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The Crime of Doing Nothing: Strict Liability For Corporate Officers Under the FDCA

By Brent J. Gurney, Esq., Howard M. Shapiro, Esq., and Robert A. Mays, Esq.

Even experienced criminal defense attorneys are surprised to learn that an executive at a company that makes, transports or stores food, pharmaceuticals, medical devices or other products regulated under the Food, Drug and Cosmetic Act can be held criminally liable for essentially any regulatory violation in the executive's area of responsibility. Under the FDCA's misdemeanor offense, executives are strictly and vicariously liable for violations. Historically, the government has not used the full scope of its discretion under this severe provision. Instead, it has brought misdemeanor FDCA charges only when the defendant was personally responsible for the violation or was at least on notice of the conduct causing the violation and failed to correct it.

However, in the recent prosecution of OxyContin manufacturer Purdue Frederick Co., the government abandoned this policy and insisted on individual misdemeanor FDCA charges in the absence of either personal involvement or knowledge on the part of the targeted executives. This is an unfortunate policy change, and one that should greatly concern food and drug executives, as well as anyone else concerned with the fair administration of the criminal laws.

The FDCA Misdemeanor Offense

The FDCA prohibits, among other things, the "adulteration" or "misbranding" of any regulated product (generally, any drug, food item, cosmetic or "device") or the introduction into interstate commerce of an adulterated or misbranded product. The statute and voluminous Food and Drug Administration regulations define "adulteration" and "misbranding" so broadly as to capture almost any conceivable error in the formulation, manufacture, labeling or marketing of a regulated product.

For example, in addition to typical labeling errors, a drug is considered "misbranded" under the FDCA if "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." 21 U.S.C. § 352(j). Any infraction is criminally punishable. Any person who takes or "causes" a prohibited action is guilty of a misdemeanor. Anyone who takes or causes a prohibited action with "intent to defraud or mislead" or after having previously been convicted under the statute is guilty of a felony.

The FDCA's misdemeanor provision is noteworthy because it creates one of the few true "strict liability" crimes in federal criminal law. It is irrelevant what the defendant intended, 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.

The 'Responsible Corporate Officer' Doctrine

Even more remarkable is that executives and managers of the companies that make regulated products can be convicted without having personally participated in the act being punished or having been an accessory to it. The government can secure a conviction if a prohibited act took place somewhere within the company and if the defendant's position within the company was one that gave him or her responsibility and authority to either prevent the violation or 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 effectively strict, vicarious liability. This vicarious aspect of FDCA liability has its roots in a pair of U.S. Supreme Court cases recognizing what is now referred to as the "responsible corporate officer" doctrine.

The first case was *United States v. Dotterweich*, 320 U.S. 277 (1943). Joseph 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 three misdemeanor counts of shipping adulterated and misbranded drugs. All three counts related to a single order from a single physician. One drug in the shipment included an improper ingredient. 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."[1] He was convicted, while the corporation was acquitted.

A 5-4 majority of the Supreme Court affirmed the conviction, reversing the U.S. Court of Appeals for the 2nd Circuit. The high court observed that the FDCA "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." The majority 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."

Other than concluding that the jury reasonably found that Dotterweich fit that description, however, the Supreme Court refused to say how one could identify those who had a "responsible share" in the offending conduct. The majority assured itself that the standard would be given fair application based on "conscience and circumspection in prosecuting officers."

More than 30 years later, in *United States v. Park*, 421 U.S. 658 (1975), the Supreme Court reaffirmed and expounded on the holding of *Dotterweich*. John Park was the president and CEO of a national retail grocery chain with 35,000 employees and 900 stores. Over a three-year period FDA inspectors had repeatedly found and notified the company of rodent infestation at two of the company's food storage warehouses. Eventually, both the company and Park were charged with five misdemeanor counts of causing the adulteration of food held for sale. The company pleaded guilty while Park went to trial.

At trial, the government introduced the company's 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." 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."

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 court said, but the question was reducible to 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." The jury convicted on all counts.

The 4th Circuit reversed the convictions. It reasoned that the effect of the trial court's instruction was to allow conviction not just without proof of "awareness of some wrongdoing," but also in the absence of "wrongful action" on the defendant's part[2] and that proof of this element was required by due process. The appeals court held that the jury should be required to find "gross negligence and inattention in discharging … corporate duties and obligations" or some other act "of commission or omission which would 'cause' the contamination of the food."

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." The Supreme Court reasoned that it is through the violation of this duty that an executive "causes" the proscribed conduct to occur.

"[T]he 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," the court wrote.

The Practical 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 of proof in such a way as to require little else. It was sufficient, the Supreme 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."

Lower courts interpreting this language have held that the *Park* standard does not "require the corporate officer actually to exercise any authority over the activity."[3] 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]."[4] In other words, while it is not enough merely to name the defendant's position, it is sufficient to name the position and then demonstrate that the position puts the defendant 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 on the *Park* standard, "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."[5]

In practice, just one thing prevents criminal charges from being brought against executives in virtually every civil or criminal FDCA case: what the *Dotterweich* court described as the "conscience and circumspection of prosecuting officers." For every rodent-infested food warehouse, every recalled drug, every mislabeled cosmetic product and every defective medical device there is a chain of managers and executives who had the authority and responsibility — at least on paper — to prevent or remedy such problems. And no matter how large or small the company, there is always an owner, company president, CEO or similar figure charged with preventing or correcting every such problem.

Thus, under the "responsible corporate officer" doctrine, every executive at a company dealing in FDCA-regulated products, and especially those at the highest echelons of the corporate hierarchy, is left to wonder 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 the executive to expensive, embarrassing and potentially career-ending personal criminal liability.

Historically, the "conscience and circumspection of prosecuting officers" has provided some measure of restraint, enough that most executives likely are unaware of even the potential severities of the FDCA's misdemeanor provision. That is cold comfort, and it is getting colder all the time.

Past Enforcement Policy With the FDCA

Fortunately, both for the companies dealing in FDCA-regulated products and for the criminal justice system, prosecutors have historically used the blunt instrument of the law's misdemeanor provision only sparingly. While disconcerting in theory, *Park* and *Dotterweich* once represented extreme examples of criminal cases filed under the FDCA. *Park* is one of just a handful of reported cases from the last half-century in which the government charged a corporate executive with misdemeanor FDCA violations based solely on the executive's position as a "responsible corporate officer."[6] The other cases have concerned the executive's own personal conduct.[7]

Of the few cases that invoke "responsible corporate officer" liability, the overwhelming majority (if not all) have involved a defendant who was aware of the conduct giving rise to the violation but failed to correct it.[8] In *Park* itself, for instance, the FDA had repeatedly notified the company about the infestation problems in its warehouses, and Park had personally received notice of at least one failed inspection.

While reported decisions do not provide a perfect barometer of the enforcement environment, the number and type of reported FDCA decisions suggest that actual *Dotterweich*-type prosecutions — that is, executives charged for violations in which they had no role and of which they had no knowledge — have been very rare. Instead, misdemeanor FDCA charges generally have been pursued only when the defendant was personally responsible for a violation or was on notice of it and failed to correct it.

The historically conservative use of the "responsible corporate officer" doctrine in FDCA prosecutions can also be seen simply by observing the number of cases in which individual misdemeanor charges could have been filed but were not. As pointed out above, nearly every civil or criminal FDCA enforcement action holds the potential for individual misdemeanor charges. But in practice even major criminal investigations that have resulted in large corporate settlements, some including allegations of intentional fraud, have not involved charges against individual executives.

For example, since 2000 there have been several large health care fraud settlements with major pharmaceutical companies, including Eli Lilly & Co., Warner-Lambert, Genentech, InterMune, Boston Scientific and Endovascular Technologies.[9] 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. It clearly could have charged individual executives with misdemeanor, if not felony, violations or demanded individual pleas as part of any settlement. But, with one recent exception discussed below, none of these settlements resulted in criminal charges against individual executives under the FDCA.[10] Clearly, the judgment of the FDA, the Justice Department and other agencies had been that the FDCA's strict-liability misdemeanor provision must be reserved for specific circumstances.

Such restraint is consistent with long-standing FDA enforcement policy. The agency's regulatory procedures manual states that, apart from certain specified exceptions, 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*."[11] This reflects long-standing FDA policy that the government relied upon in both urging and then defending the Supreme Court's decision in *Park*.

During the briefing in *Park*, the government pointed to the FDA's enforcement policy as negating the need to read a negligence or other culpability standard into the FDCA. The U.S. solicitor general, joined by FDA attorneys, acknowledged that the FDCA "contemplates reasonable exercise of prosecutorial discretion in its administration." He then represented to the Supreme Court that the FDA exercises that discretion by typically prosecuting only executives who share some culpability for the violation at issue.

"Even if investigation discloses the elements of liability and indicates that an official bears a responsible relationship to them, [the FDA] will not ordinarily recommend prosecution unless that official, *after becoming aware of possible violations*, often (as with Park) as a result of notification by FDA, *has failed to correct them* or to change his managerial system so as to prevent further violations," the solicitor general wrote.[12]

The government went on to argue that Park's prosecution conformed with these "guidelines" because he had received personal notice of the violations and failed to correct them despite having adequate opportunity to do so.

In the aftermath of the *Park* decision, Congress considered amendments to the FDCA that would have required a showing of at least negligence to support a misdemeanor conviction. In opposing those amendments, the Department of Health, Education and Welfare, then the home of the FDA, again argued that the FDA already read such a requirement into the statute. The department told one Senate committee in 1976:

> Certainly there is no basis for a claim that the act has been recklessly or injudiciously enforced. … [B]efore a case is recommended for prosecution it must not only meet a set of internal FDA enforcement guidelines but must also undergo an elaborate system of internal review, which includes the opportunity for a hearing.
>
> Nor does the law, properly construed, permit imposition of criminal penalties on an executive officer for the acts or omissions of others. It is the officer's *personal neglect* that is punishable. If the executive does his job properly, he will have established an elaborate system of checks and double-checks which will practically preclude failure by subordinates. … Of course, we recognize that no system is foolproof and that some types of occasional isolated mistakes are inevitable. When this occurs and FDA is satisfied that the responsible officer has fairly met his legal obligations, prosecution is not recommended.[13]

The Senate committee concluded from this that writing an express negligence requirement into the FDCA would simply "codify existing policy with respect to enforcement of the act."[14]

Later that year, as debate on amendments continued, the FDA's associate commissioner for compliance described the agency's enforcement policy in even stronger terms. He wrote that notwithstanding the availability of the strict-liability misdemeanor:

> 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.[15]

In short, 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. The government's policy historically has been to seek criminal charges only when the evidence showed actual fault on the part of the individual charged.

Prosecutorial Indiscretion: The OxyContin Case

In one recent case, however, the government indicated that it is no longer interested in honoring this tradition of keeping its sword half-sheathed. In May Purdue Frederick Co., the distributor of OxyContin and other drugs, entered into a global settlement with the federal government and several states to bring an end to an aggressive, five-year, wide-ranging investigation of this relatively small, privately owned company. The settlement involved the company's guilty plea to a single count of felony misbranding, based primarily on marketing claims made before July 2001 by certain sales representatives and supervisors regarding the pain reliever OxyContin.

These employees had overstated portions of the FDA-approved label and improperly described OxyContin, a controlled-release version of oxycodone, as less addictive, less subject to abuse and diversion, and less likely to cause withdrawal and tolerance than other pain medications.[16] In addition to the corporate plea, Purdue Frederick agreed to pay about $600 million in civil and criminal fines, forfeitures, and private settlements and to comply for five years with a monitored corporate integrity agreement.

The government nevertheless insisted that the settlement also include guilty pleas to misdemeanor misbranding charges by three company executives: the president and CEO, the executive vice president and chief legal officer, and a former executive vice president and chief scientific officer. As part of these pleas, the executives were required to "disgorge" millions of dollars. Much more damaging, because the executives were successful businessmen and because OxyContin abuse had been widely publicized, the executives' pleas were reported (and misreported) by virtually every major U.S. news outlet, generally as part of lead stories that talked of "fraud," felonies, "lying to doctors," and addiction, abuse and overdose deaths.

What most press reports ignored was the most remarkable aspect of the individual misdemeanor pleas: The government departed from its historic practice and insisted on criminal pleas from individual executives while acknowledging its inability to establish that any of the executives was personally involved in, or even knew of, any of the alleged improprieties. In a Senate hearing held specifically to evaluate the "propriety and adequacy" of the OxyContin criminal settlement, the U.S. attorney who oversaw the investigation acknowledged that the government did not have proof that the executives engaged in or were aware of the misconduct of others at Purdue.[17]

Similarly, the U.S. attorney told the sentencing court that the executives' pleas were purely "based on the fact that they were responsible corporate officials at the time" the misbranding occurred.[18] The judge confirmed "the absence of government proof of knowledge by the individual defendants of the wrongdoing" in accepting the agreed-upon, non-incarcerative sentences.[19] Because the individual defendants, as senior corporate executives, were "responsible corporate officers" within the meaning of Park, they were held criminally liable even though they had no knowledge of or intent to cause — and indeed launched extensive efforts to prevent — the misbranding.

So what was it about the Purdue Frederick settlement that led the Justice Department, the FDA and the many other agencies involved in the investigation to abandon the government's traditional restraint in invoking the FDCA's misdemeanor provision? Why did the government insist on strict-liability pleas without proof of culpable conduct? The only plausible explanation is the government thought that the tremendous harm associated with the abuse and diversion of OxyContin justified prosecuting Purdue's top executives whether or not actual responsibility for those harms could be proven. The government wanted to hold someone accountable, and the FDCA's strict-liability misdemeanor provision provided them with the means to do it.

Though the abuse and diversion of OxyContin skyrocketed several years after the powerful painkiller came on the market, so did all prescription drug abuse. This societal crisis had many causes having nothing to do with criminal conduct. Nonetheless, the prosecutors struggled mightily to link the abuse and diversion of OxyContin to criminal conduct by Purdue and its employees. Ultimately, they failed, but one need look no further than the U.S. attorney's public statements for evidence that he was willing to make that link in his own mind regardless of whether it could be proven. In his prepared public statement the U.S. attorney said the "*results* of Purdue's crimes were staggering," citing a 400 percent increase in oxycodone-induced deaths between 1996 and 2001, more than 400 specific oxycodone-related overdose deaths, and "dramatically higher crime rates" in Virginia communities.[20]

Those claims were good for eye-popping headlines, but they did not hold up. The government later backtracked, admitting that none of the evidence established that the misbranding acts that were the basis of the guilty pleas affected doctors' prescribing habits or caused or contributed to abuse, addiction or death. The U.S. attorney told the sentencing court that his office was unable "to identify or quantify the impact on prescribing health care providers" and that it essentially was impossible to determine "whether a certain individual was directly and proximately harmed" by the misbranding.[21] And the pre-sentence report said there were "no identifiable victims" of the misbranding, a finding that the government did not challenge.

Thus, at the end of the day, what the government was relying on in forcing individual convictions was not actual proof of harm, but a prosecutor's gut feeling that Purdue must have somehow been responsible for OxyContin abuse and related troubles. These unproven harms apparently justified a rare full invocation of the FDCA misdemeanor provision against "responsible corporate officers" who neither participated in nor knew of the conduct causing the violations.

'Magnitude of Harm' as a Substitute for Fault

As the Purdue Frederick case illustrates, there are many reasons to be concerned about the government's 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 could easily make it intolerably risky to work as an executive in an FDCA-regulated industry, such as pharmaceuticals. Even assuming that all prosecutors are well meaning and reasonable, the pharmaceutical business will always have catastrophes where products are not used as intended or simply do not work properly. 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 for events that may be entirely outside of their control. After a couple of high-profile convictions under a more freewheeling use of the FDCA misdemeanor provision, pharmaceutical industry executives might reasonably ask if this is still the business for them.

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 and because the media are more likely to cover major disasters than minor ones.

For example, it is one thing for a local bakery owner to be prosecuted for not keeping mice out of his shop, and something else entirely for a pharmaceutical executive to be prosecuted — and thus, implicitly or explicitly, blamed — for producing a lethally defective product. The degree of public attention and moral condemnation visited on the executive might be professionally and personally ruinous, whereas his actual responsibility for the violation is likely nil, unlike the baker who runs his own shop and can reasonably know what is going on in every corner of it.

The degree of moral condemnation is likely to be all the worse because of the inability of the press and of government officials to understand and accurately convey the significance of a strict-liability crime. Notwithstanding the strict-liability nature of the individual pleas in the OxyContin case or the acknowledged lack of proof that the executives had participated in or knew of the misbranding, both government officials and news reporters repeatedly suggested to the public that the case involved intentional fraud on the part of the executives. For example:

- In the U.S. attorney's press release announcing the settlement, the Labor Department's inspector general described the pleas as "a significant milestone in the fight against corruption by company officials who seek to illegally enrich corporate profits at taxpayers' expense."[22] This was absolutely false; the pleas had nothing to do with corruption;
- Similarly, the Reuters news service reported on the day of the pleas that "the company and three executives admitted that they falsely claimed OxyContin was less addictive, less subject to abuse and less likely to cause withdrawal symptoms than rival pain medications."[23] This also was inaccurate. None of the executives admitted to making any false statements. and indeed the U.S. attorney (as previously discussed) stated publicly that the evidence did not establish knowledge or intent on their part; and
- National Public Radio reported that Purdue and "three of its top executives admitted to lying about OxyContin's potential for addiction and abuse."[24] Again, there was no such admission or proof, as the government acknowledged.

Reports in local and regional sources were often even more misguided.

The lesson from these statements is that an executive convicted of a strict-liability offense has to battle the public's natural inclination to associate criminal convictions with moral fault against the backdrop of officials and media sources who themselves cannot or will not appreciate the distinction.

Third, from the standpoint of basic fairness, prior notice or actual culpability is a better guidepost for prosecutorial discretion. Unlike knowledge or prior notice, "magnitude of harm" is largely in the eye of the beholder and is not necessarily within the corporate executive's control. 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 Frank 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.[25]

Finally, it will often be the case that the perceived "harm" from the violation is not truly traceable to it. This was precisely the problem with the OxyContin case. The government was no more successful at proving that any harm resulted from the misbranding violations than it was at proving knowledge or intent on the part of any of the

executives. None of the evidence established that the misbranding acts were pervasive or that they affected doctors' prescribing habits, much less that they caused or contributed to abuse, addiction or diversion or to any death. Even the government had to concede, when pushed, that this link was never established.

In part because of the breadth of the FDCA's prohibitions, there is a real danger that the FDCA misdemeanor provision, if unrestrained, will allow prosecutors to obtain convictions or extract pleas in vindication of suspicions that cannot be proven. When something terrible has happened, a prosecutor may simply reason: "There has been a tragic event, and someone has to be held responsible. The FDCA gives me the tool with which to hold you responsible. When can you be here to plead?"

Conclusion

It makes even less sense today than it did when the FDCA was enacted to indulge the fiction that executives in pharmaceuticals or any other industry can personally carry the burden of ensuring perfect compliance with the FDCA for entire corporations. We no longer live in a world of neighborhood druggists and family-owned grocers who directly supervise their own employees and operations. Modern-day pharmaceutical and food company executives "supervise" 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 their subordinates' errors, mistakes and misbehaviors, it no longer does.

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

Notes

[1] *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).

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

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

[4] *Id.* at 1025 (emphasis added); *see also United States v. Ming Hong*, 242 F.3d 528, 531 (4th Cir. 2001) (also applying *Park* to Clean Water Act; "[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.").

[5] *United States v. New Eng. Grocers Supply Co.*, 488 F. Supp. 230, 234 (D. Mass. 1980) (reviewing convictions of three grocery chain executives under Section 331[k]).

[6] We count 13 such cases. All but three, like *Park*, involved unsanitary food storage or food preparation areas. *See Park*, 421 U.S. at 658; *United States v. Gel Spice Co.*, 773 F.2d 427 (2d Cir. 1985); *United States v. Y. Hata & Co.*, 535 F.2d 508, 515 (9th Cir. 1976); *United States v. Starr*, 535 F.2d 512 (9th Cir. 1976); *United States v. H.B. Gregory Co.,* 502 F.2d 700 (7th Cir. 1974); *United States v. Abbott Labs.*, 505 F.2d 565 (4th Cir. 1974) (contaminated IV fluids); *United States v. Shapiro,* 491 F.2d 335 (6th Cir. 1974); *United States v. Hammond Milling Co.*, 413 F.2d 608 (5th Cir. 1969); *United States v. Gen. 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.*, 577 F. Supp. 1514, 1529-31 (E.D.N.Y. 1984) (contaminated ocular implants); *New Eng. Grocers*, 488 F. Supp. 230; *United States v. Treffiletti & Sons*, 496 F. Supp. 53 (N.D.N.Y. 1980); *United States v. Acri Wholesale Grocery Co.*, 409 F. Supp. 529 (S.D. Iowa 1976)..

[7] *See, e.g.*, *Kordel v. United States*, 335 U.S. 345 (1948) (misbranding occurred through literature defendant personally distributed); *United States v. Ballistrea*, 101 F.3d 827, 836 (2d Cir. 1996) ("*Park* is irrelevant to the present case … because the government … prosecuted [the defendant] for personally violating the FDCA by his own conduct."); *United States v. Haga*, 821 F.2d 1036 (5th Cir. 1987) (personal involvement in scheme to sell steroids and hormones without prescription); *Fiore v. United States,* 696 F.2d 205 (2d Cir. 1982) (defendant was alter ego of company that pleaded guilty to felony false-statement charges); *United States v. Cassaro Inc.,* 443 F.2d 153 (1st Cir. 1971) (defendant owned and personally managed bakery in which contamination was found).

[8] *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 of infestation problems for at least a month 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); *Gen. Nutrition*, 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 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" 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*, 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 rationale 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 in the past and that the FDA had previously considered criminal charges related to those problems. *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, at A6. In addition, the company and its executives had been prosecuted for other types of conduct in the recent past. *See Abbott Firm Charged in Drug Labeling Case*, WASH. POST, May 8, 1971, at A3; *Abbott Drug Firm Cleared of False Promotion*, WASH. POST, July 9, 1968, at A3; Morton Mintz, *Abbott Again Admits Ads Misleading*, WASH. POST, June 13, 1968, at G5. In some cases, the defendant is charged with a misdemeanor FDCA violation but only 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).

[9] *See* Press Release, U.S. Dep't of Justice, Eli Lilly & 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; *United States v. Eli Lilly & Co.*, No. 1:05-cv-1884, *complaint for permanent injunction filed* (S.D. Ind. Dec. 21, 2005); Press Release, U.S. Dep't of Justice, Warner-Lambert to Pay $430 Million to Resolve Criminal and 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; Barnaby J. Feder, *Boston Scientific to Pay $74 Million to Settle U.S. Stent Case*, N.Y. Times, June 25, 2005; Press Release, U.S. Attorney, Northern District of California (June 12, 2003), *available at* http://biotech.law.lsu.edu/cases/devices/guidentpr.pdf (discussing the Endovascular Technologies settlement). *See generally Allegations of Waste, Fraud, and Abuse in Pharmaceutical Pricing: Financial Impacts on Federal Health Programs and the Federal Taxpayer*, *Hearing Before the H. Comm. on Oversight and Gov't Reform*, 110th Cong. (Feb. 9, 2007) (statement of Ronald J. Tenpas, Associate Deputy Attorney General, summarizing some recent settlements).

[10] Investigations of TAP Pharmaceutical Products and Serono have led to individual criminal charges but not under the misdemeanor provision of the FDCA. 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).

[11] FDA Regulatory Procedures Manual § 6-5-1 (Mar. 2007) (emphasis added).

[12] Brief for the United States, *United States v. Park*, No. 74-215, at 31-32 (U.S. 1975) (emphasis added).

[13] Consumer Food Act of 1976, S. Rep. No. 684, 94th Cong., 2d Sess., at 79 (1976) (statement of the Dep't of Health, Educ. and Welfare) (emphasis added).

[14] *Id.* at 30.

[15] *Sam D. Fine, The Philosophy of Enforcement, 31 Food Drug & Cosm. L.J. 324, 329 (1976) (emphasis added).*

[16] The entire factual basis for the corporate and individual pleas is set out in an agreed statement of facts. This and other plea documents from the case, *United States v. Purdue Frederick Co.*, No. 1:07-CR-00029 (W.D. Va.), are available on the District Court's Web site, http://www.vawd.uscourts.gov/PurdueFrederickCo/default.asp.

[17] *Evaluating the Propriety and Adequacy of the OxyContin Criminal Settlement: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. (July 31, 2007), at 21 (CQ Transcript) ("[SEN] SPECTER: … Didn't the government establish the underlying facts of the guilty plea, that here was intent to mislead known to the individual defendants? [JOHN] BROWNLEE: The answer is no, sir.").

[18] United States' Resp. to Ct.'s Order Directing Parties to Provide Information, *United States v. Purdue Frederick Co.*, at 12.

[19] *United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569, 576 (W.D. Va. 2007).

[20] Statement of U.S. Attorney John L. Brownlee on the Guilty Plea of the Purdue Frederick Co. and Its Executives for Illegally Misbranding OxyContin (May 10, 2007), *available at* http://web.archive.org/web/20070512165947/http://www.usdoj.gov/usao/vaw/ (emphasis added).

[21] United States' Resp., *supra* note 18, at 3, 5.

[22] Press Release, John L. Brownlee, U.S. Attorney, Western District of Virginia, *Purdue Frederick Co. Inc. and Top Executives Plead Guilty to Misbranding OxyContin; Will Pay Over $600 Million* (May 10, 2007 (emphasis added), *available at* http://www.usdoj.gov/usao/vaw/press_releases/purdue_frederick_10may2007.html.

[23] *Purdue Frederick Pleads Guilty in OxyContin Case*, Reuters (May 10, 2007), *available at* http://www.reuters.com/article/health-SP/idUSN1044304420070511.

[24] Kathy Lohr and Robert Siegel, *$634 Million Fine, No Jail for OxyContin Executives* (July 20, 2007), *available at* http://www.npr.org/templates/story/story.php?storyId=12131233.

[25] *Dotterweich*, 320 U.S. at 292-93.

Brent Gurney *and* ***Howard Shapiro*** *are partners at* ***Wilmer, Cutler, Pickering, Hale & Dorr*** *in Washington, practicing in the areas of white-collar criminal defense and complex civil litigation.* ***Rob Mays*** *is an associate at the firm's Washington office. WilmerHale represented Purdue Frederick Co. and associated companies in the investigation and settlement described in this commentary.*