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Client Alert

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Recent Prison Sentences Demonstrate Government Intent to Increase Criminal Prosecutions of Liable Corporate Officials

In late November, two former senior executives of Synthes Inc. were sentenced to nine months in prison and a third sentenced to five months in prison for their management roles in a company that marketed a medical device for an unauthorized use and conducted unauthorized clinical trials. Each defendant was also ordered to pay $100,000 in fines and will face a period of supervised release after leaving prison. Another executive, the former vice president of operations, has not yet been sentenced.

These prison sentences resulted even though the government proved no intent to commit any crimes by these executives, and in fact, each defendant denied having any knowledge that the conduct they oversaw was a violation of law. Rather, the prison sentences resulted solely from the fact that these defendants served in significant positions of corporate responsibility at the time the company conducted a clinical trial using its bone cement product in spinal surgeries for vertebral compression fractures, despite not having Food and Drug Administration (FDA) approval for this use. Of the 200 patients operated on, three died.

The key to these successful prosecutions is the policy known as the Park doctrine.[1] Under the *Park* doctrine (also known as the responsible corporate officer doctrine), a corporate officer may be held criminally liable for a company's violation of the Federal Food, Drug, and Cosmetic Act (FDCA), even if he or she did not participate in the wrongful conduct and lacked any knowledge of the wrongdoing so long as the officer shared "responsibility in the business process resulting in" the criminal violation.[2] Even though the corporate officer doctrine only supports misdemeanor prosecutions, the application of the doctrine to corporate officials in businesses regulated by FDA is particularly threatening because once a person has been convicted of a misdemeanor under the FDCA, any subsequent violation of the act is a felony, even without proof that the defendant acted with the intent to violate the law.

Although the Department of Justice (DOJ) pursued *Park* doctrine prosecutions with some regularity from the 1970s through the mid-1980s, the practice faded somewhat for a time, perhaps because of a belief by federal

1 The doctrine was affirmed as a theory of liability by the United States Supreme Court in *United States. v. Dotterweich*, 320 U.S. 277 (1943) and again in *United States v. Park*, 421 U.S. 658 (1975).
2 *Park*, 421 U.S. at 669

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prosecutors that the limited sanctions that resulted from these misdemeanor prosecutions did not justify the resources needed to bring such cases to trial. However, the FDA and the DOJ began focusing on the doctrine again as an enforcement tool in the mid-1990s, and recent actions demonstrate rather convincingly that the *Park* doctrine has made a full comeback.

In January 2010, the Government Accountability Office (GAO) issued a report that called on the FDA to strengthen its oversight of criminal investigations by the FDA's Office of Criminal Investigations (OCI). OCI was created in 1992 and does not have the authority to initiate a criminal prosecution on its own. It must convince either a U.S. attorney or the DOJ to bring a case. Before OCI was created, the FDA had a formal referral system in which any proposed criminal prosecution went from the FDA's Office of Chief Counsel (OCC) to the DOJ, where a decision to prosecute would be made. Today, few—if any—cases follow that procedure. Instead, most criminal prosecutions are investigated first by the OCI and then go from the OCI directly to a U.S. attorney's office. Of course, the OCI often consults with FDA District Offices and the OCC regarding scientific and legal issues that may be relevant to the prosecution. The OCI obtains information about possible violations from various sources, including the FDA, other federal and state agencies, current and former employees of companies, media reports, and whistleblower lawsuits. Recent statements by senior FDA officials emphasize the important role that the OCI will continue to play in ensuring that companies comply with regulatory requirements.

Last year FDA Commissioner Margaret Hamburg responded to the GAO report by stressing the agency's commitment to increase the use of misdemeanor prosecutions and highlighting the *Park* doctrine as an important deterrent to executives in the healthcare industry. The *Synthes* prosecutions reflect that intent.

In the *Synthes* case, the government prosecutor argued that prison sentences for the executives were needed to send the right message that disregarding FDA requirements and patient safety has consequences because corporate fines for illegal conduct were often viewed as simply the "cost of doing business." The defense argued that prison terms would be excessive given the defendants' backgrounds and culpability beyond their status as responsible corporate officers. Federal Judge Legrome Davis obviously disagreed, commenting that "this is shameful behavior" and stating that the government's case demonstrated a "real failure in this particular corporate culture … as to the recognition of responsibility."[3]

The message from the *Synthes* case should be appreciated not just by device and pharmaceutical companies, but by the larger healthcare industry, as well. The FDA and DOJ will not hesitate to use the *Park* doctrine to seek criminal fines and prison sentences against individuals in appropriate circumstances, despite the lack of evidence implicating a defendant's awareness and involvement in conduct that violates the FDCA.

Moreover, this and other recent criminal prosecutions against corporate officers underscore that a *Park* plea always must be seriously considered and not viewed merely as an uncomplicated way out from a challenging government investigation. Indeed, because today the FDA and DOJ are aggressively seeking to use the

3 Sentencing Hearing in *United States v. Norian Corp, et. al.*, Case No. 2:09 CR 00403.

responsible corporate officer doctrine to "send a message" to the healthcare industry, prudent company officers will use their power and influence to ensure that their companies have implemented robust compliance programs and will consider the monitoring of the effectiveness of these programs as a top priority.

In particular, senior executives should establish and maintain an adequate organizational structure to make certain all personnel who perform and assess work affecting quality and regulatory compliance have the ability, authority and resources necessary to perform these tasks. Additionally, executives should review the suitability and effectiveness of their company's compliance system at defined intervals and with sufficient frequency to ensure that the company's established quality policy and regulatory compliance objectives are being met. Only then can company officers rest assured they have taken all reasonable efforts to mitigate the risk of exposure not only to the company, but to the senior executives themselves.