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FOOD AND DRUG LAW—STANDARDS OF CORPORATE LIABILITY

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

In *United States v. Park*,[1] the United States Supreme Court reviewed the standard of liability of corporate officers under the Federal Food, Drug and Cosmetic Act of 1938.[2] The Supreme Court held that the Act, as interpreted in *United States v. Dotterweich*,[3] imposes upon persons exercising the authority and responsibility relevant to their positions in the corporations "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."[4]

Respondent Park was the president of Acme Markets, Inc., a national retail food chain. Both respondent and Acme were charged in an information with violating section 331(k) of the Act.[5] The information alleged that they had caused food that had moved in interstate commerce and that was to be offered for retail sale to be stored in insanitary conditions at Acme's Baltimore warehouse. Acme pleaded guilty to the charge, but the respondent pleaded not guilty. At the trial an FDA consumer safety officer testified that on two occasions, in late 1971 and early 1972, inspections of Acme's Baltimore warehouse revealed evidence of rodent infestation and other insanitary conditions. Testimony was also given by the Chief of Compliance of the FDA's Baltimore office that after the first inspection respondent was informed by letter of the conditions at the Baltimore warehouse.

In his defense respondent testified that, while all of Acme's employees were under his general directions, the organizational structure of the company provided that different phases of its operation were delegated to individuals and their subordinate staff. Park also testified that upon receipt of the FDA letter he conferred with the vice president for legal affairs who informed the respondent that the Baltimore divisional vice president was investigating the matter and

[1] 421 U.S. 658 (1975).

[2] Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§ 301-392 (1970). The legislative history of this Act and its predecessor, the Food & Drugs Act of June 30, 1906, ch. 3915, 34 Stat. 768, indicates that it was an attempt by Congress to safeguard the health and safety of the individual citizen from the dangers of impure or mislabeled food, drugs and cosmetics which had travelled in interstate commerce. Since there are no federal police powers which permit the regulation by Congress of the health and safety of citizens within states it was necessary for Congress to use its commerce powers to enact this legislation with the result that the alleged adulterated or misbranded item must first travel in interstate commerce before the Act applies. The 1938 version of the Act is an attempt to tighten up on the "abuses of consumer welfare growing out of the inadequacies in the Food & Drugs Act of June 30, 1906." H.R. REP. NO. 2139, 75th Cong, 3d Sess. 1 (1938).

The Act states in pertinent part:

§ 331. Prohibited acts.

The following acts and the causing thereof are prohibited:

....

(k) The alteration, 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 (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

§ 333. Penalties.

(a) Violation of section 331 of this title.

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) Second offenses; intent to defraud or mislead.

Notwithstanding the provisions of subsection (a) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

§ 342. Adulterated food.

A food shall be deemed to be adulterated—

(a) Poisonous, insanitary, etc., ingredients.

... (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health.

[3] 320 U.S. 277, 281, 284 (1943). *Dotterweich* involved the prosecution of Buffalo Pharmacal Company, Inc., and Dotterweich, its president and general manager, for violating provisions of the Act in that they had caused the shipment of misbranded drugs and adulterated drugs in interstate commerce. The case held that corporate agent, Dotterweich, could be held criminally liable, absent the element of "awareness of some wrongdoing," if it were shown that he had a "*responsible share* in the furtherance of the transaction which the statute outlaws, namely, to put into the stream of interstate commerce adulterated or misbranded drugs." *Id.* (emphasis added).

[4] 421 U.S. at 672.

[5] *See* note 2 *supra*.

would take corrective action and reply to the FDA letter. Respondent testified that he did not believe there was anything more he could have done. On cross-examination Park conceded that providing for sanitation conditions for food offered for sale to the public was a function that he was "responsible for in the entire operation of the company."[6] However, respondent further stated that this was one of the phases of operation he had assigned to "dependable subordinates."

Over respondent's objection evidence was admitted concerning a letter Park had received in April 1970 from the FDA in regard to insanitary conditions at Acme's Philadelphia warehouse. Respondent testified that the same individuals were responsible for sanitary conditions at the Philadelphia and Baltimore warehouses. He conceded that it appeared that the company's procedure for handling sanitation "wasn't working perfectly"[7] and that as president he was responsible for "any result which occurs in our company."

During Park's trial in district court the trial judge ruled that *Dotterweich* was the controlling case. The instructions[8] he issued to the jury reflect the *Dotterweich* standard of liability, *i.e.*, "the offense is committed . . . by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws."[9] Based upon the evidence presented during trial and the instructions issued by the trial judge, the jury in *Park* found the respondent guilty of violating section 331(k) of the Act. On appeal the Fourth Circuit reversed,[10] reasoning that the trial judge had failed to include in his jury charge an instruction as to the element of "wrongful action,"[11] with the result that the jury may have erroneously believed that Park could be found guilty without proof of any wrongful act on his part. The Supreme Court reversed the appellate court's decision and reinstated Park's conviction.[12]

The Court held that the trial court's instructions sufficiently focused the jury's attention on the issue of respondent's accountability with respect to the conditions that gave rise to the charges against him, and did not permit the jury to convict merely on the fact that respondent was president of the offending corporation. In addition, the Court decided that the trial court had not erred in admitting testimony given by respondent concerning a prior FDA warning he had received. It deemed such evidence relevant as rebuttal to the "respondent's defense that he had justifiably relied upon subordinates to handle sanitation matters."[13] The prior FDA warning was admissible to show that, prior to the Baltimore inspection, the respondent had knowledge that he could not depend on his system of delegation for handling sanitation matters.

An examination of prior cases reveals that *Park* did not occur as an isolated expression of statutory interpretation in the area of food and drug laws.

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[6] 421 U.S. at 664.

[7] *Id.* at 664-65.

[8] The trial judge instructed the jury:

"In order to find the Defendant guilty on any count of the Information you must find beyond a reasonable doubt on each count . . . .

. . . .

"Thirdly, that John R. Park held a position of authority in the operation of the business of Acme Markets, Incorporated.

"However, you need not concern yourselves with the first two elements of the case. The main issue for your determination is only with the third element, whether the Defendant held a position of authority and responsibility in the business of Acme Markets.

. . . .

"The statute makes individuals, as well as corporations, liable for violations. An individual is liable if it is clear, beyond a reasonable doubt, that the elements of the adulteration of the food as to travel in interstate commerce are present. As I have instructed you in this case, they are, and that the individual had a responsible relation to the situation, even though he may not have participated personally.

"The individual is or could be liable under the statute, even if he did not consciously do wrong. However, the fact that the Defendant is pres[id]ent 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 relationship to the issue. The issue is, in this case, whether the Defendent, John R. Park, by virtue of his position in the company, had a position of authority and responsibility in the situation out of which these charges arose."

Id. at 665 n.9, *quoting* the appendix to the brief on appeal, which listed the trial judge's instructions.

[9] 320 U.S. at 284.

[10] 499 F.2d 839 (4th Cir. 1974), *rev'd*, 421 U.S. 658 (1975).

[11] 499 F.2d at 841-42. The appellate court argued that the Government had misinterpreted *Dotterweich*. It claimed that the *Dotterweich* decision had dispensed with the element of "awareness of some wrongdoing" but had not dispensed with the necessity to prove "wrongful action" on the part of the defendant. However, the appellate court did not give an altogether clear definition of "wrongful action."

The Federal Food, Drug, and Cosmetic Act § 331 (k) prohibits "causing" the adulteration of food which has traveled in interstate commerce and is held for sale. We would define "wrongful action" in this context as acts of the accused which *caused* the adulteration of such food.

Id. at 841 n.4.

[12] 421 U.S. at 678.

[13] *Id.*

Instead, the foundation for the *Park* decision was laid as early as the beginning of this century. In *United States v. Balint*,[14] for instance, the Supreme Court recognized a trend away from the common law rule that scienter was a necessary element for conviction of a crime. This trend had begun to emerge in the area of statutory measures concerned with the health and well-being of the individual such as the Act on which *Park* is founded. Justice Taft, speaking for the Court in *Balint*, stated:

> While the general rule at common law was that the *scienter* was a necessary element in the indictment and proof of every crime, and this was followed in regard to statutory crimes even where the statutory definition did not in terms include it . . . there has been a modification of this view in respect to prosecutions under statutes the purpose of which would be obstructed by such a requirement. It is a question of legislative intent to be construed by the court.[15]

[14]258 U.S. 250 (1922).

[15]*Id.* at 251-52.

[16]*See, e.g.*, Morissette v. United States, 342 U.S. 246, 252-56 (1952); Sayre, *Public Welfare Offenses*, 33 COLUM. L. REV. 55 (1933). In *Morissette* the Court characterized this class of regulatory measures, stating:

> Many of these offenses are not in the nature of positive aggressions or invasions, with which the common law so often dealt, but are in the nature of neglect where the law requires care, or inaction where the law imposes a duty. Many violations of such regulations result in no direct or immediate injury to person or probability of it which the law seeks to minimize. While such offenses do not threaten the security of the state in the manner of treason, they may be regarded as offenses against its authority, for their occurrence impairs the efficiency of controls deemed essential to the social order as presently constituted. In this respect, whatever the intent of the violator, the injury is the same, and the consequences are injurious or not according to fortuity. Hence, legislation applicable to such offenses, as a matter of policy, does not specify intent as a necessary element. The accused, if he does not will the violation, usually is in a position to prevent it with no more care than society might reasonably exact from one who assumed his responsibilities.

Morissette v. United States, *supra* at 255-56.

In Sayre's article there is a detailed account of the history, trend and merits of these types of regulatory measures, which he classifies as "public welfare offenses." Sayre, *supra* at 56. The traditional element of *mens rea* is absent from such regulations in order that the public policy behind each is not defeated. The argument is that if the government were required to prove a guilty mind in each instance, the offense would often go unprosecuted because of the difficulty of establishing intent in many of these cases. The criminal sanctions imposed by these measures serves, it is believed, as an effective regulatory device facilitating compliance with the statute. Since penalties were relatively slight the harm done to an innocent offender was felt to be small when compared to the social good achieved as a result of such regulations. It is interesting to note that where the penalty involves a heavy fine or imprisonment, Sayre argues that in order to safeguard against individual interests being jeoparized the element of *mens rea* should be maintained and the burden of proving lack of criminal intent should be shifted to the defendant. Sayre, *supra* at 79.

In this regard the courts began to recognize that certain statutory measures did not require proof of such guilty intent. These measures were generally regulatory measures whose purposes were aimed more at the achievement of the health and safety of the community rather than at the punishment of the crime. The impetus for such measures resulted from the emergence of the modern industrial state where individuals were often helpless to protect themselves against the mass production and sale of foods and beverages and other consumer goods.[16]

One early case which typifies this new attitude and construction of regulatory statutes by the courts is *United States v. Mayfield*.[17] The defendants in this case were corporate officers and stockholders of a beverage company charged with violating the Food and Drugs Act of 1906[18] by introducing misbranded beverages into interstate commerce. The defendants were not directly involved in this transaction, nor did they directly manage the company's business affairs. The facts show that defendants had hired a managing agent and that it was this agent who operated the plant and managed its business affairs. The report of the case consists entirely of the district judge's jury charge. The charge noted that the mere fact the defendants were officers and stockholders in the corporation did not make them responsible under the Act. As the court stated:

> [T]heir responsibility depends altogether upon whether or not they conferred on the manager the authority to ship Celery Cola from one state into another; and whether the shipment upon which this prosecution is based was made by the manager pursuant to the authority so conferred.[19]

If the jury were to find that the defendants had conferred such authority on the manager, then the defendants would be criminally liable regardless of their lack of knowledge or intent to violate the statutory provisions of which they were charged.[20] In *Park*, the Supreme Court, with Chief Justice Burger writing for the majority,[21] considered *Mayfield* an early reflection of

[17]177 F. 765 (N.D. Ala. 1910).

[18]Act of June 30, 1906, ch. 3915, § 12, 34 Stat. 768.

[19]177 F. at 767.

[20]Since the report of *Mayfield* consisted entirely of the district court judge's jury charge, no indication is given as to the final disposition of the case by the jury.

[21]Chief Justice Burger was joined by Justices Douglas, Brennan, White, Blackmun, and Rehnquist.

> the view both that knowledge or intent were not required to be proved in prosecutions under its [Federal Food and Drugs Act of 1906] criminal provisions, and that responsible corporate agents could be subjected to the liability thereby imposed.[22]

Federal cases during this early period frequently held that the 1906 Act did not require proof of knowledge or intent on the part of the defendant.[23] Such cases represent a general trend toward stricter liability in the area of food and drug regulations in that they dispense with the scienter requirement. With the exception of *Mayfield*, federal cases recognizing the principle that a corporate officer may be criminally liable under such statutes by virtue of his "managerial position" are rare. Even the majority's opinion in *Park* fails to cite an early federal case on this point. It instead looks to various state court decisions for support.[24]

After the enactment of the Federal Food, Drug and Cosmetic Act of 1938 the Supreme Court made its first major effort to deal with the corporate officer's liability under the Act in *United States v. Dotterweich*.[25] In that case the Court dealt with the question of whether "any person" in section 303(a) included corporate agents. The circuit court[26] had previously reversed Dotterweich's conviction by holding that the words "any person" referred only to the corporation. The Supreme Court in *Dotterweich* reversed, reasoning that the only way a corporation can act is through its agents. It noted that although the Food and Drugs Act of 1906 specifically included officers and agents of a corporation within its provisions,[27] the deletion of these words in the 1938 Act was only "in the interest of brevity and good draftsmanship,"[28] since "by 1938, legal understanding and practice had rendered such statement of the obvious superfluous."[29] The purpose of the 1938 Act was, it said, "to enlarge and stiffen the penal net and not to narrow and loosen it."[30]

In reviewing *Dotterweich* Chief Justice Burger noted that in order to prevent the holding in that case from operating too harshly, since it dispensed with the need to prove an "awareness of some wrongdoing," the *Dotterweich* Court provided a limiting principle which dictates that the offense is only committed by those "who have . . . a responsible share in the furtherance of the transaction which the statute outlaws."[31] Furthermore, the Court in *Dotterweich* regarded as "too treacherous"[32] any attempt to define or to provide examples of persons standing in such a "responsible relation." It therefore left the question of responsibility to be decided by the jury, under proper guidance, based on the evidence produced at trial. Cases occurring over the three decades since the *Dotterweich* decision, some of which the Court cites in *Park*,[33] indicate a general

[22] 421 U.S. at 670.

[23] *See, e.g.*, United States v. Sprague, 208 F. 419 (E.D.N.Y. 1913); People v. Schwartz, 28 Cal. App. 2d 775, 70 P.2d 1017 (1937). In *Sprague* the defendants were copartners in a company and were charged with shipping in interstate commerce adulterated oysters. In construing the 1906 Act the district judge stated:

> Congress has seen fit to impose a penalty for such a violation, and it is no defense to claim that the person causing the violation neither knew at the time that the goods were offensive, nor intended to violate the law .... But Congress has gone much further, and in the exercise of its police power has imposed a penalty upon the sending of the deleterious or harmful substance, where the shipper is responsible for the act of sending, even though he may have nothing to do with the condition of the article sent, except as possession or ownership make him responsible.

United States v. Sprague, *supra* at 423.

[24] *E.g.*, State v. Burnam, 71 Wash. 199, 128 P. 218 (1912). In *Burnam* the defendant was the secretary-treasurer and manager of a dairy corporation. His duties included the management of the active business of the corporation, the employment and discharging of men, and the buying and general supervision of the mixing of the milk. He was convicted of having in his possession, with intent to sell and deliver, milk of a grade below the standard fixed by law. The facts showed that a chemical analysis of a sampling of milk taken from a wagon belonging to the corporation revealed that the milk had been watered and was below standard. The defendant argued in his defense that "he was not present when that particular wagon left the dairy and that his instructions were to keep the milk up to the standard fixed by law." *Id.* at 200, 128 P. at 219. The Supreme Court of Washington cited the rule to be that where a managing agent of a corporation exercises control and assists in the regulation of the business, the agent may be held liable "in the violation of a police regulation when neither a guilty knowledge nor criminal intent is made an element of the offense." *Id.* at 202, 128 P. at 219.

[25] 320 U.S. 277 (1943). *See* note 3 *supra*.

[26] United States v. Buffalo Pharmacal Co., 131 F.2d 500 (2d Cir. 1942), *rev'd*, 320 U.S. 277 (1943).

[27] Food & Drugs Act of June 30, 1906, ch. 3915, § 12, 34 Stat. 768 provided that:

> [T]he act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such corporation, company, society, or association as well as that of the person.

This section was not included in the Federal Food, Drug & Cosmetic Act of 1938, 21 U.S.C. §§ 301-392 (1970).

[28] 320 U.S. at 282.

[29] *Id.*

[30] *Id.*

[31] 421 U.S. at 669 *quoting* the majority in *Dotterweich*, 320 U.S. at 284.

[32] 320 U.S. at 285.

[33] United States v. Shapiro, 491 F.2d 335 (6th Cir.

adherence to the principles of corporate liability under the Act as announced in that early case.

In the recent case of *United States v. Cassaro, Inc.*[34] the First Circuit sustained the conviction of the defendant who, along with the bakery he worked for, was charged with storing flour that had moved in interstate commerce, under insanitary conditions resulting in its adulteration within the meaning of sections 342(a) (3), (4).[35] Defendant's defense was that he could not be found guilty because he was sick and not present at the bakery at the time of the FDA inspection, and that his brother was in charge during this period. The circuit court noted, according to *Dotterweich:*

> The offense is committed . . . by all who . . . [have] a responsible share in the furtherance of the transaction which the statute outlaws.[36]

Based upon the fact that the defendant had the overall responsibility for the management of the bakery and that the defendant had testified that "he, Salvatore, had full responsibility for operations,"[37] the court sustained his conviction. Since the *Dotterweich* decision in 1943, the extent to which the Supreme Court has seen fit to extend its principles is probably most strikingly illustrated by its decision in *United States v. Wiesenfeld Warehouse Co.*,[38] where it was held that a mere bailee may be criminally liable under the Act. In this case a public storage warehouseman was charged with violating section 301(k) of the Act.[39] The district court dismissed the charge for failure to state an offense under the Act. It reasoned that section 301(k) did not apply to the mere act of "holding" goods. On direct appeal[40] by the Government the appellee argued that as a bailee, rather than a seller, he was not holding the food within the meaning of section 301(k). The Supreme Court disagreed with appellee's construction and stated:

> The language of § 301(k) does not limit its application to one holding title to the goods, and since the danger to the public from insanitary storage of food is the same regardless of the proprietary status of the person storing it, the purpose of the legislation—to safeguard the consumer from the time the food is introduced into the channels of interstate commerce to the point that it is delivered to the ultimate consumer—would be substantially thwarted by such an unwarranted reading of the statutory language.[41]

Accordingly the Court held that the information did charge an offense under section 301(k) of the Federal Food, Drug and Cosmetic Act.

1974); United States v. 3963 Bottles, More or Less, 265 F.2d 332 (7th Cir.), *cert. denied,* 360 U.S. 931 (1959); Lelles v. United States, 241 F.2d 21 (9th Cir.), *cert. denied,* 353 U.S. 974 (1957); United States v. Kaadt, 171 F.2d 600 (7th Cir. 1948). In *3963 Bottles, More or Less* the court notes that while the Act is an example of a "public welfare statute," dispensing with the element of wrongful intent, "criminal liability is not . . . imposed automatically under this type of law upon every officer or agent no matter how remote his connection with the offending corporation." The court goes on to say that the "proper test" was "clearly enunciated" in *Dotterweich.* "Criminal responsibility . . . attaches to those who have a *responsible share* in furtherance of the transaction which the statute outlaws." The question of "responsibility" is to be left with the jury under proper guidance assuming the evidence warrants it. United States v. 3963 Bottles, More or Less, *supra* at 336.

In *Lelles* both the corporation and its president, Lelles, had been charged and found guilty of violating 21 U.S.C. §§ 331, 333 (1970). The corporation was acquitted on an order entered by the trial judge. Evidence had been produced at trial showing that the shipments in violation of the Act were made by a different corporation, but one in which appellant was also president. On appeal appellant argued that he could only be liable as an officer of the corporation and since the corporation was acquitted, appellant could not be liable. In sustaining the decision of the trial court the appellate court relied on *Dotterweich* to the effect "that a person who has responsibility in the business activities of a corporation may be personally guilty." Lelles v. United States, *supra* at 23.

In *Kaadt* appellants appealed from a jury conviction for violation of the Federal Food, Drug & Cosmetic Act. The violation concerned the introduction, and delivery for introduction into interstate commerce of certain misbranded drugs. In reviewing the trial court's instruction the appellate court noted that "physical participation" was not essential to establish criminal liability under the Act. The issue to be determined by the jury was whether the defendants had shared in the responsibility of conducting the operations of that business, and that "the duties and responsibilities of each, and the extent to which each controlled or directed the conduct of the business," were relevant to that determination. United States v. Kaadt, *supra* at 604.

[34] 443 F.2d 153 (1st Cir. 1971).

[35] 21 U.S.C. § 342 (1970). *See* note 2 *supra.*

[36] 443 F.2d at 157, *quoting* the majority in *Dotterweich,* 320 U.S. at 284.

[37] 443 F.2d at 157.

[38] 376 U.S. 86 (1964).

[39] 21 U.S.C. § 331(k) (1970). *See* note 2 *supra.*

[40] The Criminal Appeals Act, 18 U.S.C.A. § 3731 (1969), provides in part:

> An appeal may be taken by and on behalf of the United States from the district courts direct to the Supreme Court of the United States in all criminal cases in the following instances:
>
> From a decision or judgment setting aside, or dismissing any indictment or information, or any count thereof, where such decision or judgment is based upon the invalidity or construction of the statute upon which the indictment or information is founded.

[41] 376 U.S. at 92.

The principal question confronting the Court in *Park*, left unanswered by *Dotterweich* and its progeny, was whether the element of "wrongful action" is a requisite for convicting a corporate agent. The trial judge in *Park* had instructed the jury that an individual could be criminally liable under the Act "even if he did not consciously do wrong."[42] Therefore, the issue to be decided by the jury was whether, as a result of defendant's position with the corporation, he "had a position of authority and responsibility in the situation out of which these charges arose."[43] The court of appeals objected to these instructions because they might have led the jury to incorrectly believe "that Park could be found guilty in the absence of 'wrongful action' on his part."[44]

The majority in the Supreme Court disagreed with the position taken by the Fourth Circuit concerning the necessity of the Government's establishing "wrongful action." Instead the Court focused on what it believed to be the corporate agent's duty in these situations. As the majority defined it, that duty is "imposed by the interaction of the corporate agent's authority and the statute . . . ."[45] The degree of "authority" is that which would enable the individual "either to prevent in the first instance, or promptly to correct, the violation complained of . . . ."[46] In reviewing the jury instructions, the majority expressed a desire to avoid taking statements from the charge and judging them in "artificial isolation,"[47] as it felt the court of appeals had done. It sought instead to consider the instructions in the context of the entire trial. The Fourth Circuit, on the other hand, had treated the matter narrowly in concluding the trial judge's instructions were improper. It had therefore reversed and remanded the trial court decision because it felt the lower court's instructions had allowed the jury to convict the defendant solely on the basis of his position as president of the corporation. The Court majority, however, held that, when viewed as a whole, and in context, the instructions adequately focused the jury's attention on the main issue of respondent's accountability with regard to the conditions forming the basis of the charge against him. The majority concluded that the instructions

> fairly advised the jury that to find guilt it must find the respondent "had a responsible relation to the situation," [food held in insanitary conditions in a warehouse] and "by virtue of his position . . . had authority and responsibility" to deal with the situation.[48]

The Supreme Court also disagreed with the court of appeals in regard to the admission of testimony concerning a prior FDA letter warning respondent of insanitary conditions at Acme's Philadelphia warehouse. The higher court recognized that although, in the words of *Dotterweich*, "the ultimate judgment of juries must be trusted,"[49] juries may require more than "corporate bylaws" in determining one's guilt. Acting upon this realization, the majority reviewed the testimony given by respondent to the effect that in such a large operation as Acme he had no choice but to rely on subordinates whom he considered to be "dependable" and in whom he had "great confidence." Such testimony, the majority felt, created a definite need for rebuttal evidence. The "relevance and persuasiveness"[50] of the testimony concerning a prior FDA warning, "outweighed any prejudicial effect."[51] The majority concluded that the sole purpose of the testimony was to show that prior to the alleged violations respondent was aware that his system of controlling sanitary conditions at Acme's warehouses, for which he was ultimately responsible, was deficient. The trial court's admission of such evidence was therefore deemed an essential and proper part of the prosecutor's case.

On the basis of these points then, the Court reversed the court of appeals and upheld the jury verdict. This decision, however, was not unanimous on all points. In writing the dissenting opinion, Justice Stewart[52] disagreed with neither the majority's view of *Dotterweich* that "any person" specified in 21 U.S.C. § 333 included any corporate officer or employee "standing in responsible relation" to those conditions forbidden by the Act, nor the conclusion that the traditional element of "awareness of some wrongdoing" was not a requirement for criminal liability under the Act. However, he did depart from the majority's view as to the sufficiency

[42] *See* note 8 *supra*.

[43] *Id.*

[44] 499 F.2d at 841-42.

[45] 421 U.S. at 674.

[46] *Id.*

[47] *Id.* at 674, *quoting* the majority in Cupp v. Naughten, 414 U.S. 141, 146-47 (1973).

[48] 421 U.S. at 674.

[49] *Id.* at 669–70 *quoting* the majority in *Dotterweich*, 320 U.S. at 285.

[50] 421 U.S. at 678. In support of this point the majority depends on the analogy to the rule whereby the prosecution is forbidden to introduce evidence of the bad character of the defendant until the defendant has himself given evidence of his good character. *Cf., e.g.*, United States v. Ross, 321 F.2d 61, 69 (2d Cir. 1963); 2 J. WIGMORE, EVIDENCE § 302 (3d ed. 1940).

[51] 421 U.S. at 678.

[52] Justice Stewart was joined by Justices Marshall and Powell.

of the jury charge. Justice Stewart stated that as they were expressed, the instructions "were a virtual nullity, a mere authorization to convict if the jury thought it appropriate."[53] He insisted that, while a finding of guilt under the Act did not turn on the defendant's "awareness of some wrongdoing," it did require that the jury be instructed that the Government must prove beyond a reasonable doubt that respondent "enagaged in wrongful conduct amounting at least to common-law negligence."[54]

The dissent thus agreed with the court of appeals that an instruction as to "wrongful action" must be contained in the jury charge. The dissent objected to the trial judge's instruction which predicated guilt upon a finding of "responsibility" and which cautioned the jury that "the fact the Defendant is present [*sic*] and is a chief executive officer of the Acme Markets does not require a finding of guilt."[55] It was felt that such instructions left the jury with no proper guidance as to the definition of "responsibility," and in effect allowed them to acquit or convict on the basis of "its rough notions of social justice."[56] For this reason, the three dissenters refused to affirm Park's criminal conviction.

The majority in *Park* concedes to the minority that the concept of a "responsible share" in the violation of the Act indicates some degree of "blameworthiness." However, it correctly reasons that this "blameworthiness" is not the equivalent of the "wrongful action" thought to be required by the court of appeals, but is instead the "failure . . . to fulfill the duty imposed by the interaction of the corporate agent's authority and the statute . . . ."[57] It thus becomes the task of the jury to determine from the evidence whether the individual has such a duty, and if so, whether his failure to exercise that duty constitutes a "responsible share" in the violation of the Act. In regard to the principal issue, the majority concludes that the judge's instructions did not allow the jury to convict solely on the basis of respondent's position in the corporation. The trial judge had instructed the jury that "the fact that the Defendant is pres[id]ent and is a chief executive officer of Acme Markets does not require a finding of guilt."[58] By his instructions he adequately focused the jury's attention on the issue of respondent's authority with respect to the charges against him. In rendering its decision about the propriety of the instructions, the Supreme Court majority viewed them in the context of the entire trial and deemed them quite appropriate.[59]

The Court also gave its approval to the prosecution's summary to the jury which pointed out respondent's testimony that he was responsible for the system set up to monitor sanitation, and respondent's knowledge prior to the 1971 and 1972 inspections that his system did not work. The majority justifiably concludes that the jury had to be aware that their inquiry and determination should focus on the respondent's accountability with respect to the charges against him, and not on his position in the corporation. Finally, the majority's determination that the jury charge was a correct statement of the law enabled it to conclude that any request for amplification must rest in the discretion of the trial judge.[60] In this instance then, the denial of respondent's request for amplification was not an abuse of discretion.

Generally, *United States v. Park* represents a clear affirmation by the Court of a stricter standard of responsibility on the part of corporate officers and agents. While the decision in *Dotterweich* was suggestive of a stricter standard for those who had a "responsible relation" to the situation, it nevertheless left unanswered the question of who had such a responsible relation. The *Park* decision, on the other hand, makes clear by its facts that any corporate officer or agent who has the responsibility and authority to deal with matters within the coverage of the statute, must make an affirmative effort to seek out and remedy possible violations. Moreover, he must insure that effective measures are

[53] 421 U.S. at 682 (Stewart, J., dissenting).

[54] *Id.* at 683 (Stewart, J., dissenting).

[55] *Id.* at 679 (Stewart, J., dissenting), *quoting* from the trial judge's instructions. *See* note 8 *supra.*

[56] *Id.* at 682 (Stewart, J., dissenting).

[57] *Id.* at 674.

[58] *See* note 8 *supra.*

[59] Support for the Supreme Court majority's view on this point can be found in United States v. Birnbaum 373 F.2d 250 (2d Cir), *cert. denied,* 389 U.S. 837 (1967). The court in *Birnbaum* recognized the rule that:

> In evaluating the instruction to the jury, not only ıst must each statement made by the judge be examined ht in light of the entire charge, but the charge itself can be only be viewed as part of the total trial. Often isolated ts statements taken from the charge, seemingly pre- ir judicial on their face, are not so when considered in ıe the context of the entire record of the trial.

373 F.2d at 257.

[60] Support for the Supreme Court majority's conclusion on this point can be found in United States v. Bayer, 331 U.S. 532 (1947). On this point of amplification of the jury charge by the trial judge the Court in *Bayer* states the practice that is followed:

> Once the judge has made an accurate and correct charge, the extent of its amplification must rest largely in his discretion.

Id. at 536.

implemented so that violations will not occur. Anything less invites prosecution.

Specifically, the decision accomplishes two things: (1) clarification of *Dotterweich,* and (2) pronouncement of the respective roles of court and jury in determining respondent's responsibility. On the first point, *Park* demonstrates that a corporate agent may be held criminally liable under the Act for failing to exercise the authority and responsibility imposed on him by the corporation in relation to compliance with the provisions of the Act. It is not necessary for him to be the immediate cause of the criminal acts, nor is it necessary that he have any direct contact or participation in the acts. Thus proof of "wrongful action" is not an element of the Act. Second, *Park* emphasizes that the question of "responsibility" is to be decided by the jury under the proper guidance of the trial judge, and that adequate guidance in such cases would be an instruction advising the jury that "to find guilt it must find respondent 'had a responsible relation to the situation,' and 'by virtue of his position . . . had authority and responsibility' to deal with the situation."[61]

Park has clearly brought the corporate agent's accountability under the Act closer to the standard of strict liability. If, by this decision, the Court hopes someday to place the accountability of corporate agents within the strict liability standard, it will first have to deal with the problem raised by the dissenting opinion. This problem is that a strict liability standard would allow a defendant to be convicted solely on the basis of his position in the corporation and therefore suffer a criminal penalty and possible jail sentence. Since, however, the practical effect of *Park* is very close to that of a strict liability standard the Court will probably be content to leave the matter as *Park* establishes it. It is unlikely, therefore, that the Court will choose to encounter the problem presented by the imposition of a strict liability standard where criminal sanctions are involved. However, within the context of the *Park* decision there are more immediate ramifications. Because of the strict standard of accountability imposed by *Park,* there is the possibility that the more qualified individual will hesitate before taking such a responsible position within a corporation for fear of criminal prosecution. If so, then the incentives offered to such individuals by companies may have to substantially increase to offset such fears. Moreover, in applying the *Park* decision, courts will have to balance the need for competent individuals in corporate positions against the imposition of responsibility on corporate agents under the Federal Food, Drug and Cosmetic Act.

[61] 421 U.S. at 674.