District Court Rejects Fraud-on-the-FDA Theory of False Claims Act Liability

In an opinion that continues a welcome trend in False Claims Act cases, Judge Saylor of the United States District Court for the District of Massachusetts has dismissed a relator's FCA complaint for failing to plead facts demonstrating that a manufacturer's breach of the Food & Drug Administration's ("FDA") adverse event reporting requirements resulted in any false claims against federal health care programs. *United States ex rel. Ge v. Takeda Pharmaceuticals U.S.A., Inc.* (Nos. 10-11043-FDS; 11-10343-FDS) (Nov. 1, 2012). Judge Saylor's opinion, like other recent opinions of Judges Gorton and Stearns in the District of Massachusetts, reflects an appropriate judicial resistance to attempts to convert any and all alleged regulatory violations into liability under the FCA, especially when the agency in question has broad discretion in how to respond to regulatory non-compliance.

Reporting Safety Information

The FDA's reporting requirement— intended to keep the agency abreast of post-market adverse events— establishes timelines that trigger reporting obligations for manufacturers depending on the severity and likelihood of the adverse event. *See Wyeth v. Levine*, 555 U.S. 555, 608 (2009). Failure to report adverse events can trigger civil and criminal penalties ranging from monetary fines to withdrawal of the drug's approval. But while the FDA is empowered to bring appropriate enforcement action in response to reporting violations, the agency has broad discretion over which enforcement tool it will utilize and whether it will bring an enforcement action at all. *See* 21 C.F.R. §§ 80(j), 81(d); *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 (2001); *Community Nutrition Institute v. Young*, 818 F.2d 943, 950 (D.C. Cir. 1987).

The relator's allegations in *Ge* exemplify – if in the extreme – the FCA plaintiff bar's improper attempts to convert regulatory violations into per se FCA liability. The premise of relator's FCA suit was that FDA approval was a precondition for payment and that the FDA would have exercised its discretion to withdraw from the market the drugs for which Takeda allegedly failed to report adverse events. On that basis, relator asserted that *all* claims for payment of the drugs in question were false. Judge Saylor rejected this outright, for failure both to state a claim under Rule 12(b)(6) and to satisfy Rule 9(b)'s particularity requirement. The court held that the complaint failed to state factual allegations to support an inference that the FDA would have withdrawn its approval immediately had it received the proper reports. The court stressed that the withdrawal of approval was not mandatory, but instead lies within the agency's discretion.

A Trend Emerges

Judge Saylor's opinion in *Ge* joins at least two others this year in the District of Massachusetts where the court has rejected a fraud-on-the-FDA theory for failure to establish a connection between failure to report adverse events and false claims. In *United States ex rel. Tessitore v. Infomedics, Inc. et al.*, 847 F. Supp. 2d 256 (D. Mass. 2012), Judge Gorton rejected each of two relator arguments why concealment of adverse events rendered reimbursement claims for the drugs in question false. Relator had first argued that certifying compliance with reporting requirements was a pre-condition to FDA approval and that failing to report adverse events therefore necessarily rendered all subsequent reimbursement claims false. The court rejected this theory for failure to plead specific facts in support. Second, relator argued that the manufacturer's failure to report adverse events had forestalled FDA from requiring the manufacturer to issue warnings, which would, in turn, have resulted in fewer claims. This argument also failed, the court held, because there was no support for relator's theory that the adverse events in question would have motivated the FDA to require warnings immediately.

In another recent case, the court likewise dismissed a relator's FCA suit based on a medical device manufacturer's allegedly deliberate failure to report adverse events to the FDA. *United States ex rel. Provuncher v. Angioscore, Inc.*, 2012 WL 1514844 (D. Mass. May 1, 2012). In *Provuncher*, Judge Stearns rejected relator's claim under Rule 9(b), holding that the relator failed to allege fraud with sufficient particularity.

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Taken together, the decisions in *Ge*, *Tessitore*, and *Provuncher* provide welcome evidence of judicial skepticism of relators' efforts to convert any regulatory violation into a claim for liability under the FCA. Judge Saylor's opinion in *Ge* provides particularly valuable support against many FCA theories of liability that are premised on an assertion of how an agency would have exercised its discretion in response to alleged regulatory violations. We will continue to monitor developments in this area. If you would like further information, please contact the Ropes & Gray attorney who usually advises you.