THE CRIME OF DOING NOTHING: STRICT LIABILITY FOR CORPORATE OFFICERS UNDER THE FDCA

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I. INTRODUCTION

Can the government convict a pharmaceutical executive of a crime without his or her having any knowledge of or involvement in the offense? The answer is "yes," under the strict liability misdemeanor offense in the Food, Drug, and Cosmetic Act (FDCA).[1] The provision makes executives ***vicariously*** liable for the crimes of others. Traditionally, the government has not used the full scope of its discretion under this very severe provision and has brought misdemeanor FDCA charges only when the defendant was personally responsible for the violation, or when he or she was on notice of the conduct causing the violation and failed to correct it. In this Article, we discuss the history of the misdemeanor provision and an alarming contrary use of the provision in a recent case in which the government decided misdemeanor charges were justified in the absence of these factors. We argue that the government must retain its traditional caution in imposing strict, vicarious liability on pharmaceutical-industry executives under the FDCA.

II. STRICT LIABILITY UNDER THE FDCA

A. The Statutory Framework and Case Law

The basic prohibitions of the FDCA are contained at 21 U.S.C. § 331, which prohibits, among other things, "causing" the adulteration or misbranding of any drug (or food, or cosmetic, or "device") in interstate commerce,[2] or "causing" the introduction or delivery for introduction into interstate commerce of an adulterated or misbranded drug.[3] These prohibitions are augmented by numerous regulations and judicial opinions defining what it means for a drug to be "adulterated" or "misbranded." The criminal punishments for violations are set out in § 333. Any person who takes or causes any the actions proscribed in § 331 is guilty of a misdemeanor.[4] Anyone who takes or causes any of those actions with "intent to defraud or mislead," or after having previously been convicted under § 331, is guilty of a felony.[5]

Generations of law students have learned that under the common-law every crime has two elements: (1) a bad act (the *actus reus*), and (2) a culpable state of mind (*mens rea*), generally intent or recklessness.[6] Section 333(a)(1) of the FDCA, the misdemeanor provision, is noteworthy because it creates one of the few true "strict liability" crimes in federal criminal law.

Commission of the crime requires only an act. The act need not have been intentional or reckless, or even negligent. It is irrelevant what the defendant knew or should have known. If a drug is misbranded or adulterated, or if a misbranded or adulterated drug is distributed into the channels of interstate commerce, someone (and realistically, in the modern world, many people) has committed a crime.

Even more remarkable is that for certain classes of people, even a bad act is unnecessary to secure a criminal conviction under the FDCA. In particular, the executives and managers of the companies that make, distribute, and sell pharmaceuticals can be convicted for violating the FDCA without having personally participated in the act being punished or having been an accessory to it. For these persons, it is enough to secure a conviction that (a) a prohibited act took place somewhere within the company, and (b) the defendant's position within the company was one that gave him or her responsibility and authority either to prevent the violation or to correct it. In other words, the crime is being in the wrong position at the wrong time. It is not just strict liability; it is strict, ***vicarious*** liability.

1. *Dotterweich* and Park

The Supreme Court sanctioned the view that executives and managers can be strictly, criminally liable under the FDCA for the acts or omissions of their subordinates in *United States v. Dotterweich*.[7] Dotterweich was the general manager of a company that bought wholesale drugs, repackaged them, and sold them retail under its own label. He was prosecuted and convicted on two counts of shipping a misbranded drug and one count of shipping an adulterated drug, all in violation of 21 U.S.C. § 331(a). All three counts were based on a single order from a single physician. One drug in the shipment included an ingredient that had been removed from the official formula listed on the "National Formulary." Another was less potent than required by the government and than indicated on the label. Dotterweich had no personal connection to the particular shipment for which he was charged; his only connection was that he was "in general charge of the corporation's business and had given general instructions to its employees to fill orders received from physicians."[8] He was convicted, while the corporation was acquitted.

A 5 to 4 majority of the Supreme Court affirmed the convictions, reversing the Second Circuit. The Court observed that the FDCA is among a type of statutes that "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger."[9] The Court held that criminal liability under the FDCA stretches to all those having such "a responsible share in the furtherance of the transaction which the statute outlaws."[10] Other than concluding that the jury reasonably found

that Dotterweich fit that description, however, the Court refused to say how one could identify those whom had a "responsible share" in the offending conduct.[11] The majority assured itself that the standard would be given fair application based on "'conscience and circumspection in prosecuting officers.'"[12]

Thirty years later, in *United States v. Park*,[13] the Court re-visited and re-affirmed the holding of *Dotterweich*. Park was the president and CEO of a national retail food chain with over 35,000 employees and almost 900 stores. Over a three-year period, FDA inspectors had repeatedly found and notified the company of rodent contamination at two of the company's several food-storage warehouses. Eventually both the company and Park were charged with five misdemeanor counts under § 301(k) for causing the adulteration of food being held for sale. The company pled guilty while Park went to trial.[14]

The government introduced the company's standard bylaw defining the role of the CEO, as well as testimony from a company vice president that Park retained responsibility for "the big, broad, principles of the operation of the company" and "seeing that they all work together."[15] Park admitted under cross-examination that providing sanitary storage conditions for food being offered for sale was something that he was "responsible for in the entire operation of the company."[16]

The trial court instructed the jury that to find Park guilty, it had to find that he had "a responsible relationship" to the sanitary conditions in the company's warehouses. His formal title was insufficient alone to sustain a guilty verdict, the trial court said, but the question was simply whether the defendant, "by virtue of his position in the company, had a position of authority and responsibility in the situation out of which these charges arose."[17] The jury convicted on all counts.

The Fourth Circuit reversed the convictions. It reasoned that the effect of the court's instruction was to allow conviction not just without proof of "'awareness of some wrongdoing,'" but also in the absence of "'wrongful action,'"[18] and that proof of this element was required by due process. It ordered that the jury be instructed that it was required to find "gross negligence and inattention in discharging . . . corporate duties and obligations or any of a host of other acts of commission or omission which would 'cause' the contamination of the food."[19]

The Supreme Court reversed, approving the trial court's instructions. It noted that the FDCA "imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur."[20] The Court reasoned that it is through the violation of this duty that an executive-

defendant "causes" the conduct to occur that is proscribed by the Act. Accordingly, the government "establishes a prima facie case [under the FDCA] when it introduces evidence sufficient to warrant a finding by the trier of the facts that the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so."[21]

2. The Consequences of *Park* Liability

The *Park* Court agreed that the defendant's formal title and position within the corporation would be insufficient alone to support a conviction, but it defined the government's burden in such a way as to require little else. It was sufficient, the Court said, that the evidence supported a finding that the defendant "had a responsible relation to the situation, and by virtue of his position . . . had . . . authority and responsibility to deal with the situation."[22] Lower-court opinions demonstrate that the *Park* standard does not "require the corporate officer actually to exercise any authority over the activity."[23] Rather, "a person is a 'responsible corporate officer' if the person has ***authority to exercise control*** over the corporation's activity that is causing the [violation]."[24] Thus, while it is not enough merely to name the defendant's position, it is sufficient to name the position and then demonstrate that the defendant was somewhere within the corporate chain of command with "authority and responsibility" for the area in which the violation occurred. As one district court has commented, "The line . . . between a conviction based on corporate position alone and one based on a 'responsible relationship' to the violation is a fine one, and arguably no wider than a corporate bylaw."[25] This is of course especially true when it comes to CEOs, COOs, and others at the pinnacle of the corporate hierarchy, since normally there will be little if anything within the company's operations that is not, at least on paper, within their "authority and responsibility."

Is there any pharmaceutical executive who cannot be convicted under the *Park* standard? Vice presidents for sales and marketing probably are safe when the error occurs within the research or manufacturing divisions, and vice versa. Likewise, a second-tier executive would have at least a triable defense if he or she had attempted to prevent the problem before it occurred and was overruled by a superior. But what potential problems do the CEO, or even the general counsel, lack the power or authority to prevent or correct? Besides the minute fraction of problems that are raised with and addressed conclusively by the board of directors, it is hard to think of any. That leaves the average pharmaceutical executive wondering what any one of the hundreds or thousands of employees under his or her control might be doing in a given day that could subject him to career-threatening personal criminal liability.

The *Park* Court recognized that a defendant could not be convicted under its standard if it were "objectively impossible" for the defendant to have prevented the violations—or if he or she were "'powerless' to prevent or correct the violation." [26] Some lower courts have construed this language as recognizing an affirmative defense in FDCA cases resting on "responsible corporate officer" liability, or "*Park* liability."[27] Some of those courts have reduced the defendant's burden to proving, not that compliance was "objectively impossible," but that he or she acted with "extraordinary care" and yet still was unable to prevent the violation.[28] Even assuming that this is consistent with *Park*, it still places an enormous burden on pharmaceutical executives. No one can predict what a lay jury will find to be "extraordinary care." Moreover, an arguable affirmative defense rarely will keep charges from being pursued, and for many executives the primary damage of a criminal charge would be complete with the announcement of charges. Finally, there are no published reports of the "extraordinary care" defense being successfully used.[29]

At the end of the day, the only thing that prevents criminal charges from being brought against one or more executives in virtually every civil or criminal FDCA case brought by the government is the "conscience and circumspection" of prosecutors.[30] That is cold comfort, and as discussed below, it is getting colder all the time.

B. An Example: False or Misleading Statements in Marketing Materials

There are innumerable scenarios in which pharmaceutical companies could find themselves charged with violating the FDCA. Virtually any error affecting the integrity of the manufacture, storage, or labeling of a drug could make for a colorable case. And the government is taking an increasingly broad view of the Act's proscriptions. This section uses just one hypothetical scenario to demonstrate a realistic circumstance in which a pharmaceutical executive could find herself under threat of criminal charges under the FDCA.[31]

Background

You have been retained by a medium-sized pharmaceutical company, Pharmco, to represent the CEO in an on-going grand jury investigation. Pharmco has 25,000 employees and manufactures, markets, and distributes two-dozen name-brand drugs in the U.S. and abroad. Pharmco is divided into three main divisions, each headed by an executive vice-president who reports to the CEO: (i) Medical Information and R&D, (ii) Law and Regulatory, and (ii) Sales and Marketing.

Seven years ago, the company received FDA approval to market a new asthma medication, BreathEasy, and the product had been outstandingly successful, quickly becoming

the dominant preventive asthma treatment in a multi-billion-dollar market. Two years after the launch, reports began surfacing of long-term BreathEasy patients suffering fatal asthma attacks. The reactions involved only long-term patients with severe asthma, so it took a few years for Pharmco and government health experts to recognize that long-term BreathEasy use was making asthma attacks less frequent but more severe, thereby increasing the overall risk of asthma death. When the connection was made, FDA suspended its approval of BreathEasy and removed the drug from the market. There were several highly publicized child fatalities linked to BreathEasy, and the FDA's decision to withdraw the drug was front-page news for months. A national news magazine published an issue with a cover image of an asphyxiating child and a BreathEasy inhaler.

Soon after the drug was withdrawn, Pharmco received a Grand Jury subpoena from the U.S. Attorney for the Eastern District of WherEver (EDWE), asking essentially for every internal company document related to the development and approval of BreathEasy. Since that time, the company has produced millions of pages of documents and e-mails pursuant to over a hundred subpoenas from the EDWE and from the Office of Consumer Litigation (OCL) in the Civil Division of the Department of Justice. Dozens of current and former Pharmco scientists and sales and marketing personnel have testified before the grand jury. The government's investigative team includes the EDWE, OCL, the Fraud Section of the Criminal Division of the Justice Department, the Department of Health and Human Services' Office of Inspector General (OIG), the IRS, the U.S. Postal Inspection Service, and Medicaid-fraud investigators from three states.

Two years into the investigation, the prosecutors have consistently declined to meet with you or with the company's lawyers, but it is apparent from the document requests and from reports of the questioning in the grand jury that the government has investigated nearly every aspect of Pharmco's business, including the development, approval, and post-approval research on BreathEasy and several other drugs; the marketing of BreathEasy and these other drugs; Pharmco's pricing and competitive practices; its accounting and financial reporting; and its tax payments. It is also apparent that the prosecutors have failed to find any clear and significant crimes at any level of the company, and absolutely nothing suggesting that the company anticipated or should have anticipated that BreathEasy would increase the risk of asthma death. Moreover, you know from your own investigation that your client had absolutely no direct involvement in any of issues on which the government is focused.

The Government's Position

Finally, after more than two years of investigation, the Assistant U.S. Attorney (AUSA) in charge calls and says that he is wrapping up his work and is ready to meet with the company's and the executives' attorneys. At the meeting, you realize that the AUSA and his team are living in an entirely different reality than you and the other defense attorneys. He is convinced that fraud occurred in the marketing and the conduct of studies regarding BreathEasy, and that he simply has not yet found the "smoking gun" documents. He alleges grand conspiracies to defraud doctors and the FDA, mostly based on his own misconceptions of the science surrounding BreathEasy and the FDA-approval process. He describes several theories of felony liability for the company itself, but none concern you terribly. The theories seem downright silly, and none of the documents or testimony the AUSA shares at the meeting have anything to do with your client or issues she knew anything about.

Then the AUSA says something that sounds ridiculous but that alarms you nonetheless. He says that when the company is indicted, your client and the executive vice presidents in charge of sales and marketing and of medical information and R&D will likely be indicted, too. He acknowledges that he might have proof problems on any felony charges if they go to trial. But the AUSA tells you that regardless of whether he ultimately tries them on felony charges, he will charge the individuals with multiple misdemeanor counts under the FDCA, for shipping a misbranded drug.

You ask what basis there could possibly be for charges against your client. The AUSA tells you there are dozens of potential bases for charges, but that at the moment he favors two in particular. First, he tells you that it actually qualifies as "misbranding" under the Act if a product turns out to be dangerous when used according to the labeling. Because BreathEasy obviously turned out to be dangerous for some people when used as prescribed, he says that theory is a "no brainer." You ask if there is any evidence that the CEO or anyone in the company's R&D department knew or reasonably could have discovered that BreathEasy would have the side effect that it had. The AUSA says he is not aware of any, but that he does not need it.

The prosecutor's second theory relates to marketing. When BreathEasy was launched, Pharmco hired sales reps away from other companies in rural parts of the country, such as WherEver, to give Pharmco a presence in these areas. One of the district managers hired to supervise reps in the eastern part of WherEver was just a bad apple. Contrary to the company's express written policies, and contrary to express, repeated training all reps and managers received, he created his own "detailing pieces" on BreathEasy for his reps to distribute to doctors. These handouts were not reviewed through Pharmco's mandatory approval process for

all marketing materials, which required sign-off from the legal and medical-information departments.

One such handout prominently featured a claim that "studies confirm" BreathEasy had "better pediatric compliance" than similar inhalers. The manager had heard this from a sales trainer at Pharmco headquarters. In fact, it was commonly accepted among BreathEasy patients and their doctors that children were better about taking BreathEasy because it lacked the bitter aftertaste of other drugs. But Pharmco did not have study data to support this claim, and it was not a promotional claim that had been approved by the FDA. The handout was widely used by reps in eastern WherEver, even after a regional manager discovered that the district manager was making his own detailing pieces and fired him. However, at no point did anyone outside of the legal department at Pharmco headquarters know anything about the district manager's homemade marketing materials or the claim about "pediatric compliance." You ask the AUSA if he is aware of evidence indicating otherwise, and he says he is not.

You are dismissive of the AUSA's threat to pursue criminal charges against Pharmco's CEO on these facts. The drug turned out to be harmful, but no one knew or could have known that. A misleading claim had been made by the reps in WherEver, but they were not trained or encouraged by the company to make this claim, and the manager had defied company policy in making a homemade handout, especially one with an unapproved claim. Moreover, your client had absolutely nothing to do with the R&D work on BreathEasy or the manager in WherEver. You tell the prosecutor that you will have to do some research and talk to your client before responding and discussing any potential settlements. You travel back home and refresh your recollection on the criminal provisions of the FDCA.

The Law

In reviewing some earlier research on the FDCA, you discover the following: A drug is considered "misbranded" under the Act "[i]f it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."[32] A drug is also considered "misbranded" "[i]f its labeling [was] false or misleading in any particular."[33] "Labeling" is defined very broadly under the Act to include "all labels and other written, printed, or graphic matter . . . accompanying [a drug]."[34] The FDA has gone even further and provided in its regulations that "labeling" includes, among other things, any "printed, audio, or visual matter descriptive of a drug . . . which [is] disseminated ***by or on behalf of*** its manufacturer, packer, or distributor," including "[b]rochures, booklets, mailing pieces, ***detailing pieces***, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints. . . ."[35]

You are becoming more concerned. BreathEasy obvious turned out to be dangerous to health when used as directed. The homemade handout falsely suggested the presence of study data that did not exist, and it seems to qualify as "labeling" for BreathEasy. It therefore seems that someone at the company, and perhaps the company itself, could theoretically be prosecuted for misbranding. You are still certain, however, that your client could not be convicted, because there is no evidence that she ever knew of or had any role in the false claims that were made. Moreover, given the size of the company, it would be completely absurd to hold your client responsible for these claims being made, since realistically errors of this kind will happen in any company of this size irrespective of the efforts of management. Then, you find the Supreme Court's decisions in *Dotterweich* and *Park*, and you realize that as absurd as it may sound, if the AUSA decides to pursue misdemeanor charges against your client, he can do so, and she faces a very real possibility of being convicted.

So what penalties might your client face if she is charged? First, and perhaps most significant to your client, she will face the personal and professional stain of simply being charged with a crime in the first instance. The damage to her personal and professional reputation will be all the worse because of the media attention to the BreathEasy "scandal." Your client may have to step down from her position, and her chances might be ruined of advancing to a better position at another company. In fact, she may have to retire from the pharmaceutical industry simply as a matter of personal preservation, because the next time a ground-level employee of a company she is running makes an error or commits a crime, she could be charged with a ***felony***, simply by virtue of the prior conviction.[36]

Of course, your client will also face some possibility of serving time in a federal penitentiary—up to a year on each count for which she is convicted.[37] Although the FDCA caps the maximum fine at $1,000, this is superseded by 18 U.S.C. § 3571, which would authorize a fine of $100,000, $250,000, or more.[38]

III. PAST PRACTICE WITH THE STRICT LIABILITY PROVISION

As should now be clear, the strict liability misdemeanor under the FDCA, together with the "responsible relation" doctrine announced in *Dotterweich* and *Park*, creates a very harsh tool for prosecutors and health-care regulators. Fortunately, however, it traditionally has been used sparingly, especially against legitimate pharmaceutical companies.

In the last fifty years, there have been only a handful of reported decisions in which the government charged a corporate executive with a misdemeanor FDCA violation based solely on the executive's "responsible relation" to the violation.[39] Only one of these cases involved

executives from a traditional pharmaceutical company.[40] Most of the cases brought against executives under the misdemeanor provision are based on the executive's own personal conduct, not just the executive's position.[41] Of those cases that do seem to be "responsible relation" cases, the overwhelming majority involve an individual defendant who was in fact on notice of the conduct giving rise to the violation.[42] In *Park*, for instance, the company had been notified repeatedly by the FDA that there were infestation problems in its warehouses, and the defendant-president had personally received notice of at least one failed inspection.[43] Reported opinions are not a perfect barometer of the law enforcement environment. But still, the number and type of cases that are seen in the official reports strongly indicate that actual *Dotterweich*-type prosecutions—that is, executives charged for violations in which they had no role and no knowledge—have been very rare, and that misdemeanor charges generally have been pursued only when the defendant was himself responsible for the violation, or when he was on notice of it and failed to correct it.[44]

Recent data suggest that this trend has continued even in recent years, as the federal government has focused on prosecuting health-care fraud. According to the Bureau of Justice Statistics, the overall number of FDCA criminal prosecutions has been small,[45] and misdemeanor prosecutions have been rare or nonexistent.[46] This conservative use of the "responsible corporate officer" doctrine has also shown itself in a series of major settlements reached in criminal investigations of major pharmaceutical companies since 2000. Each of these cases presented circumstances in which the government clearly could have charged individual executives with misdemeanor (if not felony) FDCA violations, or demanded misdemeanor pleas as part of any settlement. Yet none of these major settlements has involved individual criminal charges under the FDCA.

For example, in December 2005 Eli Lilly pled guilty to one misdemeanor misbranding count and paid $36 million to settle allegations that the company marketed its drug Evista for off-label uses. Evista was approved for use in treating and preventing osteoporosis. According to the government, Lilly had specifically sought, and been denied, FDA approval to market Evista as a breast cancer drug. When the profits from osteoporosis use did not meet expectations, the company developed a marketing platform to position Evista as preventing not only osteoporosis, but also breast cancer and cardiovascular disease. The plan included, among other things, sales representative training materials, a press release, a consumer magazine ad, and unsolicited letters to physicians discussing Evista's use in breast cancer prevention.[47] Clearly if the government believed these allegations—which suggest intentional misconduct at some level of the company—it could have pursued misdemeanor charges against individual Eli Lilly executives, but it did not.

In May 2004, Warner-Lambert agreed to plead guilty to two felony FDCA counts and to pay $430 million to settle criminal and civil allegations that it marketed the anti-seizure drug Neurontin for off-label uses. The government alleged that a scheme was conceived and planned at the highest levels of the company to aggressively market Neurontin to treat a wide array of off-label conditions. For example, the company instructed physicians speaking on its behalf to address off-label uses of Neurontin. Warner-Lambert allegedly decided specifically not to seek approval for additional usages of Neurontin because it did not want to expand the market that would be available to generics when its patents for Neurontin expired.[48] Again, clearly the government could have pursued misdemeanor criminal charges against a number of Warner-Lambert executives if it believed these allegations to be true and thought criminal charges would be in the interest of the United States.

Many other examples could be provided, including Genentech, InterMune,[49] Boston Scientific,[50] and Endovascular Technologies.[51] Each of these settlements resulted in tens or hundreds of millions of dollars in fines and/or felony corporate pleas. In many the government alleged intentional misconduct. But none resulted in criminal charges against individual executives under the FDCA.[52] Clearly the judgment of FDA, the Justice Department, and other agencies has been that the strict liability misdemeanor has to be reserved for very specific circumstances.

This conservative approach under the FDCA is consistent with longstanding FDA enforcement policy. FDA's *Regulatory Procedures Manual* states that any FDA recommendation for criminal prosecution "should ordinarily contain proposed criminal charges that show a ***continuous or repeated course of violative conduct***. . . . This is because the agency ordinarily exercises its prosecutorial discretion to seek criminal sanctions against a person ***only when a prior warning or other type of notice can be shown***." [53] In 1976, FDA's Associate Commission for Compliance wrote that notwithstanding the strict-liability misdemeanor in the FDA,

> We insist . . . that our prosecution recommendations include a factual record which demonstrates that every individual charged either knew or should have known of the violative conditions set forth, and was in a position to do something about those conditions but failed to do so. In most cases, we have evidence that actual knowledge does exist on the part of the named individuals."[54]

Thus, it is no accident that the reported case law reflects that misdemeanor FDCA charges generally have been pursued only when the defendant either was himself responsible for the violation, or was on notice of it and failed to correct it.

IV. NEW SIGNALS: "MAGNITUDE OF HARM" AS A SURROGATE FOR PRIOR NOTICE

In one recent case, however, the government has indicated that it is no longer interested in honoring this tradition of keeping its sword half-sheathed. In discussing the resolution of a long-term, wide-ranging investigation, the government has insisted that company executives plead to misdemeanor charges, but not because they were directly involved in any alleged improprieties, and not because they knew of any improprieties and failed to take corrective action. Instead, the rationale is that criminal liability is appropriate because, in the judgment of the government, the magnitude of the harm caused by the underlying violations is so great.

There are many reasons to be concerned about the government viewing "magnitude of harm" as a surrogate for knowledge or prior notice in making criminal charging decisions. First, from a practical perspective, such a policy might make it intolerably risky to be a pharmaceutical executive. Even assuming that all prosecutors are well meaning and reasonable, the pharmaceutical business is and always will have catastrophes where products do not work or are not used as anticipated. Therefore, to make magnitude of harm an independent ground for seeking criminal charges when something goes wrong is to subject every manager and executive in the industry to potential criminal liability, and liability for events that are entirely outside of his or her control. After a couple of high-profile convictions under a more free-wheeling use of the FDCA misdemeanor, industry executives would be reasonable in asking if this is still the business for them. At a minimum, they could be expected to avoid those sectors in which catastrophes seem most likely, as with scheduled drugs, perhaps. But then with drugs that are used widely enough—the Vioxxs and Prempros—any possibility of an adverse event might be too high.

Second, it is precisely in those cases in which an unanticipated problem has arisen and caused widespread harm that imposing criminal liability upon a few individuals is least appropriate. It is in these cases that the stain of a prosecution is most severe, because the public, quite reasonably, continues to associate criminal prosecutions with allegations of fault. Moreover, there is a specific government agency—FDA—that is charged under the law with balancing risks and benefits and determining whether and how a drug should be made available. To make individual executives fair game for criminal charges in cases where a drug has become an unintended health hazard is to permit the blameless to be punished simply because lay law enforcement authorities disagree with the way FDA did its job.

Third, from the standpoint of basic fairness, it is simply preferable to have prior notice or something approaching culpability as a guidepost for prosecutorial discretion. Unlike knowledge or prior notice, "magnitude of harm" is largely in the eye of the beholder and is not easily susceptible of proof. Thus, allowing magnitude of harm to justify criminal charges is tantamount to requiring no justifications at all, and converting the FDCA misdemeanor into an all-purpose conviction tool, effective in whatever circumstances the prosecutor needs it. The prosecutor is effectively given the power both to enforce the law and to say what it is, because the burden is so low, and "misbranding" and "adulteration" are so broadly defined. As Justice Murphy observed in dissent in *Dotterweich*,

> [T]hat situation is precisely what our constitutional system sought to avoid. Reliance on the legislature to define crimes and criminals distinguishes our form of jurisprudence from certain less desirable ones. The legislative power to restrain the liberty and to imperil the good reputation of citizens must not rest upon the variable attitudes and opinions of those charged with the duties of interpreting and enforcing the mandates of the law.[55]

Finally, it will often be the case that the "harm" is not traceable to the alleged violative conduct. In our hypothetical case of BreathEasy, for example, a great amount of harm was done. But was that harm made materially worse by the fact that a few reps in WherEver made unrelated unapproved claims? How likely is it that one of those claims caused a prescription to be written and that the prescription happened to go to a patient who had a rare adverse reaction? Probably not very likely.

In part because of the breadth of the FDCA's prohibitions, there is a real danger that unrestrained, the FDCA misdemeanor will merely become a lever that allows prosecutors to obtain convictions or extract pleas in vindication of suspicions that cannot be proven. What are prosecutors likely to do when, as in the case of BreathEasy, something terrible has happened, and they are convinced that fraud occurred, but the evidence never surfaces? They are likely to use the same logic as the AUSA in the case of BreathEasy: "There has been a tragic event, and someone has to be responsible. The FDCA gives me the tool with which to hold you responsible. You can protest your innocence, but the FDCA makes you guilty. When can you be here to plea?"

V. CONCLUSION

In some ways it is not surprising that the government might be taking a more aggressive view of using the FDCA misdemeanor in investigations of pharmaceutical companies. Regulating the pharmaceutical industry was once almost solely the prerogative of the FDA. Most criminal prosecutions began with a visit from an FDA inspector, and charges rarely were filed without a prosecution recommendation from the agency.[56] Today, there is a virtual constant stream of announcements of plea deals and multi-million dollar settlements between prosecutors, led by U.S. Attorneys' Offices and the Office of Consumer Litigation, and pharmaceutical companies. These cases originate at DOJ, in the U.S. Attorneys' Offices, with civil *qui tam* complaints, and elsewhere; probably few originate or are meaningfully steered by FDA. And it is not surprising that prosecutors who know less about how the industry in fact operates take a more favorable view of a provision that essentially puts the burden on executives to ensure perfect compliance with the FDCA throughout their companies.

At the same time, it makes much less sense today than it did in 1938 to indulge the fiction that executives—in pharmaceuticals or any other industry—can personally carry this burden. We no longer live in a world of neighborhood druggists and family-owned companies that directly supervise their own employees and operations. Modern-day pharmaceutical executives "supervise" the work of sometimes hundreds of thousands of employees and scores of corporate entities in dozens of countries. If it ever made sense to have a criminal provision that holds executives and owners strictly criminally liable for errors and mixups and misbehaviors of their subordinates, it no longer does.

It certainly makes no sense for the government to broaden its use of this provision.

ENDNOTES

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1. 21 U.S.C. § 301 et seq.

2. § 331(b) & (k).

3. § 331(a).

4. § 333(a)(1).

5. § 333(a)(2).

6. *See, e.g.*, BLACK'S LAW DICTIONARY (8th ed. 2004) (defining "mens rea" as "[t]he state of mind that the prosecution, to secure a conviction, must prove that a defendant had when committing a crime; criminal intent or recklessness . . . . the second of two essential elements of every crime at common law, the other being the *actus reus*. . . . Also termed *mental element*; *criminal intent*; *guilty mind*").

7. 320 U.S. 277 (1943).

8. *See* United States v. Buffalo Pharmacal Co., 131 F.2d 500, 501 (2d Cir. 1942), *rev'd sub nom*., United States v. Dotterweich, 320 U.S. 277, 278 (1943).

9. 320 U.S. at 280-81.

10. *Id.* at 284.

11. *Id.* at 285.

12. *Id.* (quoting Nash v. United States, 229 U.S. 373, 378, (1913)).

13. 421 U.S. 658 (1975).

14. *Id.* at 660-64.

15. *Id.* at 663.

16. *Id.* at 664.

17. *Id.* at 665 & n.9.

18. United States v. Park, 499 F.2d 839, 841-42 (4th Cir. 1974) (quoting *Dotterweich*, 320 U.S. at 281).

19. *Id.* at 842 (footnote omitted).

20. *Park*, 421 U.S. at 672.

21. *Id.* at 673-74.

22. *Id.* at 674 (quotations omitted).

23. United States v. Iverson, 162 F.3d 1015, 1024 (9th Cir. 1998) (applying standard to Clean Water Act).

24. *Id.* at 1025 (emphasis added); *see also* United States v. Ming Hong, 242 F.3d 528, 531 (4th Cir. 2001) (also applying *Park* to the CWA; "[T]he pertinent question is whether the defendant bore such a relationship to the corporation that it is appropriate to hold him criminally liable for failing to prevent the charged violations of the CWA.").

25. United States v. New Eng. Grocers Supply Co., 488 F. Supp. 230, 234 (D. Mass. 1980) (reviewing convictions of three grocery-chain executives under § 331(k)).

26. *Park*, 421 U.S. at 673.

27. *See, e.g.*, *New Eng. Grocers*, 488 F. Supp. at 235-36.

28. *See, e.g.*, *id.*; United States v. Y. Hata & Co., 535 F.2d 508, 515 (9th Cir. 1976); *see also* Norman Abrams, *Criminal Liability of Corporate Officers for Strict Liability Offenses—A Comment on* Dotterweich *and* Park, 28 UCLA L. REV. 463, 470 (1981) (taking the view that the objective impossibility defense effectively creates a "extraordinary care" standard, under which "all that must be proved by the government is a deviation from that standard – something certainly less than common law negligence; it can be characterized as 'very slight' or 'slight' negligence . . . . ").

29. For failures, see United States v. Gel Spice Co., 773 F.2d 427 (2d Cir. 1985); *Y. Hata & Co.*, 535 F.2d at 508.

30. *Dotterweich*, 320 U.S. at 285 (quoting *Nash*, 229 U.S. at 378).

31. This scenario is entirely hypothetical. Any similarities to actual companies or individuals are purely coincidental.

32. 21 U.S.C. § 352(j).

33. § 352(a).

34. § 321(m).

35. 21 C.F.R. § 202.1(*l*)(2) (emphasis added).

36. *See* 21 U.S.C. § 333(a)(2) (making it a felony for anyone to violate § 331 "after a conviction of him under this section has become final"); *see also Lelles v. United States*, 241 F.2d 21 (9th Cir. 1957) (affirming a felony "responsible relation" prosecution against the president of a food manufacturer based on a previous conviction).

37. *See* § 333(a)(1) (stating that violators "shall be imprisoned for not more than one year or fined not more than $1,000, or both.").

38. *See* 18 U.S.C. § 3571. Without any additional findings or admissions, the court could impose a fine of $100,000. § 3571(b)(5). (Misdemeanor misbranding is classified as a "Class A" misdemeanor because it is punishable by up to a year in prison. *See* 18 U.S.C. § 3559(a)(6).) For crimes "resulting in death," the fine could be $250,000. § 3571(e)(4). And the fine could conceivably be even higher, because in crimes involving monetary gain or loss—for example, monetary loss to a state from prescriptions secured through false marketing claims—courts can impose fines up to twice the amount of the gain or loss. *See* § 3571(d).

39. We count thirteen such cases, including *Park* itself. *See Park*, 421 U.S. at 658 (food storage); *Gel Spice Co.*, 773 F.2d at 427 (food storage); *Y. Hata & Co.*, 535 F.2d at 508 (food storage); United States v. Starr, 535 F.2d 512 (9th Cir. 1976) (food storage); United States v. H. B. Gregory Co., 502 F.2d 700 (7th Cir. 1974) (food storage); United States v. Abbott Labs., 505 F.2d 565 (4th Cir. 1974) (contaminated intravenous fluids); United States v. Shapiro, 491 F.2d 335 (6th Cir. 1974) (food processing); United States v. General Nutrition, Inc., 638 F. Supp. 556 (W.D.N.Y. 1986) (over-the-counter sale of a drug requiring prescription); United States v. Torigian Labs., Inc., 577 F. Supp. 1514, 1529-31 (E.D.N.Y. 1984) ("devices" (eye implants)); *New Eng. Grocers*, 488 F. Supp. 230 (1980) (food storage); United States v. Treffiletti & Sons, 496 F. Supp. 53 (N.D.N.Y. 1980) (food storage);United States v. Acri Wholesale Grocery Co., 409 F. Supp. 529 (S.D. Iowa

1976) (food storage). United States v. Hammond Milling Co., 413 F.2d 608 (5th Cir. 1969) (food storage).

40. *See Abbott Labs.*, 505 F.2d at 565.

41. *See, e.g.*, Kordel v. United States, 335 U.S. 345 (1948) (misbranding occurred through circulars and pamphlets defendant distributed); United States v. Ballistrea, 101 F.3d 827, 836 (2d Cir. 1996) ("Park is irrelevant to the present case . . . because the Government did not prosecute Ballistrea for *failing to prevent* a violation of the FDCA by third parties under his authority. Rather, it prosecuted him for personally violating the FDCA by his own conduct . . . ."); United States v. Haga, 821 F.2d 1036 (5th Cir. 1987) (personal involvement in scheme selling steroids and hormones without a prescription); Fiore v. United States, 696 F.2d 205 (2d Cir. 1982) (defendant was alter ego of company that pled guilty to felony false statement); United States v. Cassaro, Inc., 443 F.2d 153 (1st Cir. 1971) (defendant owned and personally managed bakery in which contamination was found); United States v. Guardian Chem. Corp., 410 F.2d 157 (2d Cir. 1969) (individual defendant personally was responsible for marketing product for uses that required prescription); Roseman v. United States, 364 F.2d 18 (9th Cir. 1966) (defendant knowingly imported LSD); V. E. Irons, Inc. v. United States, 244 F.2d 34 (1st Cir. 1957) (defendant personally marketed product for uses requiring prescription); United States v. Hohensee, 243 F.2d 367 (3d Cir. 1957) (same, and defendant was repeat offender). *Cf.* United States v. W. Side Bakery, 181 F. Supp. 941 (S.D.N.Y. 1960) (defendant was partner in bakery charged for selling adulterated bread); United States v. Am. Stores Co., 183 F. Supp. 852 (D. Md. 1960) (facts suggest defendants were charged for their own conduct).

42. *See Park*, 421 U.S. at 658 (repeat failed inspections, with notice sent to defendant); *Gel Spice Co.*, 773 F.2d at 429-31 (violations found in multiple inspections over several years); *Y. Hata & Co.*, 535 F.2d at 511 (defendant failed to correct known problem, even after first failed inspection); *Starr*, 535 F.2d at 515 (defendant aware for at least a month of infestation problems before problems found in repeat inspection); *H. B. Gregory Co.*, 502 F.2d at 704 (defendant directly involved in operation of warehouse and aware of rodent problem); *General Nutrition, Inc.*, 638 F. Supp. at 558 n.2, 562, 564 (evidence that at least one corporate-officer defendant intended to violate FDA regulations; court noted that the defendants "deliberately" [had] gone "perilously close to an area of proscribed conduct") (citations omitted); *Torigian Labs.*, 577 F. Supp. at 1529-31 (court found "gross negligence" in the distribution of artificial eye implants that were unsterilized, and that the individual defendant had been "faced with clear warnings" of the problem); *New Eng. Grocers*, 488 F. Supp. at 237-38 (repeat failed inspections); *Acri Wholesale Grocery Co.*, 409 F. Supp. at 531-32 (warehouse failed repeat inspections and defendant acknowledged awareness of rodent problem).

The opinions in the Abbott case do not discuss the basis for the individual charges. *See United States v. Abbott Labs.*, 369 F. Supp. 1396 (E.D.N.C. 1973), *rev'd* 505 F.2d 565 (4th Cir. 1974). However, media reports make clear that the company had similar problems and that the FDA had previously considered criminal charges. *See* Morton Mintz, *Abbott Had Contamination, Mislabeling Troubles Before*, WASH. POST, Mar. 29, 1971; Morton Mintz, *U.S. Weighs Criminal Prosecution of Abbott in '71 Blood Poisoning*, WASH. POST, Apr. 12, 1972, A6. The company also was accused of criminal conduct on multiple fronts. *See Abbott Firm Charged in Drug Labeling Case*, WASH. POST, May 8, 1971, A3 (reporting that the company and two regulatory affairs executives were being tried on unrelated misdemeanor charges); *Abbott Drug Firm Cleared of False Promotion*, WASH. POST, July 9, 1968, A3 (reporting that firm had been acquitted just a few years earlier in "the first trial of a drug company on a criminal charge of falsely promoting a prescription drug"); *Abbott Again Admits Ads Misleadin*g, Morton Mintz, WASH. POST, June 13, 1968, G5 (stating that for the second time in 14 months, the company had issued "corrective letters" to doctors about misleading marketing claims, to avoid drug seizures by the FDA).

In some cases, the defendant is charged with a misdemeanor as a lesser-included-offense to a felony FDCA charge, or in addition to felony charges under another statute. *See, e.g.*, United States v. Acosta, 17 F.3d 538 (2d Cir. 1994) (defendants convicted of misdemeanor as lesser-included offense, based on their own personal conduct); United States v. Indus. Labs., 456 F.2d 908 (10th Cir. 1972) (same); United States v. Coleman, 370 F. Supp. 2d 661 (S.D. Ohio 2005) (same).

43. *See Park*, 421 U.S. at 662-64.

44. *Cf.* James T. O'Reilly, "*First the Good News: You're Not Going to Jail . . .*," 33 FOOD DRUG & COSM. L.J. 482, 483 (1978) (stating that *Park* "has been applied in a relative handful of cases, mostly those in which negligence exists or may have existed").

45. The Bureau of Justice Statistics reports that, between 1995 and 2005, 271 individuals were charged with violating § 331(a), (b), or (k), the provisions under which a pharmaceutical manufacturer would most likely be charged. That is roughly 25 charges per year. The actual number of defendants should be lower, because a single offender is often charged under more than one sub-section. The number of cases should be smaller still, because multiple offenders are often charged and tried together. *See* Bureau of Justice Statistics, Federal Justice Statistics Resource Center, *at* http://fjsrc.urban.org/analysis/t_sec/stat.cfm (section-by-section data on "number of defendants in cases filed").

46. The Administrative Office of the U.S. Courts reports **zero** misdemeanor "food and drug" charges between 1998 and 2005. *See* Bureau of Justice Statistics, Federal Justice Statistics Resource Center, *at* http://fjsrc.urban.org/analysis/ez/restart.cfm?t=new ("Defendants charged in criminal cases").

47. *See* Press Release, Eli Lilly and Company to Pay U.S. $36 Million Relating to Off-Label Promotion, Dec. 21, 2005, *available at* http://www.usdoj.gov/opa/pr/2005/December/05_civ_685.html; Complaint for Permanent Injunction, United States v. Eli Lilly and Co., No. 1:05-cv-1884 (S.D. Ind. Dec. 21, 2005).

48. *See* Press Release, Warner-Lambert to Pay $430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion, May 13, 2004, *available at* http://www.usdoj.gov/opa/pr/2004/May/04_civ_322.htm.

49. *See generally* Statement of Ronald J. Tenpas, Assoc. Deputy Attorney General, Before the Comm. on Oversight and Government, 110th CONG., Feb. 9, 2007 (summarizing recent settlements).

50. *See* Barnaby J. Feder, *Boston Scientific to Pay $74 Million to Settle U.S. Stent Case*, N.Y. TIMES, June 25, 2005.

51. *See* Press Release, United States Attorney, N.D. Cal., June 12, 2003, *at* http://www.usdoj.gov/usao/can/press/2003/2003_06_12_endovascular.html.

52. Individual executives were charged in the TAP and Serono cases, but not with misdemeanor FDCA violations. The executives in the Serono case were charged with felony violations of the Anti-Kickback statute. *See* Indictment, United States v. Bruens, No. 05-cr-10102 (D. Mass). The TAP executives were charged with felony violations of the Anti-Kickback statute and the Prescription Drug Marketing Act. *See* Indictment, United States v. MacKenzie, No. 01-cr-10350 (D. Mass).

53. FDA, REGULATORY PROCEDURES MANUAL, § 6-5-1 (Mar. 2007) (emphasis added).

54. Sam D. Fine, *The Philosophy of Enforcement*, 31 FOOD DRUG & COSM. L. J. 324, 329 (1976); *see also* Marie A. Urban, *The FDA's Policy on Seizures, Injunctions, Civil Fines, and Recalls*, 47 FOOD & DRUG L.J. 411, 411-12 (1992) (Director, Division of Compliance Management and Operations, Office of Enforcement/Regulatory Affairs, writing that "it is FDA policy that responsible persons be given notice of violations and afforded an opportunity for correction. . . . FDA is under no *legal* obligation to warn firms and individuals that they, or their products, are in violation of the law prior to the agency taking formal regulatory action. However, notice prior to initiating an enforcement action has been, and remains,

general agency policy. . . . "). *Accord* Nicholas Freitag, *Federal Food and Drug Act Violations*, 41 AM. CRIM. L. REV. 647, 664 (2004) ("Once a violation is established, the FDA usually provides the offending company an opportunity to correct the violations before taking further action. If the offender does not correct the violations or if the violations are flagrant, fraudulent, or life-threatening, the federal government may prosecute."); John W. Lundquist & Sandra L. Conroy, *Defending Against Food and Drug Prosecutions*, 21-JUL. CHAMPION 20, 21 (1997) ("As a policy objective, the FDA encourages corrective action. Generally, if a violation is suspected the FDA will provide the alleged offender with the opportunity to correct the violative conduct before taking further action.").

55. 320 U.S. at 292-93.

56. *See, e.g.*, Charles R. McConachie, *The Role of the Department of Justice in Enforcing the Federal Food, Drug and Cosmetic Act*, 31 FOOD DRUG & COSM. L. J. 333, 334 (1976) ("In almost every instance resulting in an enforcement action in a federal court, the FDA has conducted an investigation in the field and ultimately recommended prosecution."); *see also Gel Spice Co.*, 773 F.2d at 429 (quoting representations from a government brief regarding "the customary manner in which a legal action is initiated by FDA," including notice and a hearing, followed by a recommendation to the Department).