**IN THE UNITED STATES DISTRICT COURT**
**FOR THE WESTERN DISTRICT OF NORTH CAROLINA**
**STATESVILLE DIVISION**
**CIVIL ACTION NO. 5:13-CV-00110-KDB-DSC**

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| EDWARD PATT<br>LIUBOV SKIBO, | ) | |
| **Plaintiffs,** | ) | |
| **v.** | ) | **ORDER** |
| GREER LABORATORIES, INC., | ) | |
| **Defendants.** | ) | |

In this action under the False Claims Act ("FCA"), two former employees of Greer Laboratories – Plaintiffs ("Relators") Liubov Skibo and Edward Patt – allege that Defendant Greer Laboratories, Inc. ("Greer") violated the FCA by selling custom mix allergy products to physicians who then allegedly submitted "false claims" to the government when they sought payment for using those products in treating patients. Now before the Court is Greer's Motion for Summary Judgment (Doc. No. 95). The Court has carefully considered the Motion and the parties' extensive briefs and exhibits and heard oral argument from the parties' counsel during a lengthy hearing on the motion held July 25, 2019. For the reasons discussed below, the Court has determined that there is no genuine dispute as to any material fact and Greer is entitled to judgment as a matter of law. Therefore, the Court will **GRANT** Greer's motion and enter **SUMMARY JUDGMENT** in its favor.

## I. LEGAL STANDARD

Summary judgment must be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56. A factual dispute is considered genuine "if the evidence is such that a reasonable jury

could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). "A fact is material if it might affect the outcome of the suit under the governing law." *Vannoy v. Federal Reserve Bank of Richmond*, 827 F.3d 296, 300 (4th Cir. 2016) (quoting *Libertarian Party of Va. v. Judd*, 718 F.3d 308, 313 (4th Cir. 2013)).

The party seeking summary judgment bears the initial burden of demonstrating the absence of a genuine issue of material fact through citations to the pleadings, depositions, answers to interrogatories, admissions or affidavits in the record. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986); *Bouchat v. Baltimore Ravens Football Club, Inc.*, 346 F.3d 514, 522 (4th Cir. 2003). "The burden on the moving party may be discharged by 'showing' ... an absence of evidence to support the nonmoving party's case." *Celotex*, 477 U.S. at 325. Once this initial burden is met, the burden shifts to the nonmoving party. The nonmoving party "must set forth specific facts showing that there is a genuine issue for trial," *Id*. at 322 n.3. The nonmoving party may not rely upon mere allegations or denials of allegations in his pleadings to defeat a motion for summary judgment. *Id*. at 324.

When ruling on a summary judgment motion, a court must view the evidence and any inferences from the evidence in the light most favorable to the nonmoving party. *Tolan v. Cotton*, 572 U.S. 650, 657 (2014); *see also Anderson*, 477 U.S. at 255. "Summary judgment cannot be granted merely because the court believes that the movant will prevail if the action is tried on the merits." *Jacobs v. N.C. Admin. Office of the Courts*, 780 F.3d 562, 568-69 (4th Cir. 2015) (quoting 10A Charles Alan Wright & Arthur R. Miller et al., Federal Practice & Procedure § 2728 (3d ed.1998)). "The court therefore cannot weigh the evidence or make credibility determinations." *Id*. at 569 (citing *Mercantile Peninsula Bank v. French* (*In re French*), 499 F.3d 345, 352 (4th Cir. 2007)).

However, "[w]here the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial." *Ricci v. DeStefano*, 557 U.S. 557, 586 (2009) (internal citations omitted). "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted." *Anderson*, 477 U.S. at 248. Also, the mere argued existence of a factual dispute does not defeat an otherwise properly supported motion. *Id*. If the evidence is merely colorable, or is not significantly probative, summary judgment is appropriate. *Id*. at 249-50.

In the end, the question posed by a summary judgment motion is whether the evidence as applied to the governing legal rules "is so one-sided that one party must prevail as a matter of law." *Id*. at 252.

## II. RELEVANT FACTS AND PROCEDURAL HISTORY[1]

Greer manufactures allergy immunotherapy treatments, which include allergenic extracts. Immunotherapy involves the practice of introducing small amounts of an allergen such as pet dander or pollen into a patient in the hope that the patient develops an immunity to the allergen. Greer produces hundreds of different allergenic extracts under a single Biologics License in bulk in its manufacturing facility, which FDA regulates. Greer also compounds customized mixtures of its licensed allergenic extracts pursuant to prescriptions submitted by physicians for a single, identified patient ("named-patient prescriptions") in its pharmacy operation. Mixtures prepared in the pharmacy are not at issue in this case.

[1] These relevant (and undisputed except where noted) facts are taken from the voluminous evidence of record referenced by the parties and filed as exhibits in support and in opposition to the motion for summary judgment as well as other evidence reflected in the record.

## A. Custom Mixes

From the 1970s until 2015, Greer also produced "custom mixes" or “special mixes” of its licensed bulk allergenic extracts in response to orders submitted by physicians for multiple patients requiring the same mixture of extracts. For example, a doctor might order a mixture of pet dander, tree mold and other allergens in a specific formula. While custom mixes are made according to a doctor’s orders, they are not made pursuant to an individual named-patient prescription because the doctor intends to use the same mixture for multiple patients. Although physicians can purchase the individual extracts and prepare the mixture themselves in their office, they requested custom mixes from Greer because it was more efficient and reduced the chance of error, as well as the cost and work of preparation. Greer produced its custom mixes in the manufacturing facility where it produced the bulk individual allergenic extracts, which are the components for the custom mixes. Greer's Regulatory Affairs group, including Relator Patt for several years, approved every custom mix specification sheet prior to the mix being produced.

Custom mixes comprised a relatively small portion of Greer's business; the mixes totaled less than 3% of Greer's total revenue during the period. In fact, Greer testified that it could have earned more revenue by selling the individual extracts but opted to provide custom mixes as a convenience to its customers.

## B. Greer’s Preparation of Custom Mixes under FDA Regulations

Greer did not have and did not seek separate licenses for each doctor ordered custom mix because it believed such mixes were within the scope of its license for the allergenic extracts that make up the custom mixes. The relevant FDA regulation, 21 C.F.R. § 610.17, was enacted in 1947. Section 610.17 states that "[l]icensed products may not be combined

with other licensed products . . . except as a license is obtained for the combined product. Licensed products may not be combined with nonlicensable . . . substances except as a license is obtained for such combination." At the time the regulation was enacted, FDA issued product licenses (now referred to as BLAs) which defined the "product" by the category of biologic (*e.g.*, "Allergenic Extracts"), not by the individual biologics within each category. All of Greer's allergens – the components of the custom mixes – were defined as the same "product" under the license issued by FDA; therefore, Greer believed that the combination of the individual allergens did not reflect a combination of different licensed products and did not require a separate FDA license.

Consistent with its belief and understanding that each custom mix ordered by a physician fell within its existing BLA, Greer openly advertised its custom mix service. Over the course of twenty years, Greer provided FDA with copies of its product catalog which referenced the custom mix service and Greer posted the catalogs on its website. In reviewing Greer's catalogs, FDA did not raise concerns about Greer's custom mixes or express confusion over the distinction between Greer's custom mix and prescription services. Relator Skibo approved the product catalog language describing the custom mix service in her role as the head of Greer's regulatory group and did not raise concerns about the licensing of custom mixes or the potential "confusion" between Greer's custom mix service and its prescription service during her tenure at Greer.

Greer's also made proactive disclosures regarding custom mixes in correspondence with FDA that reflects their openness about the practice. In a 1992 letter to Greer denying Greer's request for additional time to convert from using non-standardized to standardized cat hair extracts, the FDA appeared to recognize the difference between an individual patient

prescription and a “special mixture” : "[Greer's] request to allow nonstandardized cat extracts that have already been incorporated into a prescription mixture for a specific patient or into a special mixture for use in a specific physician's practice to continue to be sold in interstate commerce after September 17, 1992, cannot be granted." Additional examples of Greer's affirmative disclosures regarding custom mixes include:

| **Date** | **Description** |
|---|---|
| 1981 | In a letter to FDA regarding Antigen E, Greer wrote:<br>"A survey of our records shows that we have . . . the following . . . mixes in stock.<br>A. Approximately 1193 sets (a set is 1x10 ml or 2x5 ml) of maintenance vials of patient prescription material. (Vials made up per doctor's orders for individual patients.)<br>B. Approximately 82 vials (of various sizes - mostly 30 and 50 ml) of doctor's special mixes. These are mixes prepared on a doctor's orders for his use in diagnosis and/or therapy of his patients.<br>C. Approximately 19 storage bottles of special mixes as in B (above) not yet vialed" (Ex. RR at GRLT-00104219) (emphasis added). |
| 1982 | Responding to FDA's request for a list of inventory containing short ragweed, Greer wrote: "[W]e have in stock numerous patient prescription vials and special mixes (prepared on a doctor's request) . . . ." (Ex. SS at GRLT-00002754) (emphasis added). |
| 1988 | In a letter to FDA regarding Antigen E, Greer wrote: "Even more problematic will be the impact on the very large percentage of custom mixes and individual patient prescriptions which contain Ragweed products" (Ex. TT at GRLT-00002760) (emphasis added). |
| 1997 | In a letter to FDA regarding the standardization of extracts, Greer wrote: "A majority of Greer . . . accounts purchase special physician mixes which they utilize to formulate prescription immunotherapy mixtures (build-up sets and maintenance vials) for their patients . . . . A minority of Greer . . . accounts utilize our services to compound prescription immunotherapy mixtures (build-up sets and maintenance vials) for patients" (Ex. UU at GRLT-00002752-53) (emphasis added). |

Between 1969 and 2013, FDA inspected Greer at least fifty-seven times. During inspections, Greer gave FDA full access to its facilities and provided FDA with requested documents, including Greer's catalog, production records, and Annual Product Reviews, which explicitly referenced custom mixes. Post-inspection correspondence confirms that FDA specifically reviewed custom mixes prior to 2013 and made observations relating to custom mixes but did not raise concerns about custom mixes not being separately licensed. Examples include:

| **Date** | **Description** |
|---|---|
| 1976 | FDA reviewed "'special order' RX Grass Mix, PO865-X" and issued an observation because "no temperature record was available for the refrigerator" used to hold it. (Ex. YY at GRLT-00132300) (emphasis added). |
| 1979 | FDA reviewed a custom mix during its inspection: "An exception was weed mix . . . . Ms. White stated this was a custom order and the stock mixture labels do specify components The weed mix order did not specify any details, but the order number corresponded to a detailed formula which was shown to us." (Ex. ZZ at GRLT-00134775-76) (emphasis added).<br><br>Greer's response to FDA's Form 483 states: "plans are underway to update all our mix cards, copies of which will be enclosed with all shipments of mixed extracts (excluding Greer Stock mixes ) . These cards are taken from the original order of the doctor." (Ex. AAA at GRLT-00136507) (emphasis added). |
| 2007 | FDA reviewed lot history records (containing sample labels) for five custom mixes (PMG SJ 7 Tree Mix, Schultz Tree Mix #1, Shulhafer Weed Mix, PMG SJ 5 Weed Mix, and AASC Mold-4 Mix) and issued an observation relating to Greer's investigations. (Ex. HH GRLT-00048713-14, -18). |
| 2011 | FDA reviewed AASC Weed Mix (a custom mix) during the inspection. (Ex. TT at GRLT-00107709). FDA also questioned Greer's retention sample practices during this inspection and did so with specific reference to custom mixes. (Ex. M at 197:1-198:5); (Ex. BBB at GRLT-00031149). |

Other immunotherapy manufacturers also made "custom mixes" pursuant to doctors' orders (but not individual patient prescriptions) without obtaining a separate FDA license. *See e.g.*, Amended Complaint, Doc. No. 10 at ¶¶ 93-96 (accusing several other manufacturers of similarly selling "unlicensed" custom mixes); *infra*, at II. D. There is no evidence that the FDA was not aware of the long standing industry practice to market custom mixes that were

not based upon named-patient prescriptions and were not separately licensed, or that § 610.17 was ever interpreted by the FDA to apply to immunotherapy custom mixes at any time during the over 65 years from 1947 until 2013.

**C. The FDA Raises Questions then Issues Guidance Regarding Custom Mixes**

In the course of a routine inspection of Greer's manufacturing facility in November 2013, an FDA inspector issued a Form 483 to Greer in which the FDA "observed" that each custom mix required a separate license. Greer was open with the FDA about the custom mixes during the inspection, explaining that custom mixes were "a mixture of licensed products prepared to a doctor's order" but different from individual prescriptions because prescriptions "are for named patients and custom mixes were for general use by the requesting practitioner." *See* Greer November 14, 2013 FDA CBER Summary, Doc. No. 131-25, at p.12. Greer subsequently received a follow up Warning Letter stating FDA's view that a separate license was required for each custom mix, as such mixes were not within the scope of Greer's existing licenses. Neither the Form 483 Report or the FDA Warning Letter suggested that the FDA had previously been misled about Greer's manufacturing of custom mixes.

The Form 483 report and the FDA Warning Letter did not reflect a final agency determination and did not commit the FDA to enforcement action. After receiving the Form 483 and Warning Letter and making written requests for clarification, Greer and its counsel met with FDA in June 2014. When Greer asked for guidance regarding custom mixes, FDA stated they were "not in a position to discuss custom mixes." FDA also said it could not answer Greer's question whether "the preparation of custom mixes was no longer an option," but said it hoped to address the issue that summer. FDA also told Greer that custom mixes were "an issue that is a focus industry wide and that the other manufacturers would be

notified as well." Based on these conversations, Greer continued manufacturing custom mixes based on FDA's statements that it was still formulating its position.

In 2015, the FDA issued formal "guidance" that custom mixes needed to be separately licensed under 610.17. Greer ceased manufacturing custom mixes as soon as FDA released draft guidance in February 2015. Once Greer stopped making custom mixes, physicians ordered the individual extracts and mixed them in their offices to make the custom mixes. There is no evidence that Greer has sought separate licenses for the custom mixes after the FDA's 2015 guidance.

D. **The Industry's Reaction to the FDA's 2015 Position Regarding Manufacturing Custom Mixes Without a Separate License.**

Like Greer, the Allergen Product Manufacturers' Association ("APMA") sought guidance from FDA on its apparent change in position regarding the licensure of custom mixes. In an April 2014 letter, the APMA wrote:

> 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 FDA, and includes recognition and acknowledgement of this practice, without objection, during facility inspections over the years. (Greer Ex. R (Doc. 98-16) at GRLT- 00044443).

The APMA reiterated these statements in a July 2014 letter to FDA. (Greer Ex. L (Doc. No. 98-10).

After the FDA released its 2015 Guidance where, for the first time since its enactment in 1947, FDA interpreted § 610.17 as requiring separate licenses for each custom mix, concerned physicians submitted comments to the FDA docket. 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 . . . . [T]he Draft Guidance as currently written raises important safety concerns for allergy physicians and for their patients. In addition to being safe and effective, the use of custom bulk extracts for immunotherapy is substantially cost effective. Switching patients from custom bulk extracts to individually labeled, patient-specific vials . . . would increase the cost of obtaining allergen extract mixes from a manufacturer by 10- to 20-fold. (Crawford Comment at 1-2).

The American College of Allergy, Asthma & Immunology said:

> [E]qually important, is the practice of many allergists of using special mixes of licensed allergenic extracts prepared by allergy extract manufacturers based on an allergist's special order . . . . Although the allergist could buy the extracts individually and mix them in the office for an individual patient, it is more efficient and reduces the chances of error, as well as the cost and work of preparation, if the materials are pre-mixed by the manufacturer. 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 note that there is little or no difference between, on the one hand, creating a mixture of antigens which will then be used by the allergist to prepare vials for individual patients, and, on the other hand, mixing a patient vial using individual antigens. Tn the end, the antigens all end up mixed together for use by an individual patient . . . .We believe the draft guidance should permit this longstanding practice to continue . . . . (ACAAT Comment at 1-2).

However, on March 12, 2015, the APMA companies told the FDA, in a letter signed by representatives of its member companies, that "the APMA member extract manufacturing companies have made the decision to discontinue the manufacture of what the industry terms Custom Mixes or Special Mixes that have been prepared to a physician's order not associated with a named patient." (GRLI-00131715).

### E. The Termination of Relators' Employment at Greer

Patt and Skibo joined the Regulatory Affairs department at Greer in 2008. Greer states that it terminated Relators in May 2012, approximately a year and a half before the FDA issued its Form 483 Report regarding custom mixes, for performance and interpersonal issues. Relators initially challenged their termination before the EEOC, which dismissed their claims in January

2013. Relators assert in the Amended Complaint that they were terminated for raising concerns about SLTT Short Ragweed clinical trials, Greer's retention sample practices, and the licensing of Greer Pharmacy in various states. In their briefing and at oral argument Relators also reference their alleged oral expressions of concern about custom mixes in 2010-2011. It is undisputed that Greer's potential SLTT Short Ragweed product was never commercialized and thus never became the subject of a physician's request for payment from the government.

## III. DISCUSSION

### A. False Claims Act

To prove their claim under the FCA sufficiently to avoid summary judgment, Relators must identify genuine issues of fact establishing that Greer:

1. made or caused to be made a false statement or engaged in a fraudulent course of conduct;
2. the statement or conduct was made or carried out with the requisite scienter;
3. the statement or conduct was material; and
4. the statement or conduct caused the government to pay out money or to forfeit money due.

*United States ex rel. Owens v. First Kuwaiti Gen. Trading & Contr. Co.*, 612 F.3d 724, 729 (4th Cir. 2010). To meet their burden, Relators must "adduce evidence on each element of their FCA claims that would be sufficient, if believed, to satisfy the burden of proof at trial." *United States ex rel. Davis v. Prince*, No. 1:08-cv-1244, 2011 U.S. Dist. LEXIS 77179, at *6-7 (E.D. Va. June 13, 2011).

- Greer Allegedly "Caused" a Material False Statement to be Made that Led to the Government Paying Out Money

The parties do not seriously dispute that there is at least a genuine issue of fact concerning whether Relators have established that Greer "caused" a material misstatement of fact to be made to the government that led to the government paying out money. Specifically, if, as alleged by Relators, Greer sold custom mix allergy products to doctors that could not lawfully be reimbursed by the government and the doctors were in turn expected to seek and receive payments for those products then Relators would satisfy their burden on the first, third and fourth elements of the false claims act.

- Greer Did Not Know or Have Reason to Believe That Custom Mixes Required a Separate License and Thus Lacked the Requisite Scienter

However, the Court finds that Relators have failed to raise a genuine issue of fact sufficient to establish that Greer had the required scienter to violate the FCA. To trigger liability under the FCA, a defendant must engage in knowing fraud. *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 917-18 (4th Cir. 2003). A defendant acts "knowingly" when he or she:

(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.

The Supreme Court has cautioned that the FCA's scienter requirement is "rigorous." *Universal Health Servs. v. Escobar*, 136 S. Ct. 1989, 2002 (2016). The FCA "is not intended to 'punish honest mistakes or incorrect claims submitted through mere negligence.'" *United States ex rel. Ubl v.F Data Sols.*, 650 F.3d 445, 452 (4th Cir. 2011). If the factual record developed in discovery does not present an issue of material fact supporting a finding that the defendant knew, acted in deliberate ignorance, or recklessly disregarded that the challenged conduct

violated the FCA, summary judgment must issue for the defendant. *See United States v. Medica-Rents Co.*, 285 F. Supp. 2d 742, 775 (N.D. Tex. 2003) (granting summary judgment where defendant "proffered ample uncontradicted evidence supporting their contention that they held a good-faith belief that they could properly bill" using a code).

The overwhelming evidence in the record establishes that Greer and its industry competitors openly manufactured custom allergy mixes for decades and there is no direct evidence that Greer had "actual knowledge" of any wrongdoing or illegal intent. Each of Greer's witnesses to testify on the subject testified that they believed custom mixes were permitted under Greer's existing license. When asked at oral argument to specify any record evidence that Greer had "actual knowledge" that the custom mixes were required to be separately licensed, Relators' counsel only referred the Court to Relator Skibo's deposition testimony in which she alleges that she raised questions about whether custom mixes were authorized. *See* Transcript of July 25, 2019 Hearing at pp. 96, 97; Deposition of Liubov Skibo at pp. 34-53.[2] However, those alleged communications from Skibo, which were never reduced to a writing sent to anyone at the company nor raised outside the company, do not create a disputed issue of fact that Greer had "actual knowledge" that it required a separate license for each custom mix. To the contrary, it is clear from the responses that Skibo says she received to her questions that Greer believed that it did not need a separate license and was properly

[2] Although Relators allege, as discussed below, that Greer allegedly "misled" the FDA concerning its manufacturing of custom mixes, Relators did not contend that Greer's communications with the FDA constituted evidence of actual knowledge of wrongdoing in response to the Court's question. Accordingly, Relators apparently do not view Greer's allegedly "misleading" conduct as intentional, which allegation would in any event be inconsistent with the substantial undisputed evidence that Greer manufactured and marketed the custom mixes openly for decades.

following accepted industry practice. Further, as noted above, Skibo herself continued to sign off on product catalogs that discussed custom mixes and did not raise any issue with the sale of custom mixes beyond the questions she asked at Greer.[3]

Accordingly, the remaining question is whether there is enough evidence in the record from which a jury can reasonably conclude that Greer acted "recklessly" or in deliberate ignorance of whether the relevant regulation, 21 C.F.R. § 610.17**,** required a separate license for custom mixes. The Court finds that a reasonable jury could not conclude that Greer acted recklessly or in deliberate ignorance of the interpretation attached to §610.17 that the FDA issued guidance on in 2015, which not only surprised Greer but the rest of the industry as well. *See* 65 Fed. Reg. at 56472 ("Guidance documents should be issued only when a need for guidance exists").

The following evidence establishes that Greer acted reasonably in believing that separate licenses were not required for each custom mix:

- Greer provided custom mixes to thousands of doctors for more than 40 years along with the rest of the allergenic extract manufacturing industry without any question or complaint from the FDA;
- Greer openly advertised its custom mix service;
- Greer disclosed its custom mix service to FDA (i) during inspections, (ii) in its catalogs and on its website, both of which it submitted to FDA for review repeatedly, (iii) in correspondence with FDA where it described custom mixes as distinct from its named-patient prescriptions, and (iv) in a voluntary recall of a custom mix in 2006;[4] and

[3] Also, Skibo acknowledged in her deposition that her alleged concerns were only raised in meetings "to discuss pharmacy practices or to discuss separation of pharmacy from the manufacturing facility." Skibo Deposition at p.50.

[4] Transparency by the defendant with respect to the allegedly fraudulent conduct supports an inference that the defendant did not act knowingly. *See X Corp. v. Doe*, 816 F. Supp. 1086, 1094 (E.D. Va. 1993) (finding disclosure of facts to the government underlying the false claim "provides persuasive evidence that [defendant] did not 'knowingly' make a misrepresentation");

- Greer told the FDA it understood that custom mixes fell within the scope of its existing BLAs.

In response to this evidence of longstanding industry practice among multiple manufacturers and Greer's open manufacturing, marketing and sale of custom mixes, Relators argue that Section 610.17 was unambiguous even prior to the FDA's Guidance in 2015 and point to a handful of FDA and Greer communications that it contends show either that the FDA regulation was clear or that Greer allegedly "misled" the FDA. None of Relators' cited evidence creates a genuine issue of fact; that is, a jury could not *reasonably* find based on this evidence that Greer acted recklessly or in deliberate ignorance of its licensing obligations.

First, Relators argue that Section 610.17 was unambiguous prior to the FDA's 2015 Guidance; however, this argument flies in the face of not only the long history of custom mixes throughout the industry,[5,6] but also FDA's guidance itself. If the regulation was clear there would not have been so much discussion and comment by both trade groups and doctors after the issue was raised in 2013, and the FDA would not have needed over a year to

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*see also United States ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284, 289 (4th Cir. 2002) ("government's knowledge of the facts underlying an allegedly false . . . statement can negate the scienter required for an FCA violation").

[5] There is no evidence that the FDA ever interpreted 610.17 to apply to custom mixes from the enactment of the regulation in 1947 until 2013. Relators also argue that the industry competitors did not know exactly what each other were doing with custom mixes. However, if each company independently reached the conclusion that the governing regulation did not require a separate license for each custom mix then that is only further support for a finding that Greer did not act recklessly or in deliberate ignorance of its obligations in coming to a similar interpretation of the regulation.

[6] Further, Relators have not offered any explanation why Greer's plausible interpretation of the regulation (i.e., that mixing together extracts that are themselves already licensed pursuant to a doctor's orders doesn't require a separate license) is unreasonable as opposed to incorrect as interpreted by the FDA in 2015.

consider and issue "Guidance" on how the regulation should be interpreted. S*ee* Final Rule, Good Guidance Practices, 65 Fed. Reg. 56468, 56472 (Sept. 19, 2000) ("Guidance documents should be issued only when a need for guidance exists"); *Saubers v. Kashi Co.*, 39 F. Supp. 3d 1108, 1112 (S.D. Cal. 2014) ("FDA has been actively revisiting its draft guidance . . . indicating that the agency's expert opinion is still being developed . . . ."); *Gitson v. Clover Stornetta Farms*, No. C-13-01517, 2014 U.S. Dist. LEXIS 83880, at *27 (N.D. Cal. June 9, 2014) (FDA "has re-opened the comment period . . . and has asked questions that specifically address issues that Plaintiffs claim are settled . . . . That [FDA] has raised these questions belies Plaintiffs' assertion that these issues have been settled for many years").

With respect to FDA communications, Relators state that in April 1997, FDA provided "Guidance for Industry" regarding "combination vaccines," which FDA defined as "*a combination vaccine consists of two or more* live organisms, inactivated organisms or *purified antigens combined either by the manufacturer* or mixed immediately before administration . . . ." (emphasis added by Relators). FDA's guidance noted that the "[a]pplicable regulations," 21 C.F.R. § 610.17 were "particularly important" and stated that any such "combination vaccines" of "two or more . . . antigens" "may not be combined . . . except as a license is obtained for the combined product." *Id.* Relators argue that even though this FDA guidance references "combinations vaccines," allergy extracts "fall under the vaccine umbrella of biologic," and are "antigens" so Greer should have known this also applies to custom mixes. However, as noted, the guidance relates to vaccines not allergenic extracts and, as the FDA itself stated, "while all allergens are antigens, not all antigens behave as allergens." Relators Ex. 4 at 9. Therefore, particularly in light of the ongoing use of

custom mixes throughout the industry, Greer was not "reckless" or "deliberately ignorant" in failing to view this FDA communication as applying Section 610.17 to custom mixes.

Similarly, in April 1999, FDA "provide[d] guidance on the content and format of . . . a Biologics License Application ["BLA"] for an Allergenic Extract . . . ." Relators' Ex. 10 at 1. The FDA explained how manufacturers could obtain a license to manufacture a "single or mixed allergen extract" that consists of an "allergen (or allergen mix)." *Id*. Relators claim that this should also have put Greer on notice that a license was required, but it falls far short of doing so. The purpose of the 1999 Guidance was to describe the types of information required in the Chemistry, Manufacturing, and Controls section of a biologics license application for allergenic extracts. *Id*. The 1999 Guidance does not reference § 610.17 or whether custom mixes require separate licenses, nor does it, as Relators suggest, explain *how* to "obtain a license to manufacture a 'single or mixed allergen extract' that consists of an 'allergen (or allergen mix).'"[7] Therefore, this communication is not inconsistent with Greer's understanding that custom mixes did not require separate licenses.

In addition to these FDA communications, Relators argue that Greer "misled" the FDA regarding its custom mixes. Specifically, Relators contend that Greer's disclosures to FDA were misleading or Greer should have made additional affirmative disclosures to the FDA because Greer put "Rx" on its custom mix products and otherwise made communications that led the FDA to believe that the products were supported by individual patient prescriptions. Greer

[7] The 1999 Guidance may in fact demonstrate that FDA was aware of the practice of manufacturing custom mixes. The 1999 Guidance defines "biological drug product" in relevant part as "the single or *mixed allergen extract* individually filled, *mixed with other allergens*, diluted, absorbed to alum, or lyophilized in the final container." *See* (Ex. 10 at 2) (emphasis added). It further provides "if any proprietary preparations or *mixtures are used as components*, the information should include a complete statement of composition . . . ." Id. at 12 (emphasis added).

responds to this argument by saying that its internal practice of putting Rx on a product simply meant that the product needed a doctor's order, i.e., that it was not an "over the counter" drug. Because custom mixes required a doctor's order, they were designated "Rx" at Greer.

However, even if Greer's explanation of why Rx was put on its custom mix products could be reasonably disputed, there is no evidence that the FDA was in fact misled. Nor does Greer's failure to provide a clearer explanation for the use of Rx in connection with custom mixes establish that Greer acted recklessly or in deliberate ignorance of its regulatory obligations, in the absence of any proof that Greer *intended* to deceive the FDA (of which there is none and which Relators did not assert in oral argument as described above). At most, such a failure might be negligent or poor operating practice, but it plainly does not supply the scienter for fraud under the FCA.

Finally, perhaps most instructive - and inconsistent with Relators' position - is that even Relators' FDA expert Robert Schiff testified that it would be reasonable for Greer to continue manufacturing custom mixes after Greer received the FDA warning letter in 2014 because the FDA was being "equivocal." He said it was a "judgment call" whether Greer should have stopped manufacturing custom mixes at that time. *See* Schiff Deposition at 308:1-310:8. Simply put, if Relators' FDA expert says it would be *reasonable* for Greer to continue to manufacture and sell custom mixes *after* the FDA issued a specific warning to Greer, how could it be "reckless" or acting in "deliberate ignorance" of its regulatory obligations to make and sell custom mixes *prior* to any warning?

In sum, Relators have presented insufficient evidence to support a reasonable finding that Greer knew, acted in deliberate ignorance, or recklessly disregarded that a separate license

was required when it mixed its individually licensed allergenic extracts in response to orders submitted by physicians for "custom mixes."[8]

**B. Retaliation**

In addition to their claims that Greer caused false claims to be made to the government in violation of the False Claims Act, Relators allege that Greer also violated the FCA by terminating them in retaliation for protected activity under the Act. *See* 31 U.S.C. §3730(h). (Sixty-First Claim for Relief). The FCA's antiretaliation provision states:

> [a]ny employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

31 U.S.C. § 3730(h)(1).

Accordingly, to sufficiently prove a § 3730(h) retaliation claim, a plaintiff must present evidence that establishes at least a genuine issue of fact that he or she: (1) engaged in protected activity; (2) the employer knew about the protected activity; and (3) the employer took adverse action against the plaintiff as a result. *See United States ex rel. Grant v. United Airlines Inc*., 912 F.3d 190, 200 (4th Cir. 2018); *Carlson v.DynCorp*, 657 Fed. Appx. 168, 170 (4th Cir. 2016).

As to the first element, § 3730(h) defines two types of protected activity--acts "in furtherance of an [FCA action]" (the "first prong"), or "other efforts to stop 1 or more [FCA

[8] In addition to its Federal FCA claims, Relators asserted claims under numerous state FCA statutes. The elements of the twenty-seven state false claims statutes at issue generally track those of the federal FCA. *See New York v. Amgen Inc.*, 652 F.3d 103, 109 (1st Cir. 2011). Thus, Greer is entitled to summary judgment on these claims as well.

violations]" (the "second prong"). 31 U.S.C. § 3730(h)(1). *See Grant*, 912 F.3d at 200. Relators have failed to create a genuine issue of disputed fact as to either prong and thus have failed to establish that they engaged in "protected activity" under the FCA.

With respect to the first prong, Relators were discharged in May 2012, long before this FCA action was filed. Further, there is no evidence that Relators took any action to pursue an FCA action prior to their discharge, nor do Relators contend that they did so. Also, they did not assist or testify for an FCA litigant or assist the government in bringing a false claims action. Therefore, Relators have not established they engaged in protected activity under the first "FCA action" prong.

While the second "FCA Violation" prong of Section 3730(h) does not require a connection to an FCA action, it does require that protected activity relate to company conduct that involves an objectively reasonable possibility of an FCA action. *Id*. at 201. Under this standard, an act constitutes protected activity where it is motivated by "an objectively reasonable belief that the employer is violating, or soon will violate, the FCA." *Id*. A belief is objectively reasonable when the plaintiff establishes facts sufficient to show that she believed her employer was violating the FCA, that this belief was reasonable, that she took action based on that belief, and that her actions were designed to stop one or more violations of the FCA.

Significantly, the Relator's activity must "have a nexus to an FCA violation." *Id*. at 201-202. An "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); *Mann v. Heckler & Koch Def.*, 630 F.3d 338, 347 (4th Cir. 2010) (holding relator "still would not qualify for FCA protection because the FCA requires fraud, not mere regulatory violations"); *United States ex rel. Brooks v. Lockheed Martin Corp.*, 423 F. Supp. 2d 522, 530 (D. Md. 2006) ("Under

the FCA, a general allegation of fraud does not suffice; there must be a submission of a false claim"). Merely expressing concerns about regulatory non-compliance is insufficient; instead, the Relator's complaints must allege specific illegal, fraudulent conduct against the government. *Grant*, 912 F.3d at 202. (allowing an FTC retaliation claim to proceed based on complaints concerning fraud on the Air Force through falsified airplane maintenance).

In this action, Relators have failed to provide evidence that they engaged in "efforts to stop" an FCA violation. Rather, their conduct at most reflects efforts to raise concerns over regulatory compliance, which was, at least in part, included within Relators' job duties at the company. Specifically, Relators assert in the Amended Complaint that they were terminated for raising concerns about SLTT Short Ragweed clinical trials, Greer's retention sample practices, and the licensing of Greer Pharmacy in various states. *See* Am. Compl. ¶¶ 82-89. Further, in briefing and at oral argument, Relators argued that they also raised regulatory compliance concerns (beginning in 2010, two years before they were discharged) related to custom mixes.[9]

In addition to these allegations and their deposition testimony related to their alleged regulatory concerns with Greer's operations, Relators cite two documents. The first is an April 28, 2012 email from Skibo to herself regarding alleged regulatory violations relating to the promotion of Greer's pharmacy services. (Greer Ex. 86). However, beyond the critical fact that there is no evidence that Skibo sent the email to anyone at Greer (so it is not a "report to Greer"), the email is unrelated to custom mixes. Second, Relators rely on a summary of a state board of

[9] Because the Court finds that Relators have not satisfied their burden to show they engaged in "protected activity" the Court does not reach the question of whether Relators have provided sufficient evidence of the causal connection between their termination and their allegedly protected activity. However, the timing of these alleged oral concerns about custom mixes - two years prior to their termination - raises substantial questions concerning the required causal nexus between their termination and any alleged regulatory complaints related to custom mixes.

pharmacy inspection, which dealt with concerns about Greer's pharmacy compounding bulk products (i.e., non-named patient prescriptions) and unspecified cGMP violations in the manufacturing facility, suggesting that these concerns somehow relate to custom mixes. However, when Relators' misleading "cut and pasted" quotation combining different parts of the document is ignored, it is clear that the document, fairly read, reflects that Greer informed the pharmacy inspector that an unnamed employee had raised concerns that had been fully investigated and provided the inspector a copy of the investigation record and conclusion.

In sum, Relators expressions of these regulatory concerns falls short of the required conduct to support an FCA retaliation claim based on exposing fraud on the government. Indeed, treating purported cGMP [regulatory manufacturing] issues as protected activity under the FCA without any link to a false claim "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." *United States ex rel. Rostholder v. Omnicare,* 745 F.3d 694, 702 (4th Cir. 2014)("As we previously have explained, the correction of regulatory problems is a worthy goal, but is 'not actionable under the FCA in the absence of *actual fraudulent conduct.' Mann v. Heckler & Koch Def., Inc.,* 630 F.3d 338, 346 (4th Cir.2010) (emphasis added and citation omitted")).[10] *See also, United States ex rel.*

[10] Grounding their FCA retaliation claims solely on the expression of their regulatory concerns also raises an issue as to whether Relators put their supervisors at Greer on notice of an FCA violation such that those who made the decision on their termination knew of their "protected activity." Even in the much clearer context of a government contract, "[a]n employee's allegations that he complained about his employer's errors in performing a government contract are insufficient unless the employee specifically referred to fraudulent claims for payment for those services, putting the employer on notice of potential [False Claims Act] liability." *United States ex rel. Ligai v. ETS-Lindgren Inc.*, 2014 WL 4649885, at *16 (S.D. Tex. Sept. 16, 2014) (Rosenthal, J.), *aff'd sub nom. United States ex rel. Ligai v. ESCO Techs., Inc.*, 611 Fed. Appx. 219 (5th Cir. 2015); *see also Patton*, 418 Fed. Appx. at 372-73.

*Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 237 (1st Cir. 2004)(Relator's statement that he reported his supervisors' destruction of incident reports of medical errors suggests a cover-up of regulatory failures but does not allege investigation or reporting of false or fraudulent claims knowingly submitted to the government).

Accordingly, Relators have failed to sufficiently establish that they engaged in protected activity to avoid entry of summary judgment in Greer's favor on their retaliation claim under the FCA.[11]

## IV. ORDER

**NOW THEREFORE IT IS ORDERED THAT**:

Defendants' "Motion for Summary Judgment" (Doc. No. 95) is **GRANTED**, Relators' Amended Complaint is **DISMISSED**, and **SUMMARY JUDGMENT** is hereby entered in favor of Greer on all the claims in this action. The Clerk of Court is directed to close this case.

**SO ORDERED ADJUDGED AND DECREED**.

Signed: August 22, 2019

Kenneth D. Bell
United States District Judge

[11] The Court does not reach and expresses no opinion on Greer's arguments that Relator Patt is not entitled to pursue a retaliation claim on the grounds that Greer terminated him based on his wife's (Relator Skibo) conduct. Similarly, the Court expresses no opinion on Greer's argument that the absence of commercialization of the SLTT Short Ragweed product precludes a retaliation claim as a matter of law. In light of its other findings, it is unnecessary for the Court to decide either of these issues, which may well turn on the specific facts of a particular case rather than a rule of black letter law as alleged by Greer, so the Court declines to do so.