First Circuit affirms Pfizer victory in False Claims Act case

Litigation Alert

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By: Courtney Gilligan Saleski | John M. Hillebrecht | George M. Karavetsos | Andrew J. Hoffman

The First Circuit has rejected an appeal in *United States ex rel. Booker v. Pfizer*, a False Claims Act (FCA) case alleging that Pfizer engaged in off-label promotion of the antipsychotic drug Geodon.

In its ruling on January 30, 2017, the First Circuit set strict limits on the FCA's reach, demonstrating once again that the FCA is "not an all-purpose anti-fraud statute." *See Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2003 (2016) (*citing Allison Engine Co., Inc. v. United States ex rel. Sanders*, 53 U.S. 662, 672 (2008)). The *Booker* court ruled that, at the summary judgment phase, qui tam relators must do more than merely satisfy the heightened pleading requirements of Federal Rule of Civil Procedure 9(b). In the court's words, summary judgment is the "put up or shut up moment in litigation," at which point relators must "produce competent evidence of an actual false claim made to the government."

The court also rejected the argument that Pfizer caused the submission of "reverse false claims" by allegedly violating certain provisions of the company's Corporate Integrity Agreement with the Office of the Inspector General for the Department of Health and Human Services.

Finally, the First Circuit ruled that, even if one relator was terminated after raising concerns about off-label

promotion, that termination did not give rise to a cause of action under the FCA's anti-retaliation provision because the relevant whistleblowing activity did not relate to the submission of false claims.

Off-label promotion

Relators alleged that Pfizer knowingly induced third parties to submit "false" reimbursement claims to federal health care programs by marketing Geodon for off-label uses in violation of FDA regulations implementing the Food, Drug, and Cosmetic Act. The district court granted summary judgment in Pfizer's favor. On appeal, the First Circuit affirmed the district court's ruling that, despite relators' allegations that Pfizer promoted Geodon for off-label uses, relators failed to provide sufficient evidence that Pfizer's promotion resulted in the submission of false claims to state Medicaid programs.

The First Circuit noted that, even where a relator can show that a defendant engaged in fraudulent activity, liability under the FCA only attaches where the conduct actually results in the filing of a false claim for payment from the government. While relators must satisfy Rule 9(b) at the pleading stage, "a greater showing" is required to survive summary judgment. In the context of an FCA claim for off-label promotion, a relator must produce "competent evidence" identifying, for example, the medical provider who submitted the false claim, the time period when the claim was submitted, the location at issue, the amount of the claim, and the specific government program that paid the claim.

Instead, relators' only evidence was data reflecting the aggregate amount of money expended by Medicaid for pediatric Geodon prescriptions – an off-label use – between January 2008 and March 2012. According to the First Circuit, these data were not sufficient to support a finding that the alleged off-label promotion induced parties to submit actual false claims to government programs.

Reverse false claims

Relators also alleged that Pfizer violated the FCA by failing to make required payments to Health and Human Services under the company's Corporate Integrity Agreement (CIA). Pfizer's CIA required the company to notify the Office of the Inspector General (OIG) of "probable" violations of the FCA. The CIA further stipulated that if Pfizer, after a reasonable opportunity to conduct an investigation, determined that there was a matter that a reasonable person would consider a probable violation of the FCA, Pfizer must report that matter to OIG within 30 days of making the determination. Failure to disclose such "Reportable Events" would trigger a monetary penalty ($2,500 per day). The FCA's "reverse false claims" provision imposes liability on anyone who "knowingly and improperly avoids or decreases an obligation to pay" money to the government. *See* 31 U.S.C. § 3729(a)(1)(G).

The operative complaint alleged that one of the relators, a former Pfizer employee named Alex Booker, sent an email to Pfizer's Corporate Compliance department claiming that Booker's manager directed subordinates to engage in off-label promotion. Relators alleged that Booker's email constituted a "Reportable Event," and that Pfizer's failure to disclose this information to OIG constituted a "reverse false claim."

The district court disagreed and the First Circuit affirmed: "As Pfizer explains, nowhere in [relators'] complaint do relators allege that Pfizer ever determined Booker's complaint to be in any way credible and therefore a 'Reportable Event.'" Absent this determination, Pfizer was under no obligation to disclose Booker's email to OIG, and the CIA's monetary penalties did not apply.

Retaliation

Finally, the First Circuit rejected Booker's retaliation claim, which was based on his deposition testimony about two instances when he objected to his supervisor's alleged instructions to promote Geodon for off-label uses. The First Circuit had previously held that the FCA's anti-retaliation provision only applied to activities that "reasonably could lead" to an FCA action, such as investigations, inquiries, testimonies, or other activities that concern the employer's submission of fraudulent claims to the government. Here, the court held that Booker's objections only related to off-label promotion, and not the submission of false claims. To survive summary judgment, Booker had to demonstrate that his objections related to conduct covered by the FCA, not simply an independent regulatory violation. The First Circuit did not reach Pfizer's alternative argument that the company had non-retaliatory

reasons for firing Booker. However, the court acknowledged there was “ample evidence” showing Booker had a “long history of negative performance reviews” and other employment issues in advance of his termination.

Key takeaways

Going forward, companies facing qui tam litigation should be mindful of *Booker* when crafting discovery plans and summary judgment motions. Under similar circumstances, companies should look to craft arguments including the following:

- At the summary judgment phase, relators must produce “competent evidence” that the defendant’s conduct actually resulted in the submission of a false claim to a government program.
- In the context of pharmaceutical promotion, it is not enough for relators to produce payment data reflecting the government’s aggregate spend for off-label prescriptions. To survive summary judgment, relators must provide evidence showing that the government reimbursed specific claims caused by the defendant’s promotional activities.
- The FCA’s anti-retaliation provision is only implicated if relator’s whistleblowing activity related to the submission of false or fraudulent claims for payment from the United States.
- Where off-label promotion is at issue, relators must do more than allege a violation of FDA regulations governing pharmaceutical promotion. They must also allege that this conduct resulted in the submission of claims that were ineligible for reimbursement under federal health care programs.

Find out more about this ruling by contacting any of the authors.

AUTHORS

Courtney Gilligan Saleski
Partner
Philadelphia | T: +1 215 656 3300
Washington, DC | T: +1 202 799 4000
courtney.saleski@dlapiper.com

John M. Hillebrecht
Partner
New York | T: +1 212 335 4500
john.hillebrecht@dlapiper.com

George M. Karavetsos
Partner
Miami | T: +1 305 423 8500
george.karavetsos@dlapiper.com

Andrew J. Hoffman
Partner
Los Angeles (Century City) | T: +1 310 595 3000
andrew.hoffman@dlapiper.com