Healthcare Law Blog
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Illegal Clinical Trials of Bone Cement Sends Executives to Prison

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Four ex-officers of a Pa.-based manufacturer of a bone cement product were sentenced to prison for an unapproved trial that led to three deaths. Each pled guilty to a single misdemeanor count of shipping adulterated and misbranded Norian XR in interstate commerce. The sentences, imposed in Philadelphia federal court, ranged from five to nine months in custody plus fines.

The judge said that the officials wanted to beat their competitors to market without going through the lengthy process of getting the bone cement product approved by the U.S. Food and Drug Administration. So they plotted to train select surgeons in its off-label use and then have the doctors publish their findings. The officers "approved rogue clinical trials" which used bone-void fillers "to treat vertebral compression fractures of the spine in elderly patients." The cement, approved for use elsewhere in the body, was used in the spines of 200 patients with fractured vertebrae. The program continued even after a patient died in surgery in Texas in 2003 and another died in California. The patients suffered sharp drops in blood pressure after the bone cement compound was injected into their spines. Synthes only halted the training after a third death in 2004.

Synthes Inc. pled guilty, paid a $23.2 million fine and agreed to sell the unit. Pa.-based Kensey Nash Corp. bought the entire Norian product line for $22 million in cash. As part of a long-term supply agreement, Kensey Nash will manufacture the Norian products, and Synthes will exclusively distribute the products worldwide. Johnson & Johnson now owns Synthes.

The sentences are the first since the FDA resurrected the "*Park* doctrine" in early 2011. Under a theory derived from the U.S. Supreme Court case of *United States v. Park*, 421 U.S. 658 (1975), a corporate official can be convicted of a misdemeanor if he was in a position to prevent or correct a violation of the FDCA and did not do so. There is no requirement that the official must have acted personally in the wrongdoing, or even that he had knowledge of it. The Supreme Court determined that the FDCA "imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur."

The FDA released criteria for selecting misdemeanor prosecutions The idea behind such criteria is to increase misdemeanor prosecutions against corporate officials under the *Park* doctrine. In addition to consideration of the official's position in the company, his relationship to the violation and whether he had the authority to correct or prevent the violation, the criteria are:

(1) whether the violation involves actual or potential harm to the public;

(2) whether the violation is obvious;

(3) whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;

(4) whether the violation is widespread;

(5) whether the violation is serious;

(6) the quality of the legal and factual support for the proposed prosecution; and

(7) whether the proposed prosecution is a prudent use of agency resources.

To be fair, these criteria look the same as those which must be considered in any decision of whether to proceed criminally, by misdemeanor or felony. Additionally, the criteria are non-binding: they "do not create or confer any rights or benefits for or on any person, and do not operate to bind FDA. Further, the absence of some factors does not mean that a referral is inappropriate where other factors are evidence." The FDA offers no examples of either the categories of persons that may bear a responsible relationship to a violation or the types of conduct that may be viewed as causing or contributing to a violation. Thus, the criteria provide no guidance or comfort to individuals who are potentially subject to Park liability--an incredibly harsh strict liability standard for responsible corporate officials. So the criteria are not really criteria at all.

Executives and counsel need to be aware of the FDA's increased focus on *Park* doctrine prosecutions. Liability may arise from personal or corporate involvement in wrongdoing under the Act, but it can also be based merely on an individual's executive position. While a Park misdemeanor is itself troubling, the collateral consequences of conviction may be far worse than the conviction. For example, if convicted, an executive can face debarment from federal health plans such as Medicaid and Medicare. Secondly, once an individual has been convicted of an FDCA misdemeanor, any subsequent violation of the Act becomes a felony, even without proof that the defendant acted with the intent to defraud or mislead.

For more information, please contact Bob Rose at rrose@sheppardmullin.com or (619) 338-6661.