The *Park* Criminal Liability Doctrine: Is it Dead or is it Awakening?

by John R. Fleder

The so-called *Park* doctrine, named after the United States Supreme Court decision in *United States v. Park*,[1] allows the government to seek a misdemeanor conviction against company officials for alleged violations of the Federal Food, Drug, and Cosmetic Act (FDCA)—even if a corporate official was unaware of the violation—if the official was in a position of authority to prevent or correct the violation and did not do so.

Despite extensive use of the *Park* doctrine in the 1960s and 1970s, intent to defraud or mislead felonies under the FDCA and other criminal offenses under Title 18 of the U.S. Code have almost totally supplanted the *Park* doctrine, leading many within the Food and Drug Administration (FDA)-regulated industries to ponder whether the doctrine is dead. Recent developments, however, may suggest its reemergence.

The Rise of the *Park* Doctrine

During the 1960s and the early 1970s, FDA recommended that the Department of Justice (DOJ) prosecute numerous misdemeanor cases under the FDCA pursuant to *United States v. Dotterweich*.[2] There, the Supreme Court held that the government could prosecute managers of corporations under the FDCA without any proof that the persons intended to violate the FDCA.

In 1975, the Supreme Court upheld the conviction of John Park on the theory that people who manage businesses that make and sell products regulated by FDA have an *affirmative duty* to ensure the safety of the products. The Court concluded that the government can criminally prosecute a corporate officer who is in a "responsible relationship" to some illegal activity by the company even though that officer did not personally engage in, or even know about, that activity.

In *Park*, Acme Markets, Inc. was a national retail food chain with approximately 36,000 employees, 874 retail outlets, and 16 warehouses.[3] The company's headquarters, including those of President John Park, were in Philadelphia.[4] The government charged Mr. Park and Acme with misdemeanors under the FDCA in Maryland.[5] Under the FDCA, any person who commits one of over two dozen enumerated prohibited acts is subject to prosecution for a criminal misdemeanor.[6] The government alleged that the company received foods that were shipped into interstate commerce and, while held in Acme's Baltimore warehouse, the food became accessible to rodents.[7] Acme pleaded guilty but Mr. Park went to trial and was convicted on all five counts, and fined $50 per count.[8]

Before the government filed the charges, FDA had advised Mr. Park of insanitary conditions in Acme's Philadelphia warehouse in 1970.[9] In November and December of 1971, FDA found similar conditions at the Baltimore facility and informed Mr. Park of those conditions in a letter dated January 27, 1972.[10] After Mr. Park received the 1972 letter he consulted with Acme's legal counsel, who told him that the person in charge of the Baltimore facility was investigating, and taking steps to remedy, the situation.[11] Mr. Park later testified that there was nothing further for him to do.[12] A second violative (but improved) inspection of the Baltimore facility occurred in March 1972.[13]

In affirming Mr. Park's convictions, the Court noted that criminal penalties under the food and drug laws, dating back to 1906, had been applied to persons by virtue of their managerial positions.[14] It was enough for a jury to simply find that, by virtue of the relationship the defendant bore to the corporation, he had the power to prevent the alleged unlawful act complained of.

The Court stated that food and drug laws punish neglect where the law requires care, or inaction where it imposes a duty.[15] The Court said that the law imposes a positive duty on executives and other persons to seek out and remedy violations when they occur, and also a duty to implement measures that will ensure that violations will not occur. The upshot of this doctrine is that the government believes that certain individu-

Mr. Fleder is a Principal in the law firm of Hyman, Phelps & McNamara, PC, in Washington DC.

als can be convicted of a federal crime of violating the FDCA, based on a person's position within a company.

The government's position does not preclude companies and individuals from presenting a myriad of well-recognized defenses in a *Park* case. Indeed, the Supreme Court acknowledged in that very case that a defendant cannot be convicted of even a misdemeanor in a situation where defendant's compliance was "impossible." A misdemeanor prosecution based on an alleged failure to comply with current good manufacturing practices (cGMPs) could well give rise to a defense that the defendant's conduct complied with the often vague and evolving FDA "standards" as to what compliance with cGMPs actually requires as a matter of law. Similarly, where FDA has failed to promulgate any binding regulation as to the meaning of a statutory term, or has issued conflicting guidance regarding the meaning of that term, a defendant could successfully challenge a prosecution on Due Process and other grounds.

Prior to leaving the government in 1993, this author spent over 19 years as a prosecutor for the DOJ within the Office of Consumer Litigation (OCL), the Office responsible for criminal matters under the FDCA. For the first eight or so years there, almost all of the criminal cases the government brought under the FDCA were *Park* "strict liability" cases. Most often, those cases included charges against food companies and their officials alleging that they had maintained insanitary facilities at their companies. Those cases were internally referred to as "dirty warehouse" cases. In addition, the DOJ brought some drug and device cases under the *Park* doctrine.

"305 Hearings"

In almost every instance during the height of employment of the *Park* doctrine, criminal prosecutions were preceded by a so-called "305 hearing." This refers to hearings held pursuant to 21 U.S.C. § 335, FDCA Section 305, whereby the target of a proposed FDA criminal case received an opportunity to argue to FDA why it and DOJ should not commence a criminal prosecution. Courts, however, have held that FDA is not obligated to hold 305 hearings.[16]

Those hearings have been exceedingly rare, if not nonexistent, over the past 15 years. Nevertheless many people both inside and outside the government believed that those hearings were useful because companies and their attorneys got a direct opportunity to argue to FDA why a criminal case should not be brought. Those hearings resulted in some criminal cases never being filed.

The Rise of Title 18 Offenses and Intent to Defraud or Mislead Felonies Under the FDCA

The frequent invocation of *Park* cases during the 1970s began to change in the early-to-mid-1980s. Largely because of staffing limitations at the Justice Department, a notable lack of interest in *Park* cases in many U.S. Attorneys' Offices, and the limited sanctions courts actually imposed in *Park* cases, FDA and DOJ began to focus more of their criminal resources on felony intent to defraud or mislead cases. Under this provision of the FDCA, the government can commence a criminal prosecution for a felony of individuals or companies who commit a prohibited act with the intent to defraud or mislead.[17]

In addition, part of this shift was the result of what prosecutors found were more interesting felony cases during the 1980s. They found those cases to be more challenging, much like solving a puzzle, in that they had to prove that the high-level officers of a company were intentionally involved in criminal conduct.

In contrast, the misdemeanor cases usually settled with a guilty plea. Nevertheless, DOJ attorneys had to prepare the case before charges were filed, on the assumption the case would not settle. Thus, attorneys found there was little reward in terms of professional development related to *Park* cases. Many young prosecutors wanted to devote their energies to the cases that might go to trial.

Furthermore, in the late 1980s and early 1990s, members of Congress started focusing more on FDA criminal enforcement. They pressured FDA and DOJ to bring criminal cases, usually when Congress believed that companies and their officials had intentionally violated the law. Congress seemed to have much less interest in the more traditional *Park* misdemeanor cases.

The government also increasingly targeted offenses arising under statutes codified within Title 18 of the U.S. Code. These "Title 18" offenses are some of the most familiar weapons within the prosecutorial arsenal. Judges understand these Title 18 statutes far better than they do the more technical FDCA. These statutes include criminal conspiracy, mail fraud, wire fraud, making a false statement to FDA and obstruction of justice.

Also, charging food and drug violators with one of these Title 18 offenses made it appear to the judge and the jury that the case was just a routine criminal case, involving a run-of-the-mill criminal defendant. In contrast, many of the charges filed under the FDCA sounded too technical, and may have appeared to be nothing more than a regulatory dispute between FDA and the defendants. Thus, it is no surprise that prosecutors increasingly made less and less use of the *Park* doctrine.

Penalties and Sentencing

The lower penalties and sentences associated with *Park* cases also may have played a role in decreased pursuit of *Park* cases. Misdemeanor cases often brought what prosecutors thought were mere slaps on the wrists to the persons prosecuted. During the prime of the *Park* doctrine, judges often levied fines of $30-$50 for those misdemeanor convictions.

Indeed, the possible maximum sentence that could be imposed in a misdemeanor case was quite limited. In 1984, however, Congress did increase the maximum fine amounts per count. Now, misdemeanor cases carry a year in prison and/or maximum fine of $100,000 per count for an individual (unless the crime results in death, in which case the maximum fine is $250,000) or $200,000 per count for an entity (raised to $500,000 if death occurs).[18] The fines can be increased to up to double the amount of the defendant's pecuniary gain or victims' pecuniary loss.

Pursuant to the Sentencing Reform Act of 1984, the U.S. Sentencing Commission created categories of offense behavior and offender characteristics with a goal of achieving consistent sentencing. For individuals, the Guidelines became effective in 1987. The Commission specifically adopted a Guideline (Section 2N2.1) for FDCA misdemeanor violations. Section 2F1.1 is the Guideline applicable to cases involving fraud and deceit, including FDCA intent to defraud or mislead cases.

Application of the fraud Guideline has usually resulted in the defendant serving a jail sentence, particularly in cases where large quantities of product were implicated in the fraud. However, courts' application of the regulatory 2N2.1 Guideline in misdemeanor cases typically resulted in a sentence that did not require the defendant to serve any time in prison.

In 2008, the U.S. Sentencing Commission adopted changes to the 2N2.1 Guideline that increased the likelihood that misdemeanor convictions will result in prison time. Those changes went into effect on November 1, 2008. Now, a sentencing court is to consider an upward departure in any case in which the offense created "a substantial risk of bodily injury or death." FDA reportedly has historically taken the position that any FDCA violation creates such a risk. Based on this alleged stance, one can reasonably assume that the government will routinely invoke the "substantial risk" upward departure in future misdemeanor cases.

The Sentencing Commission, however, declined to adopt additional FDA recommendations applicable to FDA crimes, including how "loss" is calculated.[19] Indeed, there was testimony before the Sentencing Commission that 2N2.1 need not be changed, and that the prior sentencing guidelines provided judges with ample ability to levy adequate sentences for misdemeanors if they chose to do so.[20]

Has There Been a Reemergence of the *Park* Doctrine?

In the past 15 years, there have been very few pure *Park* cases in which the government solely charged a misdemeanor against a company official on the ground that due to the official's position of responsibility within the company, the official should have prevented or corrected deficiencies. In fact, there appears to have been *no* recent *Park* cases. However, there have been some FDCA misdemeanor cases that fall within the following categories: the case was investigated for fraud and/or prosecuted for fraud, or a cooperating witness was allowed to plead guilty to a misdemeanor in exchange for testimony.

This apparent dearth of recent cases has led some industry experts to postulate that the *Park* doctrine is a paper tiger that is dead in all but name. Recent developments, however, suggest that the *Park* doctrine may see a resurgence.

For instance, in May 2007 the Purdue Frederick Company, Inc., pleaded guilty to felony charges for misbranding the painkiller OxyContin with the intent to defraud or mislead.[21] The government charged that Purdue Frederick falsely claimed that OxyContin was less addictive, less subject to abuse, and less likely to cause withdrawal symptoms than other pain medications.[22] Three current and former Purdue officials, however, pleaded guilty to misdemeanor charges as "responsible corporate executives" under *Park*. They were not charged with having an intent to defraud or mislead.

As previously discussed, recent changes to the U.S. Sentencing Guidelines increased the likelihood that a misdemeanor conviction could result in jail time. In addition, multiple recent food scares have created an environment of sensitivity to food safety. This returned emphasis on food safety may convince prosecutors to dust off the *Park* doctrine tool.

Food safety concerns also may motivate legislators to increase penalties for violations of the FDCA even in the absence of fraud allegations. On July 30, 2009, the House passed the "Food Safety Enhancement Act of 2009," which would substantially strengthen FDA's regulatory authority over foods.[23] The legislation, if enacted, would add to the FDCA new criminal penalties for anyone who "knowingly violates [specified prohibited acts] with respect to any food that is misbranded or adulterated," including a sentence of up to 10 years in prison.[24]

Regardless of whether the legislation is enacted, the inclusion of this provision in the House-passed bill demonstrates

heightened congressional interest in more stringent penalties for violations of the FDCA—even without any alleged fraud.

A recent plea resulting from tainted pet food could be seen as use of the *Park* doctrine. Sally Qing Miller, Stephen S. Miller and their company Chemnutra, Inc. each pleaded guilty in June 2009 to one count of selling adulterated food and one count of selling misbranded food.[25] The defendants shipped wheat gluten, tainted with melamine, which was incorporated into pet food. The government charged both the individuals and the company with the felony of conspiracy to commit wire fraud.[26] The remaining 26 counts of the indictment, however, were strict liability misdemeanors.

Another recent indictment, brought against a medical device company and its corporate officers, and a recent plea by some of those officers, also may indicate a return to the *Park* doctrine. The government indicted Synthes, Inc., its wholly-owned subsidiary Norian Corporation and four company executives for the off-label promotion of the bone filler Norian XR in spinal procedures known as vertebroplasty and kyphoplasty.[27] The defendants allegedly were involved in conducting clinical trials of a significant risk device without an approved Investigational Device Exemption, introducing into interstate commerce a device without FDA clearance or approval, and making false statements to government officials.

The government charged Norian with 52 felony counts, including making false statements in connection with an FDA inspection. The alleged false statements included statements made by Michael D. Huggins (President of Synthes North America), Richard E. Bohner (Vice President of Operations) and John J. Walsh (Director of Regulatory and Clinical Affairs, Spine Division).[28] The government charged parent company Synthes with 44 misdemeanor counts of shipping adulterated and misbranded Norian XR.

The government, however, charged Huggins, Bohner, Walsh and Thomas B. Higgins (Senior Vice President of Global Strategy of Synthes), with a single misdemeanor count of shipping adulterated and misbranded Norian XR into interstate commerce. Mr. Huggins and Mr. Walsh pleaded guilty to the misdemeanor count on July 20, 2009.[29] Huggins pleaded guilty "under the responsible corporate officer doctrine (RCO) doctrine recognized by the Supreme Court in *United States v. Park*, 421 U.S. 658 (1975)."[30] The media reports that the other two executives, Higgins and Bohner, are expected to plead guilty to the same charge.[31]

Conclusion

If the government resurrects the *Park* doctrine, it must be very careful to protect against potential abuse. Publicly-available FDA documents show that many companies inspected by FDA have at least one violation of the FDCA. This violation, with or without prior warning by FDA, subjects "responsible" individuals to the harsh possibility of a criminal prosecution. To a legitimate company and its employees, the collateral consequences of being charged with a criminal violation of the FDCA, let alone being convicted, can have devastating effects.

Thus, it will be up to the prosecutorial discretion of FDA and DOJ whether to bring such criminal charges. In an FDCA misdemeanor case, the government does not worry about intent, so there is precious little to dissuade a prosecutor who wants to forge ahead with a misdemeanor prosecution.

If the government resurrects the *Park* doctrine, FDA should consider revitalizing the practice of holding 305 hearings prior to asking DOJ to commence criminal prosecutions. In earlier times, those hearings served a valid purpose of providing the government with information it may not have known about concerning the facts of a case. That hearing might convince FDA to decide not to pursue an unmeritorious case. ⚠

Jamie K. Wolszon assisted in writing this article. Ms. Wolszon is an Associate with the law firm of Hyman, Phelps & McNamara, P.C., Washington, DC.

1 421 U.S. 658 (1975).
2 320 U.S. 277 (1943).
3 *Park*, 421 U.S. at 660.
4 *Id*. at 660.
5 *Id*.
6 21 U.S.C. § 333(a)(1).
7 *Park*, 421 U.S. at 660-661.
8 *Id*. at 660-661, 666.
9 *Id*. at 661.
10 *Id*. at 661-662.
11 *Id*. at 662-663.
12 *Id*. at 663-664.
13 *Id*. at 661-662.
14 *Id*. at 671.
15 *Id*. at 673-674.
16 *Kent v. Benson*, 945 F.2d 372 (11th Cir. (1991).
17 21 U.S.C. § 333(a)(2).
18 21 U.S.C. § 333(a)(1); 18 U.S.C.§ 3571.
19 Comment By FDA, submitted in Mar. 2008, *available at* http://www.ussc.gov/pubcom_20080328/PC20080328.htm.
20 U.S. Sentencing Commission Public Briefing Concerning FDCA Offenses (Feb. 13, 2008) (prepared remarks of John R. Fleder), *available at* http://www.fdalawblog.net/fda_law_blog_hyman_phelps/files/cleanedjrf_testimony.pdf.
21 DOJ Press Release, U.S. Attorney's Office for the Western District of Virginia (May 10, 2007), *available at* http://www.usdoj.gov/usao/vaw/press_releases/purdue_frederick_10may2007.html.

22 Johnson, Carrie, *Oxycontin Makers Admit Deception: Danger from Painkiller was Understated*, Wash. Post (May 11, 2007), *available at* http://www.washingtonpost.com/wp-dyn/content/article/2007/05/10/AR2007051000892.htm.

23 H.R. 2749, 111th Cong. (as passed by the House, July 30, 2009).

24 *Id*. § 134.

25 DOJ Press Release, U.S. Attorney's Office for the Western District of Missouri (June 16, 2009), *available at* http://www.usdoj.gov/usao/mow/news2009/miller.ple.htm.

26 Indictment, United States v. Sally Miller, et. al., (Feb. 6, 2008) (No. 08-CR-00023).

27 DOJ Press Release, U.S. Attorney's Office for the Eastern District of Pennsylvania (June 16, 2009), *available at* http://www.usdoj.gov/usao/pae/News/Pr/2009/jun/synthesrelease.pdf.

28 Indictment, United States v. Norian Corporation, et. al., (June 16, 2009) (No 09-CR-00403), available at http://www.usdoj.gov/usao/pae/News/Pr/2009/jun/synthesind.pdf.

29 Wood, Sam, *Synthes Execs Plead Guilty to Improper Testing*, Philadelphia Inquirer (July 21, 2009), *available at* http://www.philly.com/inquirer/local/pa/20090721_Synthes_execs_plead_guilty_to_improper_testing.html.

30 Plea Memorandum of Defendant Michael D. Huggins at 1, United States v. Norian Corporation, et. al., (July 17, 2009) (No 09-CR-00403).

31 Wood, Sam, *Synthes Execs Plead Guilty to Improper Testing*, Philadelphia Inquirer (July 21, 2009), *available at* http://www.philly.com/inquirer/local/pa/20090721_Synthes_execs_plead_guilty_to_improper _testing.html.

on the move

Matthew S. Fenster has joined the international law firm **Greenberg Traurig, LLP** in the New York City office as a shareholder in the Health Care Practice.

Fenster has wide-ranging experience representing health care organizations in federal and state investigations as well as in general commercial litigation, arbitration and mediation; cases involving complex fraud; and health care reimbursement disputes.

Porter Wright is pleased to announce that its Corporate Department has expanded to include four additional partners who offer clients practical, creative advice in the areas of estate planning/wealth preservation, corporate and business law, tax, health care and real estate. Marilyn J. Maag, Timothy B. Mitchell, T. Stephen Phillips, and Henry E. (Ned) Seibert are the newest members of the firm's well-established practice.

Ms. Maag has been certified by the Ohio State Bar Association as a Specialist in Estate Planning, Trust and Probate Law and is a member of the American College of Trusts and Estates Counsel.

Mr. Mitchell, a veteran health care attorney, advises industry stakeholders on issues ranging from organizational and operational matters to peer-review matters to fraud and abuse matters, among many other topics.

Mr. Phillips is also a member of the American College of Trusts and Estates Counsel and has taught Federal Estate and Gift Taxation and Estate Planning at Northern Kentucky University Chase College of Law.

Mr. Seibert works with private and entrepreneurial businesses in many industries, offering business law and tax advice and helping those companies with succession planning.

J. Carter Thompson, a shareholder at the Jackson, Miss., office of **Baker, Donelson, Bearman, Caldwell & Berkowitz PC**, has been chosen to head the firm-wide Product Liability and Mass Tort Group. He will oversee about 70 professionals in the firm's 15 offices, including Memphis. Thompson also serves as co-chair of the firm's Drug, Device & Life Sciences Team, which has more than 80 attorneys. Thompson practices in the national, regional and local defense of product liability, drug and medical device, professional liability and personal injury cases.

Dr. Michael Leek joins **The Weinberg Group** as Vice President with responsibility in our European operations. Based in the Edinburgh office, he brings a wealth of commercial expertise from the biotech sector – specializing in regenerative medicine and cell therapy for the last 18 years.