3d at 200–01 (quoting *Mann v. Heckler & Koch Def.*, 630 F.3d 338, 344 (4th Cir. 2010)). In interpreting the second prong, we apply an "objective reasonableness standard." *Id.* at 201. That is,

> A belief is objectively reasonable when the plaintiff alleges facts sufficient to show that he believed his employer was violating the FCA, that this belief was reasonable, that he took

> action based on that belief, and that his actions were designed to stop one or more violations of the FCA. However, while the plaintiff's actions need not 'lead to a viable FCA action' . . . they must still have a nexus to an FCA violation.

Id. at 201–02.

Additionally, "[t]he employee's investigation must concern 'false or fraudulent claims' or it is not protected activity under the FCA." *Glynn v. EDO Corp.*, 710 F.3d 209, 214 (4th Cir. 2013). Allegations of regulatory violations are not enough "in the absence of *actual fraudulent conduct*." *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 702 (4th Cir. 2014) (emphasis in original) (internal citations and quotation marks omitted) ("Were we to accept relator's theory of liability based merely on a regulatory violation, we would sanction use of the FCA as a sweeping mechanism to promote regulatory compliance, rather than a set of statutes aimed at protecting the financial resources of the government from the consequences of fraudulent conduct.").

2.

Appellants argue that the district court erred in granting summary judgment on their retaliation claim by ignoring the Supreme Court's decision in *Universal Health Services, Inc. v. United States*, 136 S. Ct. 1989 (2016). Appellants argue that *Universal Health Services* held protected activity includes an employee complaining about a company violating an FDA regulation. Indeed, *Universal Health Services* held, "When . . . a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services

provided." *Id.* at 1999. However, the test for when these circumstances can serve as a claim for liability is as follows: "[F]irst, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Id.* at 2001. While *Universal Health Services* can be read to support the proposition that it was enough for Appellants to demonstrate that they flagged Appellee's omissions relating to custom mixes, Appellants' reliance on *Universal Health Services* nonetheless fails because Appellants do not actually point to evidence that they identified any "half-truths" of Appellee. As the district court held, Appellants failed to provide any evidence that they "engaged in 'efforts to stop' an FCA violation," -- even an FCA violation involving "misleading half-truths." J.A. 1468 (emphasis in original).

Appellants argue that their testimony established that they undertook efforts to stop FDA regulation violations because they testified that they raised concerns about the custom mixes violating the FDA regulations. We disagree. At best, Appellant Skibo's testimony establishes that she raised concerns about Appellee's compliance with FDA regulations. The fatal flaw in Appellants' claim is that they never allege that they raised an issue of *false or fraudulent* conduct beyond a regulatory violation that would constitute an FCA violation.

Appellants' argument that the regulatory violation itself was an FCA violation is conclusory and is not supported by law or the record. Consequently, the district court was correct in holding that at most, Appellants' testimony established that Appellants raised

concerns about regulatory compliance -- part of their job description -- but that did not constitute "protected activity." Thus, we affirm the district court's grant of summary judgment on Appellants' claim of retaliation.

IV.

For the foregoing reasons, the decision of the district court is

AFFIRMED.