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**IS IT WORTH SAVING? THE IMPLICATIONS OF THE RESPONSIBLE
CORPORATE OFFICER DOCTRINE BEYOND *PARK***

ELIZABETH LAUTENBACH, J.D. CANDIDATE, 2015

I. INTRODUCTION

Health care fraud is a huge money maker for the United States government. In 2010, the government recaptured \$4 billion dollars in settlement monies.¹ In 2011, the government continued the trend and received an increase of about thirty percent more in settlements, amassing \$6.4 billion dollars from the health care arena alone.² This current movement shows no sign of stopping or slowing down anytime soon. The government collects these tremendous settlement amounts from actors in the pharmaceutical and medical device industry who are presently in a state of confusion. There is a current lack of idea and scope of prosecution, so much so that executives do not have a clear understanding of what actions can get them in trouble and the enormous criminal and civil penalties that strike both executives and companies when they are the center of a prosecution. The basis for the Food and Drug Administration (hereinafter “FDA”) and the Department of Justice (hereinafter “DOJ”) to stand is problematic: investigations and prosecution are grounded in two out of date cases and different administrative approaches.

After two significant United States Supreme Court cases and the revival of the use of the responsible corporate officer doctrine through governmental prosecutions, many within the legal

¹ *2011 Year-End Health Care Compliance Update*, GIBSON, DUNN, & CRUTCHER LLP (Feb. 6, 2012)
<http://www.gibsondunn.com/publications/Documents/2011YearEndHealthCareComplianceUpdate.pdf>.

² *Id.*

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realm are fearful of the use of the doctrine because of the absence of mens rea or knowledge to convict.³ Also, many corporate executives fear the punishments that accompany settlements in this area including imprisonment and exclusion from any federal healthcare program.⁴ Additionally, the DOJ can move forward with prosecution in any case without availing themselves of the FDA's specialized knowledge of investigations and violations.⁵ For these reasons, many industry officers and legal scholars are skeptical of the actual legality of the doctrine and advocate for the doctrine to be challenged.⁶

Although the responsible corporate officer doctrine⁷ was borne from good intentions (a public welfare statute with strict liability to protect consumers of products the FDA serves), the government has misused and will continue to misuse a doctrine that stands on shaky grounds unless the courts, government actors, and industry executives can work together to collaborate on a solution. Part II reviews the history of the Federal Food, Drug and Cosmetic Act (hereinafter "FD&C Act") as it relates to the responsible corporate officer doctrine and examines the two cases that form the basis of the doctrine: *US v. Dotterweich* and *US v. Park*. Part III introduces the government actors and actions that revived the responsible corporate officer doctrine. Part

³ Amiad Kushner, *Applying the Responsible Corporate Officer Doctrine Outside the Public Welfare Context*, 93 N.Y.U. J. CRIM. L. & CRIMINOLOGY, 681, 681 (2003).

⁴ Abraham Gitterman, *Executives Should Think Twice Before Accepting Pleas 'Relating to Fraud': The Expansion of Exclusion Under the Park Doctrine*, 25 No. 6 HTHLAW 1, 2-3 (2013).

⁵ Jennifer Bragg, *et al.*, *Onus of Responsibility: The Changing Responsible Corporate Officer Doctrine*, 65 FOOD & DRUG L.J. 525, 534 (2010).

⁶ Kushner, *supra* note 3, at 683.

⁷ The term "responsible corporate officer doctrine" is also called the "Park Doctrine" and can be used interchangeably. For purposes of this writing, except when citing an official writing, the doctrine will be referred to as the "responsible corporate officer doctrine."

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IV scrutinizes notable recent settlements identifies the lack of trials in this area. Part V sets out specific recommendations to answer these questions including: (1) judicial review, (2) narrowing the doctrine through legislative action, (3) the use of tandem prosecution to include both the FDA and DOJ in future prosecutions, and (4) industry action to safeguard corporations from possible prosecution.

II. THE *PARK* PROBLEM

A. FD&C Act Generally

In 1938, Congress granted enforcement authority to regulate several product areas including food, drugs, cosmetics, and medical devices to the FDA through the FD&C Act.⁸ The FD&C Act prohibits many actions including adulteration and misbranding of a regulated product or the introduction of an adulterated or misbranded product into interstate commerce.⁹ A person commits a misdemeanor under the FD&C Act when they “take or cause a prohibited action.”¹⁰ Furthermore, a person who commits the aforementioned violation “with the intent to defraud or mislead” or a person who has already been convicted of an FD&C Act violation commits a felony.¹¹ The Secretary of the FDA can debar a person convicted of the FD&C Act from participation in drug companies¹² while the Office of Inspector General (hereinafter “OIG”) can

⁸ 21 U.S.C. § 301 (2006).

⁹ 21 U.S.C. § 331(a)-(b).

¹⁰ 21 U.S.C. § 333(a)(2).

¹¹ *Id.*

¹² 21 U.S.C. § 335(a)(2).

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exclude a person convicted of the FD&C Act from participation in federal healthcare programs.¹³ The FD&C Act is a public welfare statute which imposes strict liability on an act, regardless of the actor's intent knowledge, or personal participation.¹⁴ The responsible corporate officer doctrine emerged from interpretation of the FD&C Act through the Supreme Court several years later.

B. Responsible Corporate Officer Cases and Comparison/Synthesis

The Supreme Court faced novel, interpretive questions posed by the two primary cases which formed the basis of the responsible corporate officer doctrine. An individual can be personally liable under the FD&C Act if there is proof of inaction when the law demands attention or where carelessness is enough to impute guilt.¹⁵ If you are a corporate executive doing business in an area regulated by the FDA, the Supreme Court through *Park* and *Dotterweich* imposes an affirmative obligation on the part of those individuals at a corporation that have the authority and power to determine whether there was a violation of the FD&C Act to make changes, take action, and remedy the situation.¹⁶

i. *US v. Dotterweich* (1943)

Joseph Dotterweich served the President and General Manager of the Buffalo Pharmacal Company, Inc.¹⁷ Buffalo Pharmacal purchased pharmaceutical drugs which they subsequently

¹³ See discussion of debarment and exclusion, *infra* p. 19.

¹⁴ See discussion of the FD&C Act as a public welfare statute, *infra* pp. 12-13.

¹⁵ *United States v. Dotterweich*, 320 U.S. 277, 285-86 (1943).

¹⁶ *United States v. Park*, 421 U.S. 658, 672 (1975).

¹⁷ *Dotterweich*, 320 U.S. at 278.

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repackaged in a new container and resold to other buyers.¹⁸ The government alleged that Buffalo Pharmacal and Dotterweich violated the FD&C Act by shipping adulterated or misbranded drug in interstate commerce.¹⁹ After a trial, both the corporation and Dotterweich were convicted in federal court.²⁰ Afterwards, both convictions were reversed on appeal.²¹

Upon granting certiorari, the novel question of whether the language of “person” in the FD&C Act can convict an individual working on behalf of a corporation faced the Supreme Court.²² Writing for the majority,²³ Justice Frankfurter answered in the affirmative and reversed the finding of the Second Circuit.²⁴ He stated that the FD&C Act is “a now familiar type” of statute which “dispenses with the conventional requirement for criminal conduct – awareness of some wrongdoing.”²⁵ Justice Frankfurter reasoned that the defendant’s rights should be balanced against the rights of the public who are defenseless against companies who release an adulterated or misbranded product on the market because the FD&C Act is a public health statute.²⁶ The Supreme Court articulated the position that a defendant who has a “responsible share in the

¹⁸ *Id.*

¹⁹ 21 U.S.C. §§ 301-92 (1938).

²⁰ *Dotterweich*, 320 U.S. at 278.

²¹ *Id.*

²² *Id.*

²³ *Dotterweich* was a close 5-4 decision with a scathing dissent written by Justice Murphy. See discussion of the aforementioned dissent, *infra* pp. 11-12.

²⁴ *Dotterweich*, 320 U.S. at 278.

²⁵ *Id.* at 280-81.

²⁶ *Id.* at 278.

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furtherance of” the transgression which the executive was charged will fail the balancing test and should be found guilty at trial.²⁷

From a policy standpoint, the executive in charge should be accountable for transgressions arising from violations occurring during their leadership whether or not they personally acted in the violation. The Supreme Court did not specify a category or set of corporate executives who would fit this new standard and left that decision to all involved in the trial process, specifically “the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries.”²⁸

The *Dotterweich* case gave life to the groundwork of the responsible corporate officer doctrine which stands for the principle that a public welfare statute like the federal FD&C Act “puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger” for the sake of the public at large.²⁹ In other words, absence of knowledge is sufficient for conviction under a public welfare statute.³⁰ They do not have to have cooperated, engaged in, or know of the violation to share in a portion of the blame or liability for any committed offenses.³¹

ii. *US v. Park* (1975)

²⁷ *Id.* at 284.

²⁸ *Id.* at 285.

²⁹ *Id.* at 281.

³⁰ Andrew Ellis, “*The Responsible Corporate Officer Doctrine: Sharpening a Blunt Health Care Fraud Enforcement Tool*”, 9 N.Y.U J. L. & BUS., 977, 986 (2013).

³¹ Amy Sepinwall, “*Responsible Shares and Shared Responsibility: In Defense of Responsible Corporate Officer Liability*”, 25 No. 6 COLUM. BUS. L. REV., 371, 378 (2014).

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The second case that lays the foundation of the responsible corporate officer doctrine came before the Supreme Court in 1975 in *US v. Park*.³² Similar to *Dotterweich*, the government argued that there were violations pursuant to the FD&C Act at Acme Supermarkets where Park served as President.³³ However, the breadth of the allegations was much different. While *Dotterweich* did not contaminate the drugs that came into his company's care, prosecutors argued that Park permitted his facilities to become infested with animals and contaminated the stored food.³⁴ Additionally, prosecutors alleged that Park knew of the unsanitary conditions in his Baltimore warehouses but did not do enough to cure the defects.³⁵ In particular, Park was aware of the defects as evidenced by an FDA warning letter as well as two FDA inspections of the warehouse in question.³⁶ Instead of personally acting to cure the defects, Park assigned that responsibility to the manager of the specific warehouse.³⁷ Park was convicted at trial in the United States District Court for the District of Maryland³⁸ and that conviction was subsequently reversed by the Fourth Circuit in 1973.³⁹

In 1975, the Supreme Court reversed the decision of the Fourth Circuit primarily with the "responsible share" language from *Dotterweich*.⁴⁰ Park's conviction is compelling because the

³² *Park*, 421 U.S. at 658.

³³ *Id.* at 658.

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.* at 661-62.

³⁷ *Id.* at 658.

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.*

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majority posited that the government does not need to prove that the defendant had any knowledge of the underlying offense as long as the person being charged is a corporate executive that had the “responsibility and authority” to take action on behalf of the company and “failed to do so”.⁴¹ After *Park*, the responsible corporate officer doctrine stands for the principle that an executive can be punished if they have the power to stop the offense from happening in the first place and they choose not to.⁴² This principle stems from the corporate executive’s positive duty to run a corporation which puts the health and wellness of the public before profit.⁴³ Additionally, an ensuing conviction of the FD&C Act after any previous conviction of the FD&C Act is deemed a felony regardless of the factual circumstances.⁴⁴

Further, Justice Burger articulates that an executive can dispute liability by raising an impossibility defense. The corporate officer who can show that they were “powerless to prevent or correct the violation”⁴⁵ can mitigate their position. Does an impossibility defense like the one explained in *Park* change the dynamics in the culpability requirements because it is available? Can the responsible corporate officer doctrine rightfully be used as a strict liability standard if the executive can raise a defense? These are questions a corporate executive can raise if one chooses to refuse a settlement offer and proceeds to a trial.⁴⁶

⁴¹ *Id.* at 673.

⁴² *Id.*

⁴³ *Id.*

⁴⁴ 21 U.S.C. § 333(a)(2).

⁴⁵ *Id.* at 673.

⁴⁶ See discussion of settlements, *infra* pp. 19-30.

**iii. Synthesis of Similarities and Differences between *Dotterweich* and
*Park***

FIGURE 1: *Dotterweich/Park* Analysis

	Individual Involved	FDA Regulated Product	FD&C Act Violations	Money	Penalties	Knowledge Aspects
<i>US v. Dotterweich</i> (1943)	Joseph Dotterweich, President and General Manager of Buffalo Pharmacal Company	Pharmaceutical Drugs	3 Misdemeanor counts of shipping adulterated and misbranded drugs into interstate commerce	N/A	Conviction under the FD&C Act	No Knowledge
<i>US v. Park</i> (1975)	John Park, President and CEO of Acme Supermarket	Food	5 Misdemeanor counts of causing adulteration of food	N/A	Conviction under the FD&C Act	Knowledge: repeated warning letters, a failed FDA inspection

There are two distinct similarities between the two aforementioned cases. The first similarity is their position. Dotterweich and Park were both presidents of their respective companies. While neither case sets out a list of specific persons who hold specific positions within a company that will be subject to prosecution through a FD&C Act investigation, these Supreme Court cases makes it certain that the executive at the top will be ultimately responsible for any violations during their watch whether they are involved in the violations in question or

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not. The second similarity between *Dotterweich* and *Park* is that both the companies and the presidents were prosecuted under the FD&C Act. The FD&C Act is a public welfare statute that enjoys the benefits of strict liability.⁴⁷

There is one substantial difference between the *Dotterweich* and *Park* cases. While the *Dotterweich* case does not go into many specifics in regards to its facts, it is clear that *Dotterweich* did not know the actions of what happened to the drugs that were the center of this violation. In fact, the dissent points out that the government did not introduce proof that *Dotterweich* had any involvement or participation in the violation.⁴⁸ 30 years later in *Park*, a much different scenario was presented. Over the course of three years, *Park* received several warning letters and a failed inspection notice from the FDA concerning contamination of a specific food storage warehouse.⁴⁹ Armed with this knowledge, it was easy for *Park* to rectify the problem because he was aware of the conduct.⁵⁰ However, *Park* did not do enough within his power to remedy the problem.⁵¹ Instead, *Park* was flippant when tasked to make changes that could improve the safety of those that consume his products.⁵² Therefore, *Park* can be distinguished from *Dotterweich* because *Park* is less problematic from a mens rea standpoint. *Park* knew of the offenses and did not stop them; he only delegated the responsibility to others.

C. Implications/Departure from Criminal Law Concepts

⁴⁷ See discussion of criminal law tenets, *infra* pp. 10-13.

⁴⁸ *Dotterweich*, 320 U.S. at 286.

⁴⁹ *Park*, 421 U.S. at 658.

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.*

i. Mens Rea Culpability Requirement

In criminal cases, an accused must have acted with the requisite mens rea to be convicted of the alleged crime.⁵³ The responsible corporate officer doctrine expanded the range of liability because the government does not need to prove knowledge or intent of the crime for executives to be culpable of FD&C Act violations as well as responsible corporate officer doctrine violations.⁵⁴ Under the tenets of criminal law, a defendant's conduct must rise to the level of intent of mens rea in order to meet the requirements of the Due Process Clause.⁵⁵ Since corporate officers without knowledge of the violation can and are found criminally accountable due solely to their position of authority within the corporation, transgression pursued under the responsible corporate officer doctrine do not meet the culpability specifications the Supreme Court articulated in *Gypsum*. Accordingly, those that were not engaged in the crime are charged and suffer severe consequences, extending the scope of liability past what criminal law tenets intended.⁵⁶

These specific concerns of the responsible corporate officer doctrine travel back to 1943 when the dissent in *Dotterweich* took issue with the lack of evidence of knowledge or participation in the federal FD&C Act violation of Mr. Dotterweich's conviction.⁵⁷ The dissent objects to the majority action of inserting an individual theory of liability into a statute that was

⁵³ Ariel Glasner, *Are Misdemeanor Prosecutions Under the Park Doctrine an Effective Mechanism for Deterring Violations of the Federal Food, Drug and Cosmetic Act?* FDLI POLICY FORUM, 1, 3 (2011).

⁵⁴ *Id.*

⁵⁵ *United States v. United States Gypsum Co.*, 438 U.S. 422, 436 (1978).

⁵⁶ Sepinwall, *supra* note 31, at 379.

⁵⁷ *Dotterweich*, 320 U.S. at 286.

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not included in the final legislation.⁵⁸ The dissent also takes offense to the extent of the scope that this ruling would have moving forward.⁵⁹ For example, Justice Murphy stated that a person should not be found guilty of a crime without an “evil intention or consciousness of wrongdoing” and public policy reasons should not run around basic tenets of criminal law.⁶⁰ A court today could take this reasoning and use it to limit the responsible corporate officer doctrine for future investigations and prosecutions.

ii. Strict Liability

Additionally, the Supreme Court could limit the responsible corporate officer doctrine because strict liability under public welfare offenses is not applicable today. The theory of strict liability derives from the notion that it is the job of the executive to make sure their products are safe for the public when corporations are making a substantial amount of money from the products.⁶¹ The majority in *Dotterweich* posited that public welfare statutes like the FD&C Act “dispenses with the conventional requirement for criminal conduct – awareness of some wrongdoing...”⁶² The Supreme Court has upheld public welfare offenses in a narrow set of cases where penalties are “relatively small, and conviction does no grave damage to an offender’s reputation.”⁶³ Nevertheless, using the public welfare offenses doctrine to offenses

⁵⁸ *Id.* at 290.

⁵⁹ *Id.* at 286.

⁶⁰ *Id.*

⁶¹ *See Id.* at 282-83 (“If the 1938 Act were construed as it was below, the penalties of the law could be imposed only in the rare case where the corporation is merely an individual’s alter ego. Corporations carrying on an illicit trade would be subject only to...a ‘license fee’ for the conduct of an illegitimate business.”).

⁶² *Id.* at 281.

⁶³ *Morisette v. United States*, 342 U.S. 246 (1952); *Staples v. United States*, 511 U.S. 600 (1994).

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under the responsible corporate officer doctrine today is short-sighted because it frustrates the criminal law tenets of knowledge and participation in the underlying offense.⁶⁴ Additionally, prosecutors are able to wield this power over defendants which could be a reason for the large number of settlements in the pharmaceutical and medical device area.

Responsible corporate officer doctrine convictions do not fall within the category of “relatively small” or “does no grave damage to an offender’s reputation.”⁶⁵ Not only do these convictions fall outside those categories, they are far from it.⁶⁶ Commentators have questioned whether it is appropriate to continue prosecution under the responsible corporate officer doctrine when the public welfare offense exception does not squarely fit and this doctrine could violate due process rights.⁶⁷ By prosecuting solely because of position within an organization and not prosecuting the ones who committed the violations, the responsible corporate officer doctrine establishes a new set of individuals that can be implicated⁶⁸ and is in contrast to corporate law principles where personally acting in the underlying offense is necessary for individual liability.⁶⁹

III. THE ROLE OF THE FDA/CONSEQUENCES FOR PROSECUTION

⁶⁴ Kushner, *supra* note 3, at 682-83.

⁶⁵ Glasner, *supra* note 53.

⁶⁶ *Id.*

⁶⁷ Bragg, *et al.*, *supra* note 5, at 525.

⁶⁸ Ellis, *supra* note 30, at 981.

⁶⁹ Kushner, *supra* note 3, at 684-85.

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Penalties for violations of various aspects of the FD&C Act had previously been applied to individuals solely because of their corporate positions through the responsible corporate officer doctrine. The responsible corporate officer doctrine, after its creation, fell into disfavor when the FDA did not want to take an active role in investigating what would be cases classified as misdemeanors.⁷⁰ The responsible corporate officer doctrine, through the FD&C Act imposes an affirmative obligation to determine whether there were violations of law happening within the organization, take action, and remedy the situation.⁷¹

A. From Bridging the Gap to Grassley

Reliance and prosecutions under the responsible corporate officer doctrine waned when the doctrine fell into disfavor after 1960s-early 1970's and was not used in the health care/pharmaceutical and medical device realm.⁷² Because of this lack of development, industry executives were not worried about being the center of a prosecution. In 2010, the Government Accountability Office, through Senator Charles E. Grassley the ranking member of the United States Senate's Committee on Finance, began to criticize the FDA for not taking a more active role in criminal prosecutions of those who commit violations under the FDA's watch when it is the responsibility of the FDA to regulate prescription and over-the-counter drugs.⁷³ They also highlighted the growing sentiment that government agencies should be to act more

⁷⁰ Gitterman, *supra* note 4, at 4.

⁷¹ *Park*, 421 U.S. at 673-74.

⁷² Ellis, *supra* note 30, at 989.

⁷³ U.S. Gov't Accountability Office, GAO-10-221, Food and Drug Administration: Improved Monitoring and Development of Performance Measures Needed to Strengthen Oversight of Criminal and Misconduct Investigations 10, at 1 (2010), available at <http://www.gao.gov/new.items/d10221.pdf>.

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aggressively with an increase in investigations.⁷⁴ Particularly, the GAO suggested that the Office of Criminal Investigations (hereinafter “OCI”) play a more critical role in investigations.⁷⁵ However, despite these sentiments, nowhere in the report did the GAO instruct the FDA to revive such a powerful tool as the responsible corporate officer doctrine.

B. Tide Turns: Commissioner Hamburg’s Signal to Industry

In response to Senator Grassley and the Committee of Finance’s sentiment, Margaret Hamburg, the Commissioner of the FDA, recommended an increase of misdemeanor prosecutions to hold corporate executives responsible for violations made on their watch.⁷⁶ The change in FDA stance was attributed to the perceived lack of investigation by the FDA in regards to FD&C Act violations.⁷⁷ FDA Commissioner Hamburg’s description of the increase of misdemeanor prosecution under the doctrine as a “valuable enforcement tool”⁷⁸ was a telling indication to all in the pharmaceutical and medical device industry that the FDA planned to resurrect a doctrine that had not been in use for decades to prosecute companies and those responsible for FD&C Act infractions in addition to including a whole new set of potential defendants.⁷⁹

⁷⁴ *Id.* at 2.

⁷⁵ Glasner, *supra* note 53, at 2.

⁷⁶ Letter from Margaret Hamburg, Comm’r, Food & Drug Admin., to Sen. Charles Grassley, at 2 (Mar. 4, 2010) available at <http://grassley.senate.gov/about/upload/FDA-3-4-10-Hamburg-letter-to-Grassley-re-GAO-report-on-Oci.pdf>.

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ Glasner, *supra* note 53, at 3-4.

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To that end, the FDA released FDA “Manual 6-5-3: Recommending *Park* Doctrine” which listed nonbinding criteria that the FDA will use to recommend criminal prosecutions against a corporate officer in the pharmaceutical and medical device industry to be considered in addition to the Supreme Court’s findings in *Park* and *Dotterweich*.⁸⁰ These 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.⁸¹

The responsible corporate officer doctrine provides that an executive can be held liable for a first time misdemeanor, and a felony violation for any additional conviction, under the federal FD&C Act without proof that the corporate official acted with intent or even negligence.⁸² Additionally, the corporate official did not have to have any actual knowledge of, or participation in, the specific offense.⁸³ Knowledge of and actual participation in the violation

⁸⁰ REGULATORY PROCEDURES MANUAL § 6-5-3 – 2011, U.S. FOOD AND DRUG ADMINISTRATION § 6-5-3, available at <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074317.pdf> (last updated Sept. 16, 2011) [hereinafter REGULATORY PROCEDURES MANUAL].

⁸¹ *Id.*

⁸² *Id.*

⁸³ *Id.*

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are not a prerequisite to a misdemeanor prosecution but are factors that may be relevant when deciding whether to recommend charging a misdemeanor violation.⁸⁴ Moreover, responsibility and control are central to the analysis of whether to bring a prosecution against an executive.

The troubling aspect of this Manual is just that: it is a non-binding guidance document and not meant to hold more weight than the DOJ's authority to prosecute.⁸⁵ The ultimate decision to prosecute lies with the DOJ regardless of whether the evidence in a particular case satisfies the aforementioned criteria.⁸⁶

C. Relationship between FDA/DOJ/OIG

There are multiple arms of the government that theoretically should play a role in investigations and prosecutions under the responsible corporate officer doctrine. The Office of Criminal Investigations (hereinafter "OCI" is the FDA's investigatory arm.⁸⁷ All referrals for potential criminal prosecution under the FD&C Act must first travel through the OCI.⁸⁸ However, the matter is not closed if the OCI decides against moving forward with potential prosecution.⁸⁹

⁸⁴ *Id.*

⁸⁵ Anne 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-doctrine-criteria.html.

⁸⁶ *Id.* "The absence of some factors does not mean that a referral is inappropriate where other factors are evident."

⁸⁷ U.S. FOOD AND DRUG ADMINISTRATION: INSPECTIONS, COMPLIANCE, ENFORCEMENT, AND CRIMINAL INVESTIGATIONS, <http://www.fda.gov/ICECI/criminalInvestigations/default.htm> (last visited Dec. 5, 2014).

⁸⁸ REGULATORY PROCEDURES MANUAL §§ 6-5-1, 6-5-2.

⁸⁹ *Id.* at §§ 6-5-1.

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There is an additional concern over prosecutions made by the DOJ under the responsible corporate officer doctrine that the FDA does not participate in. The False Claims Act allows private citizens to file suit on behalf of the government in exchange for a percentage of the monetary award.⁹⁰ A suit filed by an individual on behalf of the government is known as a qui tam action, and the private citizen who files the suit is called a relator.⁹¹ The DOJ can intervene and proceed in the action already begun by attorneys outside of the government without any specialized knowledge by FDA experts.⁹²

These governmental bodies use many penalties to punish those are convicted of a violation of the FD&C Act and deter those who are tempted to commit a violation of the FD&C Act. To further prevent corporate officers from committing a crime which would then violate the responsible corporate officer doctrine, the government is using their power to block officers and corporations from doing business in the area of federal health care programs. The FDA has the power to debar⁹³ and the OIG has the ability to exclude⁹⁴ both individuals and corporations after they are convicted under the responsible corporate officer doctrine through a violation of a statute like the FD&C Act. For individuals, there is a presumption to exclude unless there are “significant factors [that] weigh against exclusion”⁹⁵. To this end, the OIG utilizes both

⁹⁰ 31 U.S.C. §§ 3729-33 (2014).

⁹¹ *Id.*

⁹² *Id.*

⁹³ 21 U.S.C. § 306; 21 U.S.C. § 335(a).

⁹⁴ 21 U.S.C. § 335(a).

⁹⁵ Office of Inspector Gen., GUIDANCE FOR IMPLEMENTING PERMISSIVE EXCLUSION AUTHORITY UNDER SECTION 1128(B)(15) OF THE SOCIAL SECURITY ACT (Oct. 20, 2010), *available at* https://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf.

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mandatory and permissible exclusions which are codified in the “Exclusion of certain individuals and entities from participation in Medicare and State health care programs” statute.⁹⁶ The mandatory and permissive exclusions are codified.⁹⁷

Corporations who are reimbursed from federal health care programs these penalties seriously because the OIG can block payment to any enterprise that is excluded or employs or contracts with excluded individuals.⁹⁸ This is effectively a death sentence; no company or corporate executive can continue to do business in the pharmaceutical and medical device realm if they cannot sell prescription drugs within the government funded health care program realm.⁹⁹ Even if the corporate executive would like to try to get back within the industry while excluded, every company checks the FDA debarment list and OIG exclusion list before hiring.

IV. SETTLEMENTS

The pharmaceutical and medical device industry are not willing go to trial under a responsible corporate officer doctrine, evidenced by settling all prosecutions. They are scared of the potentially high penalties faced with a guilty verdict after a long trial and uncertainty of what could happen to both the corporation in question’s future and the executives themselves. Additionally, the fact that there have been no significant trials in this area is troubling because

⁹⁶ 42 U.S.C. § 1320a-7 (2010).

⁹⁷ 42 U.S.C. § 1320a-7(a)(1)-(4) (2010); 42 U.S.C. § 1320a-7(b)(1)-(16) (2010).

⁹⁸ Ellis, *supra* note 30, at 979.

⁹⁹ *Id.* at 994.

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the industry cannot look to the judiciary for guidance except for two dated cases and no trial level case since the adoption of FDA Manual 6-5-3.

There are many questions can be raised: Would the responsible corporate officer doctrine and how the government is prosecuting under it hold up in court today? What criteria of FDA Manual 6-5-3 were at issue in each settlement? Were any criteria actually used by the FDA or the DOJ? What was the FDA's role in each settlement? There have been several prominent settlements under the responsible corporate officer doctrine in the pharmaceutical and medical device area and each one contributes to the discussion of where governmental agencies will be focusing in their investigations and prosecution in this area moving forward.

A. *Perdue Frederick*

In 2007, the government brought an action against The *Perdue Frederick* Pharmaceutical Company and the chief executive officer, general counsel, and chief medical officer individually for criminal and civil violations of off-label promotion under the FD&C Act.¹⁰⁰ Specifically, the government alleged that they stated misinformation in regards to safety profile of the drug *OxyContin*.¹⁰¹ Rather than risk high punishments at trial, *Perdue Frederick* pleaded guilty to felony misbranding charges for “failure to prevent *Purdue*'s fraudulent marketing of *OxyContin*” and paid a fine of \$600 million to settle.¹⁰² Additionally, three executives of *Purdue* who were in charge at the time of the violations pleaded guilty to misdemeanor misbranding, the OIG

¹⁰⁰ *Friedman v. Sebelius*, 686 F.3d 813, 813 (D.C. Cir. 2012).

¹⁰¹ *Id.* at 816.

¹⁰² *United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569, 569 (W.D. Va. 2007).

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excluded the executives from working for any corporation receiving federal funds, and they agreed to enter into a five year corporate integrity agreement.¹⁰³

In 2009, the debarred executives sued the OIG and Health and Human Services (HHS) arguing that the government cannot exclude/debar someone by virtue of a violation based on the responsible corporate officer doctrine because of the lack of evidence and proof of personal wrongdoing.¹⁰⁴ As an alternative argument, the executives contended that the exclusion period of twenty years was inappropriate when the length of exclusion authorized by statute is considered which was “3 years, unless the Secretary determines in accordance with published regulations that...a longer period is appropriate because of aggravating circumstances.”¹⁰⁵ In 2010, the district court upheld the exclusion since the responsible corporate officer doctrine applies and they were properly excluded by the OIG stating that “section 1320a–7(b)(1) appears to permit the exclusion of anyone convicted of an offense ‘having a connection with or reference to’ fraud or financial misconduct in the delivery of a health care item or service.”¹⁰⁶

In 2012, the appellate court reversed and remanded the district court’s decision of the length of exclusion.¹⁰⁷ While the conviction for misdemeanor misbranding and the exclusion decision by the OIG were sustained because the convictions were “factually related to fraud”, the length of exclusion was technically authorized by statute and the court ordered HHS to provide

¹⁰³ *Friedman*, 686 F.3d at 816.

¹⁰⁴ *Id.* at 817.

¹⁰⁵ 42 U.S.C. § 1320a-7(b)(1) and (3) was used by the OIG since this was a permissive exclusion.

¹⁰⁶ *Friedman v. Sebelius*, 755 F.Supp.2d 98, 107–08 (D.D.C.2010) (quoting *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384, (1992)).

¹⁰⁷ *Friedman v. Sebelius*, 686 F.3d 813 (D.C. Cir. 2012).

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justification that the facts of the case and the involvement of these specific individuals justified that type of disbarment.¹⁰⁸ In fact, an explanation for the length of exclusion and reconciliation with prior exclusion decisions was not given by the Secretary.¹⁰⁹ The OIG had not come close to giving an exclusion period of this length before; the previous longest exclusion period had been lower than ten years for a misdemeanor conviction.¹¹⁰

However, the *Friedman* Court endorsed the district court's reading of the responsible corporate officer doctrine by ruling that the corporate executives had the "power and authority" to prevent the fraudulent marketing but failed to so do which justifies debarment from the federal healthcare system whether or not person had personal knowledge on which the charges were levied.¹¹¹ This finding was a resounding affirmation of the responsible corporate officer doctrine in this context and the first time a Court of Appeals agreed.¹¹²

While the underlying facts seem at first glance more analogous to the *Park* situation, the underlying facts are more analogous to the *Dotterweich* case. Like in *Park*, the company committed acts that are dangerous to the public at large for several years and had ample means to correct. Instead of correcting those misdeeds, Purdue Frederick continued those misdeeds. However, knowledge of the three executives was not found due to that fact was stipulated to in the settlement.¹¹³ The DOJ did not have a warning letter or failed inspection to bolster their

¹⁰⁸ *Id.* at 828.

¹⁰⁹ *Id.* at 825.

¹¹⁰ *Id.* at 828.

¹¹¹ *Id.* at 817.

¹¹² Ellis, *supra* note 30, at 1013.

¹¹³ *Purdue Frederick Co.*, 495 F. Supp. 2d at 571.

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argument like in the *Park* situation. In reference to the FDA Manual, it is clear that at least a majority of the Manual's criteria are satisfied with this situation: purposefully misbranding a drug with a severe risk of addiction and abuse caused very serious¹¹⁴ harm to the public¹¹⁵ and the training programs that educated sales representatives to employ these marketing techniques were obvious,¹¹⁶ widespread,¹¹⁷ and a pattern of illegal behavior.^{118 119}

B. Synthes

In 2009, the government prosecuted Synthes executives outside of the commercial management chain.¹²⁰ The government alleged violations of the FD&C Act when Synthes performed clinical trials of a bone filler medical device manufactured by its subsidiary Norian without FDA approval.¹²¹ Both Synthes and Norian pleaded guilty to shipping adulterated and misbranded medical devices in interstate commerce resulting in just over \$23 million in criminal and civil penalties while Synthes executives (the President of Synthes North America, President of Synthes Spine Division, Vice President of Operations, and Director of Regulatory and Clinical Affairs)¹²² pleaded guilty to misdemeanor misbranding under the responsible corporate officer

¹¹⁴ REGULATORY PROCEDURES MANUAL §§ 6-5-3(5).

¹¹⁵ *Id.* at §§ 6-5-3(1).

¹¹⁶ *Id.* at §§ 6-5-3(2).

¹¹⁷ *Id.* at §§ 6-5-3(4).

¹¹⁸ *Id.* at §§ 6-5-3(3).

¹¹⁹ *Purdue Frederick Co.*, 495 F. Supp. 2d at 571.

¹²⁰ U.S. FOOD AND DRUG ADMINISTRATION, *International Medical Device Maker Agrees to Plead Guilty in Connection with Shipments of Adulterated and Misbranded Bone Cement Products*, (October 4, 2010), <http://www.fda.gov/ICECI/CriminalInvestigations/ucm228273.htm>.

¹²¹ *Id.*

¹²² *United States v. Huggins*, No. 09-403-3, 201 WL 6180623, at *2 (E.D. Pa. Dec. 13, 2011).

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doctrine and sentenced to imprisonment of five to nine months.¹²³ In addition to imprisonment and monetary penalties, Norian faced exclusion by the OIG.

The Synthes case is important because the facts are a departure from the traditional responsible corporate officer doctrine prosecutions. Not only did the executives know of the underlying offenses, but they actively engaged to conceal relevant information and made false statements to the FDA.¹²⁴ That information led to a meaningful amount of jail time for Synthes executives who had agreed to a FD&C Act misdemeanor conviction, the first time that has happened within the pharmaceutical and medical device industry due to the “unprecedented nature” of the Synthes executives’ actions.¹²⁵

The Synthes facts are in no way analogous to the *Dotterweich* case and would be closer to the *Park* case. The executives had knowledge of the misdeeds from internal emails regarding off-label use of the medical device not approved of by the FDA which led to patient injuries.¹²⁶ In addition, these same executives created and ran unauthorized clinical trials against FDA policy.¹²⁷ However, imprisonment for a misdemeanor a troubling aspect of this case is imprisonment for a misdemeanor violation under the responsible corporate officer doctrine. The sentencing judge posited that this case could be distinguished from *Park*. Specifically, it was noted that “[t]his case does not involve standard *Park*-doctrine behavior, in which an unaware

¹²³ U.S. FOOD AND DRUG ADMINISTRATION, *supra* note 116.

¹²⁴ *Id.*

¹²⁵ *Huggins*, 2011 WL 6180623, at *2.

¹²⁶ *Id.* at 3.

¹²⁷ *Id.* at 5.

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corporate official is held strictly liable for the conduct of his subordinates.”¹²⁸ This point raises serious questions concerning the appropriateness of accepting a misdemeanor strict liability responsible corporate officer doctrine plea deal due to the facts that penalties such as imprisonment does an immense amount of damage to an executive’s reputation and millions of dollars in fines are no longer relatively small.¹²⁹

C. KV Pharmaceuticals

In 2011, the Chief Executive Officer of KV Pharmaceuticals, Marc S. Hermelin, was charged with misbranding drugs under the FD&C Act.¹³⁰ Over a two year period, Hermelin ordered manufacturing increases of a range of generic drugs made in house.¹³¹ Under Hermelin’s leadership, the company did not take care in producing a quality product.¹³² Specifically, the management received both internal reports of irregularly shaped and oversized prescription drugs through manufacturing controls and safety assessments as well as external reports from customers who were given the product.¹³³

As part of accepting the settlement, Hermelin stated that the labeling on KV Pharmaceuticals’ products were “false and misleading” because the specification of “uniform

¹²⁸ *Id.* at 13.

¹²⁹ See discussion of strict liability statute, *supra* pp. 12-13.

¹³⁰ U.S. FOOD AND DRUG ADMINISTRATION, 2011 *Marc S. Hermelin, Former CEO of KV Pharmaceutical, Pleads Guilty to Misbranding Drugs and Agrees to Pay United States \$1.9 Million as Fines and Forfeiture*, (March 10, 2011), <http://www.fda.gov/ICECI/CriminalInvestigations/ucm246881.htm>.

¹³¹ *Id.*

¹³² *Id.*

¹³³ *Id.*

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strength” on the labels was incorrect due to the irregularities of their products.¹³⁴ Since the products in question were shipped from St. Louis and discovered in California, the prescription drugs crossed state lines where KV Pharmaceuticals introduced the drugs into interstate commerce¹³⁵. Hermlich was sentenced to a month of prison and penalties including a million dollar fine, \$900,000 in forfeiture fees¹³⁶, and exclusion from participation in federal healthcare programs by the HHS OIG for 20 years.¹³⁷

Both KV and Hermelin’s actions satisfy many of the criteria in FDA Manual 6-5-3. The pharmaceutical drug violations were obvious,¹³⁸ serious,¹³⁹ and had the potential for harm to the public.¹⁴⁰ Be that as it may, like the executives in Synthes, Hermelin’s punishment after a settlement for a strict liability crime is much larger than the punishments anticipated by the majority in *Dotterweich*.

D. Forest Laboratories

Forest Laboratories pleaded guilty to a misdemeanor misbranding charge for marketing an antidepressant drug before FDA approval and in spite of FDA warning letters.¹⁴¹ The corporation paid monetary penalties and forfeited assets totaling hundreds of millions of

¹³⁴ *Former Drug Company Executive Pleads Guilty in Oversized Drug Tablets Case*, U.S. DEPARTMENT OF JUSTICE (March 10, 2011), <http://www.justice.gov/opa/pr/former-drug-company-executive-pleads-guilty-oversized-drug-tablets-case>.

¹³⁵ *Id.*

¹³⁶ U.S. FOOD AND DRUG ADMINISTRATION, *supra* note 131.

¹³⁷ Glasner, *supra* note 53, at 3.

¹³⁸ REGULATORY PROCEDURES MANUAL §§ 6-5-3.

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ Glasner, *supra* note 53, at 3.

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dollars.¹⁴² The OIG decided to pursue exclusion for the chairman of Forest Laboratories, Howard Solomon.¹⁴³ However, this situation was unique because Solomon was never convicted in his individual capacity in the Forest Laboratories settlement, marking this as the first time the OIG was seeking to exclude a corporate executive solely due to their position within a company that accepted a settlement offer.¹⁴⁴ While the OIG eventually decided against exclusion in light of evidence submitted on behalf of Solomon, the Forest Laboratories matter is troubling because the OIG sought to exclude Solomon with no criminal charges linking Solomon individually to the underlying offense.¹⁴⁵

E. Synthesis of Settlements/Conclusion

FIGURE 2: Synthesis of Settlements

	Individual Involved	FDCA Violations of an FDA Regulated Product	Money	Penalties	Knowledge Aspects	Compare/ Contrast with <i>Dotterweich</i> and <i>Park</i>
Purdue Frederick	Chief Executive Officer; General Counsel; and the	Drug Corporation: 1 Count of Felony Misbranding: Marketing Claims	Apprx. \$600 million in crim. fines and	Five year CIA for Purdue, 12 year exclusion for the	<u>Knowledge</u> : Purdue had “Intent to Defraud or Mislead”; <u>No</u>	While the underlying facts seem analogous to the <i>Park</i> case, the executives

¹⁴² U.S. FOOD AND DRUG ADMINISTRATION, *Forest Pharmaceuticals To Pay \$164 Million For Criminal Violations*, (March 2, 2011), <http://www.fda.gov/ICECI/CriminalInvestigations/ucm245543.htm>.

¹⁴³ Michael E. Clark, *The Responsible Corporate Officer Doctrine A Re-Emergent Threat to General Counsel and Corporate Officers*, 14 J. HEALTH CARE COMPLIANCE 5, 8 (2012).

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

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	Chief Medical Officer	<u>Individually</u> : 3 Misdemeanor Misbranding Claims	forfeiture	executives	<u>Knowledge</u> : Absence of Proof as to Individual Defendants	individually are more analogous to the <i>Dotterweich</i> case due to the misdemeanor plea and absence of knowledge.
Synthes	President (Synthes NA); President (Synthes Spine); Vice President, Operations; Director, Regulatory and Clinical Affairs	Medical Device Corporation: Felony and Misdemeanor Adulteration and Misbranding Claims <u>Individually</u> : Strict Liability Misdemeanor Adulteration and Misbranding Claims	Apprx. \$23 million in crim. and civil penalties	Five year CIA for Purdue; 9 months imprisonment; 12 year exclusion for the executives	<u>Knowledge</u> : Synthes had “Intent to Defraud or Mislead”; <u>Knowledge</u> : Synthes executives had knowledge but pled to misdemeanor violations	Similar to <i>Park</i> : The executives had knowledge of from internal emails regarding off-label use of the medical device.
KV Pharmaceuticals & Ethex	Chief Executive Officer	Drug Corporation: 2 Felony Adulteration and Misbranding Claims <u>Individually</u> : 2 Misdemeanor Misbranding Claims	<u>Corporation</u> : Apprx. \$27 million in fines and forfeiture <u>Individ-</u>	1 year imprisonment for the executive	<u>Knowledge</u> : KV had “Intent to Defraud or Mislead”; <u>No Knowledge</u> : Absence of Proof as to Individual Defendant	Similar to <i>Park</i> : CEO Hermelin received internal and external reports of irregularly shaped and oversized prescription

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			ually: Apprx. \$1 million in fines			drugs. In spite of these warnings, Hermelin ordered a manufacturing increase.
Forest Labs	Chairman	Drug Corporation: 1 Felony and 1 Misdemeanor	Corporation: Apprx. \$164 million in fines and forfeiture	Exclusion for the executive (eventually dismissed)	Knowledge: Forest Labs had "Intent to Defraud or Mislead"; <u>No Knowledge:</u> Absence of Proof as to Individual Defendant	Similar to <i>Park</i> : The corporation received an FDA warning letter alerting them to the illegal conduct occurring.

These settlements serve as an example of a current trend that should concern those who may be at the center of a future prosecution under the responsible corporate officer doctrine. Governmental arms are overreaching and misusing the responsible corporate officer doctrine in two ways. First, penalties for strict liability public welfare offenses were not intended to result in the penalties ordered by courts today (*Purdue Frederick* and *Synthes*). Additionally, they are punishing those who have not been convicted on an individual basis (*Forest Laboratories*). A conviction should be the basis on which the government penalizes a corporate wrongdoer, and the penalties should be appropriate with the spirit of the statute.

V. DEVELOPMENT/RECOMMENDATIONS

It is increasingly becoming difficult for companies to determine and difficulty in what kind of certainty and provisions to tell clients in the industry facing an investigation or prosecution under the responsible corporate officer doctrine. Observers are doubtful of the legality of the responsible corporate officer doctrine for the reasons set forth above and would support a challenge.¹⁴⁶ From a policy perspective, if the uncertainty of punishments given in the past as well as uncertainty over where settlement punishments are going in the future deters even one skilled, quality candidate that could make a difference in the company they choose to serve for the patients they choose to serve from taking a corporate executive job because of the aforementioned uncertainty, the cost of uncertainty may be too high.¹⁴⁷ The glowing endorsement given by Commissioner Hamburg suggests that the FDA will not stop using such a powerful tool and corporate executives need to pay close attention to any moves the FDA would make in this area.¹⁴⁸

The Responsible Corporate Officer Doctrine is warranted to keep corporate executives in check. Any deterrent factor the doctrine has is a positive for the industry and society.¹⁴⁹ However, one commented posited that the government should prosecute executives independent of participation in the underlying offense.¹⁵⁰ Additionally, she offered the view that executives

¹⁴⁶ Glasner, *supra* note 53, at 3.

¹⁴⁷ *Id.* at 6-7.

¹⁴⁸ REGULATORY PROCEDURES MANUAL §§ 6-5-3.

¹⁴⁹ Sepinwall, *supra* note 31, at 376.

¹⁵⁰ *Id.* at 378.

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should be punished solely on the grounds of their position.¹⁵¹ This approach seems too harsh and for the reasons set forth, should not be the effect of this doctrine.

A. Ability of judicial review?

The responsible corporate officer doctrine was borne from Supreme Court statutory interpretation.¹⁵² Nonetheless, safeguards that were placed in effect by the Supreme Court are not being used by the FDA and DOJ. For example, Justice Burger in *Park* suggested that recommending the class of executives responsible in a certain situation should be dependent on evidence produced to the jury in a trial.¹⁵³ Justice Burger's sentiment is not being followed today because there has not been one violation of the FD&C Act in the pharmaceutical and medical device industry has gone to trial after FDA Commissioner Hamburg revived the responsible corporate officer doctrine. Since there is a disparity between the uncertain utilization of the doctrine by the FDA and the DOJ, is there a way for the responsible corporate officer doctrine to be revised from the high court?

This remedy is not likely to occur right away. Although the Supreme Court can take this issue with the right case, there are several reasons why this recommendation may not be immediately possible. First, executives must be willing to risk steep penalties both professionally (debarment or exclusion) and/or personally (imprisonment). Additionally, the corporation must be willing to roll the dice and risk large fines and/or the ability to continue doing business in the

¹⁵¹ *Id.* at 380.

¹⁵² See discussion of case law, *supra* pp. 4-10.

¹⁵³ *Park*, 421 U.S. at 669.

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government funded pharmaceutical and medical device realm. While the ability of judicial review is possible, it is not probable in the near future.

B. Narrowing the Doctrine through the legislature?

Government agencies are looking to utilize the responsible corporate officer doctrine as a basis for criminal prosecutions. At the very least, the FDA should revise their manual to make a more stream-lined approach to investigating and recommending prosecution to the DOJ. The most egregious FD&C Act violations are the ones where the corporate officer responsible for the company has knowledge of the underlying offenses but fails to take action to remedy the situation.¹⁵⁴ These circumstances fit squarely within the spirit of past Supreme Court decisions (*Park* and *Dotterweich*) together with the criteria of FDA Manual 6-5-3; therefore, these situations do not raise serious concerns of prosecution of FD&C Act violations under the responsible corporate officer doctrine.

However, there are questions of whether these prosecutions have a deterrent factor for those executives who have no knowledge of the underlying offense because that seems counterintuitive: an executive cannot be deterred from committing an offense if they do not know of an offense being committed. If the FDA revised their manual to recommend prosecution against those who received warning letters and failed to take corrective action, more within the government who act in this area as well as corporate executives would have a better idea of what kinds of acts can fall within the responsible corporate officer doctrine.

¹⁵⁴ Glasner, *supra* note 53, at 5.

C. Tandem Prosecution

The specific concern lies with the fact that when a *qui tam*¹⁵⁵ action in this area proceeds without the help or specialized knowledge of FDA experts, it circumvents the intended use of the responsible corporate officer doctrine by the Supreme Court.¹⁵⁶ As such, there should be judicial concern if the FDA is not involved. If the FDA recommends that an investigation should conclude should the DOJ not pursue prosecution? The possibility of a collaborative agreement between the FDA and DOJ would likely alleviate these concerns. If a collaborative agreement is possible, the DOJ can still use their power of choosing which *qui tam* cases to intervene in and prosecute with the FDA's specialized knowledge. If a collaborative agreement is not possible, a recommendation for the DOJ to enact guidelines similar to FDA Manual 6-5-3 would be a step in the right direction.¹⁵⁷

D. Industry Action to Safeguard Itself from Possible Prosecution

The responsible corporate officer doctrine, through *Park* and *Dotterweich*, was conceived before companies throughout the industry constructed their own complex compliance programs. However, starting and maintaining a comprehensive compliance programs may be the only realistic real-time option executives in this area have because relying on the Supreme Court to decide could take ten to fifteen years if at all. This estimate is premised on the realization that a

¹⁵⁵ See discussion of the FDA's relationship with the DOJ in reference to *qui tam* actions, *supra* p. 18.

¹⁵⁶ U.S. Gov't Accountability Office, *supra* note 73, at 8.

¹⁵⁷ The concerns of FDA Manual 6-5-3, discussed *supra*, would carry over to any guidelines the DOJ enacts.

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corporation may not turn down a settlement offer because of the severe penalties one would face if they proceed to trial and assumption that the Supreme Court or a Court of Appeals may not grant certiorari to hear the case. Additionally, executives should not rely on the Legislature or pass new laws or amend existing laws to make this doctrine more clear (although submitting a citizen's petition could be faster if executives ask the government to work with industry professionals).

Industry should be aware of FDA or DOJ triggers that can alert an executive that an FDA investigation or a DOJ prosecution is near. It is uncertain whether the FDA Manual 6-5-3 criteria are used to determine which investigations to refer to the DOJ or whether the DOJ takes the criteria into account when determining which cases to prosecute and/or settle. All specific FDA feedback on any potential violations through a warning letter or a failed inspection should be reviewed with extreme caution. Industry officers would do well to work with the FDA at this stage to prevent a prosecution recommendation to the DOJ. Additionally, industry executives should monitor all available corporate integrity agreements to see where the DOJ has paid particular attention to within other companies.

Since the responsible corporate officer doctrine was formed from public policy aspects of ensuring the safety of the public at large as well as the efficacy of the federal health care programs, industry should take an introspective look at their companies and their corporate officers to determine specific offices or departments that lack oversight.

VI. CONCLUSION

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While the responsible corporate officer doctrine goes further than it should in regards to the principle tenets of criminal law, the Responsible Corporate Officer Doctrine is a necessary tool for the government to punish wrongdoers and deter others who are tempted to commit the same illegal conduct. The policy reasons of keeping corporate officers in check to ensure the safety the public at large is extremely important. However, those facing prosecution under the responsible corporate officer doctrine cannot fully contemplate punishments under the doctrine due to the misuse of the doctrine by government agencies that rely on dated cases that stand on shaky constitutional grounds. With that in mind, I propose that the question of whether the responsible corporate officer doctrine should be abolished is misplaced and instead invite the question of what can be done to retool what could be a useful device for all to comply with laws and requirements within managerial ranks of a pharmaceutical or medical device corporation.