Former Senior Executives Indicted for Illegal Marketing of a Medical Device

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Two former senior executives were indicted with violations of the Federal Food, Drug, and Cosmetic Act (FDCA) relating to the introduction of adulterated or misbranded medical devices into interstate commerce. The indictment alleges that the two executives marketed a device for uses not approved by the Food and Drug Administration (FDA), i.e., off-label uses. The executives have not been convicted.[1]

The device had been reviewed by FDA as a product providing a specific type of treatment. However, the executives later had the company market it for a different treatment that had been specifically refused by FDA. Although FDA initially refused, it might have allowed marketing for that intended use if the company had submitted further documentation to support the indication, such as additional testing and clinical data. Because the company was later sold, in large part because of the attractive revenue stream from the device, the executives have also been charged with conspiracy, securities fraud, and wire fraud.

We will not get into the details of the case here, except to note that the executives allegedly concealed the illegal promotion and distribution of the device when pursuing potential purchasers of the company.

AGG Observations

1. The company indicated to FDA that the product would be marketed for one use and later marketed it for another, even after FDA had specifically refused marketing for the second use. This is a particularly egregious fact pattern.

2. The two executives will be prosecuted by the Justice Department, with the assistance of FDA's Office of Chief Counsel. The case shows that there can be potential individual liability for the adulteration or misbranding of medical devices, and there are many agencies interested in prosecuting these cases.[2] The United States Supreme Court has upheld individual prosecution under the FDCA where the individual defendants are in a position of responsibility to stop the violation.[3]

3. Individual liability in these cases extends beyond monetary penalties; the charging statutes in this case provide for a maximum prison sentence of up to three years for each count for violations of the FDCA. There are ten counts of such violations in this case.[4] Most violations are subject only to a maximum of one year in prison or $1,000, or both. However, when a violation is found to have occurred with the intent to defraud or mislead, the penalty is imprisonment for "not more than three years or fines not more than $10,000, or both."

1 The Justice Department release can be found at http://www.justice.gov/usao-ma/pr/former-acclarent-inc-executives-charged-securities-fraud-and-crimes-related-sale-and-0.

2 The case was also investigated by the Federal Bureau of Investigation, FDA's Office of Criminal Investigations, U.S. Department of Health and Human Services' Office of Inspector General, Department of Defense Office of Criminal Investigation, and the Department of Veterans Affairs' Office of Inspector General.

3 *See United States v. Dotterweich*, 320 U.S. 277 (1943); *United States v. Park*, 421 U.S. 658 (1975).

4 In addition, the executives face maximum sentences of 20 years in prison for each wire and securities fraud count and 5 years for the conspiracy count, followed by a term of supervised release and a $250,000 fine or twice the gross gain.

4. The company was acquired in 2010 by a company specifically interested in the device at issue in the case. The case highlights the need for a very thorough diligence review prior to acquisition. The case also shows how liability can act as a Sword of Damocles for years after the actions giving rise to charges of adulteration or misbranding actually occurred. The threat of agency action and/or prosecution can and will hang over a company for many years following illegal activities.

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