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Device manufacturer's criminal and civil penalties deserve closer attention

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Today's blog post illustrates how a company's problems can escalate rapidly from an administrative warning letter to the full weight of the criminal system. The unfortunate subject is ACell, a manufacturer of medical devices derived from porcine urinary bladder material.

ACell received a Warning Letter in 2013 related to the Quality System and Medical Device Reporting for its MatriStem Surgical Matrix Thick device. Little did it know, that same year, a whistleblower filed a qui tam action alleging, among other things, off-label promotion of another one of its devices, MicroMatrix Powder Wound Dressing.

A second whistleblower filed a case in 2016 making similar allegations. The government lawyers investigating the whistleblowers' allegations coordinated with criminal prosecutors, culminating in ACell agreeing to pay $15 million, plead guilty to a misdemeanor charge, implement extensive compliance activities, and be subject to a five-year Corporate Integrity Agreement.

The criminal plea was based on the company's failure to report to FDA its decision to remove its MicroMatrix Powder Wound Dressing from the marketplace, a reporting requirement under 21 C.F.R. Part 806.

In 2012, ACell learned that approximately 30,000 units of its MicroMatrix powder were contaminated with endotoxin levels that posed a risk to health. ACell removed the affected devices but concealed the reason for the removal from health care providers and did not submit an 806 Report to FDA.

On June 11, 2019, the U.S. Attorney's Office for the District of Maryland announced that it had charged ACell with a criminal misdemeanor, imposed a fine of $3 million, and required the company to enact extensive compliance reforms.

A few notable points about the criminal portion of this case.

- No individuals are named in the plea. The failure to include an officer of ACell seems inconsistent with DOJ's mantra about holding individuals accountable.
- The Statement of Facts accompanying the criminal plea, which the parties agreed the government could prove beyond a reasonable doubt at trial, extends to activities well beyond the single 806 reporting violation, and paints a picture of a much more culpable defendant than the single misdemeanor count reveals.
- Despite the five-year statute of limitations contained in the Federal Food, Drug and Cosmetic Act, the criminal plea related to conduct that occurred seven years ago, when the reporting obligation was triggered in 2012.
- The Compliance Program contains many of the typical elements in a Corporate Integrity Agreement, but extends to include monitoring for potential violations of FDA reporting obligations.

Each of these points is worth closer examination, and perhaps even its own blog post, but for now, medical device companies simply need to recognize the potential ramifications of the government's enforcement of the 806 reporting obligations.

The criminal plea was based on the company's failure to report to FDA its decision to remove its MicroMatrix Powder Wound Dressing from the marketplace.

The civil settlement turned on entirely different conduct: the company's marketing of the MicroMatrix product. According to the settlement agreement, FDA cleared MicroMatrix only for the management of topical wounds, but ACell marketed MicroMatrix for non-topical or internal uses.

The government alleged that "ACell's promotion was false and misleading because, at the direction of management, ACell sales representatives stated to physicians that the use of powder non-topically and internally was safe and effective, when the sales representatives knew that no such clinical data existed."

The government also alleged the company provided incorrect coding recommendations for reimbursement of its devices and provided prescribers with "improper inducements" to encourage use of its devices.

The civil settlement requires ACell to pay $12 million over five years, which includes an initial payment of $500,000, and quarterly payments in amounts ranging from $475,000 to $675,000 (plus interest).

The qui tam relator will receive $2,366,004 of the settlement.

We have seen the number of straight "off-label" prosecutions diminish as the government has struggled with First Amendment considerations for distributing truthful, non-misleading information.

This case, however, turned on the "false and misleading" nature of the promotion because no clinical data existed. Thus, industry should not get too confident that off-label promotion investigations are by-gone relics, and as always, should focus on ensuring there is proper substantiation for all product claims, whether on- or off-label.

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