First Circuit Rejects Fraud-on-the-FDA Theory of FCA Liability

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by Katherine Arnold

Affirming an earlier order handed down by the United States District Court for the District of Massachusetts, the First Circuit recently denied Plaintiff D'Agostino leave to amend his complaint, finding the proposed claims were futile. *D'Agostino, et al. v. EV3, Inc. et al.*, 2016 WL 7422943 (1st Cir. Dec. 23, 2016). D'Agostino's complaint alleges False Claims Act ("FCA") violations related to the Onyx and Axium medical devices, which are used in embolization procedures.

D'Agostino alleged that the defendants made false statements during the FDA approval process for the devices, including disclaiming uses of the devices they later pursued, misstating the training that would be provided to physicians using the device, and omitting relevant information about the devices' safety. To link the alleged false statements to a claim for payment, D'Agostino relied on a theory of fraud upon the FDA, arguing that these statements constituted false claims because they could have influenced the FDA's decision to approve the devices, and but for the FDA approval, CMS would not have reimbursed physicians for the use of these devices.

The First Circuit presented numerous reasons for rejecting D'Agostino's request for leave to amend. Some of those reasons rest on basic legal principles, such as the lack of sufficient allegations to satisfy federal pleading requirements under Rule 9(b) and 12(b)(6). The design defect claim, which argued that improvements to the design of Axium demonstrate that previous versions of the device were defective, was similarly and succinctly dispatched as nonviable. The court remarked that if this standard were applied "most every car sold to the government would be per se defective."

In less charted territory, the court also rejected D'Agostino's fraud on the FDA theory of liability. The court noted that this theory would require D'Agostino to show that the allegedly false statements *actually* caused the FDA to grant approval it otherwise would not have granted—a mere showing that the statements *could have* influenced the FDA's decision would be insufficient. D'Agostino attempted to salvage his argument by relying on the FCA's materiality standard, which only requires plaintiffs to show that a statement

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has “a natural tendency to influence, or [is] capable of influencing, the payment or receipt of money or property.” In addition to finding that this argument misconstrued the FCA’s “demanding” standard of materiality, the court found that this approach improperly conflated the FCA’s materiality and causation requirements.

The court’s analysis also considered that allowing the fraud on the FDA theory to proceed would effectively permit a jury to overrule the FDA’s approval of medical devices. Although the FDA has the authority to temporarily or permanently revoke its prior approval of a medical device, it has not done so for either Onyx or Axium in the six years since D’Agostino’s complaint has been made public. The court found this to be persuasive evidence that the alleged false statements were not material to the FDA’s decision to approve the devices.

Although the court rejected D’Agostino’s use of the fraud on the FDA theory of liability in this case, the decision acknowledges that this theory may support viable FCA claims in instances where the FDA withdraws its approval of a device after discovering fraud.