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In the First FCA Appellate Case of 2021, the Fourth Circuit Affirms the Dismissal of Relators' Claims for Lack of Scienter and Failing to Engage in Protected Activity

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by Kirk Schuler, Alex Hontos, and Caitlin L.D. Hull

On January 8, 2021, in the first appellate decision of the year addressing a False Claims Act case, the Fourth Circuit affirmed the summary judgment dismissal of relators' claims that a manufacturer of allergenic extracts violated the FCA. *Skibo v. Greer Labs.*, 2021 U.S. App. LEXIS 508 (Jan. 8, 2021) (*per curiam*).

Like most FCA cases that arrive in the United States Courts of Appeals, this one started many years ago. In August 2013, two former employees filed a retaliation claim under the FCA against Greer Laboratories, Inc. ("Greer Labs") for terminating them after they raised concerns that Greer Labs' "custom mix" allergenic extracts did not comply with Federal Drug Administration ("FDA") regulations. In addition to their retaliation claim, the relators alleged a substantive FCA claim against Greer Labs for selling the custom mixes as licensed allergenic extracts to physicians, who then received reimbursement from the government for administering the custom mixes to patients. Relators contended the physicians' claims for reimbursement—allegedly caused by Greer Labs—were false because the custom mixes were not licensed allergens and Medicare and Medicaid would not provide reimbursement for unlicensed drugs.

The custom mixes at issue in the case were mixes of individual allergen extracts for general use by a physician, rather than patient-specific mixes made pursuant to patient prescriptions. To sell their products, manufacturers of allergenic extracts are required to obtain licenses from the FDA. Greer Labs had a general license, but did not seek separate licenses for its custom mixes because it believed the mixes fell under its general license. Before they were terminated in 2012, relators alleged they had complained to Greer Labs that the custom mixes were violating FDA regulations.

The district court granted defendants' motion for summary judgment and dismissed relators' claims. The district court held that relators could not prove that Greer Labs knew that a separate license was required for the custom mixes. The district court further held that relators had not engaged in protected activity to support their retaliation

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- Kirk Schuler
- Alex Hontos
- Caitlin L.D. Hull

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claim.

The Fourth Circuit affirmed, noting that the FDA did not issue formal guidance recognizing that custom mixes required separate licenses under existing regulations until 2015, and that the industry practice prior the guidance was to allow custom mixes without separate licenses. Because Greer Labs openly acted in accordance with industry practice and the common understanding of the regulatory requirements, the Fourth Circuit agreed that the relators could not show that Greer Labs acted with the requisite scienter. In addition, the Fourth Circuit held that the concerns relators raised about regulatory compliance—part of their job description—were insufficient to show that relators engaged in protected activity under the FCA because "[a]llegations of regulatory violations are not enough 'in the absence of *actual fraudulent conduct*.'" *Skibo*, 2021 U.S. App. LEXIS at 19 (emphasis in original) (quoting *United States ex rel Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 702 (4th Cir. 2014)). The Court found that "[t]he fatal flaw in [relators'] 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." *Id.* at 21.

In addition to emphasizing that regulatory violations alone are not FCA violations, the case is an important first-of-the-year reminder of the importance of a defendant's mental state when evaluating FCA claims. Since the landmark decision in *Universal Health Servs. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), a lot of attention has focused on the FCA's materiality requirement. It must be remembered, however, that *Escobar* recognized that both of "[t]hose requirements [the FCA's materiality and scienter requirements] are rigorous." 136 S. Ct. at 2002. Rigorous enough, in fact, that cases lacking sufficient evidence of scienter will be dismissed on summary judgment, as in *Skibo*.