



Abbott Laboratories Prevails in False Claims Act Case

Sara M. Lord

On April 7, 2016, following a three-week trial and after only three hours of deliberations, a federal jury in Dallas, Texas found that Abbott Laboratories had not violated the False Claims Act (FCA) when it marketed bile duct stents for off-label uses in vascular procedures. The *qui tam* lawsuit¹, which was filed by a former salesman for Abbott's predecessor, Guidant, and in which the government did not intervene, accused the company of effectively using off-label marketing to test the device on vascular patients without their informed consent. Because nearly all the patients who received the stents were elderly, the AARP Foundation acted as co-counsel in support of the lawsuit.

The relator alleged that the stents were not eligible for Medicare reimbursement because they had not been approved for vascular use and that Abbott's marketing practices of using bile stents in more complex vascular procedures resulted in false claims totaling more than \$219 million. With treble damages under the FCA, as well as statutory penalties of up to \$11,000 for each claim improperly submitted to Medicare, Abbott faced a possible \$1 billion verdict.

Abbott argued that the practice of using bile stents in vascular procedures was common throughout the industry, and that the use of the stents was actually better for the patients than the alternatives. In fact, as Abbott argued, Medicare reviewed the issue of using bile stents in vascular procedures after the lawsuit was filed, and continued to pay for the use of the stents. In a 10-1 verdict, the jury found the relator had not demonstrated that Abbott had engaged in any improper marketing practices in violation of the FCA, and discharged the company from any liability.

Reactions to the jury's decision have followed along predictable lines, with the defense bar hailing it as evidence that the tide is turning against mega-claims for off-label marketing, and the plaintiffs' bar expressing concerns that drug and device manufacturers will pursue off-label marketing in lieu of expensive clinical trials without having to pay the costs or consequences.

In the last six years, pharmaceutical and device manufacturers have paid billions of dollars in FCA penalties for alleged off-label marketing. More recently, however, the fines and penalties have tapered off. While some have attributed the decrease to increased caution on the part of the industry, others point to recent off-label marketing cases in which the defense has prevailed, including *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012) (vacating the conviction of a former salesman for off-label promotion on First Amendment grounds) and *Amarin Pharma, Inc. v. FDA*, 119 F.3d 196 (S.D.N.Y. 2015) (granting Amarin's request for preliminary injunction to prevent FDA from bringing a misbranding action).

In this instance, the case is also significant because it went to the jury. As the fines and penalties have mounted in these types of cases, companies may be more inclined to fight, rather than knuckling under to the government's or relators' demands. The speed with which this jury reached its verdict, as well as other cases in which the government has been rebuffed (see *United States v. AseraCare*, 2015 WL 8486874 (N.D. Al. 2015)), suggest that companies may wish to consider litigation over settlement.

¹ *U.S. ex rel. Colquitt v. Abbott Laboratories f/k/a Guidant Corp.*, 06-cv-01769, U.S. District Court, Northern District of Texas (Dallas).

In the meantime, however, relator's counsel in the Abbott case has stated that his client will appeal the jury's verdict, and we can anticipate further debate about off-label marketing at the appellate level.

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