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First Circuit Affirms Summary Judgment for Defendant, Rejecting the Use of Aggregate Data to Prove False Claims and Clarifying the Limited Scope of Conduct Protected by the FCA's Anti-Retaliation Provision

The First Circuit has issued an opinion affirming a complete grant of summary judgment for Pfizer, Inc. in *United States ex rel. Booker v. Pfizer Inc.*, No. 16-1805 (1st Cir. Jan. 30, 2017), a False Claims Act ("FCA") lawsuit in which Ropes & Gray led Pfizer's defense. The First Circuit's opinion addressed several recurring issues in FCA litigation. First, the Court held that aggregate data reflecting government expenditures is insufficient to support an FCA claim in the absence of evidence of specific allegedly false claims. Second, the Court emphasized that employee complaints concerning regulatory or statutory violations are not protected under the FCA's anti-retaliation provision unless the employee complaints specifically concern the submission of false claims.

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Background

In August 2009, Pfizer settled a number of cases alleging FCA violations concerning several drugs, including an antipsychotic drug called Geodon. Less than a year later, two former Pfizer sales representatives ("Relators") filed a *qui tam* complaint in the District of Massachusetts alleging that Pfizer was continuing to promote Geodon for a number of uses not approved by the FDA and paying kickbacks to doctors in the form of speaker program payments to induce those doctors to prescribe Geodon. One relator also alleged that Pfizer had violated the anti-retaliation provision of the FCA by terminating him because he objected to Pfizer's supposed instructions to promote Geodon for off-label uses. Following a district court decision granting summary judgment to Pfizer on all claims, Relators appealed.

The First Circuit's Decision

In affirming summary judgment on Relators' off-label promotion based claim, the Court found that Relators had failed to produce any evidence of an actual false claim. Relators sought to rely on the First Circuit's *Neurontin* cases to argue that aggregate NDTI data reflecting government expenditures for off-label prescriptions proves that false claims were submitted, and therefore evidence of specific false claims is not required. The Court rejected this argument, noting that more is required to plead allegedly false claims with sufficient particularity to survive a motion to dismiss under Rule 9(b), and held that evidence of specific false claims is required to survive summary judgment in an FCA case. The Court explained that the *Neurontin* cases held only that aggregate data, when accompanied by strong circumstantial evidence, could be used as proof of a causal link between promotion and prescriptions in a civil RICO context; those cases did not hold that aggregate data could be used to prove the existence of false claims in an FCA case. Indeed, the First Circuit in the *Booker* case held that aggregate data alone could not support a jury finding that false claims were submitted.

Although the First Circuit based its affirmance on Relators' failure to produce competent evidence of a false claim, the Court also suggested that summary judgment may have been independently warranted on falsity grounds. Specifically, the Court acknowledged the undisputed evidence that several state Medicaid programs had chosen to reimburse for the off-label uses of Geodon at issue. The Court noted that Relators' inability to show that any off-

label Geodon claims were filed in a non-reimbursing state might render Relators unable to demonstrate that any claims filed were ineligible for reimbursement and, thus, false.

Finally, the Court affirmed summary judgment for Pfizer on Relators' retaliation claim. The First Circuit held that complaining or "whistleblowing" about an alleged regulatory or legal violation is not protected conduct under the FCA unless the complaint itself concerned the knowing submission of false claims. In this case, the Court held that voicing concerns about supposed off-label promotion did not qualify as protected conduct. This holding substantially clarified the applicable standard in the First Circuit for FCA protected conduct.

Implications

The First Circuit's decision reaffirms that evidence of actual false claims is required to prove a violation of the FCA, and establishes that aggregate data cannot substitute for that fundamental element of an FCA cause of action. The decision is also important for FCA defendants because it sets a strict limit to the type of conduct protected under the FCA's anti-retaliation provision. The decision makes clear that the FCA does not protect conduct that merely concerns regulatory violations, including alleged off-label promotion. Rather, the FCA protects employees who raise concerns about alleged fraudulent conduct in connection with the submission of false claims for government payment.

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