

# Responsible Corporate Officer Doctrine

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## Introduction

The Responsible Corporate Officer Doctrine, also known as the “Park Doctrine”,<sup>1</sup> is a 1943 theory of liability that allows the United States Department of Justice to charge high-ranking corporate executives with strict liability misdemeanors for criminal offenses without proof of “awareness of wrongdoing” (*mens rea*). In *Park* prosecutions, the Department of Justice may hold executives criminally responsible for violations of law committed by their company, even if the executives did not have knowledge of, or participate in, the violation.

Beginning in 2010, the Park Doctrine reemerged as a theory that prosecutors use, or threaten to use, in cases brought under the United States Food, Drug, and Cosmetic Act. Despite this upsurge, very few executives prosecuted under the Park Doctrine today actually lack total unawareness of the violation.

Instead, *Park* prosecutions, although strict liability in name, tend to be brought against executives who were involved in the violation in some manner. Furthermore, while jail time is available for executives charged with criminal misdemeanors under the Park Doctrine, very few executives receive more than probation and a monetary penalty.

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<sup>1</sup> *United States vs. Park*, 421 U.S. 658 (1975).

This chapter will first examine the principal cases giving rise to the Park Doctrine. Then it will look at the increased use of Park Doctrine prosecutions and the factors the government considers when deciding to charge an executive.

Next, the chapter will examine five recent and high-profile *Park* prosecutions. Lastly, the chapter will weigh the merits of implementing such strict liability prosecutions and argue that, despite government rhetoric, the government rarely prosecutes under a true strict liability theory.

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### Origins of Park Doctrine

*United States vs. Dotterweich*<sup>2</sup> was the first Supreme Court case in which the court held a corporate officer strictly liable for criminal misdemeanor offenses carried out by his business. Joseph Dotterweich was general manager and president of Buffalo Pharmaceutical Company (“Buffalo”), which purchased drugs from manufacturers, repackaged the drugs, and shipped them in interstate commerce.<sup>3</sup> Buffalo was charged with violating Section 301 of the Food, Drug, and Cosmetic Act, which prohibits “[t]he introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded”.<sup>4</sup> The jury convicted Dotterweich of three counts of shipping misbranded and adulterated drugs in interstate commerce.<sup>5</sup>

The court stated that prosecuting Dotterweich despite his lack of *mens rea* was appropriate because “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” as opposed to putting the burden on the “innocent public who are wholly helpless” in preventing the harm.<sup>6</sup> However, the court left open the meaning of “standing in reasonable relation to a public danger” and did not state which corporate actors would fall under that heading.

Thirty-two years after the *Dotterweich* decision, the court, in *United States vs. Park*, solidified the status of the Park Doctrine as a tool prosecutors may use to assign criminal liability to executives.<sup>7</sup>

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<sup>2</sup> *United States vs. Dotterweich*, 320 U.S. 277 (1943).

<sup>3</sup> *United States vs. Dotterweich*, 320 U.S. 277, at p. 278 (1943).

<sup>4</sup> 28 United States Code, Section 331(a) (2012).

<sup>5</sup> *United States vs. Dotterweich*, 320 U.S. 277, at p. 278 (1943).

<sup>6</sup> *United States vs. Dotterweich*, 320 U.S. 277, 280-81 (1943).

<sup>7</sup> *United States vs. Park*, 421 U.S. 658, at p. 678 (1975).

John Park was the President and chief executive officer of Acme Markets, Inc. (“Acme”), a national retail food chain based in Philadelphia.<sup>8</sup> The five-count criminal information alleged that Acme stored food that was shipped in interstate commerce in warehouses infested with rodents. Such conditions amounted to selling an adulterated product in violation of Section 301(k) of the Food, Drug, and Cosmetic Act.<sup>9</sup> The evidence at trial established that Park was aware the Federal Drug Administration had sent warning letters informing the company that its storage conditions violated Federal Drug Administration regulations and had conferred with legal counsel after receiving the letters.<sup>10</sup>

Furthermore, Park admitted at trial that, as chief executive officer, he was responsible for the “entire operation of the company”, which included ensuring sanitary storage conditions. Park testified that he delegated sanitary duties to “dependable subordinates” but that he was ultimately responsible for his company’s actions.<sup>11</sup> Park was found guilty on all five counts of the information, but the Fourth Circuit of Appeals reversed the conviction.<sup>12</sup>

The Supreme Court reversed the Fourth Circuit and affirmed Park’s guilt.<sup>13</sup> In the process, the Supreme Court affirmed the responsible corporate officer theory of liability of *Dotterweich*.

The court stated that the Food, Drug, and Cosmetic Act “imposes the highest standard of care and permits conviction of responsible corporate officials who, in light of this standard of care, have the power to prevent or correct violations of its provisions”.<sup>14</sup> Furthermore, the court made clear that the Food, Drug, and Cosmetic Act does not call for criminal liability turning on “awareness of some wrongdoing or conscious fraud”.<sup>15</sup>

Instead, an agent who “by virtue of . . . managerial position or other similar relation to the actor could be deemed responsible for its

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<sup>8</sup> *United States vs. Park*, 421 U.S. 658, at p. 660 (1975).

<sup>9</sup> *United States vs. Park*, 421 U.S. 658, at p. 660 (1975).

<sup>10</sup> *United States vs. Park*, 421 U.S. 658, at p. 664 (1975).

<sup>11</sup> *United States vs. Park*, 421 U.S. 658, at p. 664 (1975).

<sup>12</sup> The Fourth Circuit reversed Park’s conviction and remanded for a new trial based on the belief that “awareness of some wrongdoing” was necessary. *United States vs. Park*, 499 F.2d 839.

<sup>13</sup> *United States vs. Park*, 421 U.S. 658, at p. 666 (1975). The trial court initially found the defendant guilty and sentenced him to pay a fine of US \$50 on each count, resulting in a total criminal liability of US \$250, but no jail time.

<sup>14</sup> *United States vs. Park*, 421 U.S. 658, at p. 676 (1975).

<sup>15</sup> *United States vs. Park*, 421 U.S. 658, at pp. 672 and 673 (1975).

commission” can be held liable regardless of specific knowledge.<sup>16</sup> The court, thus, gave meaning to what standing in reasonable relation to a public danger can entail and cemented the use of *Park* prosecutions in Food, Drug, and Cosmetic Act cases.

However, the court limited the reach of strict liability in *Park* by stating that a defendant could raise an impossibility defense. The Park Doctrine calls for the highest standard of care, but it does not require “that which is objectively impossible”.<sup>17</sup> While the impossibility defense was not applicable in *Park*, the court made clear that a future defendant could argue that he was powerless to prevent or correct the company’s violation.<sup>18</sup>

Thus, despite the strict liability nature of the charge, a corporate officer can claim that he should not be held liable. Once a defendant establishes evidence of impossibility, the burden shifts to the government to rebut the defense with the government’s own evidence.<sup>19</sup>

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## Federal Drug Administration Increased Use of Park Doctrine

### Recent Publicity

While both *Dotterweich* and *Park* relied on the Park Doctrine theory of liability, the Department of Justice rarely employed the theory following the two seminal cases. Nevertheless, since early 2010, the Federal Drug Administration has hinted at its willingness to expand the use of misdemeanor prosecutions under the Park Doctrine.

In a March 2010 open letter to Senator Charles Grassley (R., Iowa), Federal Drug Administration Commissioner Margaret Hamburg listed ways the Federal Drug Administration could better comply with the

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<sup>16</sup> *United States vs. Park*, 421 U.S. 658, at p. 670 (1975).

<sup>17</sup> *United States vs. Park*, 421 U.S. 658, at p. 671 (1975).

<sup>18</sup> *United States vs. Park*, 421 U.S. 658, at p. 673 (1975).

<sup>19</sup> *United States vs. Park*, 421 U.S. 658, at p. 673 (1975); *United States vs. New England Grocers Supply Co.*, 488 F. Supp. 230 (D. Mass., 1980), (five corporate officers found not guilty of violating the Food, Drug, and Cosmetic Act, Section 301(k), due to the impossibility defense because they “exercised extraordinary care and still could not prevent violations of the Act.”); *United States vs. Y. Hata & Co., Ltd.*, 535 F.2d 508 (9th Cir., 1976) (not accepting the impossibility defense because the executives, despite attempting to implement a number of measures to keep the birds out of a warehouse, could have implemented a successful mechanism sooner).

Government Accountability Office's recommendations for increased oversight of the Federal Drug Administration's Office of Criminal Investigations.<sup>20</sup>

Hamburg stated that the Federal Drug Administration adopted the Government Accountability Office's recommendation to "increase the appropriate use of misdemeanor prosecutions . . . to hold responsible corporate officers accountable".<sup>21</sup> Hamburg further stated that the Federal Drug Administration established selection criteria for the misdemeanor prosecutions, but did not delineate the criteria in her letter.<sup>22</sup>

In October 2010, at the Food and Drug Law Institute's Enforcement Conference in Washington, D.C., the Federal Drug Administration Deputy Chief for Litigation, Eric Blumberg, reiterated Commissioner Hamburg's statement on the likely increased use of Park Doctrine prosecutions.<sup>23</sup>

Referring specifically to Pfizer's US \$2.3-billion settlement for unauthorized marketing of a recalled drug, Blumberg stated that "[i]t's clear we're not getting the job done with large, monetary settlements. 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>24</sup> When asked later about his remarks, Blumberg said that he was speaking personally, not on behalf of the Federal Drug Administration.<sup>25</sup>

Additionally, beginning on 2 April 2013, the Federal Drug Administration sent out five warning letters to five different dietary supplement

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20 Letter from Margaret Hamburg, Federal Drug Administration Commissioner, to Senator Charles Grassley (4 March 2010), at p. 2.

21 Letter from Margaret Hamburg, Federal Drug Administration Commissioner, to Senator Charles Grassley (4 March 2010), at p. 2.

22 Letter from Margaret Hamburg, Federal Drug Administration Commissioner, to Senator Charles Grassley (4 March 2010), at p. 2.

23 Edney, "Drugmaker CEOs May Be Targets for U.S. Federal Drug Administration in Off-Label Cases, Lawyer Says", *Bloomberg News* (14 October 2010), see <http://www.bloomberg.com/news/2010-10-14/drugmaker-executives-may-become-targets-of-fda-for-off-label-promotions.html>.

24 Edney, "Drugmaker CEOs May Be Targets for U.S. Federal Drug Administration in Off-Label Cases, Lawyer Says", *Bloomberg News* (14 October 2010), see <http://www.bloomberg.com/news/2010-10-14/drugmaker-executives-may-become-targets-of-fda-for-off-label-promotions.html>.

25 Edney, "Drugmaker CEOs May Be Targets for U.S. Federal Drug Administration in Off-Label Cases, Lawyer Says", *Bloomberg News* (14 October 2010), see <http://www.bloomberg.com/news/2010-10-14/drugmaker-executives-may-become-targets-of-fda-for-off-label-promotions.html>.

distributors, expressly mentioning the Park Doctrine.<sup>26</sup> Three of the letters were from the Federal Drug Administration's Florida District Office, one letter was from the Cincinnati District Office, and the last letter was from the Philadelphia District Office.

The letters warned the distributors they were in violation of the Food, Drug, and Cosmetic Act and the Current Good Manufacturing Practices for failure to implement and comply with quality controls. All five of the companies contracted with other firms to manufacture their drugs. However, the manufacturers did not document quality control operations or package and label the drug as specified in the master record. The Federal Drug Administration wrote that, while the companies may contract out manufacturing operations for the drug, they cannot contract out ultimate responsibility for the drug. In making this point, all five letters cited *Dotterweich* and *Park* and included the following parenthetical:

“Criminal liability under the [Food, Drug, and Cosmetic Act] does not turn on awareness of wrongdoing, and that ‘agents vested with the responsibility, and power commensurate with that responsibility’ . . . can be held accountable for violations of the [Act].”<sup>27</sup>

Notwithstanding minor deviations, the five letters used the same language throughout, showing the Federal Drug Administration's resolve to use strict liability. This appears to be the first time the Federal Drug Administration has referenced the Park Doctrine expressly in a warning letter and marks a potential shift in Federal Drug Administration enforcement methods.

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<sup>26</sup> Federal Drug Administration Warning Letter to Natures Health Options LLC (2 April 2013), see <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm351946.htm>; Federal Drug Administration Warning Letter to Body Sys. Inc. (8 April 2013), see <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm351883.htm>; Federal Drug Administration Warning Letter to Glucorell, Inc. (24 April 2013), see <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm352011.htm>; Federal Drug Administration Warning Letter to Pristine Bay LLC (26 April 2013), see <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm350469.htm>; Federal Drug Administration Warning Letter to Entrenet Nutritionals, Inc. (8 May 2013), see <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm351662.htm>.

<sup>27</sup> Federal Drug Administration Warning Letter to Natures Health Options, at p. 2.

### **Park Doctrine Prosecution Factors**

A year after Commissioner Hamburg's letter to Senator Grassley, the Federal Drug Administration published a 2011 Regulatory Procedures Manual (the "Manual") that includes a Section devoted to criteria for recommending Park Doctrine prosecutions.<sup>28</sup>

The Manual states that Federal Drug Administration district offices should forward all potential Park Doctrine prosecutions to the Office of Criminal Investigations. The Office of Criminal Investigations will then consult with the Federal Drug Administration Office of Chief Counsel to decide whether to recommend the case to the Department of Justice for criminal prosecution.<sup>29</sup> According to the Manual, Park Doctrine prosecutions can have a "strong deterrent effect on defendants and other regulated entities".<sup>30</sup>

The Manual also states that the Federal Drug Administration agrees with the Supreme Court that it would be "futile to attempt to define or indicate by way of illustration" the categories of individuals who "bear a responsible relationship to a violation" and, thus, are liable under the Park Doctrine.<sup>31</sup> Instead, the Federal Drug Administration set out non-binding guidelines to consider when recommending a Park Doctrine prosecution.

The Manual states that Office of Criminal Investigations should "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".<sup>32</sup> The Manual adds that "knowledge of and actual participation in the violation are not prerequisites" to prosecution, but are factors that may be relevant in deciding whether to recommend a case to the Department of Justice.<sup>33</sup> The Manual also makes clear that an individual's negligence is not a prerequisite to prosecuting under the Park Doctrine.<sup>34</sup>

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<sup>28</sup> Federal Drug Administration Regulatory Procedures Manual, Section 6-5-3, "Special Procedures and Considerations for Park Doctrine Prosecutions" (revised 26 January 2011), see <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm>.

<sup>29</sup> Federal Drug Administration Regulatory Procedures Manual, Section 6-5-3.

<sup>30</sup> Federal Drug Administration Regulatory Procedures Manual, Section 6-5-3.

<sup>31</sup> Federal Drug Administration Regulatory Procedures Manual, Section 6-5-3.

<sup>32</sup> Federal Drug Administration Regulatory Procedures Manual, Section 6-5-3.

<sup>33</sup> Federal Drug Administration Regulatory Procedures Manual, Section 6-5-3.

<sup>34</sup> Federal Drug Administration Regulatory Procedures Manual, Section 6-5-3.

In addition to the guidelines, the Manual lays out seven factors to consider when deciding whether to prosecute under the Park Doctrine. The factors are intended to be solely for guidance, and include, but are not limited to, whether:

- (1) The violation involves actual or potential harm to the public;
- (2) The violation is obvious;
- (3) The violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;
- (4) The violation is widespread;
- (5) The violation is serious;
- (6) The quality of the legal and factual support for the proposed prosecution is sufficient; and
- (7) The proposed prosecution is a prudent use of agency resources.<sup>35</sup>

### **Health and Human Services Exclusion Factors**

In addition to the threat of a criminal misdemeanor conviction, another increasingly common threat in Food, Drug, and Cosmetic Act violation cases is the exclusion of an individual from participation in federally funded healthcare programs, such as Medicare and Medicaid. The Health and Human Services Office of Inspector General has discretion to exclude an individual or entity from federal healthcare programs in fifteen situations.<sup>36</sup> Most commonly applied in conjunction with Park Doctrine prosecutions, the Office of Inspector General may exclude an individual if he has a controlling interest in a sanctioned entity and knew or should have known of the conduct relating to the sanction.<sup>37</sup> An individual also may be excluded based solely on his position as an officer or manager in a sanctioned entity, regardless of his knowledge of the conduct underlying the sanction.<sup>38</sup>

Lastly, the Office of Inspector General may exclude an individual if he has been convicted of a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.<sup>39</sup> The latter category includes strict liability misdemeanor convictions under the Park Doctrine.

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<sup>35</sup> Federal Drug Administration Regulatory Procedures Manual, Section 6-5-3.

<sup>36</sup> 42 United States Code, Section 1320a-7(b)(1)–(15).

<sup>37</sup> 42 United States Code, Section 1320a-7(b)(15)(A)(i).

<sup>38</sup> 42 United States Code, Section 1320a-7(b)(15)(A)(ii).

<sup>39</sup> 42 United States Code, Section 1320a-7(b)(1).

In October 2010, the Office of Inspector General issued a list of non-binding factors it will consider when determining whether to exercise its permissive exclusionary authority.<sup>40</sup>

In deciding whom to exclude from the federal healthcare programs, the Office of the Inspector General will “consider the basis for the criminal conviction and/or exclusion of the entity, as well as other conduct that formed the basis for the criminal, civil, or administrative investigations, cases, charges, or resolutions”.<sup>41</sup>

Additionally, the Office of Inspector General will consider four other non-binding factors:

- (1) Circumstances of the misconduct and seriousness of the offense;
- (2) Individual’s role in the sanctioned entity;
- (3) Individual’s actions in response to the misconduct; and
- (4) Additional information about the entity such as prior convictions, size, revenues, and subsidiaries.<sup>42</sup>

On 2 March 2011, just five months after the Office of Inspector General issued the above guidelines, the Health and Human Services Chief Counsel, Lewis Morris, testified before the House Committee on Ways and Means, Subcommittee on Oversight. He stated that Health and Human Services “intend[s] to use this essential [exclusionary power] fraud-fighting tool in a broader range of circumstances”, a reference to the exclusion of an officer or manager of a sanctioned entity without a showing of individual knowledge or negligence. Paired with the Federal Drug Administration’s previous comments directed at the increased use of Park Doctrine prosecutions, there appeared to be a trend turning in favor of holding corporate officers strictly liable.

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## Recent Park Doctrine Prosecution Cases

### In General

Notwithstanding the Federal Drug Administration and Health and Human Services statements on their commitment to the increased use

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<sup>40</sup> Press Release, Office of the Inspector General for the Department of Health and Human Services, Guidance for Implementing Permissive Exclusion Authority under Section 1128(b)(15) of the Social Security Act (19 October 2010), see [http://oig.hhs.gov/fraud/exclusions/files/permissive\\_exc\\_under\\_1128b15\\_10192010.pdf](http://oig.hhs.gov/fraud/exclusions/files/permissive_exc_under_1128b15_10192010.pdf).

<sup>41</sup> Guidance for Implementing Permissive Exclusion Authority under Section 1128(b)(15), at pp. 2 and 3.

<sup>42</sup> Guidance for Implementing Permissive Exclusion Authority under Section 1128(b)(15), at pp. 2–4.

of Park Doctrine prosecutions, the following cases demonstrate that the strict liability theory is utilized more frequently in name than it is in practice.

Out of the following five cases, which represent noteworthy *Park* prosecutions since Commissioner Hamburg wrote of increasing the doctrine's use, only two cases do not specifically mention executive knowledge of the violation. The remaining cases all state that the Department of Justice is holding the officers strictly liable, but then point to overwhelming evidence that the executives had extensive knowledge of the violations.

### **Purdue Frederick Company Executives**

In May 2007, the Purdue Frederick Company, Inc. ("Purdue") pled guilty to a felony charge of misbranding OxyContin with the intent to defraud or mislead under the Food, Drug, and Cosmetic Act, Section 331(a).<sup>43</sup> The Information charged Purdue employees with falsely marketing OxyContin to health care providers as less addictive, less susceptible to intravenous abuse, and less likely to cause withdrawal symptoms than other pain medications.<sup>44</sup> The District Court in the Western District of Virginia accepted the defendant's plea agreement, which included five years' probation and a combined US \$600-million civil and criminal penalty, one of the largest pharmaceutical penalties to date.<sup>45</sup>

In addition to charging Purdue, the federal government brought criminal misdemeanor charges against Purdue's top three executives.<sup>46</sup> The government's Park Doctrine prosecution of these three executives represents one of the very few truly strict liability prosecutions. Significantly, the executives were charged solely as responsible corporate officers and were not charged with personal knowledge of the misbranding or intent to defraud.<sup>47</sup> The indictment did not allege

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<sup>43</sup> *United States vs. Purdue Frederick Co., Inc.*, 2007 W.L. 1423897 (W.D. Va., 10 May 2007).

<sup>44</sup> *United States vs. Purdue Frederick Co., Inc.*, 495 F. Supp. 2d 569, at p. 570 (W.D. Va., 2007).

<sup>45</sup> *United States vs. Purdue Frederick Co., Inc.*, 495 F. Supp. 2d 569, at p. 570 (W.D. Va., 2007).

<sup>46</sup> *United States vs. Purdue Frederick Co., Inc.*, 495 F. Supp. 2d 569, at p. 570 (W.D. Va., 2007).

<sup>47</sup> *United States vs. Purdue Frederick Co., Inc.*, 495 F. Supp. 2d 569, at p. 570 (W.D. Va., 2007).

the executives participated in the fraud in anyway, except in their general capacity as executives.

All three executives pled guilty to the misdemeanor charge of misbranding.<sup>48</sup> Although the executives could have faced up to twelve months' imprisonment and a fine of up to US \$100,000, they agreed to pay US \$34.5-million to the Virginia Medicaid Fraud Unit's Program Income Fund and an additional US \$5,000 criminal penalty per individual in exchange for avoiding imprisonment.<sup>49</sup> The government believed that strict liability convictions, even without prison sentences, would "send a strong deterrent message to the pharmaceutical industry".<sup>50</sup> The district court accepted the plea agreement considering "that in the absence of government proof of knowledge by the individual defendants of the wrongdoing, prison sentences are not appropriate".<sup>51</sup>

Based on the executives' criminal misdemeanor convictions, the Office of Inspector General subsequently excluded the executives from participation in federal health care programs for twenty years. The Office of Inspector General based the twenty-year exclusion on three aggravating factors listed in published regulations:

- (1) The underlying conduct lasted more than one year;
- (2) There was a financial loss to the government of more than US \$5,000; and
- (3) There was a significant adverse physical or mental impact upon program beneficiaries.<sup>52</sup>

The executives appealed their exclusion to the Health and Human Services Departmental Appeals Board.<sup>53</sup> During the appeals process, the Office of Inspector General reduced the length of exclusion from twenty years to fifteen years and then to twelve years, based on the fact that there was no substantial evidence showing that the "crimes

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<sup>48</sup> *United States vs. Udell*, 2007 W.L. 5830163 (W.D. Va., 10 May 2007); *United States vs. Friedman*, 2007 W.L. 5830162 (W.D. Va., 10 May 2007); *United States vs. Goldenheim*, 2007 W.L. 5830164 (W.D. Va., 10 May 2007).

<sup>49</sup> *United States vs. Purdue Frederick Co., Inc.*, 495 F. Supp. 2d 569, at p. 573 (W.D. Va., 2007); Department of Justice Press Release, John Brownlee, The Purdue Frederick Co. Inc., and Top Executives Plead Guilty to Misbranding OxyContin (10 May 2007).

<sup>50</sup> *United States vs. Purdue Frederick Co., Inc.*, 495 F. Supp. 2d 569, at p. 576 (W.D. Va., 2007) (as paraphrased by the judge in his order accepting the plea agreement).

<sup>51</sup> *United States vs. Purdue Frederick Co., Inc.*, 495 F. Supp. 2d 569, at p. 576 (W.D. Va., 2007).

<sup>52</sup> 42 Code of Federal Regulations, Section 1001.201(b)(2)(i)–(iii).

<sup>53</sup> *Friedman vs. Sebelius*, 686 F.3d 813, at p. 817 (D.C.C., 2012).

had an adverse impact on program beneficiaries”.<sup>54</sup> The executives sought review of their exclusion in the District Court for the District of Columbia, which upheld the twelve-year exclusion. They appealed that decision to the U.S. Court of Appeals for the District of Columbia.<sup>55</sup>

In their appeal, the executives argued that a misdemeanor misbranding conviction does not amount to a “misdemeanor relating to fraud” under 42 United States Code, Section 1320a-7(b)(1), the statute granting the Office of Inspector General the permissive authority to exclude an individual. Alternately, the executives argued that, even if exclusion was warranted, the twelve-year sentence was “arbitrary and capricious”.<sup>56</sup> The court disagreed, holding that a misdemeanor relating to fraud does encompass a misbranding conviction even under the Park Doctrine. The court further held that the strict liability nature of the offense did not give rise to due process concerns.<sup>57</sup>

With respect to the length of exclusion, the court remanded the case to the district court with instructions to remand the case to the Office of Inspector General because the court found that the Office of Inspector General had failed to justify the length of the exclusion.<sup>58</sup> The court noted, however, that it was “not suggest[ing] the Appellant’s exclusion for twelve years based upon a conviction for misdemeanor misbranding might not be justifiable”, but instead that the Departmental Appeals Board did not provide the necessary justification.<sup>59</sup> As of February 2015, the Office of Inspector General had not yet published a public opinion on the appropriate length of the exclusion for the executives. However, the executives remain listed as excluded on the Office of Inspector General Exclusions Database.<sup>60</sup>

### **Chemnutra Executives**

In another early resurgence of the Park Doctrine, this time with strong evidence that the executives possessed knowledge of the violation, the government indicted President Sally Miller and chief executive officer Stephen Miller, as well as their company, Chemnutra, for

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<sup>54</sup> *Friedman vs. Sebelius*, 686 F.3d 813, at p. 817 (D.C.C., 2012).

<sup>55</sup> *Friedman vs. Sebelius*, 686 F.3d 813, at p. 817 (D.C.C., 2012).

<sup>56</sup> *Friedman vs. Sebelius*, 686 F.3d 813, at p. 818 (D.C.C., 2012).

<sup>57</sup> *Friedman vs. Sebelius*, 686 F.3d 813, at pp. 823–824 (D.C.C., 2012).

<sup>58</sup> *Friedman vs. Sebelius*, 686 F.3d 826, at p. 817 (D.C.C., 2012) (stating that the Secretary has never excluded anyone for more than ten years before this case).

<sup>59</sup> *Friedman vs. Sebelius*, 686 F.3d 813, at p. 828 (D.C.C., 2012).

<sup>60</sup> Office of Inspector General Exclusions Database, see <https://exclusions.oig.hhs.gov/Default.aspx>.

illegally distributing tainted ingredients used to make pet food. In February 2008, the defendants were charged in a twenty-seven-count indictment under the Food, Drug, and Cosmetic Act for misdemeanor violations of introducing misbranded food into interstate commerce and introducing adulterated food into interstate commerce, as well as a felony charge of conspiracy to commit wire fraud.<sup>61</sup>

The defendants were in the business of importing Chinese wheat gluten and selling it to United States pet food manufacturers. Wheat gluten is required to have a minimum protein content of seventy-five per cent in order to be sold in the United States. The defendants allegedly purchased wheat gluten from a Chinese producer who illegally added melamine, a toxic chemical, to the wheat.

Melamine is inexpensive, and when added to wheat gluten, creates the appearance that the wheat meets the seventy-five per cent protein requirement. According to the government, the defendants sold more than 800 metric tons of the tainted wheat to pet food manufacturers in a three-month period, totaling profits of almost US \$850,000.<sup>62</sup> As a result, millions of pets fell seriously ill or died.<sup>63</sup>

The government first claimed that the defendants knew the wheat gluten had been tainted and conspired to ship the wheat under a shipping code that would shield the product from mandatory Chinese inspection.<sup>64</sup> However, the government dismissed all but two charges, and both the individual defendants and the defendant corporation eventually pled guilty to strict liability misdemeanor charges of distributing misbranded and adulterated food.

Although the government did not explicitly use the phrase “responsible corporate officer” or “Park Doctrine” in its press releases, the defendants were never charged with having knowledge of or an intent to commit the violation. Instead, they were held liable due to their positions as president and chief executive officer of Chemnutra. The defendants could have faced up to two years in prison and a fine of US \$200,000, but instead each individual was fined US \$5,000 and sentenced to three years’ probation.<sup>65</sup>

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<sup>61</sup> *United States vs. Miller*, Number 08-0023-01-CR-W-DW (W.D. Mo., 6 February 2008).

<sup>62</sup> Department of Justice Press Release, Matt Whitworth, Business Owners Plead Guilty to Distributing Tainted Ingredients Used in Pet Food (16 June 2009).

<sup>63</sup> *United States vs. Miller*, Number 08-0023-01-CR-W-DW (W.D., Mo., 6 February 2008).

<sup>64</sup> *United States vs. Miller*, Number 08-0023-01-CR-W-DW (W.D. Mo., 6 February 2008).

<sup>65</sup> *United States vs. Miller*, Number 08-0023-01-CR-W-DW (W.D. Mo., 10 February 2008). Chemnutra was fined US \$25,000.

### KV Pharmaceutical Executives

The KV Pharmaceutical (“KV”) prosecution represents another use of the Park Doctrine strict liability theory where there was clear evidence the executive was aware of blatant Food, Drug, and Cosmetic Act violations. KV allegedly manufactured and sold oversized morphine sulfate tablets.<sup>66</sup>

In March 2011, a two-count information charged Marc Hermelin, KV’s chief executive officer and majority stockholder, with criminal misdemeanor misbranding under the Park Doctrine.<sup>67</sup> Despite five KV internal manufacturing control tests and three complaints from pharmacies, all drawing attention to the oversized morphine, KV neither fixed the defect nor reported it to the Federal Drug Administration.<sup>68</sup>

While Hermelin was chief executive officer, KV had other interactions with regulatory and enforcement agencies. First, in 1995, KV pled guilty to misdemeanor drug misbranding charges.<sup>69</sup> KV also was the subject of three drug forfeiture lawsuits brought by the Federal Drug Administration.<sup>70</sup> Additionally, KV received warning letters from the Federal Drug Administration in 2000 regarding significant deviations from the Federal Drug Administration’s drug manufacturing regulations and, in 2002, regarding drug marketing issues.<sup>71</sup> Lastly, in 2004, KV received seven complaints from consumers who received unusually large tablets of oxycodone and hydroprmorphone.<sup>72</sup>

Beginning in 2006, in an effort to increase production, Hermelin reinstated several tablet press machines known to be less safe than

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<sup>66</sup> Press Release, Department of Justice, KV Pharmaceutical Subsidiary Pleads Guilty to Two Felonies Regarding Oversized Drugs, 2 March 2010. *United States vs. KV Pharmaceutical Co., et al.*, Case Number 4:09-cv-00334-RWS (E.D., Mo.).

<sup>67</sup> Information, *United States vs. Hermelin*, Number 11-cr-85-ERW, at p. 1 (E.D. Mo., 10 March 2011).

<sup>68</sup> Press Release, Department of Justice, KV Pharmaceutical Subsidiary Pleads Guilty to Two Felonies Regarding Oversized Drugs, 2 March 2010, see <http://www.justice.gov/opa/pr/2010/March/10-civ-220.html>; Press Release, Department of Justice, Former Executives of International Medical Device Maker Sentenced to Prison in Unlawful Clinical Trials Case, 12 November 2011, see [http://www.justice.gov/usao/pae/News/2011/Nov/synthesexecs\\_release.pdf](http://www.justice.gov/usao/pae/News/2011/Nov/synthesexecs_release.pdf).

<sup>69</sup> *United States vs. KV Pharmaceutical Company*, CR 95-0179, (D. Md., 1995); Information, *United States vs. Hermelin*, Number 11-cr-85-ERW (E.D. Mo., 10 March 2011).

<sup>70</sup> Information, *United States vs. Hermelin*, Number 11-cr-85-ERW (E.D. Mo., 10 March 2011).

<sup>71</sup> Information, *United States vs. Hermelin*, Number 11-cr-85-ERW (E.D. Mo., 10 March 2011).

<sup>72</sup> Information, *United States vs. Hermelin*, Number 11-cr-85-ERW (E.D. Mo., 10 March 2011).

newer machines.<sup>73</sup> Production increased approximately 182 per cent, from an average daily production of 4.1-million doses in 2006 to 10.6-million doses in April 2008.<sup>74</sup> Hermelin also instructed KV employees to minimize written communications about KV's oversized tablet manufacturing problems from the older model machines.<sup>75</sup>

Despite the strong evidence that he was aware of the violations and likely intended to violate the Federal Drug Administration regulations, Hermelin pled guilty to two counts of misdemeanor misbranding as a responsible corporate officer.<sup>76</sup> Hermelin was sentenced to one month in prison and US \$1.9-million in criminal penalties, including a US \$900,000 forfeiture and a US \$1-million criminal fine. Hermelin was never charged with personal knowledge or intent to violate the Food, Drug, and Cosmetic Act. In its sentencing memorandum, the government argued, “[by] virtue of his role at KV, Hermelin had the power, authority, and responsibility to prevent drug manufacturing problems in the first instance and promptly correct any drug manufacturing problems that did occur”.<sup>77</sup>

Additionally, the Office of Inspector General excluded Hermelin from participation in federal health care programs, ultimately preventing Hermelin from working in the industry in the future.<sup>78</sup>

### Synthes Executives

In *United States vs. Huggins*,<sup>79</sup> four corporate officers were convicted of shipping adulterated and misbranded drugs in interstate commerce and received the most stringent penalties of any executives under the Park Doctrine to date.

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<sup>73</sup> Information, *United States vs. Hermelin*, Number 11-cr-85-ERW (E.D. Mo., 10 March 2011).

<sup>74</sup> Information, *United States vs. Hermelin*, Number 11-cr-85-ERW (E.D. Mo., 10 March 2011); Sentencing Memorandum, *United States vs. Huggins*, Number 2:09-cr-00403-LDD-4 (E.D. Pa., 15 November 2011), at pp. 16 and 17.

<sup>75</sup> Information, *United States vs. Hermelin*, Number 11-cr-85-ERW (E.D. Mo., 10 March 2011).

<sup>76</sup> Burroughs and Rin, “Clues to the Future of the Park Doctrine”, *Food Drug and Law Institute* (November 2012). KV Pharmaceutical, itself, was sentenced to a US \$27.5-million penalty. More than US \$23.4-million of that penalty was a fine to the company, US \$2.3-million was restitution payments to Medicare and Medicaid, and nearly US \$1.8-million was a forfeiture to the United States.

<sup>77</sup> Sentencing Memorandum, *United States vs. Hermelin*, Number 11-cr-85-ERW (E.D. Mo., 10 March 2011).

<sup>78</sup> *United States vs. Hermelin*, Number 4:11-CR-85 (E.D. Mo., 10 March 2011).

<sup>79</sup> *United States vs. Huggins*, 2011 W.L. 5844253 (E.D. Pa., 2011).

The officers worked for Synthes, a large medical device manufacturer specializing in trauma products to treat damaged human bone.<sup>80</sup>

Synthes, its subsidiary, and the four executives were charged with conspiring to conduct unauthorized clinical trials of Synthes's medical devices, Norian XR and Norian SRS, in surgeries to treat vertebral compression fractures.<sup>81</sup> The surgeries were allegedly performed despite a warning on the Norian XR label prohibiting this use due to the serious medical concerns about the safety of the devices when used on the spine.<sup>82</sup>

Synthes proceeded to market its product without undergoing the Federal Drug Administration-required testing. The company and its executives understood that, in order to market Norian XR for an unapproved use, they had two options:

- (1) Secure Federal Drug Administration approval after obtaining an investigational device exemption in order to investigate the product's safety and efficacy; or
- (2) Promote XR illegally for use through a "test market" in which the company, by its own standards, would evaluate the safety and efficacy of XR in unapproved clinical trials.

The company and executives chose the illegal "test market" route in an attempt to save money and time.<sup>83</sup> The product was not taken off the market until three individuals died on the operating table.

The company ultimately pled guilty to violating Federal Drug Administration regulations and agreed to pay over US \$23-million in fines. It also entered into a divestiture agreement with the Department of Justice in which it gave up all of its assets associated with its subsidiary.<sup>84</sup>

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80 Press Release, Department of Justice, International Medical Device Maker and Four Executives Charged in Connection with Unlawful Clinical Trials (9 June 2009).

81 Press Release, Department of Justice, International Medical Device Maker and Four Executives Charged in Connection with Unlawful Clinical Trials (9 June 2009).

82 Press Release, Department of Justice, International Medical Device Maker and Four Executives Charged in Connection with Unlawful Clinical Trials (9 June 2009).

83 Press Release, Department of Justice, International Medical Device Maker and Four Executives Charged in Connection with Unlawful Clinical Trials (9 June 2009).

84 Press Release, Department of Justice, International Medical Device Maker Agrees to Plead Guilty in Connection with Shipments of Adulterated and Misbranded Bone Cement Products as Part of Unlawful Clinical Trials (10 October 2010).

The indictment demonstrated that the four executives, despite being charged with the strict liability criminal misdemeanor, were aware of the Federal Drug Administration violations. The Department of Justice indictment points to numerous communications between the four executives and their subordinates indicating awareness that XR had dangerous potential and that Synthes was deliberately skirting Federal Drug Administration requirements in order to improperly introduce XR to the market.<sup>85</sup>

The executives received harsh penalties likely due to their involvement in the scheme, despite the strict liability nature of the misdemeanor charge in name.<sup>86</sup>

### **ApothéCure Executive**

In 2012, Gary Osborn, the owner, sole director, pharmacist in charge, and president of the pharmacy ApothéCure, Inc., pled guilty to two misdemeanor criminal violations of the Food, Drug, and Cosmetic Act for introducing a misbranded drug into interstate commerce.<sup>87</sup>

ApothéCure manufactured, processed, and packaged colchicine injections for intravenous use in the treatment of neck and back pain. However, in high doses, the drug is toxic. Three patients died from receiving high doses due to the alleged mislabeling of the appropriate dose on the package.<sup>88</sup>

The only reference to Osborn's responsibility in the violation is that his role as President and Director included "oversight of employee training and quality control". His plea agreement stated that, "by reason of his position he had the responsibility and authority to prevent the misbranding".<sup>89</sup> Thus, this is a clear application of the Park Doctrine because the executive had no knowledge of the crime but was charged regardless. Osborn pled guilty and was sentenced

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<sup>85</sup> *United States vs. Norian Corp.*, Number 09-cr-403 (E.D. Pa., 15 June 2009), at paras 43, 65, 69, 75, 76, and 85.

<sup>86</sup> Press Release, Department of Justice, Former Executives of International Medical Device Maker Sentenced to Prison in Unlawful Clinical Trials Case (21 November 2011).

<sup>87</sup> Criminal Docket, *United States vs. Gary D. Osborn and ApothéCure, Inc.*, Number 3:12-CR-047-M (N.D. Tex., 2012).

<sup>88</sup> Criminal Docket, *United States vs. Gary D. Osborn and ApothéCure, Inc.*, Number 3:12-CR-047-M (N.D. Tex., 2012).

<sup>89</sup> Criminal Docket, *United States vs. Gary D. Osborn and ApothéCure, Inc.*, Number 3:12-CR-047-M (N.D. Tex., 2012).

by the District Court for the Northern District of Texas to one-year probation for each count and was ordered to pay a US \$100,000 fine.<sup>90</sup>

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## Effectiveness of Park Doctrine

### In General

In the above cases, the Department of Justice used the Park Doctrine to hold executives responsible for the corporation's underlying violations. Such a theory is predicated on the fact that the officers can be liable solely through their position in the company and not due to their direct involvement in the violation.

Nevertheless, only the *ApothéCure* and *Purdue* indictments involve executives without direct knowledge of the violation. The other cases addressed above, while prosecuted without requiring the prosecutor or court to establish the element of executive knowledge at trial or during the plea colloquy, involve executives deeply immersed in the violations. Despite Department of Justice claims of increasing the use of the Park Doctrine, the aforementioned cases demonstrate that the Department of Justice typically only uses the strict liability theory against executives who could be charged with personal knowledge.

There is much scholarship on whether strict liability executive prosecutions are beneficial to the public welfare.<sup>91</sup> The benefits and drawbacks of the Park Doctrine are detailed below.

While it may appear extreme to hold executives criminally liable for violations of which they were not aware, considering the possibility of prison sentences, Health and Human Services exclusions, and the chilling effect such rulings might have on the drug industry, the Department of Justice's current practice arguably strikes an appropriate balance. The fact that, in practice, the Department of Justice usually employs the Park Doctrine only when an executive actually has knowledge of the violation or when the violation led to consumer deaths, punishes those truly culpable while sending a deterring message to other executives.

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<sup>90</sup> Criminal Docket, *United States vs. Gary D. Osborn and ApothéCure, Inc.*, Number 3:12-CR-047-M (N.D. Tex., 2012).

<sup>91</sup> Bolte, "Shot Through the Heart: The Federal Drug Administration Gives All Health Care Executives a Bad Name", 6 *Brook. J. Corp. Fin. & Com. L.* 593, at p. 597 (2012); Samp and Andrews, "Restraining Park Doctrine Prosecutions", 13 *Engage J. Federalist Soc'y Prac. Groups* 19 (2012).

### Arguments against Park Doctrine

Opponents of the Park Doctrine have a threefold concern with such strict liability prosecutions:

- (1) Prosecutions are harmful to the workplace environment;
- (2) Prosecutions restructure the Federal Drug Administration's relationship with corporate entities; and
- (3) Prosecutions where the executive lacks knowledge were not contemplated by the Food, Drug, and Cosmetic Act or the *Park* Court.<sup>92</sup>

The anxiety about strict liability prosecutions begins with the concern that such prosecutions breed cynicism in the workplace and might deter individuals from entering the field out of fear of liability without actual fault.<sup>93</sup> Strict liability might have been more appropriate in a time when business owners could see the factory floor from their offices. However, in today's business environment where miles separate chief executive officers from workers and corporations are much larger, the attenuation between chief executive officer's involvement and an actual violation is too distant to support a strict liability conviction.

Furthermore, the threat of being held accountable for a company violation without participation in such violation might be enough to deter individuals from entering the pharmaceutical field and thus hurt the industry.<sup>94</sup>

Opponents also argue that *Park* prosecutions fundamentally alter the relationship between the Federal Drug Administration and the pharmaceutical companies.<sup>95</sup> Normally, the Federal Drug Administration

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<sup>92</sup> There is another argument dismissed by the D.C. Circuit Court that the combination of exclusion from federal programs by Health and Human Services and strict liability prosecutions violate a defendant's due process rights. *Friedman vs. Sebelius*, 686 F.3d 813, at pp. 823 and 834 (D.C. Cir., 2011). The argument states that because the Supreme Court approved of the constitutionality of strict liability Park Doctrine prosecutions when penalties were relatively small, it does not follow that it does not violate due process when the penalties are "career-ending". See *Sebelius*, 686 F.3d. at 824. The D.C. Court of Appeals, however, stated that it does not violate due process.

<sup>93</sup> See <http://www.pharmarisc.com/2012/04/the-park-doctrine-all-bark-no-bite>.

<sup>94</sup> Such violations include personal monetary penalties, probation, jail time, and Health and Human Services exclusion, which ultimately derails an individual's career.

<sup>95</sup> O'Leary, "Credible Deterrence: Federal Drug Administration and the Park Doctrine in the 21st Century", 68 *Food & Drug L.J.* 137, at p. 147.

aspires to create a cooperative environment between the company and the government agency. An example of this is that the Federal Drug Administration sends out warning letters of Food, Drug, and Cosmetic Act violations in order to give companies multiple opportunities to correct such violations before the Federal Drug Administration takes more adversarial steps against them.<sup>96</sup> However, a strict liability prosecution, without any knowledge, turns the corporation-agency relationship into one that is more adversarial than cooperative. Such a shift can harm the purpose of the Federal Drug Administration's regulatory efforts moving forward.

Lastly, the legislative history of the Food, Drug, and Cosmetic Act reveals that earlier drafts of the statute included an express provision calling for strict liability of directors. However, it was removed from the final draft.<sup>97</sup> Such an expressed preference goes directly against the Department of Justice's threats to increase strict liability prosecutions. In fact, it is likely that the drafters of the Food, Drug, and Cosmetic Act did not intend to create a truly strict liability regime.<sup>98</sup>

The *Dotterweich* and *Park* courts also did not foresee the career-ending penalties that might later attach for misdemeanor violations of the Food, Drug, and Cosmetic Act. The defendant in *Dotterweich* was sentenced to sixty days of probation and a US \$500 fine.<sup>99</sup> Similarly, the defendant in *Park* only received a US \$250 fine and no probation or prison time.<sup>100</sup>

Today, the monetary penalties for individuals held liable under the Park Doctrine are significantly higher and the "multi-year exclusions looms over misdemeanor violations in ways that were not envisioned when the doctrine was originally blessed by the Supreme Court in the mid-1970s".<sup>101</sup> It arguably is difficult to see how a strict liability theory can remain appropriate today when the penalties are

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<sup>96</sup> O'Leary, "Credible Deterrence: Federal Drug Administration and the Park Doctrine in the 21st Century", 68 *Food & Drug L.J.* 137, at p. 147.

<sup>97</sup> Baird, "The New Park Doctrine: Missing the Mark", 91 *N.C. L. Rev.* 949, at p. 974 (2013).

<sup>98</sup> Baird, "The New Park Doctrine: Missing the Mark", 91 *N.C. L. Rev.* 949, at p. 973 (2013).

<sup>99</sup> *United States vs. Dotterweich*, 320 U.S. 277 (1943).

<sup>100</sup> *United States vs. Park*, 421 U.S. 658 (1975). The penalties are significantly higher even taking inflation into account.

<sup>101</sup> Baird, "The New Park Doctrine: Missing the Mark", 91 *N.C. L. Rev.* 949, at p. 982 (2013).

decidedly more severe than when the doctrine was first implemented and the Food, Drug, and Cosmetic Act framers did not endorse strict liability.<sup>102</sup>

### Arguments Favoring Park Doctrine

Despite the anxiety associated with strict liability prosecutions, it can be argued that at least the threat of ramping up *Park* prosecutions will benefit the public good. It has become increasingly clear that large monetary penalties targeted only at corporations are not enough to deter future violations. Many companies found in violation of the Food, Drug, and Cosmetic Act are repeat offenders.<sup>103</sup> Additionally, corporate fines for violating the Food, Drug, and Cosmetic Act are increasingly seen as part of the “cost of doing business”.<sup>104</sup>

Proponents of increasing the use of the Park Doctrine maintain that the new business model for pharmaceutical companies is to profit from violations and accept the risk involved.<sup>105</sup>

Considering that corporate penalties may not be enough to deter companies from committing violations, the threat and selective use of personal liability under the Park Doctrine might be necessary to curb the violations and promote compliance.<sup>106</sup> The fear of individual liability appears to be a viable option for the Federal Drug Administration to gain the attention of corporate executives who otherwise see these violations as part of the cost of doing business.

However, individual executive liability under the Park Doctrine comes into conflict with the fear addressed above; perhaps chilling the industry due to anxiety of executive responsibility without direct fault. Such anxiety can be tempered by the fact that, while the Federal

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<sup>102</sup> Baird, “The New Park Doctrine: Missing the Mark”, 91 *N.C. L. Rev.* 949, at p. 982 (2013) (arguing that strict liability should not be used today).

<sup>103</sup> Gahart, Duhamel, Dievler, and Price, “Examining the Federal Drug Administration’s Oversight”, *Health Affairs*, see <http://content.healthaffairs.org/content/suppl/2003/12/05/hlthaff.w3.120v1.DC1>.

<sup>104</sup> Emmick and Barton, “Uncomfortable Resurgence of the Responsible Corporate Officer Doctrine”, *Federal Drug Administration Law Blog* (28 March 2012), see <http://www.fdalawblog.com/2012/03/articles/enforcement-actions/the-uncomfortable-resurgence-of-the-responsible-corporate-officer-doctrine>.

<sup>105</sup> Emmick and Barton, “Uncomfortable Resurgence of the Responsible Corporate Officer Doctrine”, *Federal Drug Administration Law Blog* (28 March 2012), see <http://www.fdalawblog.com/2012/03/articles/enforcement-actions/the-uncomfortable-resurgence-of-the-responsible-corporate-officer-doctrine>.

<sup>106</sup> Testimony of Lewis Morris, House Committee on Ways and Means, Subcommittee on Oversight, 2 March 2011, see [http://oig.hhs.gov/testimony/docs/2011/morris\\_testimony\\_03022011.pdf](http://oig.hhs.gov/testimony/docs/2011/morris_testimony_03022011.pdf).

Drug Administration and the Department of Justice threaten to use the Park Doctrine, they rarely do in its pure strict liability form. According to one commentator, “the anxiety about prosecutions as a responsible corporate officer is analogous to children’s fears of the monster in the closet. No doubt the terror is real and no doubt the closet is empty”.<sup>107</sup> As seen from the five cases discussed above, prosecutors are unlikely to actually charge a corporate officer solely based on his position as chief executive officer or president, if he did not have a strong hand in the violation.

However, the threat to do so and the prison and exclusions that follow might be enough to proactively encourage chief executive officers to implement stronger compliance programs. Additionally, using the Park Doctrine in extraordinary cases like *ApothéCure*, where the executive did not have knowledge of the violation but the violation resulted in three deaths, is an appropriate way to “calibrate enforcement to harm”.<sup>108</sup>

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## Conclusion

Beginning in 2007, the Federal Drug Administration demonstrated a commitment to increase the use of Park Doctrine prosecutions in order to hold corporate executives responsible for company Food, Drug, and Cosmetic Act violations. Holding an executive strictly liable for a corporate crime in which he did not knowingly participate may appear severe.

The United States criminal justice system rarely inflicts harsh penalties, such as prison sentences or Health and Human Services exclusions, where the defendant lacks intent or knowledge of the violation. However, the cases examined in this chapter demonstrate that the Department of Justice rarely charges executives with crimes unless the executive has some knowledge of the violation. Out of the five cases described above, there were only two cases, *ApothéCure* and *Purdue*, where the executive did not have knowledge of the violation and was prosecuted under the Park Doctrine. Furthermore, prison time was only imposed in two out of the five cases, *ApothéCure* and *Synthes*, both of which involved consumer deaths.

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<sup>107</sup> Steinzor, “High Crimes, Not Misdemeanors: Deterring the Production of Unsafe Food”, 20 *Health Matrix* 175, at p. 195 (2009).

<sup>108</sup> O’Leary, “Credible Deterrence: Federal Drug Administration and the Park Doctrine in the 21st Century”, 68 *Food & Drug L.J.* 137, at p. 147.

The Federal Drug Administration's statements and press releases might appear to support the increased use of the Park Doctrine, but such prosecutions remain rare and judges appear resistant to impose strict liability prison sentences outside egregious cases. The combination of rarely prosecuting when a corporate officer has no knowledge of the violation and the substantial consequences that come when such prosecutions do occur arguably create the proper balance between over and under deterrence while still holding responsible executives who commit egregious violations.

