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FOOD AND DRUG ENFORCEMENT

Attention, Pharmaceutical and Medical Device Executives: Ignorance Is Not Bliss



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The recent sentencings of a number of executives on so-called ''*Park* pleas'' serve as an important reminder that the Department of Justice, working with the Food and Drug Administration, holds managers, officers, and in-house counsel at drug and medical device companies to a high standard with respect to overseeing the safe manufacture and delivery of drugs and medical devices to consumers.

If the FDA and DOJ believe those executives have failed in their oversight and supervision obligations to the detriment of the public, not only does the company they work for face potential serious civil and criminal sanctions but the individual executives can be subject to criminal liability and debarment for simply being what the government deems a ''responsible corporate officer.''

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Gary Osborn and Apothécure

On October 3, the U.S. District Court for the Northern District of Texas sentenced Gary D. Osborn and his compounding pharmacy company Apothécure Inc. on two counts each of misbranding, to which both had pleaded guilty. Osborn was sentenced to one year of probation, which includes 90 days of home detention, and a $100,000 fine. The company was sentenced to five years of probation and a $100,000 fine.[1]

Osborn was charged criminally on the basis of the *Park* Doctrine, which is named after a 1975 U.S. Supreme Court decision that stands for the proposition that a ''responsible corporate officer'' may be found guilty of a misdemeanor crime under the Federal Food, Drug, and Cosmetic Act (FFDCA)—e.g., misbranding and adulteration—without any intentional wrongdoing.[2] According to the Supreme Court, neglect and inaction are sufficient because ''the Act 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.'' In so holding, the Supreme Court recognized that ''the requirements of foresight and vigilance imposed on re-

[1] *United States v. Osborn*, No. 3:12-cr-00047 (N.D. Tex.).
[2] *United States v. Park*, 421 U.S. 658 (1975).

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sponsible corporate agents are beyond question demanding, and perhaps onerous,'' but the court reasoned that ''they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them.'' This means that an executive can be convicted of a crime for conduct in which he was not directly involved and that he did not know was occurring.

Osborn's probation sentence was relatively light, but the basis in fact—or lack thereof—presented to the court in support of the prosecution is noteworthy.

One of the drugs Apothécure compounded is called colchicine, which can be injected intravenously for use in the treatment of back and neck pain related to gout. Compounding typically involves a pharmacist preparing a drug following the instructions of a licensed medical doctor. It is generally done when the drug is not available off the shelf with the desired strengths, ingredients, or dosage.

There is some debate about the FDA's authority over compounding pharmacies and whether many of those pharmacies actually are manufacturing drugs—topics worthy of their own discussions.

In any event, according to the government, three patients in 2007 who received colchicine from Apothécure died as a result of a colchicine overdose. An FDA investigation subsequently revealed that other vials from the same lot used for these patients were super-potent (~640 percent of the declared potency on the label). Nonetheless, the defendants in the criminal proceedings did not admit that their product caused the deaths.

Both Osborn and Apothécure were charged with two counts of misdemeanor misbranding on the theory that the drug label did not include correct dosage information. With respect to Osborn, the government's theory of liability was that he was guilty because he had the responsibility and authority to prevent the misbranding and failed to do so. Specifically, Osborn admitted that as the owner, registered agent, president, sole director, and pharmacist-in-charge of Apothécure, he was ''the person responsible for the procedures and equipment'' and ''for ensuring pharmacists and pharmacy technicians were properly trained and supervised in the compounding of drugs.''

Nowhere in the criminal information or agreed-upon facts presented to the court is there mention that Osborn was aware of any discrepancies with respect to the manufacture of the super-potent drug that allegedly killed the three patients. Nor is there mention that he was aware of specific issues related to inadequate procedures or deficient equipment in the intravenous lab (IV lab) generally. The worst allegation against Osborn is that, prior to the creation of the lots in question, ''Osborn was advised on at least one occasion by a pharmacist at Apothécure that the IV lab should be supervised by a pharmacist or biochemist. Osborn replied that he was personally supervising the workers in the IV lab.''

By contrast, even in *Park* itself, John Park, the president of the retail food chain at issue, was aware that the FDA had discovered rodent issues in earlier inspections of the company's warehouses. His delegation of sanitation issues to subordinates without acceptable oversight was enough to find him criminally liable for adulteration by continuing to store food in rat-infested warehouses.

Nonetheless, Osborn pleaded guilty to the two counts of misdemeanor misbranding.

Synthes Defendants

While Osborn's probation sentence was in line with the result of some prior *Park* Doctrine prosecutions, the prison sentences imposed on four former Synthes Inc. officers demonstrate how the FDA and DOJ are seeking to achieve specific deterrence and punishment by using the much easier to prove misdemeanor *Park* Doctrine prosecutions.[3]

The following sentences were handed out in November and December 2011 by the U.S. District Court for the Eastern District of Pennsylvania:

- Michael D. Huggins, former chief operating officer, was given nine months in prison;

- Thomas B. Higgins, former president of Synthes Spine and later senior vice president of global strategies reporting to Huggins, was sentenced to nine months in prison;

- Richard E. Bohne, former vice president of operations in charge of regulatory affairs, was sentenced to an eight-month term of imprisonment; and

- John J. Walsh, former director of regulatory affairs, received five months in prison.

All four executives pleaded guilty to one count of the strict liability misdemeanor offense of misbranding and adulteration related to Synthes's off-label promotion of a bone cement used in back surgery. The government alleged that from August 2003 through January 2004 Synthes engaged in a rogue clinical trial by training spine surgeons to use the bone cement to treat a type of spine fracture common in the elderly notwithstanding known patient risks and despite the fact that the FDA-approved label warned that the product was not intended for such surgeries. During the illegal ''test market,'' three elderly patients died on the operating table. Unlike the Apothécure case, the Synthes indictment was 58 pages long and alleged particularized knowledge and wrongdoing by each of the individual defendants.

Before pleading guilty, the individual defendants executed plea agreements with the government that included a written statement of the ultimate facts that the government would have proven with respect to the conduct of their employer, Synthes, had the case gone to trial. The executives conceded that they had a duty to prevent or stop crimes committed at Synthes by others at the company, including those whom they supervised, and that they failed to prevent or stop the illegal tests on humans. When it came time for sentencing, however, the government asked for the maximum sentence (12 months' imprisonment) in light of the egregious facts and alleged wrongdoing by the individual defendants. It presented 81 exhibits alleging facts that went well beyond the agreed-upon facts.

The government's strategy at sentencing, which it defended as wholly consistent with its representations during the plea negotiations, resulted in a slew of motions and a two-day evidentiary hearing. In the end, the

[3] *United States v. Norian Corp.*, No. 2:09-cr-00403 (E.D. Pa.).

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court denied most of the defendants' motions and objections and considered much of the government's evidence to provide the court with all relevant facts and circumstances concerning the offense conduct. The result was unprecedented prison sentences for misdemeanor *Park* Doctrine prosecutions.

Prior to the Synthes sentencings, the only other recent *Park* Doctrine prosecution that resulted in any jail time was the 2011 prosecution of Marc S. Hermelin, the former chief executive officer and chairman of St. Louis-based KV Pharmaceutical Co.[4] The information in that case alleged that KV Pharmaceuticals had a string of regulatory and criminal drug manufacturing problems under Hermelin's leadership, including entering into a civil consent decree with the FDA in 2009. The problems culminated in KV Pharmaceutical's manufacture and sale of oversized (and therefore misbranded) morphine tablets. KV Pharmaceutical received complaints about the size of some of its tablets and eventually investigated.

However, according to the charges, Hermelin ''instructed KV employees to minimize written communications about KV's oversized tablet manufacturing problems and the company's investigation of these issues, and limit distribution and discussion of any documents discussing these problems given the 'business risk' created by these written materials. Defendant wanted KV's Quality Assurance personnel to not be involved with the investigation of oversized tablets, state that the Quality Assurance employees should be out of the 'information flow,' and suggested his views on what the root cause finding of the investigation should be.''

Hermelin was sentenced to 19 days' imprisonment (which was later reduced to 17 days), one year of probation, and a $1 million fine.

It remains to be seen whether the Synthes and KV Pharmaceuticals prosecutions will represent a watershed with respect to sentences for *Park* Doctrine cases or anomalies based upon their particular facts.

It Gets Worse: Debarment

Not only do responsible corporate officers have to worry about criminal strict liability under the *Park* Doctrine, but they may also be excluded from federal and state health care programs on the basis of their convictions. The Department of Health and Human Services Office of Inspector General possesses the discretion to debar individuals who are convicted of misdemeanors involving fraud. This means that no company employing them will be eligible to receive reimbursement for services or drugs through programs such as Medicare and Medicaid. Exclusion is a death knell in the pharmaceutical and medical device world because companies rarely hire people on the excluded list due to the private sector's dependence on government funds.

In 2007, Purdue Frederick Co. and three of its top executives—Michael Friedman, president and chief operating officer, Howard Udell, executive vice president and chief legal officer, and Paul D. Goldenheim, former executive vice president of worldwide medical affairs—were charged with misbranding by promoting OxyContin as less addictive than other pain medications despite medical evidence to the contrary.[5] The company pleaded guilty to one count of felony misbranding. Each of the three executives pleaded guilty to one count of misdemeanor misbranding pursuant to the *Park* Doctrine. The court sentenced the executives to three years of probation and a $5,000 fine each, and they agreed to disgorge $34.5 million of their profits to the Virginia Medicaid Fraud Control Unit's Program Income Fund.

But after the criminal case was over, the HHS OIG exercised its discretion and excluded the three executives for 20 years. The executives appealed the exclusion all the way to the U.S. Court of Appeals for the District of Columbia Circuit. During the pendency of the first round of the appeal, the OIG reduced the exclusion to 15 years. Subsequently, the HHS Departmental Appeals Board upheld the exclusions but reduced them to 12 years. The D.C. Circuit in July upheld OIG's exclusion, but it remanded the case to HHS to reconsider the appropriate length of the exclusion.[6]

What *Friedman* means is that executives who plead guilty to misdemeanor *Park* Doctrine FFDCA crimes are at risk of being excluded from Medicare, Medicaid, and other federal health care programs if the conduct underlying that conviction is factually related to fraud. Accordingly, it was not surprising that the OIG exercised its authority to exclude all four Synthes executives effective October 18.

Conclusion

The Apothécure, Synthes, and Purdue prosecutions are examples of the FDA's recent commitment to increase the use of misdemeanor *Park* Doctrine prosecutions as a valuable enforcement tool.

Today, the FDA's official policy, consistent with the FFDCA, interprets the *Park* Doctrine to be a strict liability criminal offense. That means that ''a responsible corporate official can be held liable for a first time misdemeanor (and possible subsequent felony) under [the Act] without proof that the corporate official acted with intent or even negligence, and even if such corporate official did not have any actual knowledge of, or participation in, the specific offense.''[7] According to that policy, two of the factors the FDA is to consider when deciding whether to recommend a *Park* Doctrine prosecution is the corporate officer's knowledge of and actual participation in the violation, but neither is a prerequisite to a misdemeanor prosecution.

Despite this strict interpretation, prosecutors have traditionally shied away from applying the *Park* Doctrine except in cases like Synthes and Purdue where the government believes there is evidence of personal involvement, or at least gross negligence, by the corporate officers. The recent prosecution of Osborn, however, at least as presented publicly to the court, is an example of a strict liability *Park* Doctrine prosecution.

The recent jail sentences, long debarments, and hefty fines and disgorgements imposed on individuals who pleaded guilty to *Park* Doctrine misdemeanors demonstrate that the efforts of the FDA, HHS, and DOJ to

[4] *United States v. Hermelin*, No. 4:11-cr-00085 (E.D. Mo.).

[5] *United States v. Purdue Frederick Co.*, No. 1:07-cr-00029 (W.D. Va.).

[6] *Friedman v. Sebelius*, 686 F.3d 813 (D.C. Cir. 2012).

[7] FDA Regulatory Procedures Manual, Sec. 6-5-3—Special Procedures and Considerations for Park Doctrine Prosecutions.

achieve specific deterrence through the use of the *Park* Doctrine are gaining some teeth. Together with the tragic facts, the Apothécure, Synthes, and Purdue cases serve as an important reminder that pharmaceutical and medical device executives must take any safety-related issues seriously and make sure appropriate practices and procedures are in place. Delegation without appropriate oversight and follow-up may not be sufficient to avoid criminal liability if serious problems come to the attention of authorities.

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