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First Circuit Rejects Whistleblower's Fraud on the FDA FCA Theory

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On December 23, 2016, the First Circuit held that a relator under the federal False Claims Act ("FCA") failed to plausibly plead that defendant medical device manufacturers caused the submission of false claims for reimbursement by fraudulently obtaining Food and Drug Administration approval ("FDA") for a medical device. Citing the fact that FDA had not withdrawn its approval of the device in the years since relator filed his qui tam suit, the panel in *D'Agostino v. ev3, Inc.*, No. 16-1126, 2016 WL 7422943 (1st Cir. Dec. 23, 2016) held that relator failed to plead a causal connection between the alleged misrepresentations to FDA during the device approval process and the government's subsequent payment of claims involving the device. For this and other reasons discussed below, the panel affirmed the district court's ruling that further amendments to the complaint would be futile.

Background

Relator Jeffrey D'Agostino, a former sales representative for defendants ev3 and MTI, first filed suit in October 2010 in the United States District Court for the District of Massachusetts. Over the course of several years, relator amended his complaint three times. After the government declined to intervene in the case, the case was unsealed, and defendants moved to dismiss.

Relator responded to the motions to dismiss by filing a fourth amended complaint without seeking leave of the court. The district court construed this filing as a motion to amend and denied it under Fed. R. Civ. P. 16(b)'s "good cause" standard. Subsequently, after briefing and argument on the motions to dismiss, the district court dismissed the then-operative version of the complaint. Relator appealed, and the First Circuit reversed and remanded in *United States ex rel. D'Agostino v. ev3 Inc.*, 802 F.3d 188 (1st Cir. 2015), holding that the district court should have evaluated relator's request for leave to amend under Rule 15(a)'s more lenient standard instead of Rule 16(b).

On remand, relator moved to amend and proffered yet another amended complaint. Relator alleged that defendants caused the submission of false claims for Onyx and Axium, two medical devices used to treat brain abnormalities through minimally invasive endovascular procedures. Relator's principal theory regarding Onyx was that MTI had defrauded the FDA during the premarket approval process by allegedly overstating the planned extent of its physician training program, denying that it intended to promote the device for off-label uses, and concealing the link between Onyx and another device that was ultimately recalled for safety reasons. Relator asserted that but for this supposed fraud, FDA would not have approved Onyx. Government health care programs generally only pay for devices that have been approved or cleared by FDA, so relator argued that every claim for an Onyx procedure was false under the FCA.

In addition to alleging that every Onyx claim was false due to this supposed fraud on the FDA, relator also alleged that Onyx claims submitted by physicians who had not attended defendants' training programs were false, under the theory that use by untrained physicians was not medically reasonable or necessary. Finally, Relator alleged that every claim for Axium was false because the device was defectively designed and defectively manufactured.

The First Circuit's Holding

A unanimous panel of the First Circuit agreed with the district court that relator's proposed amended complaint was futile. Devoting the bulk of its analysis to relator's "fraud on the FDA" theory, the First Circuit held that if the FDA has not withdrawn its approval from a device or taken another official action confirming that it was defrauded, then a relator cannot base an FCA claim on the theory that FDA approval was fraudulently obtained. The panel noted that FDA does not itself pay claims for medical devices. Rather, such claims are paid by federal healthcare programs such as the Centers for Medicare and Medicaid ("CMS") services, on the condition (with some exceptions) that the devices involved were approved or cleared for marketing by FDA. Because the supposed fraud was directed to FDA rather than CMS, the panel reasoned that if FDA was not, in fact, defrauded, then defendants could not have caused the submission of false claims to CMS as a matter of law.

The panel was notably alert to the practical implications of its ruling. It explained that allowing "fraud on the FDA" FCA theories in the absence of official FDA recognition of the alleged fraud would "turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so." 2016 WL 7422943 at *6. It also acknowledged that its ruling poses the "theoretical risk" that the government might seek to prevent a would-be relator from recovering under the FCA by filing its own suit after relator notified FDA and sought official recognition of the fraud. *Id.* The panel concluded, however, that such risk is small, and that deterring whistleblowers is generally counter to the government's own interest.

The court quickly dispensed with relator's three other theories of liability. It held that relator failed adequately to allege that FDA required physicians to attend defendants' training programs and, further, that relator had failed to allege that any supposedly untrained users had actually submitted claims for reimbursement to the government, as required by Fed. R. Civ. P. 9(b) and First Circuit precedent. Regarding Axium, the panel held that relator had not plausibly alleged that every claim for Axium was false. The panel concluded that relator's manufacturing and design defect allegations respectively established, at best, that only certain lots were defective and that later generations of the device improved upon the original design, which did not make the earlier generations defective.

Implications of the Court's Decision

This case marks the first time that a federal court of appeals has held that "some official action by the FDA confirming that its approval was actually procured" by fraudulent representations is necessary in order for a "fraud on the FDA" FCA theory to be viable. *Id.* Not only will this holding likely be a significant impediment to FCA cases based on such theories in the First Circuit, but its reasoning may also convince other circuits to follow suit.

If you have any questions or would like to discuss the foregoing or any related matter, please contact the Ropes & Gray attorney with whom you regularly work, or an attorney in our False Claims Act or Government Enforcement practices.