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# FDA Enforcement Heating Up

*Law360, New York (November 20, 2009)* -- Recent statements by U.S. Food and Drug Administration and Department of Justice officials, including FDA Commissioner Margaret Hamburg, promised an increase in enforcement. Recent events on several fronts demonstrate that this is no idle threat.

On Oct. 28, 2009, the government announced a criminal indictment against Stryker Biotech and four current or past executives.

The indictment, filed in federal court in Massachusetts, alleges that the company and the named executives promoted an unapproved combination of two orthopedic products used as bone fillers.

Each product had been separately cleared by FDA (one under the Humanitarian Device Exemption or HDE process). However, the combined use of the products was not tested or cleared by FDA, and the product labeling did not provide adequate instructions for use.

In addition, the indictment alleges that the company knowingly sold more than the 4,000 units permitted under the HDE provisions.

According to the indictment, Stryker begin receiving reports of patient issues with the product combination, and employees began raising questions about the combined use.

Despite these regulatory and patient issues, the indictment alleges that Stryker and the named individuals instructed the sales force to continue to promote the combined use.

The indictment alleges a scheme to defraud physicians, hospitals and payors under the wire fraud statute, misbranding under the Food Drug and Cosmetic Act, making false statement to the government and conspiracy.

This case raises some important points and issues for all companies:

- The company's compliance processes seem to have failed to prevent these issues.

- The government continues its pattern of indicting individual executives, from the CEO to several sales executives.

- The government continues to use economic statues such as wire fraud in addition to the traditional misbranding counts.

- The government is focusing on potential false statements made to the government during inspections or investigations. Here, the government also alleges that certain individuals provided false information to a law firm which had been asked to opine on certain regulatory issues.

- The government is watching companies with past compliance issues. In 2007, Stryker entered into a Non Prosecution Agreement to resolve certain fraud and abuse issues.

As part of that agreement, Stryker asserted that it had an effective compliance program in place. As was also seen in the recent Pfizer settlement, the government has no patience with what it perceives to be a repeat offender.

Increased enforcement efforts can be seen on other fronts as well.

The Tenth Circuit recently upheld the imposition of civil monetary penalties against TMJ Implants for failing to report adverse events. A trial is currently underway against Janssen Pharmaceutica, a part of J&J, for off-label promotion of the drug Risperdal.

Congress is also getting into the act. Congressman Joe Barton, R-Texas, recently introduced H.R. 3932, which strengths the power of the FDA to debar or exclude clinical trial investigators.

Other members of Congress have introduced another bill that would increase the funding for investigations into health care fraud and increases the jail time for convicted offenders.

New hires at the FDA also signal a "get tough" attitude.

Recent additions to senior policy positions at the FDA include a long-time senior member of Ralph Nader's Public Citizen advocacy group, a long-time industry critic from California Representative Henry Waxman's staff and a director of communications from the national plaintiffs lawyer association.

Taken together, the FDA's statements about increased enforcement must be taken seriously by the regulated community.

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