Massachusetts Federal Judge Grants Summary Judgment to Medical Device Company, Abbott Laboratories, and Finds Whistleblower's Retaliation Claim Not Tied to Any Protected Activity

The case is *Elliott-Lewis v. Abbott Laboratories, Inc.,* No. 14-13155, U.S. Dist. LEXIS 193621 (D. Mass Nov. 6, 2019).

Last week, Judge Patti B. Saris, Chief Judge for the United States District Court for the District of Massachusetts, granted Abbott Laboratories' summary judgment motion on a former medical science manager's whistleblower retaliation claim arising under the False Claims Act ("FCA").

The court reasoned that while the Plaintiff did complain repeatedly about off-label marketing and violations of federal regulations that were a requirement for reimbursement by Medicare and Medicaid, such violations were "not actionable under the FCA in the absence of actual fraudulent conduct." Merely reporting such violations without any evidence that the reports concern FCA-violating activity falls "outside the purview of the FCA's anti-retaliation provisions."

WHAT YOU NEED TO KNOW

Plaintiff Ebonia Elliott-Lewis claimed Abbott terminated her in retaliation for raising internal concerns about the company's off-label marketing and pre-approval promotion of its products. She initially brought claims against Abbott in 2014 in a qui tam suit alleging violations of the FCA and Anti-Kickback Statute ("AKS"). The court dismissed her FCA and AKS claims in 2016, but through some procedural maneuvering, Elliott-Lewis amended her complaint to include FCA retaliation and wrongful termination claims.

The FCA imposes civil liability on anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the federal government. 31 U.S.C. § 3729(a)(1)(A). The FCA also prohibits an employer from retaliating against an employee because of lawful acts done in furtherance of an FCA action or other efforts to stop violations of the FCA. 31 U.S.C. § 3730 (h)(1). To establish retaliation under the FCA, the plaintiff must show 1) the employee's conduct was protected under the FCA; 2) the employer knew that the employee was engaged in such conduct; and 3) the employer discharged or discriminated against the employee because of his or her protected conduct.

Citing to another First Circuit case, the court explained that protected conduct includes any activity that "reasonably could lead to an FCA action," such as "investigations, inquiries, testimonies or other activities that concern the employer's knowing submission of false or fraudulent claims for payment to the government." The court further noted that while "the plaintiff need not prove the employer actually violated the FCA . . . [t]he conduct the plaintiff objects to or reports . . . must relate to the submission of false claims."

Throughout 2012 and 2013, Elliott-Lewis repeatedly raised concerns about what she perceived to be legal and ethical violations by her colleagues. She claimed that one of her colleagues was being "aggressive" with a physician and seemed to be offering things in exchange for trying to get the physician to change his research conclusions. She also claimed that other colleagues were engaging in pre-approval promotion of a new coronary stent product through presentations at industry conferences.

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In early 2014, Elliott-Lewis filed a compliance report with Abbott's Office of Ethics and Compliance claiming that she had been harassed by her colleagues and that "her supervisors were trying to push her out because she refused to participate in unlawful marketing." Elliott-Lewis claimed that there was an "evolving tolerance for noncompliance in the form of medical device off-label promotion and pre-approval promotion."

In evaluating Elliott-Lewis' claims, the court found that she had not shown any violations of the FCA, holding that her "theories of how the misconduct she reported led to the submission of false claims are too attenuated to transform her complaints about regulatory violations into protected conduct under the FCA." The court noted, for example, that there is no evidence the physician actually changed or falsified his research results in response to the alleged pressure by Elliott-Lewis' colleague, nor could she show any connection between the alleged unlawful pre-approval marketing and the submission of false claims to the Government. Thus, the court concluded that Elliott-Lewis "has not established that she engaged in protected conduct under the FCA because she complained primarily about her relationship with her managers, violations of company policy, and regulatory violations that have an unlikely connection to the submission of fraudulent claims to the Government."

WHAT YOU NEED TO DO

The court's reasoning in this case emphasizes that it is not enough for plaintiffs to merely complain about potential violations in order to qualify for protection under the retaliation provisions of the FCA. The law does not require the plaintiff to connect all of the dots between an alleged violation and the submission of a false claim, but there has to be a stronger nexus between the two elements to constitute protected conduct. The court's decision adds to a growing number of FCA cases in the First Circuit that are favorable precedent for employers, especially in the pharmaceutical and medical device space. Despite the favorable ruling, employers should still commit to investigating every good faith claim raised by employees about potential FCA violations. Given the highly regulated environment of the pharmaceutical and medical device industries, it is imperative that employers commit to compliance best practices including multiple channels to report issues, carefully crafted investigation protocols and comprehensive training on relevant statutes and regulations to their employees, especially front-line managers who must understand the critical role they play in responding to concerns raised by subordinates.

FOR MORE INFORMATION

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