July 22, 2016: Medical Device Manufacturer Acclarent Inc. to Pay $18 Million to Settle False Claims Act Allegations

Food and Drug Administration
Office of Criminal Investigations

U.S. Department of Justice Press Release

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District of Massachusetts

BOSTON – The U.S. Attorney's Office announced today that California-based medical device manufacturer Acclarent Inc., a subsidiary of Ethicon, a Johnson & Johnson company, has agreed to pay $18 million to resolve allegations that it caused health care providers to submit false claims to Medicare and other federal health care programs by marketing and distributing one of its products, the Relieva Stratus, for use as a drug delivery device without U.S. Food and Drug Administration (FDA) approval of that use.

"The FDA plays a fundamental role in ensuring the safety and efficacy of medical devices and drugs in this country," said United States Attorney Carmen M. Ortiz. "Every time that patients receive a medical device or fill a prescription they should be able to take for granted that the FDA's requirements have been met. We will vigorously pursue those who ignore or seek to circumvent these important patient protections."

"The FDA approval process serves an important role in ensuring that federal health care participants receive devices that are safe, effective and medically appropriate," said Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Justice Department's Civil Division. "We will not permit companies to circumvent that process and put profits over patient safety."

"The FDA's requirement for premarket approval of medical devices is designed to ensure the health and safety of patients," said George M. Karavetsos, Director of the FDA Office of

Criminal Investigations. “The FDA will continue to aggressively pursue those who place the public health at risk and compromise the integrity of the regulatory system.”

“Companies cannot ignore the regulatory process to boost their bottom line,” said Harold H. Shaw, Special Agent in Charge of the Federal Bureau of Investigation's Boston Division. “The FBI hopes this sends a clear message to those who disregard the laws and protections the public relies on for their safety.”

“Marketing medical devices for other than FDA approved uses can expose patients to questionable medical treatments while asking taxpayers to pick up the Medicare cost," said Special Agent in Charge Phillip M. Coyne of the Department of Health and Human Services Office of Inspector General. "Our investigators, working closely with our law enforcement partners, will continue to pursue allegations of such misconduct and deter those tempted to launch such illegal scams.”

“We are pleased to have contributed to this outstanding multi-agency investigation,” said Jeffrey G. Hughes, Special Agent in Charge of the U.S. Department of Veterans Affairs, Office of Inspector General, Northeast Field Office. “The VA makes every attempt to ensure pharmaceutical and medical devices have gone through the necessary FDA approval processes and have been determined to be safe and effective. When individuals and companies circumvent that process, patients and our veterans suffer.”

Acclarent sold a variety of medical devices used in sinus surgeries, including a device known as the Relieva Stratus MicroFlow Spacer (Stratus). In 2006, Acclarent received FDA clearance to market the Stratus as a spacer to be used only with saline to maintain sinus openings following surgery. The government alleged that Acclarent intended for the Stratus to be used instead as a drug-delivery device for prescription corticosteroids, including Kenalog-40, and that the device was specifically designed and engineered for this use.

The government further alleged that Acclarent marketed the Stratus as a drug delivery device even after the FDA rejected the company’s 2007 request to expand the approved uses for the Stratus. For example, Acclarent employees trained physicians using a video that demonstrated the Stratus being used with prescription corticosteroid Kenalog-40 and also used a white, milky substance resembling Kenalog-40 when demonstrating the Stratus.

In 2010, after the acquisition by Ethicon, Acclarent added a warning to its label regarding use of active drug substances in the Stratus. By May 2013, Acclarent discontinued all sales of the Stratus and the company agreed to withdraw all FDA marketing clearances for the device, which is no longer commercially available in the United States. Ethicon also cooperated with the government’s investigation.

On Wednesday, July 20th, Acclarent’s former Chief Executive Officer, William Facteau, 47, of Atherton, California and former Vice President of Sales, Patrick Fabian, 49, of Lake Elmo,

Minnesota were convictedfollowing a six-week jury trial of 10 misdemeanor counts of introducing adulterated and misbranded medical devices into interstate commerce.

This settlement illustrates the government's emphasis on combating health care fraud and marks another achievement for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by the Attorney General and the Secretary of Health and Human Services. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. One of the most powerful tools in this effort is the False Claims Act. Since January 2009, the Justice Department has recovered a total of more than $30 billion through False Claims Act cases, with more than $18.3 billion of that amount recovered in cases involving fraud against federal health care programs.

This matter was investigated by the Commercial Litigation Branch of the Justice Department's Civil Division; the Food and Drug Administration, Office of Chief Counsel; the Federal Bureau of Investigation, Boston Field Division; the Department of Health and Human Services, Office of Inspector General; the Defense Health Agency; the Food and Drug Administration, Office of Criminal Investigations; Department of Defense, Office of Inspector General, Defense Criminal Investigative Service; the Department of Veterans Affairs, Office of Inspector General. The matter was handled by District of Massachusetts Assistant U.S. Attorneys Sara Miron Bloom, Patrick Callahan and Department of Justice Trial Attorneys Colin Huntley and Ross Goldstein.