I. Introduction

The Federal Food, Drug, and Cosmetic Act of 1938 provides criminal sanctions for those violating its provisions. The Act since its inception has been applied to corporations, but judicial decision has extended its coverage to individual officials whose corporations have violated the Act. The standards applicable to individuals prosecuted under the Act have been generally ill defined in two related areas: first, the officials who can be charged with violations of the Act; and second, the necessary degree of the defendant’s involvement in the violation in order to make out a prima facie case. United States v. Park presented the United States Supreme Court with an excellent opportunity to clarify the law in this area. The Park case arose in the following manner. As a result of an inspection of its Baltimore warehouse, Acme Markets, Inc., a large national retail food chain, and its president, John R. Park, were charged with violations of the Act. Each count of the information alleged that the defendants had received goods shipped in interstate commerce, and that while the food was being held in an Acme warehouse, they caused it to be exposed to contamination. These acts allegedly resulted in the food becoming adulterated within the meaning of the Act, which provides that:

A food shall be deemed to be adulterated—(a) . . . (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have

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2 21 U.S.C. § 333(a) (1970) provides that “[a]ny person who violates a provision of section 331 of this title [Prohibited Acts] shall be imprisoned for not more than one year or fined not more than $1,000, or both.”
4 These two issues are of course closely connected. A determination of the kind and quality of action necessary to sustain a conviction under the Act necessarily implies that certain kinds of actors will be held liable. However, for purposes of analysis, this paper will treat the issues of the elements of liability and those persons who may be held liable as distinct.
6 Its size is indicated by the following statistics: Acme employs approximately 36,000 people, has 874 retail outlets, 12 general warehouses and four special warehouses. 421 U.S. at 660.
become contaminated with filth, or whereby it may have been rendered injurious to health. . . .”

The adulterated food triggered a violation of § 331(k) of the Act which states:

The following acts and the causing thereof are prohibited:

. . . .

(k) the adulteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale . . . after shipment in interstate commerce and results in such article being adulterated or misbranded.8

Acme pleaded guilty; Park, not guilty. At trial, the government established that Park previously had been warned by officials of the United States Food and Drug Administration (FDA) of violative conditions in a different Acme warehouse (in Philadelphia), and that Park was responsible for the entire operation of the company.

The judge’s instructions to the jury, based on United States v. Dotterweich9 (and challenged by respondent Park as not being a fair reflection of that decision), were in relevant part as follows:

The main issue for your determination is . . . whether the Defendant held a position of authority and responsibility in the business of Acme Markets . . . .

The individual is or could be liable under the statute, even if he did not consciously do wrong. However, the fact that Defendant is President and is a chief executive officer of the Acme Markets does not require a finding of guilt. Though he need not have personally participated in the situation, he must have had a responsible relation to the issue.10

The jury found Park guilty on all counts, and he was then sentenced to pay a fine of fifty dollars per count.11

9 320 U.S. 277 (1943).
10 421 U.S. at 665 n.9.
11 21 U.S.C. § 333(a)-(b) (1970) provides:
(a) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.
(b) Notwithstanding the provision of subsection (a) of this section, if any person commits such a violation after a conviction of him under this section has become
The court of appeals, with one dissent, reversed and remanded for a new trial. Judge Boreman, writing for the Fourth Circuit, found that the judge’s instruction had incorrectly stated the applicable law as formulated in *Dotterweich*. According to the Fourth Circuit, the fatal flaw in the instruction was that it left the jury with the impression that a conviction could be based merely on Park’s position as president of the offending corporation. Because there had been no evidence of a wrongful act or omission by the defendant introduced at trial, the government had failed to establish the necessary element of wrongful action. *Dotterweich*, according to the majority, had dispensed with the need to prove any awareness of wrongdoing, but not the necessity to prove a wrongful action. Accordingly, the court held that at a subsequent trial the jury must be instructed that a guilty verdict must be predicated upon some wrongful action by Park, which could consist of gross negligence in discharging his corporate duties. The court also found prejudicial error in the admission into evidence of the earlier FDA warning letter which Park had received pursuant to an inspection of the other Acme warehouse.

Judge Craven, dissenting, disagreed with the court’s holding that the instructions had equated corporate presidency with responsibility for the violations. Rather, Judge Craven believed the conviction to be based on the prosecution’s showing that the defendant was responsible for sanitation and that he did not correct the situation which resulted in the violation charged. The dissenter also shared the government’s fear that the majority’s decision would undermine the congressional intent which led to the passage of the Act, *i.e.* protecting the innocent public from contaminated food.

The Supreme Court granted the government’s petition for certiorari to consider two issues. First, were the requirements of *Dotterweich* met by an instruction which permitted the jury to convict if they found that the defendant had a responsible relation to the situation, if the instruction did not also require a finding of particular acts, omissions, or gross negligence by the defendant officer? Second, was the evidence that Park had previous notice of unsanitary conditions at the Philadelphia warehouse admissible to rebut his defense

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2. The court’s choice of gross negligence as an example of a possible standard of guilt suggests its preference for a higher scienter requirement than simple negligence.
of justifiable reliance on his subordinates with respect to the conditions at Acme's Baltimore warehouse?

The Supreme Court, in a six to three decision, reversed the court of appeals and reinstated Park's conviction. The opinion discussed without clarifying the standard of liability used in determining the guilt or innocence of individuals under the Act; it formulated a definition of the wrongful action sufficient to convict the official; and it appeared to open prosecution under the Act to a new class, high ranking executives of large corporations.

This note will (1) review the case law under the Act, (2) show how Park has the potential of wide-reaching change in the law, and (3) analyze the likelihood that the potential wide-reaching effects of the decision will or will not materialize.

II. Evolution of the Law through Park

A. The Dotterweich Case

*Dotterweich*, the first major Supreme Court decision construing the 1938 Food, Drug and Cosmetic Act,16 resembled Park in that the case involved charges against a corporation, Buffalo Pharmacal Company, Inc., and its president and general manager, Joseph Dotterweich. The facts of the two cases differ in that Buffalo Pharmacal was a small concern with its executive officer, Dotterweich, exercising much of the day to day authority over the corporation's business. The company was a jobber in drugs—*i.e.* it purchased the drugs from various manufacturers and shipped them under its own label to its customers. The violations charged arose out of alleged misbranding and adulteration16 of drugs obtained and distributed in the manner described above. "Any person" violating this particular provision was "guilty of a misdemeanor."17 The jury convicted Dotterweich as charged, although it found the corporation not guilty.18

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18 One explanation for this somewhat surprising result is that

*The printed Record* . . . shows not only that Dotterweich was personally responsible for every aspect of the corporate defendant's business but also that he testified at trial in a manner which emphasized that personal responsibility.
Dotterweich's argument, which was accepted by the court of appeals in reversing his conviction, was that, although the literal terms of the statute imposed liability on Dotterweich himself, a more proper construction of the statutory language would exculpate him. Another section of the Act provided that a "person" may avoid liability by obtaining a guaranty from the supplier. Dotterweich reasoned that because such a guaranty would be obtained by the principal (i.e. the corporation itself) and not by an agent (either Dotterweich as executive officer or any other employee), it was difficult to believe that Congress expected the guilt of an agent to turn on whether his principal had obtained a guaranty.

In reinstating Dotterweich's conviction, the Supreme Court rejected the lower court's rationale. Justice Frankfurter, writing for the Court, determined that to limit culpability as the court of appeals had done went against the central purpose of the Act, which was the protection of the public. Therefore, the Court construed the term "person" to include corporate officials.

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

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The evidence showed that the corporate defendant had been "created" by Dotterweich, in the words of the defense counsel, and was owned by him...

The verdict is explainable by the extent to which the defendants' evidence had been identified with Dotterweich personally... while the corporate defendant was infrequently referred to except in the formal identification of documents and other exhibits.


19 21 U.S.C. § 321(e) (1970) defines person to include "individual, partnership, and association."


21 320 U.S. at 280-81. Given the court of appeal's holding that the statute by its literal terms imposed liability on Dotterweich and the Court's own holding that "person" included corporate officials, it can be argued that it was unnecessary for the Court to reach this second issue.

By this "now familiar type of legislation," Justice Frankfurter doubtless was referring to the class of offenses, generally statutory, grouped under the common rubric of "public welfare offenses." See Sayre, Public Welfare Offenses, 33 COLUM. L. REV. 55 (1933). Although they dispense with the general common law requirement of some culpable mental element (mens rea), whether negligence or purposeful action, these statutes have been justified on the ground that the behavior they seek to control has a potential for inflicting direct and widespread injury
This type of liability, strict criminal liability, was a modification of the general common-law rule that a *mens rea* or a guilty mind was a necessary element in the proof of the crime. The need to allege and prove criminal intent was removed; therefore a defendant's defense based on due care or reasonableness became irrelevant, and the sole question for the trier of fact was whether or not the defendant committed the act proscribed by the statute.

Although it has been an influential case in the area of food and drug law, *Dotterweich* has been subject to criticism because of its vagueness in two areas. First, it has been suggested that *Dotterweich* failed to distinguish clearly between strict liability and vicarious liability. Vicarious liability dispenses with the need to show a personal act committed by the defendant. When vicarious liability is imposed, the actions of a third person are imputed to the defendant, who stands in a certain legal relationship (e.g. employer) to the actor. Strict liability, on the other hand, requires the prosecution to show that the defendant personally acted, or failed to act when he had an obligation to do so, although the defendant did not necessarily have a guilty mind or an awareness of wrongdoing that caused the violation with which he is charged.

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This concept of strict liability has been widely attacked as being both inefficacious (punishment based on a statute dispensing with intent does not deter the actor) and unjust (the actor is subjected to the stigma of criminality without being morally blameworthy). For a limitation on strict liability, see Morissette v. United States, 342 U.S. 246 (1952). See also Packer, *Mens Rea and the Supreme Court*, 1962 Sup. Ct. Rev. 107. For the opposite viewpoint, see Wasserman, *Strict Liability in the Criminal Law*, 12 Stan. L. Rev. 731 (1960), which provides answers to the various criticisms.

The general *mens rea* requirement itself can be further compartmentalized. For example, the *Model Penal Code* § 2.02 (Proposed Official Draft, 1962), lists the kinds of culpability as: purpose, knowledge, recklessness, and negligence. In the *Model Penal Code*, Comment (Tent. Draft No. 4, 1955), the authors of the Code explain that the purpose in articulating the distinctions between the different kinds of culpability is to clarify and rationalize the mental element in crime, which has been obscured by such terms as "general criminal intent," "*mens rea,*" and "scienter."


23 A single statute can also impose both strict and vicarious liability, although the latter does not necessarily follow from the former. See W. LaFaye and A. Scott, *Handbook on Criminal Law* 223 (1972). Thus a defendant could be held liable for the actions of an employee, whose own actions were not based on any culpable mental state. The distinction between strict and vicarious liability, in terms of *Dotterweich*, can be phrased as follows: was it incumbent upon the government to show that the defendant himself acted in such a way as to cause the violation without showing that he so intended? Or did the prosecution need only show that some other person (for example, an employee of Dotterweich) violated the Act and that the action was imputed to Dotterweich himself as a responsible official?
The dissenting opinion in *Dotterweich*, written by Mr. Justice Murphy,²⁴ took the view that the court had confused the two types of liability and had in fact imposed a vicarious liability standard. According to the dissent, guilt had been imputed to Dotterweich solely on the basis of his corporate position, based on an act in which the accused did not participate and of which he had no personal knowledge. In Justice Murphy's view, the legislative intent expressed in the 1938 Act was insufficiently clear on the issue to allow the Court to impose a type of criminal liability which ran counter to the established canons of law.

The second problem which followed in the wake of *Dotterweich* and which has concerned courts for the last thirty years was the unanswered question of which corporate officials are responsible, and thus subject to prosecution. *Dotterweich* itself offers little if any guidance. Indeed, according to Justice Frankfurter, it would be "too treacherous to define or even indicate by way of illustration the class of employees" standing in such responsible relation. Rather, the Court entrusted the determination to "the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries."²⁵

B. Post-Dotterweich Decisions

A review of post-*Dotterweich* cases indicates confusion on the part of courts in dealing with the two problem areas discussed in the previous section: vicarious versus strict liability, and a definition of responsible officials.²⁶

Generally, the lower federal courts have imposed both vicarious and strict liability. The prosecution has not been required to show criminal intent on the part of the individual defendant, nor has it been required to show proof of personal participation by the individual.²⁷ However, the courts have limited vicarious liability in two ways. First, only those officials deemed responsible have been convicted.

²⁴ He was joined by Justices Roberts, Reed and Rutledge, *Dotterweich* being a five to four decision.
²⁵ 320 U.S. at 285.
²⁶ For an excellent analysis of these decisions, see O'Keefe and Shapiro, supra note 22.
²⁷ See generally, United States v. Shapiro, 491 F.2d 335 (6th Cir. 1974); Golden Gruin Macaroni Co. v. United States, 209 F.2d 166 (9th Cir. 1953); United States v. Kaadt, 171 F.2d 600 (7th Cir. 1948); United States v. Parfait Powder Puff Co., 163 F.2d 1008 (7th Cir. 1947), cert. denied 332 U.S. 851 (1948); United States v. Diamond State Poultry Co., 125 F. Supp. 617 (D. Del. 1954).
Courts have interpreted the term "responsible" to mean those officials holding a sufficiently high position to exercise control over the company's activities. Second, those individuals held responsible have in fact had a close connection to the operation in which the violation occurred, apart from holding a corporate position or possessing general authority for the overall conduct of the business. In other words, although the courts have not made the showing of particular, personal actions by the defendants an element of the crime, courts have nevertheless imputed the violations to these officials because these officials did have supervisory control over the daily activities of their corporations.

Thus the dual requirements for responsibility—a position that permits broad exercise of control, and a close connection with the particular operation in question—have confined the conviction of defendants on a vicarious liability theory to high officials in small companies. The individual defendants have resembled the defendant in Dotterweich: they had a close, supervisory relationship over their employees (usually few in number) and to the business (usually small in size and scope of operation).

One notable case of the post-Dotterweich era was the Supreme Court's decision in United States v. Wiesenfeld Warehouse. Although the case involved only a corporate defendant, the decision contained important implications for future prosecutions of individual officials. The Court in Wiesenfeld Warehouse appeared to retreat from an automatic application of strict and/or vicarious liability in Food and Drug Act prosecutions, and indeed the Court hinted at the possibility of a defense based on a showing of due care:

It is argued . . . that the Government in this case is seeking to impose criminal sanctions upon one "who is, by the very nature of his business, powerless" to protect against this kind of contamination, however high the standard of care exercised. Whatever the

28 Such officials have been convicted in the face of defenses based on claims, for example, that the defendant was expressing scientific opinion and thus was not violating the Act in mislabeling drugs, Kordel v. United States, 335 U.S. 345 (1948); that the defendant exercised due care in carrying out his duties. United States v. Diamond State Poultry Co., 125 F. Supp. 617 (D. Del. 1954); and that the defendant, having contracted to sell his business, was no longer a "responsible official" at the time of the alleged violations, United States v. Shapiro, 491 F.2d 335 (6th Cir. 1974).
29 See O'Keefe and Shapiro, supra note 22.
30 Another possible analysis of these cases is that the courts were imposing liability based on the officers' own omissions.
truth of this claim, it involves factual proof to be raised defensively at a trial on the merits.\textsuperscript{33}

Therefore, at the time the Supreme Court granted certiorari in \textit{United States v. Park} there was uncertainty both as to the application of strict and/or vicarious liability, and to the question of who was responsible. A concomitant of this latter problem was the fact that jury instructions by lower courts had been distressingly vague.\textsuperscript{33}

C. \textit{The Supreme Court Decision in Park}

Chief Justice Burger’s opinion in \textit{Park} placed great emphasis on the Act’s purpose in protecting the public, and to that end endorsed any technique (within reason) that would increase the efficacy of the Act. The opinion began with a review of \textit{Dotterweich} and placed that decision in historical perspective. Although not using either term, the Court traced the development of both strict and vicarious liability in areas other than food and drug law, to show that the \textit{Dotterweich} rule of subjecting officials to criminal liability who had a share in the violative transaction “was not formulated in a vacuum.”\textsuperscript{34} Accordingly, the Court held that the Act imposed rigorous standards on all those coming within its ambit. Not only did the Act require positive action in seeking out and remedying violations, but it also imposed a primary duty to implement preventive measures to insure against future violations. Although the burdens imposed are “demanding,” “stringent,” and “perhaps onerous,”\textsuperscript{35} Chief Justice Burger advanced two justifications for these heavy burdens. First, the purpose of the Act was public protection, which was maximized by punishing distributors of food for their neglect or inaction even when they lacked bad intent or personal participation. Second, those prosecuted

\textsuperscript{32} \textit{Id.} at 91.

\textsuperscript{33} The instruction given by the trial judge in \textit{United States v. Kaadt}, 171 F.2d 600, 604 (7th Cir. 1948), is illustrative:

[\textit{If} \ldots any or all of the defendants shares responsibility in conducting the business and \textit{if} the operation of that business resulted in unlawful distribution \ldots, the defendants who shared such responsibility might be found guilty \ldots

[\textit{In determining whether the defendants did have a responsible share in the conduct of the business, [the jury] must take into consideration the work that each defendant did at the Kaadt Diabetic Clinic or Institute, the duties and responsibilities of each and the extent to which each controlled or directed the conduct of the business.}}

\textsuperscript{34} 421 U.S. at 670.

\textsuperscript{35} \textit{Id.} at 672.
under the Act had assumed their positions voluntarily, and had the power to devise measures to assure their corporations' compliance with the Act. Furthermore, the Court emphasized that the Act does not require that which is impossible. Citing *Wiesenfeld Warehouse*, the Court recognized a defense of powerlessness to prevent or correct the violation.36

The Court's discussion of the quantum of wrongful action which must be proven by the prosecution also reflects Chief Justice Burger's position that the Act should be construed so as to fully effectuate its purpose. The Court rejected the proposition that no wrongful action need be shown, and did not agree that a conviction may be predicated solely on a defendant's corporate position. By implication, these findings reject vicarious liability. However, the Court was able to find sufficient evidence of such wrongful action on the part of the defendant in *Park* to uphold his conviction. This wrongful action was of a less stringent type than the Fourth Circuit's requirement of gross negligence.7 The Supreme Court equated "wrongful action" with "some measure of blameworthiness."38 Such action could be established by evidence tending to show that the defendant, by reason of his corporate position, had responsibility and authority to prevent or correct the violation, and that he failed to do so.39

Using this standard, which seems to approximate simple negligence, the Court then evaluated the actual instruction given to the *Park* jury. While upholding the instruction, Burger did concede that it was deficient (although apparently not fatally so). The Chief Justice acknowledged that isolated portions of the instruction could be read as allowing guilt to be based solely on Park's official position. Viewed in its entirety, however, the charge was not misleading, and was therefore not an abuse of the trial judge's discretion.

The Court's treatment of the second issue, the admissibility of the earlier FDA warning letter, can be seen in the context of the powerlessness defense. By attempting to show that his reliance on

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36 If such a claim is made, the defendant has the burden of going forward with the evidence to support it. The government for its part must prove beyond a reasonable doubt that the defendant could correct or prevent the violation, and was not in fact powerless. A successful showing of powerlessness would negate the defendant's need to show that he acted with due care, since all possible care could not have prevented the violation from occurring. *See Section III(B) infra.*

37 499 F.2d at 842.

38 421 U.S. at 673.

39 It follows that the government need not allege particular acts or omissions in regard to particular shipments of food in order to show the requisite wrongful action.
CASE NOTE

subordinates was dictated by Acme's size, and that this reliance was justified, Park was basing his defense on his powerlessness to correct the violation at the Baltimore warehouse. This testimony, according to the Court, created the "need" for rebuttal evidence. The rebuttal evidence (i.e., evidence of Park's receipt of the letter) was therefore properly used by the government to demonstrate that Park had been put on notice that "he could not rely on his system of delegation to subordinates."

The dissenting opinion was written by Mr. Justice Stewart, who had written for the Court in Wiesenfeld Warehouse. He did not object to the Court's formulation of the standards applicable to individuals prosecuted under the Act. Instead, his dissent was based on a view that the jury instructions given by the trial court in Park were not consistent with the law as expounded by the majority. Stewart concluded that the majority had in fact imposed a negligence standard. According to Stewart, a conviction may be secured as follows: first, the prosecution must show that an individual's corporate position is such as to create a duty of due care to maintain the standards of the Act. Second, when the food is found to be in a condition which violates the Act, a jury may infer that the condition was caused by a breach of that standard of care. "This is the language of negligence, and I agree with it," concluded the dissent.

III. IMPLICATIONS OF PARK

The posture in which United States v. Park reached the Supreme Court (with its major issue being the adequacy of the jury instructions), presented the Court with an excellent opportunity to clarify the two problem areas which had plagued courts since Dotterweich. Because of the fact pattern present in Park, the Court could have clearly established what (if any) evidence of personal action on the part of the defendant need be shown—i.e. whether a conviction could be based on vicarious liability without a showing of personal wrongdoing. At the same time, the Court could have dealt with the issue of intent, or mens rea, and the availability of possible defenses,

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421 U.S. at 677.
Id. at 678.
He was joined by Justices Marshall and Powell.
Several courts and commentators have suggested that this type of standard would be proper for prosecutions under the Act. See, e.g., Morissette v. United States, 342 U.S. 246 (1952); Packer, supra note 21; and Wasserstrom, supra note 21.
421 U.S. at 679.
thus refining the issue of strict liability. In light of the fact that *Dotterweich* had made the determination of responsibility a jury question, a thorough discussion of jury instructions would have been extremely helpful in defining those officials who are responsible.

In fact, however, the Supreme Court did not take full advantage of its opportunity to clarify the somewhat muddled state of post-*Dotterweich* law. The following is a discussion of both the implications and shortcomings of *Park*.

### A. The Requirement of a Wrongful Act

The Court's treatment of vicarious liability has interesting implications. Imposition of this type of liability has been much criticized,\(^4\) and the Court indeed avoided imposing it by requiring (and finding in *Park*) a certain minimal quantum of wrongful action necessary for conviction. By restricting the kind of liability imposed by the Act, it would seem to follow that *Park* would thereby restrict the class of persons who could be successfully prosecuted under the Act. However *Park* is susceptible of a broader, although not necessarily more correct, reading. Since the nature of the action which Chief Justice Burger describes as wrongful—*i.e.* having some measure of blameworthiness—is so broad and general, an expansive reading of the case could open prosecution to an entirely new class of individual defendants. This class would consist of those officials who, because of the large size of their businesses, would escape liability if a more direct, personal participation in the violative activity were required.\(^6\) The implications of this definition of wrongful action are potentially enormous. As discussed earlier,\(^7\) individual prosecutions under the Act have been limited to officials of small businesses whose close ties to the daily activity of the company and its employees could be used to infer direct participation in the violative act. After *Park* it would appear that the highest officials of corporations which are large in size and scope of operations may be subject to criminal prosecutions.

The Court eschewed the much maligned principle of vicarious liability (which heretofore had been applied to officials of small businesses) while defining the requisite wrongful action so broadly as to

\(^4\) See, e.g., O'Keefe and Shapiro, *supra* note 22.

\(^6\) Of course, these persons could be convicted if a vicarious liability standard was used, and was not limited, as in the post-*Dotterweich* cases, to officials of small businesses who had daily contact with the operations. See text at note 29 *supra*.

\(^7\) See Section II(B) *supra*.
allow high ranking officials of large corporations to be caught in the prosecutorial net. It is somewhat ironic that by “limiting” liability to those who committed wrongful acts, the Court has potentially broadened the class of those subject to prosecution under that newly defined requirement of wrongful action.

B. Limits on Liability

Although Park raises the possibility that many top corporate officials will be paraded before the courts on charges of criminal violations of the Food, Drug, and Cosmetic Act, a careful reading of Chief Justice Burger’s opinion provides some indication that this will not actually occur. The Park decision fashions a two-step process to determine those individuals who can be successfully prosecuted under the Act. First, the defendant must have a duty to comply with the statute. This duty is imposed by an individual’s corporate position. Second, the officer with the requisite duty to prevent or correct the violation of the Act must fail in that duty. From this two-step process, two defenses are opened. First, since any wrongful act or omission upon which a defendant’s liability is predicated can only be attributed to a corporate official with a duty not to violate the Act, a defendant can claim that he had no such duty. Second, the Court (relying on Wiesenfeld Warehouse) allowed a defense based on a defendant’s powerlessness. This latter defense admits the possibility of a defense based on due care. The relationship between the two (powerlessness and a due care standard) is illustrated in the Court’s discussion of the admissibility of the prior FDA warning letter. As discussed earlier, Park’s defense of reasonable reliance on subordinates was properly rebutted by the prosecution’s introduction of the FDA letter. Had the Court not implicitly agreed that due care was a proper defense to the charge, it would not have recognized the need for the government to present testimony rebutting the defendant’s attempt to show his due care.

C. Refinement of Strict Liability

A recognition of the two defenses discussed above allows the conclusion that the Court, following Wiesenfeld Warehouse, is turning to a criminal negligence standard of liability for individual prosecutions under the Act. If indeed (as the Park dissent believes) a

See note 36 supra.
negligence standard is imposed by the Court, the strict liability standard cannot remain. The two standards cannot exist side by side: if strict liability is imposed, a defendant's intent is irrelevant, and furthermore he cannot claim that he acted with due care. Negligence, on the other hand, has been treated as a culpable mental state. The imputation of negligence means that a defendant did not intend his actions to be harmful, but that he failed to act as a reasonable person would have acted.

Perhaps Park represents the beginning of a radical change in the standard used to determine individual liability under the Act. The case law interpreting the Act almost universally repeats the Dotterweich holding that an awareness of wrongdoing, or mens rea, is not an element necessary to be proved in order to obtain a conviction. Park itself discusses this aspect of Dotterweich, and the former case certainly did not overrule the latter. However, the two cases are inconsistent with respect to the standard used to determine guilt, at least in one important respect. By recognizing that the jury's sole function is to ascertain whether or not the accused shares responsibility in the violative act (the only issue if the strict liability standard is used), Dotterweich effectively negated any jury consideration of whether the defendant took adequate precautions to comply with the Act, and thereby eliminated a defense based on reasonable care. Park, on the other hand, admits the possibility that a jury will be allowed to consider evidence that the defendant acted reasonably and exercised due care.

One shortcoming of the Park decision is that the Court did not use the available opportunity to clarify what jury instructions are proper for individual prosecutions under the Act. The upholding of the trial judge's instructions in Park is notable for two reasons: first,

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49 See note 21 supra.
50 The two standards have certain similarities. Unlike a crime requiring proof of mens rea, in which the prosecution must show that the defendant has acted with bad intent, in both strict liability and negligence a defendant's intent is irrelevant. A related similarity involves the use of an external standard to judge each defendant's actions: the jury in a criminal negligence prosecution asks only whether the activity of the defendant violated some standard of care which a reasonable member of the community would not have violated. To the extent that strict liability statutes can be interpreted as legislative judgments that conduct which produces or permits certain consequences is unreasonable, strict criminal liability is similar to a jury determination that conduct in a particular case was unreasonable.

See Wasserstrom, supra note 22, at 744.
51 See Packer, supra note 21.
the Court obviously is straining to let the instructions stand, and second, the hint of a due care standard, as reflected by what a jury may be allowed to consider, is given in this rather oblique reference by the Court:

there was no request [by the defendant at trial] for an instruction that the Government was required to prove beyond a reasonable doubt that respondent was not without power or capacity to affect the conditions which founded the charges in the information.

This constitutes the only guidance which the Court provides for proper instructions in future cases. It suggests that proper instructions must be framed in terms of basing a defendant's guilt upon the absence of the one defense which the Court recognizes as being open to him, i.e. that he was powerless to prevent or correct a violation of the Act.

Admittedly, the Court is not explicitly reformulating the standard of guilt for prosecutions under the Act, and is not directly abandoning the traditional strict liability standard of Dotterweich. However, it is possible to find in Park hints of a sharp departure from existing law because of its allowance of the powerlessness defense and its suggested jury instructions.

D. Jury Instructions on Responsibility

The interplay between liability and jury instructions is discernible in another area. In addition to instructions on what standard of liability is to be used, the jury must also be informed of the class of persons who can be found liable. Dotterweich gave the simple answer that all responsible officials may be held liable. The Park Court also addressed this issue and attempted to further define the concept of responsibility. In upholding the trial court's jury instructions, however, the majority was led into a circular argument. In order to sustain the instructions, the Court had to find that the instructions did not allow the jury to predicate guilt solely on the defendant's corporate position; otherwise, the Court's requirement that the defendant must have engaged in wrongful action would be meaningless. To establish the requisite personal wrongdoing, the jury must have found that the defendant had the authority and responsibility "to deal with"

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22 This may be explained partially by the Court's view of the Act's purposes and the availability of the "powerlessness" defense.

23 421 U.S. at 676.
the situation, i.e. to prevent or correct it. However, the defendant's authority and responsibility was a result of, and inextricably bound up with, his corporate position.

The dissent recognized this problem. Since a guilty verdict was required if the jury found responsibility and since the jury had been cautioned by the trial judge that Park's formal position alone did not require a finding of responsibility, the dissent perceived the result as follows:

"[R]esponsibility" as used by the trial judge therefore had whatever meaning the jury in its unguided discretion chose to give it.

The instructions, therefore, expressed nothing more than a tautology. They told the jury: "you must find the defendant guilty if you find that he is to be held accountable for this adulterated food." In other words; "You must find the defendant guilty if you conclude that he is guilty." 5

*Park* has added little to the law in regard to defining responsible officials. Further, the decision offered only an oblique reference to the standard to be used in determining guilt. Hence if *Park* is to be read as a portent of a radical change in the standard of guilt from strict liability to reasonableness or due care, the decision leaves future trial courts with little guidance as to precisely what the new standard is. Nonetheless, trial courts in the future will be forced to interpret *Park* in formulating their instructions. Based on an analysis of *Park*, including its shortcomings, two predictions can be advanced as to the possible influence of the decision on future instructions.

The first and more favorable prediction is that, because of the vagueness of the *Park* standards, trial judges will read between the lines in order to find possible proper instructions. For example, the powerlessness defense may be used and juries may be instructed that the defendant is liable if he was not powerless to prevent or correct its occurrence. Alternatively, a court may adopt a general tort negligence standard (following the dissent) and instruct the jury that an individual defendant is liable if he failed to exercise reasonable care in performing his corporate duties so as to allow the violation to occur or go uncorrected.

A second possible effect which *Park* may have on trial judges is to sanction the type of instruction given in *Park*, which the Court

\[\text{Id. at 679. Stewart further noted that the trial judge had felt bound by Dotterweich to give these particular instructions.}\]
itself implied was inadequate. Thus the Court may have given an
impetus to sloppy, tautological charges that give juries no guidance.
A negligence standard of guilt would result in clearer and more help-
ful instructions to juries. But since the Court itself did not specifically
adopt a negligence standard, trial courts may easily overlook the
possibility of using such a standard.

Even if the possibility of using a negligence standard is brought
to the attention of the lower courts, it is somewhat doubtful that they
will adopt such a standard. It would seem that any test of guilt based
on negligence, or the defendant's lack of a powerlessness defense,
would necessarily preclude an imposition of strict liability. Since the
Court dealt so obscurely with strict liability, and given Dotterweich's
well known stance on the issue, it may prove extremely difficult for
courts to issue instructions which completely ignore strict liability.

In summary, although it is possible to read Park as signaling the
demise of strict liability under the Food, Drug and Cosmetic Act,
most lower courts will likely take the more conservative and tradi-
tional view that liability under the Act is strict, and therefore will not
limit the jury solely to the issue of negligence. Thus future instruc-
tions may well reflect a confusing mixture of strict liability diluted
by some form of the powerlessness defense (e.g., "you may find
defendant guilty if you determine that he was a responsible official
who had power to prevent or correct the situation leading to the
violation"). Such an instruction would simply perpetuate the above
mentioned shortcomings of Park.

Other possible methods of analyzing the powerlessness defense
which may be useful to future trial courts are suggested by two Common-
wealth cases, Sweet v. Parsley,55 and Kilbride v. Lake.56 Sweet
involved the construction of a section of the Dangerous Drugs Act
1965 (Eng.) which prohibited the management of premises where
cannabis was used. Several tenants of defendant, unknown to her,
used cannabis in the house which she rented to them. In construing
the statute, Lord Reid pointed to two possibilities other than impos-
ing strict liability on the one hand and placing the full burden of
proving mens rea upon the prosecution on the other hand. The first
suggestion was to transfer to the defendant the onus of disproving
mens rea, so that the defendant "must convince the jury that, on

balance of probabilities he is innocent of any criminal intention.\textsuperscript{57} Lord Reid's second idea was to substitute a gross negligence standard for that of strict liability. Interestingly, the court of appeals in Park adopted the latter suggestion.

\textit{Kilbride v. Lake} involved a traffic regulation which required that all vehicles display a current warrant of fitness. The facts indicated that the warrant on defendant's car was properly displayed when he parked it, and that upon his return the warrant had disappeared. Although both prosecution and defense framed their arguments around the issue of whether or not the statute imposed strict liability, the court stated that this emphasis had obscured the real issue. Instead of focusing on the mental element necessary to establish criminal liability, the court looked to the basic criminal law requirement that the defendant do an overt act or omit to do some act which he was legally obligated to do. Thus a defendant must be shown responsible for the physical ingredient of the crime to be convicted. A defendant cannot be held criminally responsible for an act or omission unless it was committed (or omitted) under circumstances in which there was some other course open to him. This analysis can easily be transferred to the context of an individual prosecution under the Food, Drug and Cosmetic Act, particularly when the defendant has made a powerlessness defense. That defense is essentially grounded on an individual's claim that the course of action (or inaction) followed by him would \textit{not} have prevented the violation.

E. \textit{FDA Enforcement Policy}

In order to gauge more precisely the impact which \textit{Park} is likely to have on the law under the Food, Drug, and Cosmetic Act, it is relevant to discuss exactly which defendants (corporate and individual) are prosecuted under the Act. Generally, prosecution results from a recommendation by FDA and a decision to prosecute by the Justice Department. An elaborate system of internal review within FDA\textsuperscript{58} is calculated to prevent harsh or unfair application of the Act.\textsuperscript{59} Generally, the FDA requires the following conditions to be

\begin{itemize}
  \item \textsuperscript{57} [1970] A. C. at 150.
  \item \textsuperscript{58} See O'Keefe and Shapiro, \textit{supra} note 22 at 27.
  \item \textsuperscript{59} Congress expressed its concern that minor violations not be the subject of criminal prosecution by including § 306 of the Food, Drug, and Cosmetic Act (1938), 21 U.S.C. § 336 (1970), which provides that:

  Nothing in this chapter shall be construed as requiring the Secretary to report
satisfied before recommending prosecution: (1) at least one responsible official must be identified and included in the prosecution; (2) substantial evidence must show that the individual had authority to correct the violative conditions; and (3) evidence must exist that background warnings (e.g. a letter or citation) had been sent to the firm and the individual. Hence, individual criminal prosecutions under the Act are limited to (1) corporate officials who, although possessing sufficient knowledge and authority to correct the situation leading to the violation charged, failed to do so; and (2) defendants whose companies have been guilty of continuing violations of the Act resulting in prior warnings being sent to an appropriate official.

Thus the powerlessness defense recognized by Park becomes almost meaningless when viewed in light of the present government policy in regard to prosecutions under the Act. Although Park provided a corporate officer the general defense of powerlessness, and hinted that such an officer might be deemed powerless if he justifiably relied on subordinates, the only individuals who could avail themselves of this defense will never (at least theoretically) be prosecuted in the first place.

The import of Park is this: as long as the government continues to use pretrial devices which prevent certain classes of persons from being prosecuted, the Court will give FDA and the Justice Department leave to carry on as they have been. The classes of persons who may not be prosecuted include both employees who lack authority or knowledge to insure corporate compliance, and officials of first time offender corporations (who had no reason to doubt their subordinates' compliance). The safeguard of the powerlessness defense mentioned in Park is available if needed to protect individuals from unfounded prosecutions or harassment. But if the government continues to use its prosecutorial discretion wisely, which the Court appar-

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for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

60 There are no written criteria defining responsibility. However, the following factors are taken into account by FDA and Justice Department officials: the extent of a defendant's personal participation in the violative acts; the individual's position in the business; his duties and responsibilities in that position; and facts relating to whether the individual knew or should have known the requirements of the law. See O'Keefe and Shapiro, supra note 22, at 26.

61 O'Keefe and Shapiro, supra note 22, at 27.

62 It can be assumed that the Court was aware of this policy, since it was quoted in the government's brief. Other federal agencies may not necessarily follow the same policy in their prosecutions.
ently believes it has done, then no barriers to continued implementa-
tion of current policy will be established by the Court.

Thus it appears that Dotterweich's trust in "the good sense of
prosecutors" has become the major enforcement policy of the Act,
while its reliance on "the wise guidance of trial judges," in light of
the lack of such guidance given to the Park jury, has been tabled.

IV. Conclusion

Park has the potential of being a landmark case in the area of
individual prosecutions under the Food, Drug, and Cosmetic Act. As
has been demonstrated, it may be read as signaling a demise of strict
liability, replacing this with a simple negligence standard. The deci-
sion has both tacitly approved FDA enforcement policy and sanc-
tioned prosecution of a new class of individual defendants—highly
placed executives of large corporations. Prosecution of such defen-
dants will add greatly to the effectiveness of the Act. Such prosecu-
tions will be fair if the FDA continues its present enforcement policy,
and if courts continue to require some act or omission by the individ-
ual defendant while allowing him the defense of powerlessness and
exculpation by way of reasonable reliance on subordinates. Read in
this manner, Park would have a salutory effect both on the effective-
ness of enforcement and the fairness of the individual prosecutions.
The decision, however, is ambiguous enough to perpetuate and possi-
bly add to, the confusion now existing in the area. It is to be hoped
that lower courts will be able to deal with Park's shortcomings and
apply the decision to its best advantage for both of the interests
mentioned above: enforcement of the Act, and protection of individu-
als.

Beatrice M. Friedlander