

## Health Fraud Defense Attys Riding High As Wins Pile Up

By **Jeff Overley**

Law360, New York (April 8, 2016, 9:04 PM ET) -- A jury verdict for Abbott Laboratories in a \$200 million False Claims Act trial involving off-label marketing joins a string of recent defense wins in high-profile health fraud cases and suggests that the tide is turning after years of harsh financial penalties, attorneys say.

**Abbott's triumph** on Thursday followed a two-week trial and only three hours of jury deliberations in Texas federal court. The company convinced jurors that it acted reasonably by promoting its stents to treat common blood vessel problems despite only having approval to treat relatively uncommon bile duct problems.

With the victory in hand, the defense bar is officially on a winning streak in cases involving off-label promotion. Things started in late 2012, when the Second Circuit's **Caronia decision** vacated a drug salesman's misbranding conviction on free speech grounds. Subsequent victories have been notched since mid-2015 by Amarin Pharma Inc., Pacira Pharmaceuticals Inc. and Vascular Solutions Inc.

"It is fair to say that the tide has really shifted in terms of the off-label theory," said Laurence J. Freedman of Mintz Levin Cohn Ferris Glovsky and Popeo PC.

From the view of the plaintiffs bar, the outcome is distressing, suggesting that drug and device makers can avoid costly clinical trials and still reap many of the financial benefits that they offer without being held accountable.

"It's unfortunately one of the lessons of a verdict like this that defense lawyers will take is to advise their client that they might be able to get away with this kind of behavior," said Shayne C. Stevenson, a Hagens Berman Sobol Shapiro LLP partner who brought a similar, now-settled case against Medtronic Inc. in 2011. "I'm sure they will find this verdict heartening."

Off-label promotion has led to billions of dollars in FCA payouts under the Obama administration, but experts have **previously predicted** that the monster penalties would taper off. A report last week from consumer group Public Citizen confirmed those predictions, finding that federal fines linked to unlawful promotion plunged 90 percent in 2014-15 compared with 2012-13.

The predictions of fewer mega-settlements were largely grounded in a belief that manufacturers had been chastened by years of aggressive enforcement and that most of the obvious schemes had already been ferreted out. To the extent that off-label cases are still being waged, they may be less likely to involve clear-cut misconduct, or even any misconduct at all.

"I think we're past the point in the pharma and medical device industries of the easy, low-hanging fruits," said John C. Richter, a King & Spalding LLP partner who successfully represented Vascular Solutions. "And so as the government and relators' counsel [look for] more cases, it's a little more challenging to find them."

Attorneys offered some caveats about the significance of Abbott's win.

For one, the U.S. Department of Justice didn't join the whistleblower case, casting doubt on its viability. In addition, even under statistics cited by the whistleblower, off-label stent use was extremely common and produced complications in less than 1 percent of patients, perhaps making Abbott's promotion look innocuous. And furthermore, decisions from juries carry less weight than decisions from judges.

"I don't think people will read too much into a particular jury verdict," Stevenson said.

At the same time, the fact that the matter actually went to a jury is noteworthy, and it points to another potential trend: In recent months, several big health fraud cases have gone to trial, something corporations usually avoid for fear of huge financial penalties or exclusion from Medicare and Medicaid.

For example, Abbott was accused of more than \$200 million in bogus billing, and its liability could have topped \$1 billion under the FCA's damages and penalties structure. Elsewhere, hospice chain AseraCare Inc. went to trial last year despite the threat of \$200 million in FCA penalties, and it **won a complete victory** over the DOJ. And in the criminal context, Vascular Solutions rejected a plea deal and in February **escaped charges** of illicit off-label promotion.

"It used to be that no one's going to fight these things, and now that's no longer the case," Freedman said.

The outcomes are especially refreshing for defense attorneys, who have long griped about being bulldozed into unfair settlements simply because the risks of losing an FCA trial are too great. For them, the hope is that the successful defenses mounted by Abbott, Vascular Solutions and others will prompt a bit of reflection on the other side of the aisle.

"These cases should reinforce to plaintiffs' lawyers and to prosecutors that they still carry the burden of proof," Richter said, "and if their case lacks merit, their case lacks merit."

The case is U.S. ex rel. Colquitt v. Abbott Laboratories et al., case number 3:06-cv-01769, in the U.S. District Court for the Northern District of Texas.

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--Additional reporting by Jess Davis. Editing by Jeremy Barker and Patricia K. Cole.