

JURY ACQUITS LIBBYHOOPES' MEDICAL DEVICE SALES EXECUTIVE-CLIENT OF ALL FEDERAL FELONY CHARGES

On July 20, 2016, a federal Boston jury acquitted LibbyHoopes' client, Patrick Fabian, of all 14 felony fraud charges brought by the government against the medical device executive. In particular, the jury unanimously acquitted Fabian (and his co-defendant William Facteau) of the single conspiracy count, three counts of wire fraud and 10 counts of distributing adulterated and misbranded medical devices, "with intent to defraud or mislead."

The *Wall Street Journal* quoted Fabian lead counsel and LibbyHoopes partner Frank Libby: "After five years investigation and a six week trial, the jury flatly rejected the government's core fraud and conspiracy theories."

Importantly, proof at trial made clear that no injuries were associated with use of the implantation device, widely used by surgeons to successfully treat patients with chronic sinus problems.

Mr. Fabian had been Vice President of Sales, while Mr. Facteau was CEO at medical-device maker Acclarent, a unit of Johnson & Johnson. In April 2015, a federal grand jury indicted Fabian and Facteau on felony charges including conspiring to market a sinus-opening device for an "intended use" not approved by the U.S. Food and Drug Administration, and conspiring to commit securities fraud by not disclosing the alleged conduct to Johnson & Johnson when it acquired Acclarent in 2010 for \$785 million.

In addition to the felony counts, the indictment included 10 "strict liability" misdemeanor misbranding and adulteration counts under the Food, Drug & Cosmetic Act (FDCA). These counts required no proof of any wrongful intent – indeed, required no evidence that the defendant even knew of any wrongful conduct - in order to convict. Under the law governing these counts, the jury could deem Facteau and Fabian "responsible corporate officers" and thus hold them individually liable for lack of filing premarket notification to the U.S. Food and Drug Administration of its intended use.

With these lowest-of-threshold counts available as part of the overall indictment, the jury specifically rejected the government's theories that the device's labeling was false and misleading, and that the device lacked "adequate directions for use" but ultimately convicted the two executives for the misdemeanors on this "strict liability" theory.

Law 360 reported: "Libby... said that even after the jury verdict Wednesday, 'the fight is far from over. It's a case that could reverberate in the medical device field.' Appeals issues will include due process and First Amendment concerns, Libby said. Defense lawyers argued that because of the First Amendment, the convictions could not be based on truthful, non-misleading statements about the off-label use of the Stratus. 'The takeaway here is that executives in the healthcare field or the device fields are looking at ... these confusing, chaotic regulations which require no proof of wrongful intent,' Libby said. 'That's a major concern. We're not done'."

The LibbyHoopes trial team included: Frank A. Libby Jr., Kristen A. Kearney, Daniel C. LaPenta and Brian J. Sullivan of LibbyHoopes PC.

Facteau is represented by Reid Weingarten, William Hassler and Jessica Urban of Steptoe & Johnson LLP, Michael J. Pineault of Clements & Pineault LLP and Leo Cunningham and Lisa Davis of Wilson Sonsini Goodrich & Rosati PC.

In recognition of the foregoing, the *American Lawyer's* "AmLaw Litigation Daily" recently named Libby and Weingarten "Litigators of the Week."

The case is U.S. v. Facteau et al., case number 1:15-cr-10076, in the U.S. District Court for the District of Massachusetts.