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# RESTRAINING PARK DOCTRINE PROSECUTIONS AGAINST CORPORATE OFFICIALS UNDER THE FDCA

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## Note from the Editor:

This paper analyzes the FDA's "Park Doctrine" for prosecutions against corporate officials under the Federal Food, Drug, and Cosmetic Act. As always, The Federalist Society takes no position on particular legal or public policy initiatives. Any expressions of opinion are those of the author. The Federalist Society seeks to foster further discussion and debate about the Park Doctrine. To this end, we offer links below to various sides of this issue and invite responses from our audience. To join the debate, you can e-mail us at [info@fed-soc.org](mailto:info@fed-soc.org).

## Related Links:

- Federal Food, Drug, and Cosmetic Act: <http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdact/default.htm>
  - Jose Sierra, *The Park Doctrine: All Bark and No Bite*, April 6, 2012: <http://pharmarisc.com/2012/04/the-park-doctrine-all-bark-and-no-bite/>
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### Introduction

The Park Doctrine (also known as the Responsible Corporate Officer Doctrine) has long occupied an obscure corner of American criminal law. It allows corporate officers to be charged with a crime for wrongdoing that occurred "on their watch," without any showing of personal fault or even knowledge on their part—other than a showing that they were "in charge" at the time the wrongdoing occurred. Such no-fault crimes are rare in American jurisprudence, but the U.S. Supreme Court has upheld such convictions under narrow circumstances.

Recently, the U.S. Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) have been pursuing Park Doctrine convictions with increased vigor against senior executives at pharmaceutical companies whose employees improperly promoted drug sales, then using those convictions to impose draconian penalties on the executives. This trend raises serious constitutional questions and concerns about the outer limits, if any, of Park Doctrine liability. A divided panel of the U.S. Court of Appeals for the District of Columbia Circuit recently upheld what may amount to a lifetime ban from the pharmaceutical industry for three senior executives after they pled guilty to misdemeanor Park Doctrine charges.<sup>1</sup> The appeals court upheld the exclusion without giving any meaningful consideration to the constitutional implications of imposing such severe penalties on those not proven to have any knowledge of wrongdoing.

Such consideration is long overdue. Although the Supreme Court has sanctioned criminal convictions in the absence of scienter in a narrow range of cases, it has done so with the understanding that such prosecutions are largely regulatory in

nature and that those convicted are subject to only relatively mild sanctions. A lifetime ban from one's profession is not normally considered a "relatively mild" sanction. If HHS and FDA persist with their current policy, either the courts or Congress should step in to impose meaningful due process limits on this troublesome trend.

### I. THE PARK DOCTRINE: A SHARP BREAK FROM THE COMMON LAW

The Park Doctrine draws its name from a 1975 Supreme Court decision: *United States v. Park*.<sup>2</sup> John Park was the president of a large national food chain that operated several warehouses that FDA determined to be infested with rodents. Park was convicted of a misdemeanor violation of the Federal Food, Drug, and Cosmetic Act (FDCA)<sup>3</sup> for having held for sale "adulterated" or "misbranded" food.<sup>4</sup> A federal appeals court overturned the conviction, finding that it was "predicated solely upon a showing that the defendant, Park, was the President of the offending corporation."<sup>5</sup> Concluding that as "a general proposition, some act of commission or omission is an essential element of every crime," the appeals court held that due process barred Park's conviction in the absence of a finding that he had engaged in some "wrongful action."<sup>6</sup>

The Supreme Court reinstated the conviction. The Court recognized that Park, as the president of a corporation with more than 36,000 employees nationwide, was unlikely to be in a position to directly supervise each employee and to ensure that all acted in compliance with the FDCA. The Court nonetheless determined that § 331 of the FDCA imposes on senior corporate executives an unwavering "duty to implement measures that will insure that violations will not occur."<sup>7</sup> The Court explained that imposition of this duty was justified by the strong "public interest in the purity of its food":

The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question

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demanding, and perhaps onerous, but 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.<sup>8</sup>

*Park* was the culmination of a 20th Century trend marked by a somewhat increased willingness among American courts to uphold imposition of criminal sanctions against individuals lacking any blameworthy *mens rea*. That trend represented a sharp departure from common law tradition. English common law unqualifiedly accepted the proposition that criminal punishment was unwarranted in the absence of a showing that the defendant harbored a blameworthy mental state.<sup>9</sup> That common law rule persisted throughout most of the 19th Century.<sup>10</sup>

The increased government regulation of the business community that accompanied the industrial revolution led many government officials to seek to use the criminal laws to enforce their regulations, and to conclude that *mens rea* requirements could interfere with enforcement efforts. As the Supreme Court explained in its 1952 *Morrisette* decision, the 19th Century witnessed:

[An] accelerating tendency, discernable both here and in England, to call into existence new duties and crimes which disregard any element of intent. The industrial revolution multiplied the number of workmen exposed to injury from increasingly powerful and complex mechanisms, driven by sources of energy, requiring higher precautions by employers. Traffic of velocities, volumes and varieties unheard of came to subject the wayfarer to intolerable casualty risks if owners and drivers were not to observe new cares and uniformities of conduct. Congestion of cities and crowding of quarters called for health and welfare regulations undreamed of in simpler times. Wide distribution of goods became an instrument of wide distribution of harm when those who dispersed food, drink, drugs, and even securities, did not comply with reasonable standards of quality, integrity, disclosure and care. Such dangers have engendered increasingly numerous and detailed regulations which heighten the duties of those in control of particular industries, trades, properties, or activities that affect public health, safety, or welfare.<sup>11</sup>

By the late 19th and early 20th Centuries, American courts began to accommodate those concerns by approving criminal prosecutions without proof of *mens rea* in a limited number of cases, which came to be known as “public welfare offenses.”<sup>12</sup> One characteristic repeatedly recognized by courts that distinguished public welfare offenses from other criminal offenses was the relatively light penalties imposed on offenses falling into the former category. Prosecutions for public welfare offenses were seen primarily as a means of encouraging compliance with government regulations, not as a means of punishing evil people.<sup>13</sup> Indeed, as the Supreme Court has recognized, “the small penalties attached to such offenses complemented the absence of a *mens rea* requirement: In a system that generally requires a ‘vicious will’ to establish a crime, . . . imposing severe punishments for offenses that require no *mens rea* would seem

incongruous.”<sup>14</sup> For example, John Park’s criminal sentence was very light: the trial judge imposed a \$50 fine for each of the five counts on which he was convicted.<sup>15</sup>

## II. CRIMINAL SANCTIONS IN THE ABSENCE OF MENS REA CONTINUE TO BE DISFAVORED

The U.S. Supreme Court has rejected arguments that imposition of criminal sanctions in the absence of *mens rea* violates a defendant’s due process rights in all instances.<sup>16</sup> Nonetheless, the Court has made clear that such prosecutions continue to be “disfavored” under the law.<sup>17</sup> *Morrisette* is but one of many instances in which the Court expressed its preference that criminal sanctions be reserved largely for those who intended an action prohibited by the law:

The contention that an injury can amount to a crime only when inflicted by intention is no provincial or transient notion. It is as universal and persistent in mature systems of law as belief in freedom of the human will and a consequent ability and duty of the normal individual to choose between good and evil. A relation between some mental element and punishment for a harmful act is almost as instinctive as the child’s familiar exculpatory ‘But I didn’t mean to.’<sup>18</sup>

That preference has led the Court categorically to reject prosecutors’ efforts to eliminate *mens rea* requirements with respect to crimes having their origin in the common law.<sup>19</sup> Moreover, with respect to statutory crimes not based on the common law (many of which are silent with respect to whether *mens rea* is an element of the crime), the Court has adopted a presumption that some level of *mens rea* is a necessary element, in the absence of evidence of a contrary congressional intent.<sup>20</sup> Thus, in a criminal case brought under the National Firearms Act for possession of a machine gun, the Court required prosecutors to demonstrate that the defendant knew that the gun he possessed had automatic firing capability;<sup>21</sup> in a criminal case brought under the Sherman Act, it required prosecutors to demonstrate that the defendants knew that their challenged practice (checking on each others’ prices on a daily basis) would restrain trade;<sup>22</sup> and in a criminal case brought under a statute prohibiting the theft of federal government property, it required prosecutors to demonstrate that the defendant knew that the government had not abandoned the property he took.<sup>23</sup> None of the federal statutes at issue in those cases included an explicit scienter requirement. The Court nonetheless interpreted each of the statutes as requiring prosecutors to prove intent—based largely on the disfavored status of criminal prosecutions in which criminal intent is not an element.

## III. THE PARK DOCTRINE: ONE STEP BEYOND RECOGNITION OF PUBLIC WELFARE OFFENSES

During the early 20th Century, federal and state courts generally upheld convictions for public welfare offenses (*i.e.*, prosecution in which no *mens rea* was established) only in those cases in which the defendant had some direct involvement with the offense. Thus, in 1910 the Massachusetts Supreme Judicial Court upheld the conviction of a driver for transporting a barrel of liquor into a city without a license, despite the absence

of evidence that he knew that the barrel contained liquor; but the court also made clear that the driver's supervisor could not be convicted of the crime if he was not aware that the barrel in question was being transported.<sup>24</sup> The Park Doctrine goes at least one step beyond traditional understandings of public welfare offenses by permitting criminal prosecution of supervisors for the acts of subordinates, even when the supervisor was unaware of those acts and even in the absence of a finding that the supervisor was negligent in failing to more closely supervise the subordinate.

The origins of the Park Doctrine are often traced to a 1943 Supreme Court decision, *United States v. Dotterweich*.<sup>25</sup> Like *Park*, *Dotterweich* was a prosecution for violations of § 331 of the FDCA. Joseph Dotterweich was the president and general manager of a "jobber"—a company that purchased pharmaceuticals from their manufacturer, repacked the drugs under its own label, and then distributed them for retail sales. Unbeknownst to Dotterweich, some of the drugs that his corporation purchased and later shipped were adulterated and misbranded. Dotterweich was convicted of having transported adulterated and misbranded drugs in interstate commerce, in violation of the FDCA. The statute at issue provided that "any person" who commits the offense was guilty of a misdemeanor.<sup>26</sup> A Second Circuit panel (which included Judge Learned Hand) overturned the conviction, holding that the term "any person" referred only to the corporation (or sole proprietor) who was sanctioned as the "drug dealer," not to individual employees of the corporation.<sup>27</sup> Its reading of the statute was based in large measure on its view that a literal reading of the statute—by sweeping within its purview all employees who played *any* role in the shipping process, regardless whether they were aware of the adulteration and misbranding at issue—would be patently unfair and thus could not have been what Congress intended.<sup>28</sup>

In a 5-4 decision, the U.S. Supreme Court reinstated the conviction, finding that the statutory term "any person" encompassed Dotterweich.<sup>29</sup> The Court saw no unfairness in subjecting senior-level employees like Dotterweich to criminal sanctions for public welfare offenses, viewing such prosecutions as "an effective means of regulation:"

The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as an effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger.<sup>30</sup>

In other words, Dotterweich was subject to criminal sanction based solely on his supervisory relationship to the corporation's actions, without regard to his awareness of wrongdoing and even without regard to whether his conduct could be deemed negligent.

The Court recognized the potential unfairness of the FDCA if it were construed to apply to "any person however remotely entangled in the proscribed shipment."<sup>31</sup> To avoid that unfairness, the Court construed the FDCA's "any person" language somewhat narrowly, deeming it to apply only to those

employees who stand in "responsible share to the furtherance of the [prohibited] transaction."<sup>32</sup>

Four justices dissented; they would have adopted the Second Circuit's limiting construction of the FDCA.<sup>33</sup> The dissenters saw significant due process concerns with the majority's approach:

It is a fundamental principle of Anglo-Saxon jurisprudence that guilt is personal and that it ought not lightly to be imputed to a citizen who, like the respondent has no evil intention or consciousness of wrongdoing. . . . Before we place the stigma of a criminal conviction upon any such citizen the legislative mandate must be clear and unambiguous.<sup>34</sup>

Thirty years later, *Park* expanded *Dotterweich*'s rationale. Although Joseph Dotterweich arguably had had a direct hand in shipping the adulterated and misbranded drugs (and instead had based his defense on a lack of awareness that the drugs were either adulterated or misbranded), John Park—as the President of a corporation with 36,000 employees—as several levels removed from decisions involving rodent infestation at two warehouses and the shipment of food from the warehouses. The Court indicated in *Park* that there is a sufficient basis to impose criminal liability on a responsible corporate officer if the officer "had the power to prevent the act complained of."<sup>35</sup> Company presidents can virtually always be held accountable under that standard; because they generally possess hiring and firing authority over all company employees, they always have the ability to prevent wrongdoing by an employee by firing him before the employee has an opportunity to act.

As these cases make clear, the Park Doctrine does not require the government to prove that the corporate officer's acts or omissions were either unreasonable or negligent. Indeed, three justices dissented in *Park* precisely because the majority refused to require a finding of negligence as a prerequisite to liability.<sup>36</sup> Not only does the Park Doctrine require no proof that the officer knew of the facts creating liability, it does not even require proof that a reasonable officer *should have* known of the existence of those facts. FDA's written guidelines indicate that FDA shares this understanding of the Park Doctrine's long reach: its guidelines provide that a corporate officer can be subjected to criminal sanctions under the Park Doctrine without proof that the officer "acted with intent or even negligence."<sup>37</sup>

In short, under the Park Doctrine, a senior corporate officer can be held criminally liable even though a jury could have found that the officer's acts or omissions were entirely reasonable. Because the commission of a criminal act by an employee necessarily means that the corporate officer failed to prevent the violation, he will have virtually no defense to a misdemeanor charge, regardless of the reasonableness or blameworthiness of his conduct or lack of awareness.<sup>38</sup> As some commentators have recently suggested, under the FDA's application of the Park Doctrine, "criminal liability requires the same proof of intent or knowledge—that is to say, none whatsoever—to convict corporate managers as tort law imposes on possessors of wild animals."<sup>39</sup>

#### IV. APPLICATION OF THE PARK DOCTRINE TO EXECUTIVES OF

PURDUE FREDERICK CO.

Federal officials have exhibited increased interest in recent years in pursuing Park Doctrine prosecutions against senior executives within the pharmaceutical industry. Most prominently, they have espoused a particularly broad application of the Park Doctrine in connection with their efforts to impose severe penalties against three former top executives of Purdue Frederick Co. A recent decision from the U.S. Court of Appeals for the District of Columbia Circuit largely endorsed those efforts, thereby opening the door to potentially troubling expansion of the Park Doctrine.

Purdue Frederick developed and originally marketed OxyContin, an opioid medication approved by FDA to treat moderate to severe pain over a 12-hour period. Because OxyContin is highly subject to abuse by addicts, it is classified as a Schedule II controlled substance by the Drug Enforcement Administration, and its label warns that it is subject to abuse.

Following a five-year investigation, federal prosecutors concluded in 2007 that certain unidentified Purdue employees, when promoting OxyContin to doctors, had deviated from the FDA-approved labeling by describing OxyContin as less addictive and less subject to abuse than other opioid medications. Under the FDCA, an FDA-approved drug is deemed “misbranded” if its manufacturer makes promotional statements about the drug that deviate from the drug’s FDA-approved labeling.<sup>40</sup> Based on the prosecutor’s findings, Purdue Frederick agreed in 2007 to plead guilty to felony misbranding charges.<sup>41</sup> As part of the plea deal, three senior executives of Purdue Frederick agreed to plead guilty to Park Doctrine misdemeanor offenses. Although both sides agreed that the executives themselves were unaware of the illegal promotional activity, the executives conceded that they were responsible corporate officers at the time that the activity took place.<sup>42</sup> Indeed, there would have been little point in contesting the charges, because their status as senior executives with hiring and firing authority during the relevant time period was not subject to serious question. The trial judge sentenced each of the executives to three years probation, 400 hours of community service, and fines of \$5,000.

HHS thereafter decided to impose additional and far more substantial punishment. Based solely on their misdemeanor pleas, HHS sought to exclude the three executives from federal health care programs for 20 years (later reduced to 12 years). Given their advanced ages, that punishment essentially amounted to a lifetime exclusion from the pharmaceutical industry.<sup>43</sup> The Social Security Act grants HHS discretionary authority to exclude individuals from federal health care programs if they have been convicted of misdemeanors “relating to fraud.”<sup>44</sup> Even though the three executives were never accused of fraud (nor of any bad acts, for that matter), HHS contended that they were excludable because their misdemeanors related to the fraudulent acts of others.

The executives sought judicial review of the exclusion, arguing that federal law did not permit exclusion on the basis of their misdemeanor pleas and that use of the Park Doctrine to exclude them for life from the pharmaceutical industry would violate their due process rights. In a July 2012 decision,

a divided D.C. Circuit rejected both claims.<sup>45</sup> The majority held that federal law permits exclusion when, as here, the misdemeanor conviction is “factually related” to fraud—even when, as here, the fraud at issue was undertaken by others and the excluded individuals were unaware of the fraud.<sup>46</sup> The majority brushed off the executives’ due process challenge in a single paragraph:

Finally, the Appellants and their amici argue, because the Secretary’s interpretation permits her to impose “career-ending disabilities” upon someone whose criminal conviction requires no *mens rea*, it raises a serious question of validity due under the Due Process Clause of the Fifth Amendment to the Constitution of the United States. Quoting *Morissette v. United States*, 342 U.S. 246, 256 (1952), they note that the Supreme Court upheld the constitutionality of strict liability crimes “in part, because their associated penalties ‘commonly are relatively small, and conviction does no grave damage to an offender’s reputation.’” Section 1320a-7(b)(1) [the “relating to fraud” exclusion provision], however, is not a criminal statute and, although exclusion may indeed have serious consequences, we do not think excluding an individual under 42 U.S.C. § 1320a-7(b) on the basis of his conviction for a strict liability offense raises any significant concern with due process. Exclusion effectively prohibits one from working for a government contractor or supplier. Surely the Government constitutionally may refuse to deal further with senior corporate executives who could have but failed to prevent a fraud against the Government on their watch.<sup>47</sup>

The D.C. Circuit’s rejection of the due process claims is highly problematic. The severity of the punishment being inflicted on the three Purdue Frederick executives does not lose its constitutional significance simply because it is being imposed pursuant to a civil statute. Exclusion is potentially permissible under § 1320a-7(b)(1) because the three executives pled guilty to a Park Doctrine misdemeanor and for no other reason. While HHS was entitled to convene a hearing for the purpose of determining whether the three executives were sufficiently trustworthy to continue to participate in federal health care programs (and to order their exclusion if they were deemed untrustworthy), it chose not to convene such a hearing. Instead, HHS chose to exclude the three executives based solely on their Park Doctrine pleas. Under those circumstances, the decision to exclude the executives from federal health care programs is most logically characterized as a criminal punishment.

Nor can one realistically argue that a 12-year, career-ending exclusion is not a severe punishment. Under those circumstances, the D.C. Circuit should have faced the issue of whether due process permits such severe punishments to be imposed on individuals for a Park Doctrine conviction that was based on nothing more than the defendants’ status as responsible officers of a corporation at which some employees (unbeknownst to the defendants) engaged in improper promotion of an FDA-approved drug. The Supreme Court has repeatedly stated that a major reason why due process permits criminal sanctions to be

imposed in the absence of *mens rea* for public welfare offenses is that such offenses generally entail very minor penalties.<sup>48</sup>

The three executives have sought rehearing *en banc* in the D.C. Circuit. In light of the serious due process concerns raised by the case, further appellate review is warranted.

The three executives are not alone in receiving severe punishment following misdemeanor convictions for Park Doctrine offenses. In 2009, three former executives of Synthes, Inc., an orthopedic medical device company, pled guilty to a single misdemeanor under the FDCA based on the company's shipment of misbranded and adulterated bone cement in interstate commerce.<sup>49</sup> The defendants pled guilty based solely on their status in the company, and expressly did not agree to a sentence in their plea agreement. Two defendants were eventually sentenced to nine months in prison and the third was sentenced to five months in prison. Each defendant was also ordered to pay \$100,000 in fines. FDA has argued that the harsh sentences were warranted because the Synthes executives had direct knowledge of the illegal activity at their company. If so, one can legitimately fault prosecutors for failing to charge the executives with those more severe offenses. Instead, they relied on an easy-to-prove Park Doctrine offense, then sought sentences far in excess of the mild sanctions that are a "cardinal principle of public welfare offenses."<sup>50</sup>

#### V. RECENT FDA PRONOUNCEMENTS

For years, strict-liability prosecutions were rare, but regulators are increasingly viewing the Park Doctrine as a powerful tool in the government's arsenal. Prosecution of the Purdue Frederick executives was not an anomaly. Park Doctrine prosecutions are on the rise, and the FDA has begun trumpeting a newfound enthusiasm for Park Doctrine prosecutions. On March 4, 2010, FDA Commissioner Margaret Hamburg wrote a letter to U.S. Senator Charles Grassley announcing the intention of FDA's Office of Criminal Investigations (OCI) to "increase the appropriate use of misdemeanor prosecutions . . . to hold responsible corporate officers accountable."<sup>51</sup> Commissioner Hamburg also revealed that specific criteria had been developed internally for misdemeanor prosecutions, which would result in revised policies and procedures on the appropriate use of criminal sanctions.

On April 22, 2010, Eric M. Blumberg, FDA's Deputy Chief Counsel for Litigation, gave a highly publicized speech at the Food and Drug Law Institute (FDLI) in which he warned corporate officials of impending misdemeanor prosecutions. Blumberg, one of the authors of the government's briefs in the *Park* case, reportedly told the gathering: "Very soon, and I have no one particular in mind, some corporate executive is going to be the first in a long line."<sup>52</sup> He echoed these sentiments just a few months later, on October 13, 2010. Speaking at the FDLI's "Enforcement and Litigation Conference," Blumberg said "Unless the government shows more resolve to criminally charge individuals at all levels in the company, we cannot expect to make progress in deterring off-label promotion."<sup>53</sup>

On May 27, 2010, Deborah Autor, Director of the Center for Drug Evaluation and Research's Office of Compliance, announced at a congressional hearing that the FDA was seeking

to increase criminal enforcement: "The agency is working to increase our enforcement on the criminal side and to connect carefully what we do on the criminal side with what we do on the civil side."<sup>54</sup> She also disclosed that a recent series of Tylenol recalls by non-prescription drug manufacturer McNeil Cosmetic Healthcare, a division of Johnson & Johnson, had been "referred to the FDA's crime division."<sup>55</sup>

In January 2011, following a protracted Freedom of Information Act (FOIA) litigation by the law firm Ropes & Gray, FDA released its long-awaited criteria for authorizing Park Doctrine prosecutions.<sup>56</sup> Unfortunately, these non-binding criteria provide little guidance to individuals who are potential targets of Park Doctrine liability. FDA insists that the criteria "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 evidenced."<sup>57</sup>

The seven listed criteria include:

- (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.

Because these criteria are identical to those considered in almost every decision to seek a criminal sanction, they are not especially helpful. As one commentator has remarked, "the criteria are not really criteria at all."<sup>58</sup>

On November 2, 2011, Assistant Attorney General Tony West underscored the Government's newfound commitment to prosecuting corporate officers under the Park Doctrine. Addressing the 12th Annual Pharmaceutical Regulatory and Compliance Conference, West emphasized that "demanding accountability means we will consider prosecutions against individuals, including misdemeanor prosecutions under the Park Doctrine, which provides that responsible corporate officers can, in appropriate circumstances, be held strictly liable for criminal violations of the Food, Drug, and Cosmetic Act."<sup>59</sup>

These announcements are both noteworthy and curious. They are noteworthy because they represent a clear desire on the part of FDA and the DOJ to use the Park Doctrine to increase the numbers of criminal convictions of corporate officers. They are curious, however, to the extent that they purport to be predictive of *future* criminal activity. Take, for example, Blumberg's assertion that "very soon," "some corporate executive is going to be the first in a long line." Ordinarily, a prosecutor is unable to say what crimes will be prosecuted in the future, because those crimes have not even occurred yet, much less been investigated. It is a unique attribute of the Park Doctrine that conduct that is perfectly legal in one year may, under the scrutiny of a zealous prosecutor, become illegal in the next year.

VI. PROBLEMS WITH CURRENT APPLICATION OF THE PARK DOCTRINE

FDA and DOJ are obviously seeking to test the boundaries of Park Doctrine liability through the creative use of their authority to exclude individuals from federal health care programs. This effort marks a crucial shift in the government's use of strict liability offenses. In many cases, especially those involving the off-label promotion of pharmaceuticals by outside sales representatives, it is virtually impossible for corporate officers to personally guarantee that each sales person is following the complex rules. As one federal judge has observed, "[t]he line . . . between a conviction based on corporate position alone and one based on a 'responsible relationship' to the violation is a fine one, and arguably no wider than a corporate bylaw."<sup>60</sup> Indeed, it is highly unlikely that a CEO or COO exists who cannot be convicted under the Park Doctrine, as there is little if anything within most companies' operation that is not, at least on paper, within their supervisory authority and responsibility. And because of the breadth of the FDCA's prohibitions, the very real danger exists that an FDCA misdemeanor, coupled with the harsh threat of exclusion, will be seen by federal prosecutors as a powerful leveraging tool to obtain convictions or extract pleas in vindications of suspicions that otherwise could never be proven.

Yet it is far from clear that either the Supreme Court or Congress ever intended that the Park Doctrine and the FDCA to be used in quite this way. Although the basis for allowing strict liability crimes has broadened over the years, two crucial considerations have remained: the size of the penalty and the impact on the individual's reputation.<sup>61</sup> The Supreme Court has justified the existence of strict liability crimes only in certain narrowly defined cases where the penalties are small and there is no grave damage to the defendant's reputation.<sup>62</sup> For example, in *Park*, the Court affirmed a \$250 fine; in *Dotterweich*, the Court affirmed a \$500 fine and 60 days probation.<sup>63</sup> The penalties imposed on the Purdue Frederick and Synthes executives cannot plausibly be described as small. Unlike the relatively modest penalties imposed in *Park* and *Dotterweich*, a lengthy exclusion from federal health care programs will not only ruin an executive's reputation, it will effectively end his or her career.

The Purdue Frederick case provides federal courts with an opportunity to rein in over-aggressive application of the Park Doctrine by federal officials. If neither the D.C. Circuit nor the Supreme Court agrees to further review, Congress ought to step in to make clear that it never intended to permit such severe criminal penalties to be imposed on individuals based solely on their status within a corporation. We should not so lightly abandon the centuries-old understanding that imposition of criminal sanctions in the absence of *mens rea* is highly disfavored under the law.

Endnotes

- 1 Friedman v. Sebelius, 686 F.3d 813 (D.C. Cir. 2012).
- 2 421 U.S. 658 (1975).
- 3 Pub. L. 75-717, 21 U.S.C. §§ 301 *et seq.*, Ch. 675 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-92).

- 4 21 U.S.C. § 331(k).
- 5 United States v. Park, 499 F.2d 839, 841 (4th Cir. 1974).
- 6 *Id.* at 841-42.
- 7 United States v. Park, 421 U.S. 658, 672 (1975).
- 8 *Id.* at 671-72.
- 9 See, e.g., 4 WILLIAM BLACKSTONE, COMMENTARIES ON THE LAW OF ENGLAND \*21 (1769) (to constitute any crime, there must first be a "vicious will").
- 10 Morissette v. United States, 342 U.S. 246, 251 (1952).
- 11 *Id.* at 253-54.
- 12 See Francis Sayre, *Public Welfare Offenses*, 33 COL. L. REV. 55 (1933).
- 13 U.S. v. Balint, 258 U.S. 250, 253-54 (1922).
- 14 Staples v. United States, 511 U.S. 600, 616-17 (1994) (quoting 4 WILLIAM BLACKSTONE, COMMENTARIES \*21).
- 15 United States v. Park, 421 U.S. 658, 666 (1975).
- 16 United States v. Balint, 258 U.S. 250, 252 (1922). *Balint* rejected the due process challenge of a defendant convicted of selling opium and cocaine without providing the required IRS forms (in violation of the Narcotic Act of 1914), despite the absence of a finding that the defendant knew that the substances being sold were opium and cocaine.
- 17 United States v. U.S. Gypsum Co., 438 U.S. 422, 438 (1978) ("While strict-liability offenses are not unknown to the criminal law and do not invariably offend constitutional requirements, . . . the limited circumstances in which Congress has created and this Court has recognized such offenses . . . attest to their generally disfavored status.") (internal citations omitted).
- 18 Morissette v. United States, 342 U.S. 246, 250-51 (1952).
- 19 *U.S. Gypsum*, 438 U.S. at 437.
- 20 Staples v. United States, 511 U.S. 600, 606 (1994).
- 21 *Id.* at 619.
- 22 *U.S. Gypsum*, 438 U.S. at 443-44.
- 23 *Morissette*, 342 U.S. at 273.
- 24 Commonwealth v. Mixer, 207 Mass. 141, 142-43 (1910).
- 25 320 U.S. 277 (1943).
- 26 21 U.S.C. § 333(a) (criminalizing violations of § 301(a) of the FDCA, 21 U.S.C. § 331(a)).
- 27 United States v. Buffalo Pharmacal Co., 131 F. 500, 503 (2d Cir. 1942).
- 28 *Id.*
- 29 *Dotterweich*, 320 U.S. at 277.
- 30 *Id.* at 280-81.
- 31 *Id.* at 284.
- 32 *Id.* The Court declined further elaboration regarding just which employees would meet the "responsible role" standard, although the Court clearly intended to limit that class of employees to those at a fairly senior level within the company. *Id.* at 285. The Court stated that "there was sufficient evidence to support [the jury's] verdict" that Dotterweich—as president and general manager—had a direct and responsible role in the specific drug shipment at issue. *Id.*
- 33 *Id.* at 285-93 (Murphy, J., dissenting).
- 34 *Id.* at 286.
- 35 United States v. Park, 421 U.S. 658, 671 (1975).
- 36 See *id.* at 683 (Stewart, J., dissenting) (refusing to join the majority because "a jury must find—and must be clearly instructed that it must find—evidence beyond a reasonable doubt that he engaged in wrongful conduct amounting at least to common-law negligence").
- 37 See FDA, INSPECTIONS, COMPLIANCE, ENFORCEMENT, AND CRIMINAL

INVESTIGATIONS: SPECIAL PROCEDURES AND CONSIDERATIONS FOR PARK DOCTRINE PROSECUTIONS § 6-5-3, available at [http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProcedures Manual/ucm176738.htm](http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm)

38 See *id.* (“When considering whether to recommend a misdemeanor prosecution against a corporate official, consider the individual’s position in the company and relationship to the violation, and whether the official had the authority to correct or prevent the violation.”).

39 Dahlia Rin, John P. Pucci, & Robert L. Ullmann, *The Misinterpretation of the Park Doctrine as Creating Strict Liability*, FDLI UPDATE, November/December 2011, at 9.

40 21 U.S.C. § 352.

41 See 21 U.S.C. § 333(b) (making it a felony to knowingly violate 21 U.S.C. § 331(a), which prohibits the introduction of misbranded drugs into interstate commerce).

42 The executives admitted to misdemeanor violations of 21 U.S.C. § 333(a), the same FDCA misbranding provision that Joseph Dotterweich was convicted of violating.

43 Because drug companies may not employ excluded individuals if they wish to participate in federal health care programs and because all drug companies obtain a substantial portion of their revenues from federal programs such as Medicare and Medicaid, an HHS exclusion renders an individual unemployable in the industry.

44 42 U.S.C. § 1320a-7(b)(1).

45 Friedman v. Sebelius, 686 F.3d 813 (D.C. Cir. 2012).

46 *Id.* at 824.

47 *Id.* at 823–24. Judge Williams dissented without reaching the constitutional issue. He concluded that HHS’s application of the fraud exclusion statute violated the Administrative Procedure Act because HHS had failed to articulate any standard by which one could measure whether the misdemeanor conviction was sufficiently related to fraud to warrant exclusion. *Id.* at 829–32. Although it upheld exclusion, the majority remanded the case to HHS for reconsideration of the 12-year exclusion period. Noting that HHS had never before excluded anyone under the fraud exclusion provision for more than four years, the majority directed HHS on remand to provide a reasoned explanation regarding why a far longer exclusion period was required in this case than in past cases. *Id.* at 826–28.

48 See, e.g., *Morissette v. United States*, 342 U.S. 246, 256 (1952); *Staples v. United States*, 511 U.S. 600, 616–17 (1994); see also *Hanousek v. United States*, 528 U.S. 1102, 1104 (2000) (Thomas, J., dissenting from denial of writ of certiorari) (“it is a ‘cardinal principle’ of public welfare offenses that the penalty not be severe”) (quoting Francis B. Sayre, *Public Welfare Offenses*, 33 COLUM. L. REV. 55, 72 (1933)). In *Park*, the Court affirmed a \$250 fine; in *Dotterweich*, the Court affirmed a \$500 fine and 60 days probation.

49 See *United States v. Norian Corp.*, No. 2:09 CR 403 (E.D. Pa. Nov. 2011).

50 *Hanousek v. United States*, 528 U.S. 1102, 1104 (2000) (Thomas, J., dissenting from denial of writ of certiorari)

51 Letter from Margaret Hamburg, Commissioner of Food and Drugs, to Sen. Charles E. Grassley, Ranking Member, Senate Committee on Finance (Mar. 4, 2010), available at <http://finance.senate.gov/press/Gpress/2010/prg030410b.pdf> (last visited Feb. 13, 2012).

52 Parija Kavilanz, *Recall Fallout: FDA Puts Execs On Notice*, CNN MONEY (Aug. 24, 2010) (quoting Eric M. Blumberg), available at [http://money.cnn.com/2010/08/23/news/companies/fda\\_recall\\_prosecutions/index.htm](http://money.cnn.com/2010/08/23/news/companies/fda_recall_prosecutions/index.htm) (last visited Feb. 16, 2012).

53 *Drug firms get warning over off-label marketing*, BLOOMBERG NEWS (Oct. 15, 2010), available at [http://www.nj.com/business/index.ssf/2010/10/drug\\_firms\\_get\\_warning\\_over\\_of.html](http://www.nj.com/business/index.ssf/2010/10/drug_firms_get_warning_over_of.html) (last visited May 15, 2012).

54 *Johnson & Johnson’s Recall of Children’s Tylenol and Other Children’s Medicines: Hearing Before the H. Comm. On Oversight and Gov’t Reform*, 11th Cong. (2010) (statement of Deborah Autor, Director of the Office of Compliance,

Center for Drug Evaluation and Research, FDA) available at <http://www.gpo.gov/fdsys/pkg/CHRG-111hrg63140/pdf/CHRG-111hrg63140.pdf>.

55 Julianne Pepitone, *Tylenol Recalls Referred to FDA Crime Division*, CNN MONEY (May 27, 2010), available at [http://money.cnn.com/2010/05/27/news/companies/tylenol\\_hearing/](http://money.cnn.com/2010/05/27/news/companies/tylenol_hearing/) (last visited Feb. 14, 2012).

56 FDA, INSPECTIONS, COMPLIANCE, ENFORCEMENT, AND CRIMINAL INVESTIGATIONS: SPECIAL PROCEDURES AND CONSIDERATIONS FOR PARK DOCTRINE PROSECUTIONS § 6-5-3, available at <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProcedures Manual/ucm176738.htm>.

57 *Id.*

58 Anne K. Walsh, *FDA Finally Releases “Non-Binding” Park Doctrine Criteria*, FDA LAW BLOG (Feb. 6, 2011), [http://www.fdalawblog.net/fda\\_law\\_blog\\_hyman\\_phelps/2011/02/fda-finally-releases-non-binding-park-Doc-trine-criteria.html](http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/02/fda-finally-releases-non-binding-park-Doc-trine-criteria.html).

59 Tony West, Assistant Attorney General, Address at the 12th Annual Pharmaceutical Regulatory and Compliance Congress (November 2, 2011), available at [www.justice.gov/iso/opa/civil/speeches/2011/civ-speech-111102.html](http://www.justice.gov/iso/opa/civil/speeches/2011/civ-speech-111102.html) (last visited Feb. 22, 2012).

60 *United States v. New Eng. Grocers Supply Co.*, 488 F. Supp. 230, 234 (D. Mass. 1980).

61 See *United States v. Freed*, 189 Fed. Appx. 888, 891–92 (11th Cir. 2006).

62 See *supra* note 15.

63 See *United States v. Park*, 421 U.S. 658, 666 (1975) (affirming a \$250 fine); *United States v. Dotterweich*, 320 U.S. 277, 277 (1943) (affirming a \$500 fine and 60 days probation).

