



Federal Jury Convicts Two Former Acclarent, Inc. Executives on Misdemeanor Charges Related to Off-Label Marketing of Medical Device; Acquits on Felony Charges

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On July 21, 2016, two former executives of Acclarent, Inc., a medical device company owned by Johnson & Johnson, Inc., were found guilty of ten misdemeanor violations of the Federal Food, Drug and Cosmetic Act (FDCA), following a six-week jury trial in Boston. The former executives were acquitted on fourteen felony counts, including conspiracy, securities fraud, wire fraud, and violations of the FDCA. The charges against the former executives, former Chief Executive Officer William Facteau and former Vice President of Sales Patrick Fabian, stemmed from Acclarent's marketing of its sinus spacer product as a steroid delivery device without U.S. Food and Drug Administration approval.¹

The acquittals of the former company executives on the substantive, intent-based felony counts, with convictions only on the strict liability misdemeanor counts, follows the recent acquittal of former Warner Chilcott CEO Carl Reichel, who was charged with violating the Anti-Kickback Statute. These cases, along with the March 2016 acquittals of a medical device company, Vascular Solutions, Inc., and its CEO and founder, Howard Root, of felony FDCA charges in Texas, suggest that the Department of Justice's efforts to hold individuals accountable for corporate wrongdoing, including under the recent Yates Memo, may not find favor with juries.

On Friday, July 22, 2016, Acclarent, Inc., reached a settlement agreement with the Department of Justice, agreeing to pay \$18 million to resolve allegations that it caused healthcare providers to submit false claims to Medicare and other federal healthcare programs.

¹ *United States v. Facteau et al*, U.S. District Court, District of Massachusetts, No. 1:15-CR-10076.

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