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Criminal Liability of Corporate Officers for Strict Liability Offenses — Another View*

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The Supreme Court has utilized a "responsible share" standard to determine whether corporate officers should be held criminally liable for acts committed by their subordinates in violation of the penal provisions of a corporate regulatory statute. In a recent article Professor Abrams postulated that courts will interpret the responsible share standard to contain an element of culpability. In this article Professor Brickey maintains that the Court's language and analysis support a strict liability interpretation of the responsible share standard. Noting that administrative enforcement practices tend to mitigate the potential harshness of a strict liability standard, Professor Brickey concludes that this standard, rather than the standard proffered by Professor Abrams, advances the goals of public welfare statutes and promotes increased corporate responsibility.

I. INTRODUCTION

The proliferation of statutes regulating corporate conduct and containing criminal penalties[1] has increased the risk of unwitting violations of the penal laws. In consequence, corporate officers, managers, and supervisors face greater exposure to criminal prosecution for acts they commit in their official capacities. Many regulatory statutes, moreover, render corporate officials vulnerable to

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1. *See, e.g.*, Tobacco Statistics Act § 3, 7 U.S.C. § 503 (1976); Dumping or Destruction of Interstate Produce Act § 1, 7 U.S.C. § 491 (1976); National Housing Act of 1933 § 21, 12 U.S.C. § 378 (1976); Securities Act Amendments of 1975 § 27(d), 15 U.S.C. § 77yyy (1976); Foreign Corrupt Practices Act of 1977 §§ 103(a), 103(b), 104, 15 U.S.C. §§ 78dd-1, 78dd-2, 78ff (1976 & Supp. I 1977); Securities Exchange Act of 1934 § 32, 15 U.S.C. § 78ff (1976); Federal Trade Commission Act §§ 10, 14, 15 U.S.C. §§ 50, 54 (1976); Emergency Petroleum Allocation Act of 1973 § 5, 15 U.S.C. § 754 (1976); Toxic Substances Control Act §§ 15-16, 15 U.S.C. §§ 2614-2615 (1976); Wholesome Meat Act § 406, 21 U.S.C. § 676 (1976); Bank Secrecy Act §§ 209-210, 31 U.S.C. §§ 1058-1059 (1976); Oil Pollution Act § 6, 33 U.S.C. § 1005 (1976); Federal Water Pollution Control Act § 309, 33 U.S.C. § 1319 (1976).

prosecution for criminal conduct in which they did not personally participate and about which they had no personal knowledge.[2]

Changing perceptions about the need to affix personal responsibility for conduct that entangles the corporation in criminal violations have accompanied the emergence of such patterns of federal statutory law.[3] When combined with the possible imposition of greater penalties than in the past,[4] this enhancement of a corporate officer's vulnerability to federal criminal prosecution makes essential an understanding of the bases of individual liability for business-related offenses.

The principal theories under which courts have held corporate officers liable for criminal violations occurring within the corporation are three in number.[5] First, one who performs an act consti-

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2. The Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§ 301-92 (1976), has served as the primary vehicle for articulation of this premise and was the basis of the prosecutions in the cases considered in this Article. *See also* Free Trade Zone Act § 19, 19 U.S.C. § 81s (1976) ("In case of a violation of this chapter, or any regulation under this chapter . . . by . . . any officer, agent, or employee . . . responsible for or permitting any such violation shall be subject to a fine . . . ."); Obstructing Navigable Waters Act § 16, 33 U.S.C. § 411 (1976) ("Every person and every corporation that shall violate [§§ 407, 408, and 409 of the Act] shall be guilty of a misdemeanor . . . ."); Longshoremen's and Harbor Workers' Compensation Act § 38, 33 U.S.C. § 938 (1976) ("Any employer required to secure the payment of compensation under this chapter who fails to secure such compensation shall be guilty of a misdemeanor . . . ."); *infra* note 186 and accompanying text.

3. *See, e.g., Saxbe to Get Tough With Price-Fixers,* [July-Dec.], ANTITRUST & TRADE REG. REP. (BNA) No. 683, at A-5 (Oct. 8, 1974) (summarizing a speech by then Attorney General William B. Saxbe). In his speech, Saxbe expressed the following Justice Department policy:

> [D]uring the past fiscal year, the Department filed 34 criminal cases compared to 33 civil—and criminal defendants totaled 84 persons. The emphasis on criminal antitrust cases will continue—particularly on price fixing. . . . [W]e will generally seek prison terms—for all who are convicted or who plead guilty or no contest. The time for unequal justice is long since past.

Id.

See also Hearings on Kepone Contamination in Hopewell, Va., Before the Subcomm. on Agricultural Research and General Legislation of the Senate Comm. on Agriculture and Forestry, 94th Cong., 2d Sess. 30 (1976) (statement of Senator Patrick J. Leahy) ("I hope the U.S. Attorney, if he does decide to bring indictments, also brings indictments against individuals, instead of corporate entities. . . . Maybe then the kind of responsibility that everyone talks about having will actually come about.").

4. *See, e.g.,* Antitrust Procedures and Penalties Act of 1974 § 3, 15 U.S.C. §§ 1, 2, 3 (1976) (reclassifying violations of § 1 of the Sherman Act from misdemeanor to felony, increasing maximum fines for individual violators from $50,000 to $100,000, increasing maximum term of imprisonment from one year to three years, and also creating corporate fines of up to $1,000,000).

5. Conspiracy doctrine provides a fourth theory under which a corporate officer may be held accountable for crimes committed in furtherance of corporate activities. While the importance of conspiracy doctrine in corporate criminal prosecutions is difficult to assess, see Duke, *Conspiracy, Complicity, Corporations, and Federal Code Reform,* FORDHAM COR-

tuting a criminal offense is personally accountable for the crime even though the act complained of was an official act performed during the course of the actor's employment.[6] Courts historically

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PORATE LAW INSTITUTE, CRIMINAL LAW AND THE CORPORATE COUNSEL 56, 57 (1979), conspiracy is among the most frequently charged federal crimes. *See* Marcus, *Conspiracy: The Criminal Agreement in Theory and in Practice*, 65 GEO. L.J. 925, 947 (1977); Selz, *Conspiracy Law in Theory and in Practice: Federal Conspiracy Prosecutions in Chicago*, 5 AM. J. CRIM. L. 35, 48-50 (1977). Conspiracy doctrine is important, however, not only because it is invoked so commonly by federal prosecutors, but also because it provides a basis for imposing vicarious liability for crimes committed in furtherance of the object of the conspiracy.

In addition to their liability for the conspiracy offense, parties to a conspiracy may be liable under the *Pinkerton* rule for substantive offenses that they did not personally commit. The rule was first enunciated in Pinkerton v. United States, 328 U.S. 640 (1946). Noting the well-settled principle that the overt acts of one conspirator may constitute the acts of all parties to the conspiracy, the Court found that "[t]he governing principle is the same when the substantive offense is committed by one of the conspirators in furtherance of the unlawful project." *Id.* at 647. When parties join together in a conspiracy, they each contemplate conduct that furthers the conspiracy or achieves its unlawfnl object, and they all possess the requisite intent to complete the crime. Finding the case at hand analogous to those involving the liability of an aider and abettor, the Court found the theories underlying both to be premised on the same principle and concluded that if an overt act "can be supplied by the act of one conspirator, we fail to see why the same or other acts in furtherance of the conspiracy are likewise not attributable to the others for the purpose of holding them responsible for the substantive offense." *Id.* Thus, participation in a conspiracy may result in imposition of liability for a crime consummated by another on the basis of a theory that is wholly independent of established principles of accomplice liability. *Cf.* United States v. Cowart, 595 F.2d 1023 (5th Cir. 1979) (conspiracy is an offense separate and distinct from aiding and abetting); *infra* notes 9-10 and accompanying text.

The Court in *Pinkerton* limited this species of liability, however, by acknowledging that the case would have heen different if one of three possibilities had materialized: (1) the substantive offense had happened to be committed by one of the conspirators but was not committed in furtherance of the conspiracy; (2) the offense, even though committed to further the conspiratorial objectives, had not been within the scope of the unlawful project; or (3) the offense had been "merely a part of the ramifications of the plan which could not be reasonably foreseen as a necessary or natural consequence of the unlawful agreement." 328 U.S. at 647-48.

6. United States v. North Am. Van Lines, Inc., 202 F. Supp. 639, 644 (D.D.C. 1962); *see, e.g.*, United States v. Amrep Corp., 560 F.2d 539 (2d Cir.), *cert. denied*, 434 U.S. 1015 (1977) (affirming convictions of corporation and officers for mail and interstate land sale fraud); United States v. Sherpix, Inc., 512 F.2d 1361 (D.C. Cir. 1975); United States v. American Radiator & Standard Sanitary Corp., 433 F.2d 174 (3d Cir. 1970), *cert. denied*, 401 U.S. 948 (1971) (upholding price-fixing convictions of corporate president, vice president, board member, and sales manager); United States v. Andreadis, 366 F.2d 423 (2d Cir. 1966), *cert. denied*, 385 U.S. 1001 (1967) (affirming convictions of corporation and its president for mail and wire fraud, misbranding drug, and conspiracy); United States v. Carter, 311 F.2d 934 (6th Cir.), *cert. denied*, 373 U.S. 915 (1963) (upholding conviction of corporate president and chief executive officer for making unlawful payments to union representatives); Farrell v. United States, 321 F.2d 409 (9th Cir. 1963), *cert. denied*, 375 U.S. 992 (1964) (upholding conviction of vice president and director for mail fraud, securities fraud, and conspiracy); United States v. Empire Packing Co., 174 F.2d 16 (7th Cir.), *cert. denied*, 337 U.S. 959 (1949) (upholding conviction of president and owner of company for filing false claims for government subsidies); Nye & Nissen v. United States, 168 F.2d 846 (9th Cir.

have recognized that proposition despite the corporate agent's claim that he was acting for the corporation in an official or representative capacity.[7] A corporate agent may not use the corporate entity as a shield against personal liability for his own misdeeds.[8]

1948), *aff'd*, 336 U.S. 613 (1949) (affirming convictions of corporation and its president for conspiracy to defraud the United States); United States v. Hare, 153 F.2d 816 (7th Cir.), *cert. denied*, 328 U.S. 836 (1946) (upholding convictions of president, treasurer, and secretary for violation of Emergency Price Control Act); United States v. Bach, 151 F.2d 177 (7th Cir. 1945) (upholding conviction of salesman for violation of Emergency Price Control Act); C.I.T. Corp. v. United States, 150 F.2d 85 (9th Cir. 1945) (upholding conviction of sales manager for conspiracy to make false statements); Gates v. United States, 122 F.2d 571 (10th Cir.), *cert. denied*, 314 U.S. 698 (1941) (upholding convictions of owner and officer for mail fraud, securities fraud, and conspiracy); Mininsohn v. United States, 101 F.2d 477 (3d Cir. 1939) (upholding convictions of corporation and its officers for conspiracy to defraud the government); United States v. Colosse Cheese and Butter Co., 133 F. Supp. 953 (N.D.N.Y. 1955) (denying motion to dismiss prosecution of manager for violation of Food, Drug, and Cosmetic Act). *See generally* 3A W. FLETCHER, CYCLOPEDIA OF THE LAW OF PRIVATE CORPORATIONS §§ 1348-49 (perm. ed. 1975).

7. *See, e.g.*, Elsberry v. State, 52 Ala. 8, 10 (1875) (upholding conviction of defendant stockholder and superintendent for conducting corporate business without required license: "it is the natural persons in and by whom it [the corporation] lives, moves, and operates that the law generally holds responsible for its offences against the public"); State v. Great Works Milling & Mfg. Co., 20 Me. 41, 44 (1841) (holding indictment of corporation improper: "when a crime or misdemeanor is committed under color of corporate authority, the individuals acting in the business . . . should be indicted"); Moore v. State, 48 Miss. 147 (1873), *writ dismissed*, 88 U.S. 636 (1875) (indictment of corporation's agent for selling lottery ticket); Cowley v. People, 83 N.Y. 464 (1881) (upholding conviction of agent of incorporated benevolent association for endangering the welfare of a child); State v. Patton, 26 N.C. 16 (1843) (indictment of president and directors of turnpike company for letting turnpike become ruinous: "the individuals . . . were bound, by virtue of their offices, faithfully to exert all their powers and apply all their means, as such officers, to the keeping of the road in order; and . . . for a default in this public duty they were liable"); The Queen v. Stephens, 1 L.R.-Q.B. 702 (1866) (upholding conviction of quarry owner whose employees discharged waste into river without his knowledge); *cf.* State v. Morris & E. R.R. Co., 23 N.J.L. 360 (1852) (holding potential liability of agent no bar to prosecution of corporation); *Ex parte* Schmidt, 2 Tex. App. 196 (1877) (local agent of company that conducted marine and fire insurance business liable for delinquent tax); The Queen v. Great North of England Ry. Co., 115 Eng. Rep. 1294 (Q.B. 1846) (holding corporation indictable though responsible individuals may also be liable). Corporate officers were indicted for Sherman Act violations in 40 cases between 1890 and 1914 alone. United States v. Wise, 370 U.S. 405, 407 n.1 (1962).

For the historical context within which this principle developed, see generally Brickey, *Corporate Criminal Accountability: A Brief History and an Observation*, 60 WASH. U.L.Q. 393 (1982).

8. State v. Cooley, 141 Tenn. 33, 206 S.W. 182 (1918); Milbrath v. State, 138 Wis. 354, 361, 120 N.W. 252, 254-55 (1909). *See also* Kopald-Quinn & Co. v. United States, 101 F.2d 628, 632 (5th Cir.), *cert. denied*, 307 U.S. 628 (1939) (upholding conviction of corporation and certain agents for fraudulent sale of worthless stock); Wood v. United States, 204 F. 55 (4th Cir.), *cert. denied*, 229 U.S. 617 (1913) (affirming conviction of president and sole stockholder of incorporated distillery despite forfeiture of distillery to government); State v. McBride, 215 Minn. 123, 130, 9 N.W.2d 416, 420 (1943) (conviction of company president for illegal sale of liquor by employee).

Second, corporate employees may be accountable, under general principles of accomplice liability, for crimes committed by their cohorts and subordinates.[9] Anyone who aids, counsels, commands, encourages, or otherwise assists another to engage in conduct constituting an offense is liable for the crime in the same manner as the actual perpetrator.[10]

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9. For an historical perspective on accomplice liability, see Brickey, *supra* note 7, at 415-21.

10. One who aids and abets a crime is one who assists in its perpetration. Accomplice liability therefore requires a showing of some affirmative participation that at least constitutes encouragement of the perpetrator. *See, e.g.*, Dukich v. United States, 296 F. 691 (9th Cir. 1924) (proprietor present at time of unlawful sale of alcoholic beverages and nodded to bartender).

The character of the participation, however, need not qualify as perpetration of an element of the substantive offense. Instructing another to commit an offense is a sufficient basis for imposing liability, *see, e.g.*, United States v. Berger, 456 F.2d 1349 (2d Cir.), *cert. denied*, 409 U.S. 892 (1972) (upholding conviction of president and chief executive officer of corporation who instructed bookkeeper to remove invoices of foreign subsidiary—which enjoyed favorable tax position—to enable corporation to pay same thereby reducing its income and increasing that of subsidiary, for willful evasion of corporate income tax); Meredith v. United States, 238 F.2d 535 (4th Cir. 1956) (upholding conviction of bank employee who instructed subordinates to make false entries in bank records), as is authorizing another to commit the offense, *see, e.g.*, United States v. Precision Medical Laboratories, Inc., 593 F.2d 434 (2d Cir. 1978) (owner knowingly authorized employees to sign false medicaid and medicare claims); Kinnebrew v. State, 80 Ga. 232, 5 S.E. 56 (1887) (general authority from employer to his clerk to make unlawful sales of alcoholic beverages sufficient to impose liability on employer for any single sale). Procuring neglect of an affirmative duty also may provide a basis for imposing liability. *See, e.g.*, United States v. Van Schaick, 134 F. 592 (C.C.S.D.N.Y. 1904) (corporate officers and fleet commodore procuring corporation and master to provide bad life preservers when good ones were required).

Mere presence at the scene of the crime, association with the perpetrator, and knowledge of illegal activity, on the other hand, are insufficient standing alone, as would be mere approval or acquiescence without expressed concurrence or other contribution to the offense. *See, e.g.*, United States v. Thomas, 469 F.2d 145 (8th Cir. 1972), *cert. denied*, 410 U.S. 957 (1973); United States v. Joiner, 429 F.2d 489 (5th Cir. 1970). *But cf.* United States v. Andreadis, 366 F.2d 423 (2d Cir. 1966), *cert. denied*, 385 U.S. 1001 (1967) (upholding conviction of corporate president who reviewed and approved advertising campaign that included false claims though he did not specifically authorize the making of false claims). To be liable for aiding and abetting one must associate himself with the venture, participate in it as something he wishes to bring about, and through his action seek to make it succeed. Nye & Nissen v. United States, 336 U.S. 613, 619 (1949); United States v. Pellegrino, 470 F.2d 1205, 1209 (2d Cir. 1972), *cert. denied*, 411 U.S. 918 (1973); United States v. Peoni, 100 F.2d 401, 402 (2d Cir. 1938). The aider and abettor must share the principal's criminal purpose, even though he need not know every detail of the substantive offense. It is unnecessary for the aider and abettor to have knowledge of the illegality of the conduct, but he must know that the forbidden activity is occurring and must intend to assist the perpetrator. *See, e.g.*, United States v. Amrep Corp., 560 F.2d 539 (2d Cir. 1977); United States v. Schilleci, 545 F.2d 519 (5th Cir. 1977), *cert. denied*, 434 U.S. 1015 (1978); United States v. McDaniel, 545 F.2d 642 (9th Cir. 1976).

Exceptional cases exist, however, in which passive acquiescence or uncommunicated assent to an unlawful course of conduct may warrant a finding of encouragement of the con-

Last, criminal responsibility may derive from failure to control corporate misconduct. One who has control over activities that lead to a subordinate's violation of a statute may incur liability for failure to fulfill the duty, commensurate with his position of authority in the corporate hierarchy, to prevent or correct such violations.[11]

The questions whether and when a corporate officer will be

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duct by implication. In most of these cases there exists a special relation between the direct actor and the silent approver, such as that of employer and employee, that vests in one the right to control the conduct of the other. *See, e.g.*, Moreland v. State, 164 Ga. 467, 139 S.E. 77 (1927) (owner-occupant of automobile, who failed to prevent chauffeur from driving at excessive rate of speed during a rainstorm, liable for involuntary manslaughter of occupant of vehicle with which owner's collided); *accord*, Story v. United States, 16 F.2d 342 (D.C. Cir. 1926), *cert. denied*, 274 U.S. 739 (1927); *Ex parte* Liotard, 47 Nev. 169, 217 P. 260 (1923).

In a corporate setting an officer, manager, or supervisor might similarly be held criminally responsible for conduct of a subordinate that was known to him and that he did not attempt to halt. The agent's misconduct might consist of making a sale, accepting deposits, or other acts that constitute elements of his daily routine. *See, e.g.*, Morgan v. United States, 149 F.2d 185 (5th Cir.), *cert. denied*, 326 U.S. 731 (1945) (selling ice at prices exceeding the maximum allowed under Emergency Price Control Act of 1942); Carr v. State, 104 Ala. 4, 16 So. 150 (1894) (manager who knew bank was insolvent guilty even though he was not present and did not authorize receipt of particular deposits, and though teller had no guilty knowledge); Kinnebrew v. State, 80 Ga. 232, 5 S.E. 56 (1887) (unlawful sale of alcoholic beverages); State v. Cramer, 20 Idaho 639, 119 P. 30 (1911) (vice president and general manager of bank, knowing bank to be insolvent, permitted or consented to cashier continuing to receive deposits); Commonwealth v. Nichols, 51 Mass. 259 (1845) (unlawful sale of alcoholic beverages); State v. Mueller, 38 Minn. 497, 38 N.W. 691 (1888) (unlawful sale of alcoholic beverages); State v. Wiggin, 20 N.H. 449 (1846) (unlawful sale of alcoholic beverages). Assent to specific wrongful acts may be inferred from conferment of general authority to engage in that type of conduct. *See, e.g.*, Kinnebrew v. State, 80 Ga. 232, 5 S.E. 56 (1887) (general authority from employer to his clerk to make unlawful sales of alcoholic beverages sufficient to impose liability on employer for any single sale). Presence during the commission of the acts unaccompanied by any expression of objection to them may also support a finding of assent to specific wrongful acts, *see, e.g.*, State v. Mueller, 38 Minn. 497, 38 N.W. 691 (1888) (proprietor on premises and generally supervising some activity when alcoholic beverages sold to minors), as may knowingly permitting continuation of the wrongful act, *see, e.g.*, Carr v. State, 104 Ala. 4, 16 So. 150 (1894) (permitting subordinate to continue accepting deposits in insolvent bank); State v. Cramer, 20 Idaho 639, 119 P. 30 (1911) (permitting subordinate to continue accepting deposits in insolvent bank); State v. Crawford, 151 Mo. App. 402, 132 S.W. 43 (1910) (proof of druggist's knowledge that employee permitted drinking on premises sufficient in absence of evidence it was without consent).

Glanville Williams has also suggested that one may incur criminal liability for procuring a crime by implication, as when an employer requires a driver to meet a time schedule that can only be kept if the driver exceeds the lawful speed limit. G. WILLIAMS, CRIMINAL LAW: THE GENERAL PART § 123, at 363 (2d ed. 1961); *see, e.g.*, Newman v. Overington, Harris and Ash, Ltd., 93 J.P. 46 (K.B. 1928) (owners of motor coach, which was restricted by law to maximum speed of 12 m.p.h., who advertised departure and arrival times necessitating average speed of 18 m.p.h. without allowing for stops or posted limits, liable as aiders and abettors to driver's operation of coach at 35 m.p.h.).

11. This category of liability is the subject of this Article.

personally responsible if a subordinate violates a penal statute gained importance with the rise of the public welfare offense. Statutes defining such offenses typically require neither intent nor guilty knowledge; instead they simply penalize proscribed conduct or results without regard to mens rea.[12] Strict liability is imposed because the conduct constituting the violation exposes the public to an unacceptable risk of injury that is unaffected by the intent of the violator.[13]

The Food, Drug, and Cosmetic Act[14] fits the public welfare offense pattern, and prosecutions thereunder have served as the principal vehicles for exploring the potential liability of a corporate officer for violations in which he played no direct role. Prosecutions under the Act are particularly appealing vehicles for analysis because the Supreme Court in *United States v. Dotterweich*[15] and *United States v. Park*[16] upheld convictions of corporate officers who did not personally participate in the conduct constituting the violation. In neither case, however, did the Court clearly articulate a bright line standard of liability under the Act. Despite the absence of an express statutory mens rea requirement, the Court declined to state expressly that liability under the Act is strict liability. But the Court also failed to specify that it was adopting a standard requiring a culpable mental state. Instead, the Court in both instances utilized a "responsible share" standard to determine whether the corporate officer stood in such a relation to the

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12. This pattern of liability has its historical antecedents. *See, e.g.*, State v. Burnam, 71 Wash. 199, 202, 128 P. 218, 219 (1912) (vicarious liability should be extended to managing agents "when the offense consists in the violation of a police regulation when neither a guilty knowledge nor a criminal intent is made an element of the offense") (conviction reversed on other grounds); *see also* Brickey, *supra* note 7, at 418-21; *cf.* People v. Detroit White Lead Works, 82 Mich. 471, 479, 46 N.W. 735, 737 (1890) (upholding nuisance convictions of president, vice president, treasurer and manager who, as officers and directors of the corporation, "are the persons primarily responsible").

13. Morissette v. United States, 342 U.S. 246, 256 (1952). Individuals who may be prosecuted under statutes defining public welfare offenses usually are capable of preventing a violation by exercising the degree of diligence that those who seek positions of responsibility may reasonably be expected to exercise. *Id.*; *see* Commonwealth v. Koczwara, 397 Pa. 575, 155 A.2d 825 (1959).

Although strict liability is imposed because of the risk to the public and not because the offense is *malum prohibitum*, Morrisette v. United States, 342 U.S. 246, 259-60 (1952), some courts have stressed the distinction between *malum in se* and *malum prohibitum* offenses as partial justification for imposing strict liability. *See, e.g.*, United States v. United States Steel Corp., 328 F. Supp. 354, 356 (N.D. Ind. 1970), *aff'd*, 482 F.2d 439 (7th Cir.), *cert. denied*, 414 U.S. 909 (1973) (construing the Refuse Act of 1899).

14. 21 U.S.C. §§ 301-92 (1976).

15. 320 U.S. 277 (1943).

16. 421 U.S. 658 (1975).

offending transaction that he could be held criminally accountable under the Act.[17]

Professor Norman Abrams in a recent article on *Dotterweich* and *Park*[18] has suggested that the language the Court used in the opinions is sufficiently ambiguous that it is susceptible of at least two disparate interpretations. The first is what he characterizes as a "corporate responsibility view,"[19] under which one may read the opinions as adopting a rather rigid standard that holds a corporate officer strictly liable for violations occurring in connection with a transaction over which he had at least a minimal measure of control.[20] The second interpretation that Abrams finds plausible is what he calls a "negligence view" of the cases,[21] under which a more liberal reading of the Court's language would hold a corporate officer liable only when the facts support a finding of "a departure from a standard of care."[22]

His brief analysis of two subsequent Ninth Circuit decisions upholding convictions of corporate officers[23] leads Abrams to conclude that while the language of the two opinions suggests that the court applied a standard of care test of liability[24] and thereby rejected "the idea" of a strict liability standard,[25] the results in the two cases are more consistent with a corporate responsibility stan-

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17. *Park*, 421 U.S. at 673-75; *Dotterweich*, 320 U.S. at 284.

18. Abrams, *Criminal Liability of Corporate Officers for Strict Liability Offenses—A Comment on* Dotterweich *and* Park, 28 U.C.L.A. L. REV. 463 (1981).

19. *Id.* at 469.

20. *Id.* at 475.

21. *Id.* at 469.

22. *Id.* While recognizing that *Dotterweich* and *Park* articulate a standard of individual liability for corporate officers and employees, Abrams briefly considers the application of the responsible share standard to the corporation under both a corporate responsibility view and a standard of care view of the cases. *Id.* at 472-73. This brief digression from his thesis is prompted by two judicial decisions that cite *Dotterweich* and *Park* even though corporate defendants were involved. *See* United States v. FMC Corp., 572 F.2d 902, 906 (2d Cir. 1978) (citing *Dotterweich* and *Park* as authority for proposition that omission to perform a duty, in addition to performing an affirmative act, may be basis of corporation's liability under Migratory Bird Treaty Act); United States v. Morton-Norwich Prods., Inc., 461 F. Supp. 760, 764 (N.D.N.Y. 1978) (citing *Dotterweich* and *Park* as authority for proposition that the Food, Drug, and Cosmetic Act imposes a standard of absolute liability). Inasmuch as neither case purports to apply the responsible share standard to a corporate defendant, this Article omits any discussion of that portion of Professor Abrams' article and considers exclusively the standard of liability imposed upon corporate officers and employees.

23. United States v. Y. Hata & Co., 535 F.2d 508 (9th Cir. 1976); United States v. Starr, 535 F.2d 512 (9th Cir. 1976).

24. Abrams, *supra* note 18, at 470-72.

25. *Id.* at 476.

dard.[26] One senses that he finds those results profoundly unsatisfactory.[27]

Professor Abrams finds a requirement of culpability more desirable than a strict liability standard,[28] and he postulates that the negligence view of *Dotterweich* and *Park* is more likely to prevail.[29] Suggesting that courts are fundamentally uncomfortable with the notion of strict criminal liability,[30] he maintains that judges have therefore historically engaged in a process of "reinterpreting and modifying a strict liability approach"[31] to avoid unfairness. While faulting the Supreme Court for its inability or unwillingness "to develop a doctrinal modification of strict liability for corporate officers in unambiguous terms that avoids introducing confusion and uncertainty into the law,"[32] he finds that the Court's decisions under the Food, Drug, and Cosmetic Act have at least the merit of laying a foundation that enables courts to avoid applying a strict liability standard without expressly stating a culpability requirement.[33] Abrams suggests that with such a foundation in place, it is but a short step to direct or indirect adoption of a requirement of culpability,[34] and he cites introduction of such devices as the "voluntary act and causation concepts" as examples of indirect methods of arriving at a culpability requirement.[35]

This Article offers an alternative analysis of the doctrine articulated by the Supreme Court in *Dotterweich* and *Park* and its subsequent application by the Ninth Circuit. In the course of so doing, it suggests that Professor Abrams has lost sight of the public welfare offense model that provided the analytical framework within which the cases were decided and that his postulates may thus be faulted as lacking in context. The analysis in this Article demonstrates that the responsible share standard of liability has, from the outset, incorporated the requirement of an act *or omission* to act and that of causation as well, and that these two ele-

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26. *Id.* at 472.

27. *See infra* text accompanying notes 146-48 & 156-57.

28. Abrams, *supra* note 18, at 476-77.

29. *Id.* at 469, 475.

30. "We tend to resist the idea of strict criminal liability, and our resistance often takes the form of reinterpreting the applicable doctrine to introduce a limited measure of culpability." *Id.* at 475.

31. *Id.*

32. *Id.*

33. *Id.* at 476.

34. *Id.* at 475.

35. *Id.*

ments of liability, when considered together with administrative enforcement policy, should assuage apprehension regarding the possible unfairness of holding corporate officers strictly liable for violations of the Act. This Article also suggests that the food and drug cases have important implications regarding the system of delegation upon which corporate officers find it essential to rely.

II. *United States v. Dotterweich*

The first significant decision under the Food, Drug, and Cosmetic Act was *United States v. Dotterweich*.[36] In *Dotterweich* a closely divided Supreme Court[37] upheld the conviction of the president and general manager of the Buffalo Pharmacal Company. Both Dotterweich and Buffalo Pharmacal had been indicted for shipping adulterated and misbranded drugs in interstate commerce.[38] The Government neither claimed nor proved that Dotterweich had possessed any knowledge of the facts that constituted the violation, nor did it claim that he had actively participated in the distribution of the offending articles. Instead, Dotterweich's conviction seemed to rest on his position of authority within the corporation.

Writing for a majority of the Court, Justice Frankfurter noted that the Food, Drug, and Cosmetic Act puts a seller of goods at risk to know the properties of the commodity he distributes through the channels of commerce. The Act's regulatory scheme dispenses with "the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interests 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."[39]

The test the Court adopted for ascertaining the existence of personal guilt is whether the individual officer or agent "shares responsibility in the business process"[40] that results in introduction of adulterated drugs in commerce. "The offense is committed . . .

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36. 320 U.S. 277 (1943).

37. Chief Justice Stone and Justices Black, Douglas, and Jackson joined Justice Frankfurter's majority opinion. Justice Murphy wrote a dissenting opinion in which Justices Roberts, Reed, and Rutledge joined.

38. Dotterweich was convicted, the corporation acquitted. 320 U.S. at 278.

39. *Id.* at 281. The Court rejected the proposition that a nonparticipating officer must use the corporation as his alter ego before he is liable under the Act. *Id.* at 282. If it were otherwise, the corporate fine might simply serve as an institutional cost of conducting business in an illegitimate manner. *But see supra* note 38.

40. 320 U.S. at 284.

by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws . . . ."[41]

While cognizant of the potential hardship that might result from imposing liability on corporate officers absent a statutory requirement of intent or knowledge, the Court concluded that Congress had weighed that hardship against the hazard to the public if the rule were otherwise. As between the two, corporate agents "have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce . . . ."[42] Consumers, on the other hand, are "wholly helpless" to do so.[43]

Although *Dotterweich* made clear that corporate officers may be criminally accountable for violations of a penal statute containing no express requirement of a culpable mental state provided that they share responsibility in the business process that results in the offense, the opinion of the Court left doubt about the contours of this doctrine.[44]

The opinion in *Dotterweich* did not resolve, for instance, the importance of the officer's personal role in the operation of the company. Defendant Dotterweich was president and manager of a relatively small company, and he exercised supervision over its day to day operations.[45] Would he have had a responsible share in the offending transaction if he had not personally supervised any of the operations, or if he had presided over a large conglomerate? The question of the degree of involvement required to hold an officer personally accountable for a criminal violation remained unanswered. The opinion also neglected to address the related issue of what class or classes of employees might have had a responsible share in the unlawful transaction. The opinion left us to wonder whether all supervisory personnel would fit within the class of liable agents and, indeed, whether low level employees who innocently implemented Dotterweich's instructions to fill a drug order would have shared responsibility in the business process resulting in the violation.

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41. *Id.*

42. *Id.* at 285.

43. *Id.*

44. *See generally* O'Keefe & Shapiro, *Personal Criminal Liability Under the Federal Food, Drug, and Cosmetic Act—The Dotterweich Doctrine*, 30 FOOD DRUG COSM. L.J. 5 (1975).

45. Brief for the Respondent at 10, 11, United States v. Dotterweich, 320 U.S. 277 (1943) [hereinafter cited as Brief for the Respondent].

Surely Frankfurter entertained some of these questions in his own mind, for in the last paragraph of his opinion he pointedly declined to address them.

> It would be too treacherous to define or even to indicate by way of illustration the class of employees which stands in such a responsible relation. To attempt a formula embracing the variety of conduct whereby persons may responsibly contribute in furthering a transaction forbidden by an Act of Congress . . . would be mischievous futility. In such matters the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries must be trusted.[46]

Although Professor Abrams finds that Justice Frankfurter's opinion reasonably may be interpreted either to impose strict liability or to adopt a poorly articulated standard of culpability, he asserts that the most commonly accepted view of *Dotterweich* is that the Court "established *strict, vicarious liability* for corporate executives."[47] While that may be the prevailing view, its formulation should not be accepted uncritically. Assuming for the moment that the Court did indeed adopt a strict liability standard, Justice Frankfurter's opinion failed to resolve the question whether liability was vicarious or personal. The point is of some doctrinal significance,[48] and the opinion of the Court may be faulted for neglecting to remark upon it.[49]

The Court's opinion left in doubt whether Dotterweich was liable because culpable acts of the underling who actually shipped the drugs were imputable to him, or whether he was liable because his own inaction to prevent the violation constituted a punishable omission to perform a positive duty imposed by law. Though technical, the question is far from academic.

The Buffalo Pharmacal Company was a drug jobber. The company filled mail orders with drugs that it had purchased from wholesalers and then repackaged and relabeled under the Buffalo

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46. *Dotterweich*, 320 U.S. at 285.

47. Abrams, *supra* note 18, at 464 (emphasis added).

48. Apart from the doctrinal significance discussed in the text, whether vicarious liability is necessarily strict is a point on which there may be some disagreement. *Compare* W. LAFAVE & A. SCOTT, HANDBOOK ON CRIMINAL LAW § 32 (1972) *with* Miller, *A Primer of Absolute Liability*, 1957 WASH. U.L.Q. 99.

49. Justice Murphy's dissent in *Dotterweich* contended that the majority had treated this as a case of vicarious liability. He viewed as unjust the imputation of criminal guilt to an individual for "an act in which the accused did not participate and of which he had no personal knowledge" absent a clear congressional directive. *Dotterweich*, 320 U.S. at 286. To hold Dotterweich accountable to the corporation and its stockholders "for negligence and mismanagement" would be more appropriate than to hold him responsible for a criminal violation of the Act. *Id.*

Pharmacal name.[50] If the theoretical basis of Dotterweich's liability was that of vicarious liability, then the focal point of the inquiry should be the agents whose conduct actually resulted in the introduction of adulterated and mislabeled drugs into commerce. It would be necessary to find that the employees who packaged, labeled, and shipped the drugs either personally committed a criminal violation of the statute or caused the corporation to do so. If they did neither, then there would be no crime to impute to Dotterweich. This theory of liability might plausibly follow from Frankfurter's opinion, which explicitly recognized that introduction of adulterated drugs "must be accomplished, and may be furthered by persons standing in various relations to the incorporeal proprietor"[51] without regard for intent or gnilty knowledge.

It is equally plausible that the Court predicated Dotterweich's liability on his own omission to perform some affirmative duty imposed by law and that his liability for the violation was therefore personal. If that were the case, the focus of the inquiry necessarily would change. Since Dotterweich's liability under this theory would rest on his own inaction, the employees who engaged in the conduct constituting the violation might or might not be criminally responsible for their participation in the transaction, depending on whether the Act also imposed a corresponding duty on them. The inquiry relevant to Dotterweich's liability would consist of ascertaining the precise nature and exact scope of the legal duty imposed, including a determination of whether the duty to prevent the violation was absolute or qualified.

Professor Abrams obliquely approaches the latter point by explaining that under a common view the strict liability doctrine is made more palatable by an underlying assumption that "some minimally culpable action or inaction"[52] at least amounting to negligence is present whenever a violation occurs.[53] Under this explanation, he maintains, the doctrine of strict liability is not as much concerned with abrogation of a culpability requirement as it is concerned with relieving the prosecution of the burden of producing affirmative proof of culpability.[54] "If one accepts this perception of

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

51. *Dotterweich*, 320 U.S. at 283.

52. Abrams, *supra* note 18, at 465.

53. *Id.* at 465-66.

54. "Under this view, strict liability does not dispense with a culpability approach so much as it frees the prosecutor from having *to prove* culpability in the particular case." *Id.*

strict liability, then the idea of a responsible share requirement seems naturally to follow."[55] Furthermore, Abrams suggests, the concept of responsibility connotes some measure of culpability.[56] While proof that a corporate officer had some control over the troublesome business process would not necessarily prove that he was negligent, the underlying assumption of minimally culpable conduct "makes one more comfortable with the imposition of criminal liability even though negligence has not been proved in the particular case."[57] Thus, even if the responsible share standard was from the outset one of strict liability, one might find reassuring a presumably warranted assumption of some unspecified variety of culpability.

Alternatively, Professor Abrams finds some grounds for concluding that the *Dotterweich* opinion left room for later explicit imposition of a culpability requirement.[58] While Justice Frankfurter declined to define a standard of culpability,[59] one might read his opinion as merely eliminating conscious fraud and conscious wrongdoing as required culpable mental states, but leaving open the possibility of requiring some other state of mind such as negligence.[60] Indeed, Abrams suggests, language in the Government's brief which the Court might have construed as an argument that

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at 466 (emphasis in original).

55. *Id.*

56. *Id.* at 465.

57. *Id.* at 466.

58. *Id.* at 464, 466. Indeed, Ahrams observes, one might argue that Justice Frankfurter adopted a culpability requirement inasmuch as his opinion incorporated "language and concepts that implied such a requirement." *Id.* at 465. The opinion noted that distribution of adulterated or misbranded drugs may be attributed to the activities of numerous individuals holding different positions and possessing varying degrees of authority within the corporation. Frankfurter wrote that "[t]o speak with technical accuracy, under § 301 a corporation may commit an offense and all persons who aid and abet its commission are equally guilty." *Dotterweich*, 320 U.S. at 284. Citing Johnson v. Youden [1950] 1 K.B. 544, Professor Abrams notes that characterization of corporate employees as aiders and abettors is consistent with a requirement of a culpable mental state. Abrams, *supra* note 18, at 465. *See also* W. LAFAVE & A. SCOTT, *supra* note 48, at 512 (liability without fault inconsistent with accomplice liability); G. WILLIAMS, *supra* note 10, at 395 (liability of secondary parties subject to common-law requirement of mens rea).

59. Abrams, *supra* note 18, at 466.

60. *Id.* The late Herbert Packer's reading of this part of Frankfurter's opinion presents an interesting contrast. After quoting at length from the opinion of the Court, Packer complained that Justice Frankfurter had forwarded a "primitive and rigid view of *mens rea*." H. PACKER, THE LIMITS OF THE CRIMINAL SANCTION 125 (1968). According to Packer, the Court seemed to have said that "'[c]onscious fraud' and 'awareness of some wrongdoing' are impossibly high standards . . . and that leaves only strict liability." *Id.*

Dotterweich was negligent[61] "may have influenced the Court's response" to Dotterweich's claim that he was not a person liable under the Act.[62]

While detailed analysis of the Court's language is essential to the process of making judgments about the policy and content of the standard of liability adopted, an additional dimension is added when that language is considered in the context of the specific violations with which Dotterweich and the corporation were charged.

The first violation consisted of interstate shipment of misbranded cascara compound.[63] Buffalo Pharmacal had purchased the compound from a wholesaler and repackaged and relabeled it under the Buffalo Pharmacal name. The Buffalo Pharmacal labels that the company affixed to the cascara packages specified that the drug supplied was cascara compound prepared according to the Hinkle formula and that it contained, among other ingredients, strychnine sulphate.[64] While the Hinkle formula had at one time

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61. Abrams quotes from the Government's brief a passage in which the Government noted that defendants had produced no evidence that the corporation had tested the potency of the drugs before reselling them and that Dotterweich alone "had the . . . opportunity to provide for such a test and he failed to do it . . . ." Abrams, *supra* note 18, at 466 (quoting Brief for the United States at 20, n.14, United States v. Dotterweich, 320 U.S. 277 (1943)). Abrams unpersuasively asserts that the change in the focus of the argument in this passage from that of identifying Dotterweich as a responsible person possessing control over the troublesome business process to that of Dotterweich's failure to seize the opportunity to test the drugs, "amounted to *explicitly* attributing *negligent* inaction" to him. *Id.* (emphasis added). It would seem, however, that the Government was merely noting that an omission to perform a duty that it was possible to fulfill could support a conviction under the Act. This argument presaged the Court's later injection of the so-called "objective impossibility" defense in United States v. Park, 421 U.S. 658 (1975). *See infra* text accompanying notes 108-66. Abrams seems closer to the mark when he admits that the shift in emphasis in the footnote passage is "slight." Abrams, *supra* note 18, at 466.

62. Abrams, *supra* note 18, at 466-67.

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

64. The legend on the label read as follows:

No. 200
1000 TABLETS
CASCARA
COMPOUND
No. 2
S. C. Pink
(Hinkle)

Cascarin	1/4 gr.
Aloin	1/4 gr.
Podophyllia	1/6 gr.
Ext. Belladonna	1/8 gr.
Strychnine Sulpbate	1/60 gr.
Oleo. Ginger	1/16 gr.

included strychnine sulphate, that ingredient was removed from the National Formulary before the offending shipment occurred.[65] Thus, the label would be false or misleading "in that it would lead the purchaser or the public to believe that the tablets contained only the ingredients designated in the official formula for Hinkle pills"[66] while in fact the compound contained the additional listed, but unauthorized, strychnine ingredient.[67]

The second violation consisted of interstate shipment of digitalis tablets that were less than half the potency represented on the label.[68] Buffalo Pharmacal also had purchased these tablets from another pharmaceutical supplier and repackaged them under the Buffalo Pharmacal label. Although the issue of fact was disputed,[69] the jury found that the dilution in potency occurred sometime prior to the time when Buffalo Pharmacal reshipped the drug.[70] Moreover, the discrepancy in the represented and actual strength of the medication would not have been immediately apparent to anyone at Buffalo Pharmacal,[71] and detection of the problem probably would have required chemical analysis of samples of the shipment.[72]

Arguments on behalf of Dotterweich with respect to the misbranded cascara violation lack strong appeal under either a strict liability or a culpability standard. A uniform standard for the content of a compound bearing the name of an officially approved formula binds drug manufacturers and suppliers alike.[73] Just as a duty is imposed upon the manufacturer to change its formula for any compound when the standard for that drug is changed, a corresponding duty is imposed upon the jobber to discard old labels and print new ones that are technically and factually accurate.

Record at 4-5, United States v. Dotterweich, 320 U.S. 277 (1943) (Information No. 2104C) [hereinafter cited as Record].

65. United States v. Buffalo Pharmacal Co., 131 F.2d 500, 501 & n.1 (2d Cir. 1942), *rev'd sub nom.* United States v. Dotterweich, 320 U.S. 277 (1943).

66. *Buffalo Pharmacal Co.*, 131 F.2d at 501-02.

67. Record, *supra* note 64, at 4-5 (Information No. 2104C), 41 (testimony of Solomon M. Berman).

68. United States v. Buffalo Pharmacal Co., 131 F.2d 500, 502 (2d Cir. 1942), *rev'd sub nom.* United States v. Dotterweich, 320 U.S. 277 (1943).

69. *See* Brief for the Respondent, *supra* note 45, at 21-25.

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

71. *See* Brief for the Respondent, *supra* note 45, at 18-19.

72. *Id.*

73. For an explanation of the respective roles of the National Formulary and the Pharmacopeia at that time, see Record, *supra* note 64, at 71-77.

While the manufacturer and the jobber might have been free to sell a cascara compound containing strychnine sulphate as something other than Hinkle pills,[74] they were required to discontinue selling the drug under that particular designation once the standard was changed.

Dotterweich was active in managing the day to day operations of the company, and only he had real authority to direct and supervise those operations.[75] The responsibility for implementing measures to ensure that labels bearing the Buffalo Pharmacal name did not misrepresent the identity of the compound bearing those labels reposed in Dotterweich. He did not claim that he had even attempted to discharge that duty. Whether his default was the product of a culpable economic decision to use all of the old labels or merely resulted from an unawareness of the change in the National Formulary should make no difference. A claimed lack of intent to defraud or unawareness of a published change in the National Formulary surely would not have exonerated the chief chemist of the drug manufacturer had he continued to produce the old compound as Hinkle pills, and there is no apparent reason why such a claim should affect the liability of the president and general manager of a small drug supplier such as Buffalo Pharmacal. That is especially true in a case such as *Dotterweich* in which there is not a shred of evidence that some corporate mechanism equipped to handle routinely so basic a responsibility as the accurate labeling of its products even existed.

The argument favoring a culpability requirement with respect to the digitalis violation has, at least facially, somewhat greater appeal than it has in the context of the cascara violation. Assume, for example, that Buffalo Pharmacal had ordered digitalis tablets with a potency of three grains, but that, unbeknownst to any of its employees, tablets with a potency of only one and one-half grains were supplied. Since the problem originated at the manufacturer's plant and the discrepancy was not readily ascertainable, one might argue that to hold Dotterweich criminally liable for reselling them as three grain tablets is unfair.

Perhaps the Court anticipated this argument, for in holding that Dotterweich could be held criminally liable for shipping the adulterated and misbranded digitalis even absent proof of con-

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74. *See* Brief for the Respondent, *supra* note 45, at 6.

75. *See* Record, *supra* note 64, at 25-46 (testimony of Irene Steinhauser and John S. Faries).

scious fraud, Justice Frankfurter stated that "[i]t was natural enough to throw this risk on shippers with regard to the identity of their wares."[76] This hardly seems a radical requirement. If a seller of goods who has a direct economic interest in placing his own label upon the goods he sells is not at risk to know the character and properties of that which he labels as his own, pray tell who is?[77] And who should be?

Suppose, however, that Buffalo Pharmacal was not equipped to perform the chemical analysis required to determine whether the digitalis it received from the manufacturer was actually the desired potency. Apart from considerations of the fairness of imposing strict liability under such circumstances, this factual modification raises the question whether the Food, Drug, and Cosmetic Act implicitly requires independent chemical analysis before one may resell a drug without incurring the risk of criminal liability. The answer would seem to be a qualified no.

The answer would be no, because the statute provides that no person shall be subject to criminal penalties under section 333 of the Act "if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person . . . from whom he received in good faith the article, to the effect . . . that such article is not adulterated or misbranded."[78] Thus, if the Buffalo Pharmacal Company had obtained a guaranty from its supplier, the company and its executive would not have borne the risk of liability

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76. *Dotterweich*, 320 U.S. at 281 (quoting United States v. Johnson, 221 U.S. 488, 497-98 (1911)).

77. Compare the legend on the digitalis label:

No. 267
100
TABLETS
DIGITALIS
CT
ONE USP UNIT
Represents
(0.1 gram
equals
1.543 grains)
Powdered Ditigalis
Manufactured from HIGH QUALITY
materials for
BUFFALO
PHARMACAL CO.
Buffalo, N.Y.

Record, *supra* note 64, at 8-9 (Information No. 2190C).

78. Food, Drug, and Cosmetic Act § 303(c), 21 U.S.C. § 333(c) (1976).

for introducing into interstate commerce a drug considered adulterated or misbranded under the Act because the label misrepresented the drug's potency.[79]

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79. The Second Circuit Court of Appeals had reversed Dotterweich's conviction largely on the hasis of the guaranty provision. *Buffalo Pharmacal Co.*, 131 F.2d at 503. The court was concerned that the language of this provision seemed not to extend its protection to innocent agents who unwittingly take part in interstate shipment of adulterated drugs. The proprietor rather than the agent is the person likely to obtain the guaranty, and the agent thus would have no control over the dealer's decision to ohtain or to forgo that protection. Moreover, the agent would be unlikely to be the party who "received" the article from the guarantor. *Id.*

The court found it inconceivable that Congress would expect "anyone except the principal to get such a guaranty, or to make tbe guilt of an agent depend upon whether his employer had gotten one." *Id.* The court, therefore, concluded that the statute must mean that only a proprietor, either a corporation or an individual, "causes" the unlawful introduction of drugs into commerce for purposes of the penal provisions. In tbis case no evidence existed to show that Dotterweich had set up a sham corporation to use as his agent and that he was, therefore, the principal at whom the statutory injunction was directed. Instead, the Buffalo Pharmacal Company—a legitimate business entity—was the object of the regulation. *Id.*

The Supreme Court found the court of appeals' reading of the guaranty provision to be so restrictive that it "cut down the scope of the penalizing provisions of the Act" contrary to congressional intent to stiffen penalties for criminal violations. *Dotterweich*, 320 U.S. at 280. The Court concluded:

> The Act is concerned not with the proprietory relation to a misbranded or an adulterated drug but with its distribution. In the case of a corporation such distrihution must be accomplished, and may be furthered, by persons standing in various relations to the incorporeal proprietor. If a guaranty immunizes shipments of course it immunizes all involved in the shipment. But simply because if there had been a guaranty it would have been received by the proprietor, whether corporate or individual, as a safeguard for the enterprise, the want of a guaranty does not cut down the scope of responsibility of all who are concerned with transactions forbidden by § 301.

Id. at 283-84.

The Court recognized that its adoption of this view left open the possibility that all who participate in the introduction of adulterated or misbranded products, and who are therefore "responsible," may incur liability simply because the proprietor neglected to obtain a guaranty. *Id.* at 284. The Court believed, nonetheless, that tlie appellate court liad read the provision in a vacuum and tlius had effectively neutralized the penalty section. *Id.* at 280, 284.

Tlie Government also seemed to be aware of the potential for abuse if the Court were to construe tlie Act in accordance with tlie Government's view. Its brief therefore specifically addressed tliis issue by noting that Food and Drug Administration policy liad been "to avoid prosecution of underlings acting under instructions." Brief for tlie Government at 32, United States v. Dotterweich, 320 U.S. 277 (1943). The Government observed tbat tlie instant case illustrated well tlie operation of the agency's policy, for the employees who had actually bottled, labeled, and shipped the drugs in question were not prosecuted. *Id.* n.24. Of 204 criminal prosecutions involving corporate defendants in 1942, about 30% had also involved individual defendants. Tlie Government noted tliat tlie individual defendants liad been persons wlio, like Dotterweich, were at tlie policy-making level of the corporate hierarcliy or wlio liad some discretionary functions and were "abeve tlie level of mere hired hands following instructions." *Id.* at 32-33.

The Government cautioned, however, that the Act sliould not be construed to eliminate tlie possibility of prosecuting those who are mere clerks, inasmuch as it would be "incon-

The answer would be qualified, however, because one forgoes the protection afforded by a guaranty at his peril. Without the guaranty he must either run an independent analysis or run the risk of incurring criminal liability if he inadvertently misrepresents what he sells.

Justice Frankfurter suggested why such an interpretation of the Act would be consistent with congressional purpose. In the course of concluding that shippers ought to be required to assume responsibility for knowing what they sell, Frankfurter's opinion noted that penal legislation that dispenses with the traditional requirement of culpability "puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger."[80] This passage vividly recalls to mind the function of legislation defining public welfare offenses. Public welfare legislation utilizes criminal sanctions to regulate conduct that poses an unacceptably high risk of danger to the public at large.

Viewing the digitalis violation charged in *Dotterweich* within this framework, then, one might reasonably inquire how important it is that a prescribing physician be in a position to know the potency of the medication he prescribes[81] and what consequences would follow ingestion of an improper dosage of digitalis. In the case at hand the dosage was only half as strong as expected. A heart patient might suffer no untoward consequences from the drug itself under these circumstances, but the result desired by the prescribing physician might not be achieved.[82] If the disparity had been the opposite and the digitalis tablets were actually twice as potent, the medication could cause the patient to become ill.[83]

Imposing on a drug jobber an obligation either to perform a chemical analysis to ascertain the properties of a drug or to obtain a guaranty from the supplier serves to ensure that *some* party in the distributive chain assumes responsibility for the contents of

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ceivable that Congress intended to spare clerks who act with 'intent to defraud or mislead' or who negligently and contrary to instructions act so as to cause a violation of the Act." *Id.* at 33-34.

80. *Dotterweich*, 320 U.S. at 281.

81. *See* Record, *supra* note 64, at 96 (testimony of Harold J. Tagett).

82. *Id.* at 102-05 (testimony of Herbert A. Braum (recalled)). A recent study of outpatients with heart failure suggests that the desired result might not be achieved in any event, notwithstanding administration of the proper dosage. *See* Lee, Johnson, Bingham, Leahy, Dinsmore, Goroll, Newell, Strauss & Haber, *Heart Failure in Outpatients: A Randomized Trial of Digoxin Versus Placebo*, 306 NEW ENG. J. MED. 699 (1982) (concluding that while many heart patients respond to digitalis treatment, some may not benefit clinically from administration of the drug).

83. *See* Record, *supra* note 64, at 102-05.

the package labeled three grain digitalis tablets.[84] A requirement of an identifiable responsible party should in theory minimize the risk that adulterated or misbranded drugs which pose a hazard to the consumer will be marketed to an unsuspecting public.

Similarly, with respect to the cascara violation, even though the label truthfully disclosed all of the ingredients contained in the compound, the misleading designation of the drug as Hinkle pills could bring about dire consequences. It is conceivable, for example, that after strychnine sulphate was removed from the National Formulary a physician might have recommended Hinkle pills to a patient who was allergic to the strychnine that formerly had been an approved component of the compound. If the patient ingested so-called Hinkle pills distributed by the Buffalo Pharmacal Company, the result could be disastrous.

Thus, even though the conduct that provided the basis of the prosecution in *Dotterweich* might be consistent with a finding of culpability—negligence, for instance—if one weighs the elementary requirement that a seller of drugs know and correctly designate the identity of his wares against the risk to public health if this requirement is not fulfilled, this case poses a classic example of the type of situation that prompts enactment of public welfare offenses.

III. The Aftermath of *Dotterweich*

During the three decades following the *Dotterweich* decision courts accomplished little in the way of clarifying ambignities in the responsible share test. Most reported decisions concerning prosecutions of corporate officers were factually similar to *Dotterweich*,[85] and courts routinely approved indictment and conviction of officers who exercised continuing supervision over their businesses.[86] Although most successful prosecutions resulted only

84. *See supra* note 77.

85. Although most of the violations involved adulterated or misbranded drugs and food, at least one court extended the principles of *Dotterweich* to a transaction violating the cosmetics provisions of the Act in a prosecution naming only the corporate defendant. *See* United States v. Parfait Powder Puff Co., 163 F.2d 1008 (7th Cir. 1947), *cert. denied*, 332 U.S. 851 (1948) (upholding conviction of corporation for violation committed by independent contractor).

86. *See, e.g.*, United States v. Shapiro, 491 F.2d 335 (6th Cir. 1974) (upholding revocation of probation of convicted owner, president, and sales manager of cookie company); United States v. H.B. Gregory Co., 502 F.2d 700 (7th Cir. 1974), *cert. denied*, 422 U.S. 1007 (1975) (upholding conviction of president and treasurer of bakery supply warehouse who had personal responsibility for all operations); Lelles v. United States, 241 F.2d 21 (9th

in imposition of a modest fine, jail sentences and terms of probation occasionally were imposed.[87]

In addition to holding title to a relatively high office or possessing general authority over the business, the individuals who were targets of Food, Drug, and Cosmetic Act prosecutions usually had a close relationship with the business operation resulting in the violation. Because of that prosecutorial pattern, it appeared that small businessmen were subject to "a particularly high risk

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Cir.), *cert. denied*, 353 U.S. 974 (1957) (upholding conviction of owner of mushroom company); United States v. H. Wool & Sons, 215 F.2d 95 (2d Cir. 1954) (upholding conviction of part owner and secretary of dairy products wholesale company who was active in the management of its affairs and was dominating factor in company); Golden Grain Macaroni Co. v. United States, 209 F.2d 166 (9th Cir. 1953) (upholding conviction of president of company who managed plant and indicating that physical presence of responsible officer when violation occurred was unnecessary); United States v. Kaadt, 171 F.2d 600 (7th Cir. 1948) (upholding convictions of operators of diabetic clinic under instruction that jury must consider the work they performed, their duties and responsibilities, and extent to which they each controlled business of clients); United States v. Diamond State Poultry Co., 125 F. Supp. 617 (D. Del. 1954) (upholding convictions of two major officers who made corporate policy and were personally involved in operations of company). *See also* Kordell v. United States, 335 U.S. 345 (1948) (holding that pamphlets sent separately from drug shipment but to same consignee constituted labeling, and that conviction of individual who wrote and shipped them was proper, even though he may have believed pamphlets were permissible advertising). For a discussion of the foregoing cases, see O'Keefe & Shapiro, *supra* note 44, at 9-18.

Among these cases United States v. Shapiro, 491 F.2d 335 (6th Cir. 1974), is notable. Shapiro was co-owner, president and sales manager of the Tasty Cookie Company. He and his partner had been convicted of violating the Act, and following their convictions the plant was shut down for clean-up operations. They subsequently reopened the plant, but also decided to sell it. During negotiations with a prospective buyer the partners had some disagreements, and Shapiro bought out his partner in order to complete the transaction. The purchaser hired someone to take charge of production, and six days later they signed an agreement giving the purchaser "operations and management" of the plant as of April 10. On April 18 a stock purchase agreement was signed. The final closing date was set for April 27. An FDA inspector appeared at the plant April 23 and 24 and found unsanitary conditions amounting to another violation of the Act.

Shapiro claimed that the signing of the agreement passed equitable title to the purchaser and therefore absolved him of personal responsibility for the violations. Rejecting that argument, the Sixth Circuit noted that he remained president of the company and owner of all the assets during that period, and he clearly possessed both "the power and the authority to devise whatever measures were necessary to assure compliance with the FDA regulations." *Id.* at 337. He had the options of closing the plant until the new owner could assume complete control, requiring the purchaser to provide written assurances that the purchaser would not distribute adulterated food products during the period in question, or of cleaning up the plant himself. "It is clear that appellant failed to implement adequate safeguards at any time." *Id.* His involvement in this unlawful enterprise violated the terms of his probation under the prior conviction and constituted grounds for revoking it. *Id.* at 336.

87. *See, e.g.*, United States v. Shapiro, 491 F.2d 335 (6th Cir. 1974) (revoking probation); United States v. Siler Drug Store Co., 376 F.2d 89 (6th Cir. 1967) (sentence of one year in prison).

since they generally are involved in plant operations, in addition to their overall responsibilities."[88] Subsequent developments, however, created good reason to reevaluate that perception.

In 1972 the General Accounting Office reported to Congress a significant increase in sanitation problems in the food industry.[89] The report prompted accelerated Food and Drug Administration enforcement efforts, which included a communication to trade associations in the food industry warning that enforcement activity would be stepped up.[90] Apparently regarding the response to the warning as inadequate, FDA officials directed a subsequent communication to the presidents of several food chains. This letter contained the same warning, with the following additional embellishment:

> We regard you as the person who ultimately has the authority to order correction of such conditions, and thus who ultimately must bear the responsibility for any failure to correct them. Should it become necessary to bring criminal action to prevent a continuation of violative conditions, therefore, we wish you to understand that you and the other high corporate officials in your organization who are specifically responsible for sanitation practices will be held accountable.[91]

That action set the stage for a spate of criminal prosecutions involving the food industry generally,[92] and in particular for a prosecution that would revive debate about the long-dormant responsible share test.

IV. *United States v. Park*

The vehicle for renewed consideration of the test was *United States v. Park*.[93] Unlike *Dotterweich* and its progeny the *Park*

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88. O'Keefe & Shapiro, *supra* note 44, at 20.

89. *Id.* at 29.

90. The letter was written by Sam Fine, FDA Associate Commissioner for compliance. *Id.*

91. *Id.*

92. Over a five year period 81% of the 352 criminal prosecutions under the Act involved the food industry. *Id.* These statistics, however, include prosecutions initiated in years preceding the GAO Report and the increased FDA enforcement activity generated by the report.

93. 421 U.S. 658 (1975). Justices Douglas, Breunan, White, Blackmun, and Rehnquist joined Chief Justice Burger's majority opinion. Justice Stewart wrote a dissenting opinion in which Justices Marshall and Powell joined. For commentaries on *Park* and its impact on the liability of corporate officers, see O'Keefe & Isley, Dotterweich *Revisited—Criminal Liability Under the Federal Food, Drug, and Cosmetic Act*, 31 FOOD DRUG COSM. L.J. 69 (1976); Rodwin, *A Violation of the Federal Food, Drug, and Cosmetic Act—A Crime in Search of a Criminal*, 31 FOOD DRUG COSM. L.J. 616 (1976); Sethi & Katz, *The Expanding Scope of Personal Criminal Liability of Corporate Executives—Some Implications of* United States

prosecution targeted a corporate executive who presided over a large company with national operations. Park was president and chief executive officer of Acme Markets, Inc., a national retail food chain with 874 outlets, sixteen warehouses, and 36,000 employees. Acme's headquarters and Park's office were located in Philadelphia; the violations in question occurred in the Baltimore warehouse.

In 1970 the FDA advised Park in writing that inspection of the Philadelphia warehouse revealed sanitation problems. In 1971 the FDA sent a second communication to Park indicating that similar problems existed in the Baltimore warehouse. Characterizing the conditions in Baltimore as "reprehensible," the FDA concluded that they either had existed over a "prolonged period of time without any detection" or else had been "completely ignored."[94] The letter characterized the need for additional corrective action as "urgent."[95] In response to the second letter Acme's Baltimore division vice president indicated that he and Park had taken action to correct the violations in both Philadelphia and Baltimore. Although a subsequent inspection of the Baltimore warehouse in 1972 revealed improvement of the problem, the FDA nevertheless discovered evidence of continued rodent activity and food contamination.

The Government charged Acme and Park with five counts of violating the Food, Drug, and Cosmetic Act. Acme pleaded guilty, Park not guilty. Park moved for judgment of acquittal at the close of the Government's case-in-chief, asserting that because the prosecution had failed to establish Park's personal involvement in the violation, it also had failed to establish his individual liability. Citing *Dotterweich,* the trial court denied the motion.

As the sole defense witness, Park testified that while all of Acme's employees were, in a general sense, under his direction, the organizational structure of the company included a system whereby certain business operations were assigned to department heads who supervised their own staffs. He stated that upon receiving the 1972 FDA letter he consulted the vice president for legal

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v. Park, 32 FOOD DRUG COSM. L.J. 544 (1977); Recent Development, *The Standard for Criminal Responsibility Under the Federal Food, Drug and Cosmetic Act*—United States v. Park, 13 AM. CRIM. L. REV. 299 (1975); Case Note, *Prosecution of Corporate Officials Under the Federal Food, Drug, and Cosmetic Act*— United States v. Park, 37 OHIO ST. L.J. 431 (1976).

94. *Park,* 421 U.S. at 662 n.6.

95. *Id.*

affairs, who told him that the Baltimore division vice president "was investigating the situation immediately and would be taking corrective action . . . to reply to the letter."[96] Park expressed his belief that he could not personally have handled the situation more constructively than the manner in which he was told it was being handled by his subordinates.

Rejecting a renewed motion for acquittal at the close of the defense evidence, the trial court instructed the jury that it could find Park guilty if it found that Park's position was one of "authority and responsibility in the business for Acme Markets" and that he had "a responsible relation to the situation, even though he may not have participated personally."[97] The jury convicted Park on all five counts, and he was sentenced to pay a fine of $50 on each count.

The court of appeals reversed his conviction,[98] holding that the instruction could have misled the jury into believing that it could convict Park simply because he was president of the company.[99] That interpretation, the court concluded, went well beyond

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96. *Id.* at 664.

97. *Id.* at 665, n.9.

98. United States v. Park, 499 F.2d 839 (4th Cir. 1974), *rev'd*, 421 U.S. 658 (1975).

99. The instruction included the following language:

"[Y]ou must find beyond a reasonable doubt . . . .

. . . .

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

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

. . . .

. . . An individual is liable if it is clear . . . . that the individual had a responsible relation to the situation, even though he may not have participated personally.

. . . [T]he fact that the Defendant is pres[id]ent and is a chief executive officer of the Acme Markets does not require a finding of guilt. . . . The issue is, in this case, whether the Defendant, 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."

Park, 421 U.S. at 665 n.9 (quoting trial judge's instructions to the jury).

The majority opinion in *Park* recognized that if parts of the instruction were viewed in isolation of each other one might possibly conclude that the jury was misled. The Court cautioned, however, that the charge must be read in its entirety and in the context of the entire trial, and it concluded that the jury could only have considered the trial judge's references to "the situation" to mean food that was stored in unsanitary conditions and that consequently became contaminated. *Id.* at 674. Although faulting the imprecision of the langnage, the Court concluded that the instruction was adequate. *Id.* at 675.

The dissenting Justices found the deficiency in the language fatal and concluded that the instruction was circular and "expressed nothing more than a tautology." *Id.* at 679 (Stewart, J., dissenting).

the parameters of *Dotterweich,* which did not purport to dispense with the requirement of a wrongful act or omission to act bearing a causal relationship to the unsanitary conditions.

The United States Supreme Court reversed and reinstated Park's conviction. Finding that both corporate agents who personally participate in conduct constituting an offense and those whose relation to the subordinates is managerial may be held accountable for an offense,[100] the Court stated that in the latter case liability is predicated upon an omission or failure to act. The Food, Drug, and Cosmetic Act created a scheme of liability that holds a manager responsible for a violation if the manager, by virtue of his relationship to the corporation, had the power to prevent the act constituting the violation.[101]

The Court explained that *Dotterweich* imposed liability on those who possess authority and supervisory responsibility when their failure to exercise such authority and to discharge their responsibility results in a violation.[102] The rationale of *Dotterweich,* which had been reaffirmed in later cases, was that the degree of public interest in preventing contamination of food and drugs was sufficiently great to warrant imposing " 'the highest standard of care' "[103] on those in the chain of distribution "who execute the corporate mission."[104]

The Court then identified two specific positive duties imposed by the Act: (1) "primarily, a duty to implement measures that will insure that violations will not occur";[105] and (2) an affirmative duty to seek out and remedy violations that do occur. The Act imposes the highest duty of foresight and vigilance,[106] and while imposition of such a standard is perhaps onerous, the Court observed, the public is entitled to the exercise of that degree of care by those who hold positions of authority in business enterprises affecting public health and welfare. They must protect those from whom they profit[107] by exercising their power to do whatever is necessary to prevent or correct violations of the Act.

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100. *Id.* at 670. The Court explained at length that the responsible share test "was not formulated in a vacuum" but instead was a rather natural extension of an existing theory of managerial liability. *Id.* at 670-71.

101. *Id.* at 671.

102. *Id.*

103. *Id.* (quoting Smith v. California, 361 U.S. 147, 152 (1959)).

104. *Park,* 421 U.S. at 672, 673.

105. *Id.* at 672.

106. *Id.*

107. *Id.*

The Court, however, left open the possibility that even if a defendant was vested with authority to prevent or remedy violations he may nonetheless raise, by way of defense, the impossibility of so doing. A corporate officer is not accountable for "causing" a violation if he can establish that he was "powerless" either to prevent or to correct it.[108]

Professor Abrams argues that while it is doubtful that the Court intended to adopt a negligence or "limited culpability" standard,[109] the majority opinion nevertheless may be read to support the premise that criminal liability may be imposed "only where there is a departure from a standard of care."[110] Abrams maintains that Chief Justice Burger's opinion is "replete with language which smacks of negligence,"[111] such as " 'the defendant's . . . power, in light of the duty imposed by the Act, to prevent or correct . . . some measure of blameworthiness . . . the scope of the duty, provide[s] the measure of culpability.' "[112]

When the Court spoke of blameworthiness and culpability in this portion of its opinion, however, it was addressing the issue of factual rather than moral blame. "The concept of a 'responsible relationship' to, or a 'responsible share' in, a violation of the Act indeed imports some measure of blamewortliiness," Chief Justice Burger wrote.[113] But he further noted that "Congress has seen fit to enforce the accountability of responsible corporate agents dealing with products which may affect the health of consumers by penal sanctions cast in rigorous terms . . . . The considerations which prompted the imposition of this duty, and the scope of the duty, provide the measure of culpability."[114] The Chief Justice explained that proof that the officer had the responsibility and the power to prevent the violation and that he failed to fulfill the duty to do so establishes the required causal link between the officer and the violation.[115] Thus, while a corporate officer cannot be blamed for a violation unless he is factually connected with it, the prosecution may establish the required factual connection without

108. *Id.* at 673 (citing United States v. Wiesenfeld Warehouse Co., 376 U.S. 86, 91 (1964)).

109. Abrams, *supra* note 18, at 473.

110. *Id.* at 469.

111. *Id.*

112. *Id.* (citing *Park*, 421 U.S. at 673, 674).

113. 421 U.S. at 673.

114. *Id.* at 673-74.

115. "The failure thus to fulfill the duty imposed by the interaction of the corporate agent's authority and the statute furnished a sufficient causal link." *Id.* at 674.

also proving a culpable state of mind.

That the Court did not intend its reference to blameworthiness in this passage to connote any requirement of a culpable mental state is reinforced by its explicit rejection, in the same passage, of the Fourth Circuit's position regarding the Government's burden of proof. The court of appeals had stated that Park could not be found guilty unless the Government established "some wrongful action" on his part.[116] The appellate court continued, "[t]hat action may be gross negligence and inattention in discharging his corporate duties and obligations or any of a host of other acts of commission or omission."[117] A required showing of "personal wrongdoing," according to the court, would be consistent with the concepts of "fairness and justice."[118] The Fourth Circuit, then, "wr[o]te into the statute some small degree of mens rea or scienter as a prerequisite to liability."[119]

The Supreme Court prefaced its discussion of what makes a corporate officer's failure to prevent a violation blameworthy with express disapproval of the standard adopted by the lower court. "We cannot agree with the Court of Appeals that it was incumbent upon the District Court to instruct the jury that the Government had the burden of establishing 'wrongful action' in the sense in which the Court of Appeals used that phrase."[120] Thus, while one might well conclude that the Court's language, perhaps within another context, would support the proposition that liability must be predicated upon a finding of minimal culpability or negligence, within the context of the *Park* opinion the premise is unsound.

On the effect of the objective impossibility notion introduced in *Park,* Professor Abrams writes that the Court's recognition that a corporate officer might avoid criminal liability if he can demonstrate powerlessness to prevent or correct the violation further refines the content of the responsible share standard articulated in *Dotterweich.*[121] The concept of power thereby becomes intimately related to that of responsibility, as "[r]esponsible share implies a measure of control over the situation; powerlessness negates the existence of that control."[122]

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116. *Park,* 499 F.2d at 842.
117. *Id.*
118. *Id.*
119. *Id.* at 845 (Craven, J., dissenting).
120. *Park,* 421 U.S. at 673.
121. Abrams, *supra* note 18, at 468.
122. *Id.*

Abrams suggests, however, that the Court's choice of extreme terminology—the term "powerlessness" and the phrase "objectively impossible"—injects too much rigidity into the standard of liability.[123] Under a "corporate responsibility view of *Park*," which he terms a "narrow reading" of the case, a corporate officer could avoid liability only if he were able to demonstrate that he had no responsibility and authority with respect to the business activity that led to the violation.[124] "No other kind of claim that he was powerless would be acceptable."[125] Thus, he posits, even if the inability to prevent the violation were attributable to external forces, the officer would not be powerless within the meaning of the Court's pronouncement unless he lacked authority to control the business process in question.[126]

Moreover, Professor Abrams perceives the defense of powerlessness as a procedural device that, like the doctrine of strict liability, serves to shift the burden of going forward on the issue of responsibility.[127] He concludes that under a "corporate responsibility" interpretation of *Park*, "the issue of whether the defendant had responsibility in the corporate structure over the activity that produced the violation is not in the case unless the defendant first produces evidence on the issue."[128]

Professor Abrams' observations about the effect of engrafting the notion of objective impossibility upon the responsible share standard may be quarreled with on several scores. First, his conclusion that the issue would not be "in the case" unless the defendant raised it himself is contradicted both by the manner in which the Government constructed its case against Park and by the Court's treatment of the burden of proof issue.

It is notable that the Government called as its final witness Acme's vice president for legal affairs and assistant secretary, who read to the jury the corporate bylaw that specified the duties of the chief executive officer. Those duties included responsibility for "general and active supervision of the affairs, business, offices and employees of the company,"[129] in addition to reporting to the

123. *Id.*

124. *Id.* at 469.

125. *Id.* at 468.

126. *Id.* at 468-69.

127. *Id.* at 473.

128. *Id.* at 474. Abrams also concludes that this proposition would obtain under a standard of care view of *Park*. *Id.*

129. 421 U.S. at 663 n.7.

board. The legal officer testified that although Park had delegated "normal operating duties" such as matters involving sanitation, he assumed personal responsibility for "the big, broad, principles of the operation of the company" and for "seeing that they all work together."[130] It seems clear, then, that the Government took the initiative on the issue of Park's responsibility. It seems equally clear that the Government was required to do so.

In the course of considering what burden of proof the Government must satisfy in order to establish a violation, the Supreme Court rejected the court of appeals' holding that the prosecution must establish some specific wrongful action on the part of Park. Adopting a contrary position, the Court stated:

> it is . . . clear that the Government establishes a prima facie case when it introduces evidence sufficient to warrant a finding by the trier of the facts that the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so.[131]

It would seem, then, that if the Government introduced no evidence on this issue, or merely introduced evidence of a corporate officer's title and position without also establishing the accompanying responsibilities, the case could not go to the jury.

The Court's statement, moreover, belies the conclusion Abrams would draw, under a corporate responsibility view of the case, regarding the availability of the claim of powerlessness. "Under this view of the case, a court would be required to reject a corporate officer's claim that even though he had responsibility over the activity in question, he had been powerless to prevent the violation because an outside force—e.g., sabotage—had intervened."[132] Inasmuch as the Court made clear that a causal relationship between the accused officer's nonfeasance and the violation is required, however, Abrams' proposition is stated too broadly. The Government establishes a prima facie case by proving the defendant's corporate office, his responsibility to prevent or correct the violation, and his failure to do so. Proof of "[t]he failure thus to fulfill the duty imposed by the interaction of the corporate agent's authority and the statute furnishes a sufficient causal link."[133]

Suppose, however, that the clean-up efforts at the Baltimore

130. *Id.* at 663.
131. *Id.* at 673-74.
132. Abrams, *supra* note 18, at 468-69.
133. *Park*, 421 U.S. at 674.

warehouse were successful and that all contaminated food was removed. Suppose further that a competitor of Acme Markets thereafter hired a saboteur to impersonate an FDA inspector and, unobtrusively while in the warehouse, to deposit rat and mouse pellets in strategic locations throughout the storage facility. If a genuine FDA inspection occurred the following day, could Park succeed in his claim that he was powerless to prevent the violation? It is submitted that he could.

Under the facts just posed it would have been objectively impossible for Park to prevent the recontamination of the warehouse.[134] The Government might well be able to establish a prima facie case against Park, for it could prove that he held a position of authority carrying with it the responsibility to prevent violations resulting from the storage of food under insanitary conditions and that he had failed to do so.[135] It must be remembered, however, that this is only prima facie evidence of a violation for which he may be accountable. While on its face the Government's evidence would establish a sufficient causal link, Park could raise in his defense the claim that he was " 'powerless' " to prevent this particular violation because of the intervention of external forces.[136] If credible, the claim would destroy the requisite causal relationship and would therefore exculpate the officer from criminal accountability. Even under a corporate responsibility view of *Park* that result would obtain because the Food, Drug, and Cosmetic Act does not require a corporate officer to do that which is beyond his power or which is objectively impossible for him to do. The scope of liability under the Act is not, therefore, coextensive with that of insurer, as Professor Abrams' hypothesis suggests.

V. The "Objective Impossibility" Defense

The Supreme Court noted the possible existence of a defense of objective impossibility as early as 1964, when a public storage warehouseman argued that the Government was seeking to punish the one " 'who is, by the very nature of his business powerless' "[137] to prevent food from being contaminated no matter how high the standard of care he exercised. The Court concluded that the claim

134. He would not be powerless, however, "to seek out and remedy" the violation once it did occur. *Id.* at 672.

135. *Id.* at 673-74.

136. *Id.* at 673 (quoting United States v. Wiesenfeld Warehouse Co., 376 U.S. 86, 91 (1964)).

137. United States v. Wiesenfeld Warehouse Co., 376 U.S. 86, 91 (1964).

was premature, however, because of the procedural posture of the case.[138]

Shortly thereafter corporate and individual defendants raised the same argument in a prosecution for storing food in unsanitary conditions.[139] Upholding the defendants' convictions, the Fifth Circuit noted that the prosecution's evidence unquestionably established that the defendants had neglected to take all necessary steps to prevent the unwholesome conditions. The court thus concluded that the case did not raise a genuine issue regarding the propriety of convicting an individual who was powerless to prevent the violation.

After *Park*'s reminder that objective impossibility might be raised defensively, two Ninth Circuit opinions provided some insight into how courts might treat such a claim.[140] In Professor Abrams' view the Ninth Circuit opinions reflect a very narrow reading of *Park*. He finds that while they incorporate language that suggests a standard of care approach to liability under the Act, they actually apply a "corporate responsibility" standard of liability.

In the first of the cases, *United States v. Y. Hata & Co.*, [141] a corporation and its president were convicted of violating the Food, Drug, and Cosmetic Act when rice became contaminated by "thieving and untidy birds"[142] in the company's Hawaiian food storage warehouse. Unlike the defendant in *Park*, the defendants in *Hata* requested an objective impossibility instruction, but the trial judge denied the request. The Ninth Circuit Court of Appeals assumed that such an instruction must be given if warranted by the facts,[143] and it therefore viewed the issue to be whether a material question of fact existed regarding proof of the elements of the defense.[144]

The defendants argued that when the FDA cited them for the

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138. As the *Wiesenfeld* decision reversed a dismissal of a criminal information against the warehouse company, the defendant had not yet had an opportunity to prove the claim at a trial on the merits. *Id.* at 92.

139. United States v. Hammond Milling Co., 413 F.2d 608 (5th Cir. 1969), *cert. denied*, 396 U.S. 1002 (1970).

140. United States v. Y. Hata & Co., 535 F.2d 508 (9th Cir.), *cert. denied*, 429 U.S. 828 (1976); United States v. Starr, 535 F.2d 512 (9th Cir. 1976).

141. 535 F.2d 508 (9th Cir.), *cert. denied*, 429 U.S. 828 (1976).

142. 535 F.2d at 511.

143. *Id.* at 510 & n.3 (citing United States v. Park, 421 U.S. 658, 673, 676 (1975)).

144. 535 F.2d at 510-11 (analogizing the evidentiary standard to that applicable to the defense of entrapment).

violations they had plans to enclose the food storage area in a huge wire cage but that they were powerless to construct the device at that time because the needed materials had not yet arrived from the mainland United States.

The court noted that the defendant had failed to consider the obvious remedy of a cage until shortly before the inspections and rejected any suggestion that it was objectively impossible for the defendants to conceive of the idea much before that time. Use of a caging device is hardly a novel idea, and one who exercises far less than the highest standard of foresight and vigilance, a standard required under *Park,* would realize that a caging device would substantially resolve the problem. The *Park* duty to remedy violations of the Act when they occur includes the duty to consider and experiment with such commonplace devices. The defendants produced no evidence tending to show that they had considered the remedy and that their inability to obtain the required materials had frustrated implementation of the plan.[145] Thus, the Ninth Circuit agreed with the trial judge that an objective impossibility instruction was not warranted.

Of the opinion in *Hata,* Professor Abrams complains that despite the defendants' offer of proof of the corrective efforts that preceded the decision to build the cage, the court seems to have held that the earlier efforts were insufficient as a matter of law.[146] Finding more than a hint of unfairness in this, he exclaims that "[t]he court seems to have been saying that under a claim of powerlessness a defendant must show that he took *all* possible measures *immediately!*"[147] The problem inherent in this premise is, in Abrams' view, that the court "seems to overlook the natural and arguably reasonable tendency in a situation of this nature to try different remedies sequentially, building up each time to the next more complex and expensive remedial measure."[148]

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145. It is notable that the Government argued that the objective impossibility defense should not be available to a corporate defendant. In the Government's view, the defense should be available only to a corporate officer, and then only when he was "in fact powerless to prevent or correct the violation, even by suspending the corporation's food warehousing activity if necessary." *Id.* at 511. Since the court concluded that no factual support existed for the defense in this case, it did not attempt to resolve that issue.

Although the Supreme Court has not expressly addressed this question, the Court first acknowledged that impossibility might constitute a defense in the context of a prosecution that apparently involved only a corporate defendant. *See* United States v. Wiesenfeld Warehouse Co., 376 U.S. 86, 91 (1964).

146. Abrams, *supra* note 18, at 471.

147. *Id.*

148. *Id.*

If one were inclined to find fault with the ameliorative effects of the objective impossibility defense, it would be difficult to marshal a weaker set of facts from which to mount an attack. The evidence established that the defendants in *Hata* were aware of the existence and nature of the problem as early as August 1971.[149] The two FDA inspections that led to the indictment occurred in May and June of 1972.[150] On those two occasions the inspectors observed birds fiying in and out of the food storage facility, birds perching on overhead sprinklers, birds perching on and eating from bags of rice, and bird droppings on some of the bags of rice.[151]

While the court did not require a showing of minimal culpability or negligence in order to sustain the conviction, the violation in *Hata* clearly was a culpable violation. The defendants *knowingly* held food for sale under insanitary conditions for a period of about ten months. To suggest that the warehouse operators may have acted reasonably and that they were therefore entitled to an instruction on objective impossibility is tantamount to a claim of entitlement to continue storing and selling foodstuffs one knows to be contaminated, provided that some ongoing effort, however ineffectual, is being made to correct an obvious and elementary sanitation problem. It is submitted that neither Congress nor the *Park* Court would have countenanced such a premise under the Act.

In the second Ninth Circuit case considered by Abrams, *United States v. Starr*,[152] a corporation and Starr, the corporation's secretary-treasurer, were convicted of violating the Act by allowing food stored in a company warehouse to become contaminated. The first inspection leading to the indictment revealed numerous violations, and the inspector personally detailed them to the assistant treasurer of the corporation. In the presence of the inspector the assistant treasurer reprimanded Marks, the warehouse janitor, and instructed him to take corrective action. Marks had not done so as of one month later when a second inspection occurred. Marks admitted to the inspector that he had not taken the corrective measures he had been ordered to take, and he later falsely suggested that additional violations existed. Starr and the corporation were charged with and convicted of violating the Act. Starr appealed.

Although Starr was responsible for the actual operation of the

149. *Hata*, 535 F.2d at 511.
150. *Id.*
151. *Id.* at 509.
152. 535 F.2d 512 (9th Cir. 1976).

warehouse and, therefore, had " 'the responsibility out of which the violation grew,' "[153] he asserted two grounds for the defense of impossibility. First, he contended that the infestation resulted from a natural phenomenon in that the plowing of a nearby field caused mice to seek sanctuary in the warehouse. The court rejected this argument, stating that "with only a minimum of foresight"[154] one would reasonably expect rodents to flee from freshly plowed fields. Starr's second argument was that the janitor sabotaged the company by refusing to comply with the order to correct the violations. Starr testified that Marks was hired to take care of such problems and that he felt Marks should have done so.

The trial judge indicated that the passing of a month between the first inspection—when Marks was reprimanded—and the second inspection was significant. During this time Starr could have taken additional steps to cure the violation. He could not simply delegate the responsibility to the janitor and consider the matter at an end, because ultimately it was Starr's responsibility to maintain a sanitary warehouse. Starr testified that he never checked on the progress of the ordered clean-up. Indeed, he was ignorant of the noncompliance until the second inspection occurred.

The court concluded that Starr failed to satisfy the foresight and vigilance standard required by *Park*. Even though the janitor was told to correct the problem, "Starr should have foreseen that, through neglect or design, Marks might fail to follow the orders. . . . Starr *expected* that Marks would obey his orders, but this is not to say that noncompliance was unforeseeable, for indeed it was not."[155]

Professor Abrams is critical of the *Starr* decision. In his view the court's treatment of the claim of powerlessness can only make "one wonder what kind of evidence might suffice to substantiate the claim."[156] Indeed, he argues, if employee sabotage of the responsible officer's efforts to correct a problem does not legitimate a claim of powerlessness, "then it is hard to conjure up a fact situation where there will not be liability if efforts to correct violations turn out to be unsuccessful."[157]

As this Article notes in its analysis of *Park*, the work of a saboteur may provide a sufficient factual basis for sustaining a claim

153. *Id.* at 514-15 (quoting the district court's findings).
154. *Id.*
155. *Id.* at 516.
156. Abrams, *supra* note 18, at 472.
157. *Id.*

of objective impossibility.[158] It may be prudent, however, to draw a general line between external forces that contribute to a violation, such as a saboteur posing as an FDA inspector, and internal forces that interfere with its correction, whether they consist of employee sabotage, insubordination, or incompetence.

On the whole, *Starr* is not so different from *Park*. Recall that Park was the sole defense witness at his trial. On cross-examination, Park stated that the responsibility for sanitation matters was delegated to " 'dependable subordinates.' "[159] He did acknowledge, however, that with one exception[160] the same employees were responsible for sanitation in both Philadelphia and Baltimore. The two critical FDA reports about conditions in the Baltimore warehouse, Park conceded, indicated that the organizational process for managing sanitation problems " 'wasn't working perfectly.' "[161]

Park testified that he delegated responsibility for sanitation matters to dependable subordinates and that he trusted the organizational system in the company to function as it was intended to. The Court viewed the apparent purpose of the testimony as an effort to establish that because he presided over a large, national corporation, Park "had no choice but to delegate duties to those in whom he reposed confidence, that he had no reason to suspect his subordinates were failing to insure compliance with the Act, and that, once violations were unearthed, acting through those subordinates he did everything possible to correct them."[162]

While declining to decide whether the evidence would have warranted an instruction on Park's power or powerlessness to affect the conditions at the Baltimore warehouse,[163] the Court did find that the testimony created a need for rebuttal evidence. The prosecution satisfied that need by introducing the 1970 FDA letter regarding unsanitary conditions at the Philadelphia warehouse. The 1970 letter established that Park had notice that his reliance on the system was misplaced, and the evidence was properly considered in response to Park's defense that reliance on his system of

158. *See supra* text accompanying notes 132-36.

159. *Park*, 421 U.S. at 664 (quoting Park's testimony in trial court).

160. The one exception was the Baltimore division vice president. *Id.*

161. *Id.* at 664-65 (quoting Park's testimony in trial court). He also admitted that as chief executive officer of the company he bore responsibility for " 'any result which occurs in our company.' " *Id.* at 665 (quoting Park's testimony in trial court).

162. *Id.* at 677.

163. The Court pointedly noted that Park neglected to request an instruction that the prosecution must prove beyond a reasonable doubt that Park had the power or capacity to do so. *Id.* at 676.

delegation was justifiable.[164]

Although *Park* does not articulate a general rule that corporate officers may not justifiably rely on subordinates to perform their assigned tasks responsibly, it does impose limits on the privilege to do so with impunity. Park was given specific assurances that a problem in a distant city would be corrected. The Baltimore division vice president was aware of the problem and detailed, in a letter to the FDA, corrective measures that had been taken. It is apparent that the Baltimore Chief had immediate responsibility for handling this matter, and the Government's own evidence established that following the 1971 inspection "a great deal of effort" had gone into cleaning up the warehouse.[165]

Nevertheless, because Park knew that the system for handling sanitation matters was unreliable, he could not justifiably continue to depend upon the very corporate mechanism whose malfunction led to repeated sanitation problems to correct those same problems. Even though it may be objectively impossible for the chief executive officer of a nationwide retail chain to supervise personally every facet of the business at its nearly 900 locations, that is not equivalent to a colorable claim that as president of the company he has no power to ensure that measures correcting elementary problems would be implemented.[166] Park neglected to follow through and to verify that the unsanitary conditions at the Baltimore warehouse had *in fact* been corrected, and that neglect provided a legally adequate basis for his conviction.

Although the facts in *Park* did not involve allegations of employee sabotage as did those in *Starr,* the Supreme Court's treatment of the delegation issue brings into question Starr's privilege to continue relying upon delegate Marks. Marks, who was janitor of the warehouse when the violation occurred, was reprimanded for permitting the unsanitary conditions to exist. The sole measure taken by management to correct the violation was that of instructing Marks to do what he should have done in the first instance. And while the discovery of sanitation problems in the warehouse should have alerted management to Marks' unreliability, as was true before the first FDA inspection no one bothered to supervise his work or to check on his progress in cleaning up the warehouse.

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164. *Id.* at 677-78.
165. Brief for the Government at 4, United States v. Park, 421 U.S. 658 (1975).
166. *Park,* 421 U.S. at 677 n.19.

Is the reason that Marks failed to clean up the warehouse, then, relevant to the issue of the manager's liability? Should it make any difference whether the janitor's failure to follow instructions to correct the violation was a product of sheer laziness, gross neglect, intoxication, simple incompetence, or intentional failure to carry out instructions—for example, sabotage? Probably not. The *Starr* Court articulates what the *Park* Court suggests—a requirement that a party with authority to follow through must bear the responsibility for supervising or ensuring proper supervision once a violation has occurred. Continued reliance on a demonstrably unreliable employee or corporate mechanism falls far short of powerlessness to correct elementary sanitation problems.

VI. Administrative Enforcement Policy

Although Professor Abrams finds that the *Park* formulation of liability under the Food, Drug, and Cosmetic Act is an improvement over a pure strict liability standard, he voices concern that *Park* still permits imposition of criminal liability under circumstances in which it would be "unjust."[167] Citing as an example the possibility of criminally prosecuting an officer of a large corporation who neither participated in the violation nor had knowledge of it,[168] he concludes that "[i]f we are really serious about the unfairness of strict liability, we should be careful not to substitute for it a doctrine that verbalizes a less extreme standard but nevertheless in practice produces the equivalent of a strict liability result."[169] While recognizing the need to hold corporate officers to a high standard of care when the health of the populace is at stake, he is concerned that the standard ultimately adopted "should not be so high . . . that in the corporate setting it is simply *unfair* to impose criminal liability on the individual."[170]

Professor Abrams observes, however, that adoption of a culpability approach in most instances would have minimal impact on the ultimate result reached because the culpability of the individu-

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167. Abrams, *supra* note 18, at 476.

168. *Id.* In forwarding this hypothetical, Abrams distinguishes *Dotterweich* on the ground that the defendant "directly supervised the activity in question," which occurred within the setting of a small corporation. *Id.* He distinguishes *Park* on the basis of "specific evidence . . . of his culpability in his failure to take sufficient remedial steps after he was informed of the violations." *Id.*

169. *Id.* at 477.

170. *Id.* (emphasis in original).

als who are prosecuted is "plausible on the facts"[171] even though the government need not prove such culpability. This point is deserving of further amplification because it is consistent with articulated administrative enforcement policy[172] and with empirical data as well.[173]

Even though the Food, Drug, and Cosmetic Act does not require a warning procedure,[174] as a general rule the FDA does not recommend criminal prosecution without first sending the potential defendants a warning letter.[175] Most defendants, therefore, will have received notice of the existence of the violation and will have had an opportunity to correct it before they become targets of a criminal prosecution.

An FDA investigation normally begins after a field inspection reveals a violation. The inspector prepares a report to a supervisor in the field office detailing his findings. If the conditions at the inspected facility are believed to warrant additional scrutiny, the field office forwards the report to the Chief of the Compliance Branch, who reviews it and decides whether or not further legal or administrative action is desirable.[176] Issuance of a warning letter more often than not precedes institution of legal proceedings,[177] and the letter may be followed by another inspection to determine whether adequate compliance measures have been taken. If the inspection reveals that the violation has not been corrected, the FDA may institute additional administrative or legal procedures.

The FDA subjects any decision to prosecute to multilevel re-

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171. *Id.* at 476.

172. *See generally* Fine, *The Philosophy of Enforcement*, 31 FOOD DRUG COSM. L.J. 324 (1976); McConachie, *The Role of the Department of Justice in Enforcing the Federal Food, Drug and Cosmetic Act*, 31 FOOD DRUG COSM. L.J. 333 (1976); O'Keefe, *Criminal Liability: Park Update*, 32 FOOD DRUG COSM. L.J. 392 (1977).

173. *See generally* Rabin, *Agency Criminal Referrals in the Federal System: An Empirical Study of Prosecutorial Discretion*, 24 STAN. L. REV. 1036 (1972) (a study of major categories of agency criminal referrals to the Justice Department, including referrals from the Food and Drug Administration). For a comparable comprehensive empirical study of criminal prosecutions under state regulatory statutes, see Remington, *Liability Without Fault Criminal Statutes—Their Relation to Major Developments in Contemporary Economic and Social Policy: The Situation in Wisconsin*, 1956 WIS. L. REV. 625.

174. O'Keefe & Shapiro, *supra* note 44, at 26.

175. *Id.* at 25. Both FDA and Department of Justice policy favors prosecuting responsible individuals along with the corporate entity. *Id.* at 27; McConachie, *supra* note 172, at 335.

176. O'Keefe & Shapiro, *supra* note 44, at 25.

177. "In cases of imminent hazard to health, filthy conditions, or other extraordinarily serious matter, the warning letter may be bypassed and legal proceedings may be instituted instead." *Id.*

view before the case is referred to the Department of Justice.[178] Experience has shown that the FDA normally only refers for criminal prosecution cases involving repeated violations.[179] Moreover, the criteria used in reviewing a case before referral for criminal prosecution generally include consideration not only of the seriousness of the violation—that is, whether it concerns an obvious gross violation such as maintenance of a filthy facility or whether the violation exposes the public to risk of potential danger—but also the existence of evidence of knowledge, intent, or some other culpable mental state.[180] In most cases that are referred for criminal prosecution the FDA has some evidence that the individuals who will be prosecuted had knowledge of the violation.[181]

Finally, an FDA recommendation does not require the Justice Department to prosecute the case. The Justice Department, however, declines to prosecute relatively few FDA cases,[182] and it is thought that FDA enforcement policies "are shaped by the agenc[y]'s prediction of the prosecutor's response to the existence of alternative remedies."[183] The fairly consistent result is that "repeated violators are prosecuted for acts which are handled in a noncriminal fashion where a first or infrequent offender is concerned."[184]

Thus, articulated administrative enforcement policy, which is consistent with empirical data, tends to ameliorate the apparent harshness of a strict liability standard under the Food, Drug, and Cosmetic Act and to minimize the potential for unfairness in the prosecution of corporate officers who are remote from the violation. This suggests that the first of the mechanisms Justice Frankfurter was willing to trust to fairly identify responsible parties—that of "the good sense of prosecutors"[185]—may have proven reliable after all.

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178. *Id.* at 26-27. "[I]n practice, FDA officials recognized the possibility of some unevenness of application, and it is for this reason that the Agency has provided for the multiple review of cases to assure as much fairness and uniformity of action as possible." *Id.* at 27.

179. Rabin, *supra* note 173, at 1060.

180. Fine, *supra* note 172, at 328-32; O'Keefe, *supra* note 172, at 400-02.

181. Fine, *supra* note 172, at 329. *See also supra* note 79.

182. The Justice Department declines to prosecute about 10% of referred cases concerning food and drug violations, as contrasted with an estimated 40% of referred cases concerning gun control violations. Rabin, *supra* note 173, at 1091.

183. *Id.* at 1060.

184. *Id.*

185. United States v. Dotterweich, 320 U.S. 277, 285 (1943).

VII. Concluding Observations

The Supreme Court's analysis of liability under the Food, Drug, and Cosmetic Act has potentially far-reaching practical and legal implications. *Dotterweich* and *Park* may have profound impact on corporate structure and governance, for instance. Since personal involvement in the offending transaction is not a prerequisite to holding a corporate officer personally accountable, the responsible share standard of liability seems destined to affect the system of delegation upon which managers of the modern business corporation must rely.

Insofar as *Dotterweich* and *Park* may influence subsequent judicial developments, cases decided under the Food, Drug, and Cosmetic Act seem not to provide a unique occasion for employing a responsible share standard of liability. Indeed, there is at present some evidence that the various components of the Court's analysis in those cases may prove useful within other regulatory contexts.[186] In that event, courts will be called upon to make discerning judgments about the outer parameters of the doctrine and to ascertain appropriate limitations on its applicability to other federal statutes. The characteristics of the regulatory scheme that prompted adoption of the responsible share standard and the theoretical un-

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186. Various components of the *Dotterweich-Park* analysis have been cited with approval in cases concerning criminal violations of such statutes as (1) the Migratory Bird Treaty Act §§ 2-7, 16 U.S.C. §§ 703-708 (1976), *see* United States v. FMC Corp., 572 F.2d 902 (2d Cir. 1978) (using *Park* and *Dotterweich* as authority for proposition that omission to perform duty may be hasis of corporation's liability), (2) the Economic Stablization Act of 1970 § 205, 12 U.S.C. § 1904 (1976), *see* United States v. Gulf Oil Corp., 408 F. Supp. 450 (W.D. Pa. 1975) (applying *Park* and *Dotterweich* in context of statutory requirement of willfulness), (3) the Sherman Act, 15 U.S.C. §§ 1-7 (1976), *see* United States v. Wise, 370 U.S. 405 (1962); *see also* United States v. Rachal, 473 F.2d 1338 (5th Cir.), *cert. denied,* 412 U.S. 927 (1973) (prosecution under Securities Act of 1933, quoting *Wise* extensively); *but cf.* United States v. United States Gypsum Co., 438 U.S. 422 (1978) (holding intent required), (4) the Federal Hazardous Substances Act, 15 U.S.C. §§ 1261-1276 (1976), *see* United States v. Klehman, 397 F.2d 406 (7th Cir. 1968) (but dismissing criminal information against individual defendant because prior testimony under subpoena conferred immunity), (5) the Filled Milk Act, 21 U.S.C. §§ 61-64 (1976), *see* Carolene Products Co. v. United States, 140 F.2d 61 (4th Cir. 1944) (upholding convictions of individual defendants responsible for promoting interstate business without evidence of personal participation in or knowledge of offending shipments), (6) the Occupational Safety and Health Act, 29 U.S.C. §§ 651-678 (1976), *see* United States v. Pinkston-Hollar, Inc., 4 O.S.H. Cas. (BNA) 1697 (D. Kan. 1976) (citing *Park* as authority supporting prosecution of corporate vice president as aider and abettor of corporation), and (7) the Federal Water Pollution Control Act §§ 301-309, 33 U.S.C. §§ 1311-1319 (1976), *see* United States v. Frezzo Bros., 602 F.2d 1123 (3d Cir. 1979), *cert. denied,* 444 U.S. 1074 (1980) (citing *Park* and *Dotterweich* as authority for proposition that defendants' argument that they could not be held individually responsible when indictment charged them as corporate officers was meritless).

derpinnings of liability under that standard are thus critically significant.

That the penal provisions of the Food, Drug, and Cosmetic Act fit the public welfare offense model is of primary importance. The Act is designed to protect human health and safety, and a violation of the statute will usually, though not necessarily,[187] endanger these important interests. Since the public welfare offense model provided the analytical framework within which the Court formulated the responsible share standard of liability, that model also provides an essential context for assessing the content, limits, and fairness of the standard. If one loses sight of that context, inferences and assumptions that might otherwise be sound may be unwarranted given the factual, legal, and analytical framework of *Dotterweich* and *Park*.

Professor Abrams, for example, postulates that certain language in *Park* may be read to require culpability as a prerequisite to criminal liability under the Act.[188] Reading the Court's language in isolation from the underlying characteristics of the regulatory scheme, Abrams neglects to note that the Court used language that customarily connotes moral blame or mental culpability for the very different purpose of supplying the requirement of a causal relationship between the responsible officer and the violation.[189] One may be deemed culpable under the Act if he is factually connected to the violation, the Court tells us. That required nexus, however, may be established without also proving a culpable state of mind.

A second important characteristic of the scheme of liability under the Food, Drug, and Cosmetic Act is that the statute imposes two affirmative duties upon corporate officers and employees—the duty to prevent violations from occurring, and the duty to discover and correct violations if they do occur—and personal responsibility for a violation may be predicated upon a failure to discharge those duties effectively.[190] Contrary to Abrams' postulate that the question of corporate responsibility is not in issue unless raised by the defendant,[191] however, the responsibility of the of-

187. *See, e.g.*, United States v. H. Wool & Sons, 215 F.2d 95 (2d Cir. 1954) (prosecution for repackaging butter weighing less than a pound in cartons labeled one pound net weight). Whether the consequences of a violation are in fact injurious may be wholly fortuitous. Morissette v. United States, 342 U.S. 246, 258 (1952).

188. *See supra* text accompanying notes 110-12.

189. *See supra* text accompanying notes 113-15.

190. *See supra* text accompanying notes 100-02.

191. *See supra* text accompanying note 128.

ficer or employee is of critical importance to the Government's case. The Act imposes the duties in question only on those within the corporation who have a responsible relation to the business process that leads to a violation.[192] Thus, the essential elements of a prima facie case are proof that the officer held a corporate position carrying with it the responsibility and authority to prevent and correct such violations, and proof that he failed to do so.[193]

A third essential point that must be considered in tandem with the second is the Court's recognition that a claim of objective impossibility or powerlessness may relieve a corporate officer of criminal responsibility for a violation. Such recognition serves the function of qualifying the officer's duty to prevent the violation. Although Professor Abrams maintains that unless it is viewed within a standard of care context, a claim of powerlessness amounts to no more than a claim that the officer lacked responsibility and authority over the troublesome transaction,[194] the Court's requirement of a causal relationship between officer and violation undercuts a necessary predicate of the hypothesis. A corporate officer may establish powerlessness to prevent a violation, even in the face of proof that he had responsibility and authority in the matter, by injecting into the case a factual element that negates the existence of an otherwise apparent causal link between his position of authority and the violation.

To constitute a criminal omission, a corporate officer's failure to prevent a violation must be related to that which it was within his power to do. One may possess and exercise general responsibility and authority over the business process through which a violation occurs and still be powerless to prevent the particular violation. It would be possible to conclude, for example, that an officer would possess the power to prevent violations resulting from the failure of a corporate mechanism over which he held a measure of control, while at the same time concluding that it would have been objectively impossible for him to have prevented a violation resulting from external intervention.[195]

Finally, inasmuch as the Act imposes liability for mere failure to prevent or correct a violation without requiring proof that the defendant possessed a culpable mental state, inattention to detail in the handling of corporate assignments may result in a violation

192. *See supra* text accompanying notes 100-01.
193. *See supra* text accompanying note 131.
194. *See supra* text accompanying notes 123-25.
195. *See supra* text accompanying notes 132-36.

for which a corporate officer may be personally accountable. As Professor Abrams observes, however, while this aspect of the established standard of liability leaves open the potential for unfairly singling out a corporate officer for a violation about which he had no knowledge and with which he had no personal involvement, the facts in the reported cases generally seem consistent with an inference of at least minimal culpability.[196] Indeed the statutory scheme, though authorizing imposition of strict liability, is tempered by a selective enforcement policy that screens out technical violations and seeks to utilize the criminal process when a very serious violation has occurred and when grounds for inferring a culpable state of mind are present.[197]

It is this last point that engenders real concern about the potential unfairness inherent in a strict liability regulatory scheme. Concern over judicial decisions that embrace the responsible share standard of liability must relate in some measure to the impact of the standard on the time honored privilege of corporate officers and managers to delegate responsibility and authority. The increased size and complexity of the modern business corporation correspondingly require delegation of greater authority to more employees.[198] Because extensive delegation is essential, it is conceivable that high ranking officers and managers may have little or no involvement in the sphere of operations where wrongdoing for which they may be held personally accountable occurs.

These facts of modern corporate life may well prompt the complaint that within the large business corporation, it is impractical to require that officers with authority over a business process must prevent even menial employees from allowing a violation to occur. In other contexts the blunt judicial response to such a suggestion has been that "[t]he checking and elimination of . . . obviously illegal practices is not shown to [be] any more difficult than other details of a nation-wide industry."[199]

That the response in cases decided under the Food, Drug, and Cosmetic Act has been equally direct may be a function of judicial concern that the goals of the regulatory scheme under considera-

196. *See supra* text accompanying notes 167-73.

197. *See supra* text accompanying notes 174-85.

198. That being the case, " '[t]here are not enough seats on the Board of Directors,' " nor enough official titles for all corporato employees who have been delegated the " 'power, authority, and responsibility for decision and action.' " Commonwealth v. Beneficial Finance Co., 360 Mass. 188, 275, 275 N.E.2d 33, 83 (1971) (quoting the trial judge in the first trial).

199. United States v. Armour & Co., 168 F.2d 342, 343 (3d Cir. 1948).

tion would not otherwise be achieved. The purposes of the Food, Drug, and Cosmetic Act, like those of many other regulatory statutes, are in large measure directly related to functions normally delegated to subordinate employees who "often exercise more responsibility in the *everyday operations* of the corporation than the directors or officers."[200] Thus, while it is clear that a system of delegation is essential within the corporate setting, the Court in *Dotterweich* and *Park* made equally clear its view that corporate executives must bear the responsibility for "execut[ing] the corporate mission."[201] Given that responsibility, the Court has engrafted upon the power to delegate a corresponding duty to supervise and control those to whom management of the details of the corporate mission have been entrusted. The scheme of liability under the Act will countenance delegation of immediate, but not of ultimate, authority and responsibility.

200. Commonwealth v. Beneficial Finance Co., 360 Mass. 188, 275, 275 N.E.2d 33, 83 (1971) (emphasis in original).

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