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Food Drug Cosmetic Law JOURNAL

The Expanding Scope of Personal Criminal Liability of Corporate Executives—Some Implications of United States v. Park

. . . . . S. PRAKASH SETHI and ROBERT W. KATZ

The Legality of the Administrative Restraint Provision of the Medical Device Amendments of 1976: Some Constitutional Considerations

. . . . . LOUIS SANTUCCI

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TO THE READER

"The Expanding Scope of Personal Criminal Liability of Corporate Executives—Some Implications of *United States v. Park*" by *S. Prakash Sethi* and *Robert W. Katz*, explores the question of who should be held responsible in the area of criminal liability and within what guidelines? Their discussion centers around the *Park* case, but includes the theory of "responsible relation" to the offense as established by *Dotterweich*. Mr. Sethi is a professor in the School of Management at the University of Texas at Dallas. Mr. Katz is a lecturer in the School of Business Administration at the University of California at Berkeley. The article begins on page 544.

Louis Santucci, an attorney for the Pharmaceutical Manufacturers Association, discusses the detention authority of the Food and Drug Administration to keep a suspect product off the market, asserting that its seizure action in this area was too slow. In his article, "The Legality of the Administrative Restraint Provision of the Medical Device Amendments of 1976: Some Constitutional Considerations," which begins on page 571, the author cites numerous court cases demonstrating the lack of due process for the manufacturer. He states that the statute is unconstitutionally vague leading to the problems of defining the theory of "reason to believe" a product is adulterated. The paper was delivered on August 10, 1977, at The American Bar Association's Annual Meeting in Chicago.

The Federal Food, Drug and Cosmetic Act of 1938, and the regulation of medical devices, is the beginning point of an article by *Thomas G. Field, Jr.* and *Dominic S. Piacenza*. "Informed Consent and the Investigational Use of Medical Devices: A Comparison of Common Law Duties With Those Imposed on Researchers Under Section 520(g) of the Medical Device Amendments of 1976," explores the various studies leading up to the 1976 Amendments while concentrating on the issue of informed consent of the patient to treatment. The article, which begins on page 585, was delivered at the Symposium on Medical Devices and Legal Responsibilities on October 26, 1977, at the Massachusetts Institute of Technology. Mr. Field is Associate Professor at the Franklin Pierce Law Center in Concord, New Hampshire. Mr. Piacenza is a second-year student at the Law Center.

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The Expanding Scope of Personal Criminal Liability of Corporate Executives— Some Implications of United States v. Park

By S. PRAKASH SETHI and ROBERT W. KATZ

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ON JUNE 9, 1975, the United States Supreme Court upheld the conviction of John R. Park, President of Acme Markets, Inc., Philadelphia, for rat contamination found by Food and Drug Administration (FDA) inspectors in the supermarket chain's Baltimore warehouse. The Court decided that the Chief Executive of a Corporation can be found personally guilty of criminal charges if unsatisfactory conditions anywhere in his company contaminate food or otherwise endanger health or safety.[1]

The *Park* case was the latest in a long string of cases that have consistently broadened the scope of the liability of a corporate

[1] *United States v. John R. Park*, 421 US 658, 44 L Ed 2d 489 95 S. Ct. 1903 (1975).

executive originally set forth in *United States v. Dotterweich*[2] which held a corporate president personally criminally liable under the Federal Food, Drug, and Cosmetic Act[3] (hereinafter referred to as "The Act") for introducing adulterated and misbranded products into interstate commerce even though there was no prior knowledge, criminal intent, or involvement on the part of the executive.[4]

Both the scope and reach of "The Act" under the *Dotterweich* doctrine is now all-inclusive and far-reaching. Not only does it cover drugs, but also foods and cosmetics as well.[5] Furthermore, its reach includes corporate officers, partners, manufacturers, distributors-wholesalers, retailers, and warehouse operators. In fact, any "responsible" person under the Act is subject to absolute and vicarious liability for theoretically any violation of the Act.[6]

This paper is an attempt to analyze some recent developments in the area of personal legal liability of corporate executives and its implications for corporate management and public policy. Although not novel in its conception, the notion of holding an executive personally liable for the actions of his company and employees which may be held to be in violation of a particular law is receiving increasing currency in a spate of new laws enacted by the Congress in the last few years.[7] The broad expansion in the scope of personal

[2] "The purposes of this legislation (Food and Drug Administration Act, 1938) thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words. . . Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of larger good, it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger. . ." Justice Frankfurter in *United States v. Dotterweich*, 320 U. S. 277, 280-81 (1943).

[3] Federal Food, Drug, and Cosmetic Act Sec. 1, 21 USC Sec. 301 (1970).

[4] For a brief history of the evolution of the concept of absolute and vicarious criminal liability of corporate executives under "The Act" and the *Dotterweich* doctrine see, Daniel O'Keefe, Jr., and Marc H. Shapiro, "Personal Criminal Liability under the Federal Food, Drug, and Cosmetic Act, The Dotterweich Doctrine," 30 FOOD DRUG COSMETIC LAW JOURNAL 5 (January 1975).

[5] Id. at 18.

[6] Id.

[7] A survey of 27 Federal health or safety-related statutes incorporating criminal penalties for corporate executives was reported in O'Keefe and Shapiro, supra note 4, 51-78. The statutes cited were: Federal Food, Drug, and Cosmetic Act (1938, 1962); Filled Milk Act (1923); Imported Milk Act (1927, 1940, 1953); Egg Products Inspection Act (1970); Poultry Products Inspection Act (1957, 1968); Meat Inspection Act (1907, 1967); Diseased Livestock and Poultry Act 21 USC § 122 (1884, 1926, 1928, 1962); Animal Quarantine Act 21 USC § 122 (1903); Diseased Livestock and Poultry Act 21 USC

(Continued on next page.)

criminal liability of corporate executives, without direct involvement, knowledge or intent, presumably rests on the assumption that it would act as an effective deterrent to corporate conduct that is contrary to public welfare.

Unfortunately, there have been no systematic studies to show the deterrent effect of personal criminal penalties when applied to corporate law violations. Analogies can be drawn only from criminal law where the effects of incarceration on overall crime prevention are not clear. True, any expansion of the imposition of criminal liabilities on corporate executives should be carefully studied in terms of its probable impact on achieving desired corporate behavior, keeping in perspective the negative effects it might have on corporate efficiency and thereby economic and social welfare of millions of people. History also shows that such laws are not easily enforced to their maximum limits, and the penalties imposed are often small and symbolic. An executive's peer group and large segments of society may not view his actions as criminal, thereby negating any deterrent effect through setting an example. Last, but not least, an over-emphasis on personal criminal liability for corporate executives may distract us from a serious consideration of other measures that might be more effective in directing corporate behavior in directions considered more socially desirable.

Issues For Analysis

The decision of the Supreme Court in *United States v. John R. Park* has substantial implications for both executives and corporations in such areas as organizational structures and decision-making processes, centralization and decentralization of authority within the corporation, product innovation, and marketing strategies. It intro-

(Footnote 7 continued.)
§ 134 (1962); Transportation of Quarantined Animals 21 USC § 124-127 (1905, 1928, 1962); Importation of Diseased Animals 21 USC § 104 (1890); Virus, Serum and Toxin Act (1913); Drug Abuse Prevention and Control Act (1970); Federal Water Pollution Control Act (1948, 1972); Clean Air Act (1955, 1962, 1965, 1967, 1970); Consumer Product Safety Act (1972); National Traffic and Motor Vehicle Safety Act (1966); Radiation Control for Health and Safety Act (1944, 1968); Economic Poison Control Act (1947, 1959, 1964, 1970, 1972); Environmental Pesticide Control Act (1947, 1972); Federal Hazardous Substances Act (1960, 1966); Flammable Fabrics Act (1953, 1967); Poison Prevention Packaging Act (1970); Federal Aviation Act (1958); Occupational Safety and Health Act (1970); Federal Coal Mine Health and Safety Act (1969); Fair Packaging and Labeling Act (1966); Federal Trade Commission Act (1914, 1938, 1950). The first year listed in the parentheses denotes the year in which the statute was first enacted. The subsequent years denote the dates when an act was significantly amended.

duces a new element of uncertainty into the chief executive's discretion in dealing with corporate internal affairs and creates further strains in the interaction between corporations and other social groups, including government agencies.

(1) What are the economic, social, and political implications of a broad expansion in the scope of personal criminal liability of corporate officers for the activities of their subordinates? How might it affect the ability of the private sector to respond effectively to social problems and social pressures for change?

(2) What types of organizational structures and decision-making processes should be developed to maximize the discovery of illegal actions by subordinates without unduly restricting their initiative and discretionary decision-making? Should changes be made in a company's reward system to discourage employees from engaging in activities that could be illegal or have the potential of exposing the company and its officers to civil and criminal penalties?

(3) Under what circumstances should a corporate officer be held personally liable for acts of his subordinates? Should the liability be related to personal knowledge or awareness of criminal wrongdoing on the part of all employees in the organization? Should such liability be limited to certain classes of company activities, such as food adulteration, or should it cover all activities?

(4) Are there certain marketing and promotional practices which are especially susceptible to causing public harm out of proportion to their contribution to the company's growth and profits? What kinds of safeguard mechanisms can be built within the company organization so that the second-order effects of such practices are carefully evaluated before these marketing practices are implemented?

Facts of the *Park* Case

Acme Markets Inc. is a national retail food chain. It has approximately 36,000 employees, 874 retail stores and 16 warehouses in various parts of the United States. Its headquarters and the office of the president are located in Philadelphia, Pennsylvania. Acme's "Division 6" was headed by a divisional vice-president, Robert W. McCahan, with his office in Towson, Maryland; it consisted of a warehouse complex in Baltimore and approximately 110 retail outlets. The Baltimore warehouse complex was approximately 250,000 square feet including an older building of three stories with a basement.[8]

[8] *United States v. John R. Park*, No. 74-215, Petition for a writ of Certiorari to the United States Court of Appeals for the Fourth Circuit (1974), 5.

In November-December, 1971, a Federal FDA investigator, upon investigation of the basement of the company's Baltimore warehouse "found extensive evidence of rodent infestation in the form of rat and mouse pellets throughout the entire perimeter area and along the wall." He also found that the doors leading to the basement of the warehouse from the rail-siding had openings large enough to permit the entry of rodents. Rodent pellets were found on a number of different packages of boxes of various items stored in the warehouse. At a later date, the investigator was able to establish that he had seen other unsanitary conditions such as rat and mouse leavings and nesting material in and around food, live and dead rodents in the warehouse, and liquid drain cleaner stored near cooked ham. Extremely overcrowded conditions and accumulated trash were also evident.

Following the inspection, Dr. Norman Kramer, Chief of Compliance of the FDA's Baltimore office, wrote to Park on January, 1972, advising him of the conditions at the Baltimore warehouse. The letter specifically informed Park that the Baltimore warehouse was "actively and extensively inhabited by live rodents" and that these conditions had "obviously existed for a prolonged period of time without any detection, or were completely ignored."[9] Dr. Kramer also sent a copy of the letter to Robert W. McCahan, Vice-President of the Acme Baltimore division. On February 7, 1972, McCahan upon the direction of Park, responded to the letter from Dr. Kramer. The letter claimed that the warehouse and adjacent property were cleaned, that increased efforts were made in baiting for rodents, that the building was inspected, and rodent entry points repaired, hazardous household products were relocated away from food products, and additional cleaning equipment had been purchased, and additional personnel hired to keep the warehouse clean. In March, 1972, the FDA conducted a second inspection of the Baltimore warehouse. The inspector noted some improvement in the sanitary conditions of the warehouse but nonetheless still found evidence of rodent infestation. The warehouse still contained rodent nesting material, dead rodents, damaged liquid bait traps, poorly fitting exterior doors and rodent contaminated food products. Subsequent to the second inspection, a second letter was sent by the FDA to Park with a copy to McCahan. McCahan again responded and stated that close to $70,000 had been expended, the said $70,000 including the cost of merchandise destroyed,

[9] *United States v. John R. Park*, No. 74-215, on writ of Certiorari to the United States Court of Appeals for the Fourth Circuit, Brief for the United States (1974), 5.

cost of new doors, rodent proofing alterations, automatic sweeping equipment, hiring of additional personnel and other items. In June, 1972, there was a meeting at the Baltimore office of the FDA which was attended by McCahan and other officers of Acme. Park was not present.[10]

The Legal Proceedings

The District Court (For the District of Maryland at Baltimore)

In March, 1973, the United States filed a suit against Acme and Park charging them with five counts of violations of Section 301(k) of the Food, Drug, and Cosmetic Act.[11] The first four counts in the indictment related to violations discovered during the November and December, 1972 inspection. The fifth count related to the March, 1972 inspection. This action was one of two similar prosecutions filed within a year after the release of a report by the Comptroller General of the United States recommending increased enforcement by the FDA.[12]

[10] *United States v. John R. Park*, No. 74-215, on writ of Certiorari to the United States Court of Appeals for the Fourth Circuit, Brief for Respondent (1974), 5-6.

[11] Section 301(k) of the Federal Food, Drug and Cosmetic Act of 1938, 52 Stat. 1042, as amended, 21 USC 331(k) provides: The following acts and the causing thereof are prohibited:

(k) The alterations, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

Sections 303(a) and (b) of the Federal Food, Drug, and Cosmetic Act of 1938 52 Stat. 1043, as amended, 21 USC 333(a) and (b) provide:

(a) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000.00 or both.

(b) Notwithstanding the provisions of subsection (a) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such a person shall be imprisoned for not more than three years or fined not more than $1,000.00 or both.

Section 402(a) of the Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1046, as amended, 21 USC 342(a), provides in part:

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

[12] Comptroller General of the United States, *Dimensions of Insanitary Conditions in the Food Manufacturing Industry, Report to the Congress*, No. B-164031 (a) (April 18, 1972). The other case involved Food Fair, Inc. headquarters in Philadelphia, Pennsylvania and a Food Fair vice-president based in Towson, Maryland. Both were charged with violations of sections 301(k) of the Federal Food, Drug, and Cosmetic Act, based on the presence of rodents in Food Fair's Baltimore warehouse. The charges

(Continued on next page.)

Acme pleaded guilty to all five counts in the information. Park pleaded not guilty and sought to determine the basis upon which the government alleged liability. The government responded by stating that the evidence "will not show that the defendant, (Park) personally performed the acts" described in the information but that the "Government's evidence will simply show that the defendant was a corporate officer who, under law, bore a relationship to the receipt and storage of food which would subject him to criminal liability" under the principles set forth in *United States v. Dotterweich*,[13] a decision of the U. S. Supreme Court issued in 1943.[14]

There was a jury trial. At the trial, all parties stipulated that the items of food described in the information had been shipped in interstate commerce and were being held for sale in the Baltimore warehouse. The following points were made:

For The Prosecution: The Government's case was that "Mr. Park was responsible for seeing that sanitation was taken care of, and he had a system set up that was supposed to do that. This system didn't work three times. At some point in time, Mr. Park has to be held responsible for the fact that his system isn't working."[15]

(1) The Government showed that Park was aware of the sanitation problems in the Baltimore warehouse having received the correspondence from the FDA with copies to McCahan, and McCahan's responses to the FDA's communications.

(2) Park acknowledged that on March 24, 1970, he was advised by the FDA that discarded paper and other debris, providing potential rodent harborage, ill-fitting doors providing potential rodent entryways, and "rodent nesting, rodent excretion pellets, rodent stained bale bagging and rodent gnawed holes" had been observed at Acme's Philadelphia warehouse.

(3) Through cross-examination of Park, the prosecution showed that with the exception of the divisional vice-president, the same corporate officials had responsibility for sanitation in both Baltimore and Philadelphia.

Park conceded that sanitation "is a thing that I am responsible for in the entire operation of the company" and stated that he assigned this phase of the company's operation to "dependable subordinates."[16]

(Footnote 12 continued.) against the individual corporate officer were subsequently dismissed at the request of the government. Food Fair, Inc. pleaded guilty. Supra note 10 at 4-5.

[13] *United States v. Dotterweich*, 320 U. S. 277 (1943).

[14] Supra note 10 at p. 7.

[15] Supra note 9 at 9-10.

[16] Id. at 16.

Park admitted that since the same problem with regard to sanitation occurred twice, once in Philadelphia and then again in Baltimore, it would indicate that the system that he had set up for handling sanitation, a system of delegated responsibilities, was not working. He also said that although he would consider McCahan responsible for the failure of the system in Baltimore, ultimately he, Park, was responsible. Being the Chief Executive officer, ultimately he was responsible for the entire organizational structure, and for bringing about any changes in the system.[17]

(4) The Government also established that the Company's bylaws provided that the chief executive officer shall have "general and active supervision of the affairs, business, offices and employees of the company."[18]

For The Defense: Counsel for respondent Park contended that as the president of a large 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.[19]

The basic facts were clearly established and not in dispute. The corporation had pleaded guilty to the five counts. Thus, it appeared quite clear that in the case against Park, the government had no difficulty in establishing the existence of the unsanitary conditions. There was objection to introduction into evidence of the earlier finding of unsanitary conditions in March, 1970, at the Philadelphia warehouse of Acme. The government argued that admission into evidence of the existence of the unsanitary conditions in 1970 was for the purpose of demonstrating that Park had prior knowledge of unsanitary conditions in the Acme warehouses.

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[17] Supra note 9 at 8-9.

[18] The bylaws provided in pertinent part:

"The Chairman of the board of directors or the president shall be the chief executive officer of the company as the board of directors may from time to time determine. He shall be subject to the board of directors, have general and active supervision of the affairs, business, offices and employees of the company. . . .

"He shall from time to time, in his discretion or at the order of the board, report the operations and affairs of the company. He shall also perform such other duties and have such other powers as may be assigned to him from time to time by the board of directors." *United States v. John R. Park*, 421 US 658, 44 LEd 2d 489, 95 S. Ct. 1903, (1975) at 495.

[19] *United States v. John R. Park*, 421 US 658, 44 L Ed 489, 95 S. Ct. 1903 (1975) at 503-504.

After presentation of the prosecution's case, Park moved for judgment of acquittal as he did after the close of the presentation of evidence and again after the verdict against him.

Counsel for respondent Park also argued that (1) "Statutes such as the ones the Government sought to apply in the *Park* case were criminal statutes and should be strictly construed," and (2) the fact that John Park was president and chief executive officer of Acme Markets, Inc., "does not itself justify a finding of guilty under Counts I through V of the Information."[20] The jury found Park guilty on all five counts of the information and the court sentenced Park to a fine of $50 on each count for a total of $250.00. Park appealed.

Decision Of The Court Of Appeals For The Fourth Circuit

Park's major contention on his appeal was that the district court erred in its instructions to the jury. He also contended that the prejudicial evidence of warnings of alleged prior violations of the Act was improperly admitted.

The district court's instructions to the jury read, in part, as follows:

"In order to find the Defendant guilty on any count of the Information, you must find beyond a reasonable doubt on each count, that the food that was held, was held for sale in the Acme warehouse after shipment in interstate commerce. *Secondly*, that the food involved was held in unsanitary conditions . . . *Thirdly*, that John R. Park held a position of authority in the operation of the business of Acme Markets, Inc. However, you need not concern yourselves with the first two elements of the case. The main issue for your determination is only with the third element, whether the *defendant held a position of authority and responsibility in the business of Acme Markets.* (Emphasis added).

The corporation, Acme Markets, Inc. has already entered a plea of guilty to the charge placed against it, and while that plea does not imply . . . the defendant, Park is guilty, the fact that . . . foods (were) held under unsanitary conditions are issues that are beyond questions in the case and must be accepted by you.

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

The individual is or could be liable under the statute even if he did not consciously do wrong. However, the fact that the Defendant is present and is a chief executive officer of the Acme Markets does not require a finding of guilt. Though, he need not have personally participated in the situation, he must have had a responsible relationship to the issue. *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.* (Emphasis added)."[21]

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[20] *United States v. John R. Park*, 421 U. S. 658, at 503.

[21] Supra note 10 at 9-10.

Park's counsel objected to the instructions on the ground that they were not consistent with this Court's decision in *Dotterweich* and did not sufficiently define the standards applicable to Park's responsibility. However, the District Court judge overruled the argument saying that *Dotterweich* and subsequent cases had indicated that the definition of the "responsible relationship" was really a jury question . . . and not even subject to being defined by the Court."[22]

It has long been established as a principle of law that in order for a court to find criminal liability to be present, there must be an intent and deliberate or aware wrongdoing. Park argued that there was not intent on his part to violate the statute and in addition, there was no overt wrongful action which could be construed either as negligence or inattention to discharging his duties. Thus, to impose a liability upon a person who was "responsible" but was not in direct proximity or actual involvement with the alleged wrongdoing was a departure from the established common law principles of criminal liability in the absence of wrongdoing in view of the statutory provisions. Park had testified that he had employed a system through which he relied upon his subordinates and that he was ultimately responsible for the system. He further testified that the subordinates had invariably been dependable and justified his confidence. He further stated 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. It was clear that violation of the Act had occurred and that Park's system apparently had indeed broken down.

A divided court of appeals reversed the judgment, the judgment of conviction and remanded the case for a new trial. The majority held that the charge did not correctly state the law as declared in *United States v. Dotterweich*.[23] The Court of Appeals held that *Dotter-*

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[22] *United States v. John R. Park*, No. 74-215, 11.

[23] *United States v. Dotterweich*, 320 U. S. 277 (1943).

In the *Dotterweich* case, the Supreme Court in a five-to-four decision held that individual corporate officers and employees, as well as corporations, may be convicted for doing or causing the acts prohibited in Section 301 of the Federal Food, Drug, and Cosmetic Act of 1938, 21 USC 331. In that decision, this Court also restated the standard of responsibility for the corporate officers and agents through whom corporations handling food and drugs must act: those standing in a responsible relation to the prohibited acts may be criminally liable for failure to take steps to prevent their occurrence, even though the officers are not aware of wrongdoing.

As *Dotterweich* was postured when it reached the Supreme Court the primary question was whether "only the corporation was the 'person' subject to prosecution" under the Act. Therefore, the Supreme Court's opinion reveals very

(Continued on next page.)

weich dispensed with the need to prove "awareness of wrongdoing" by Park but did not dispense with the need to prove that Park was "in some way personally responsible for the act constituting the crime." The Court concluded that since the statute prohibits "causing" the adulteration of food, the conduct required to be proved would be "acts of the accused which *cause* the adulteration of such food." (Emphasis by the court of appeals). The court enlarged upon this standard by stating that such "action" by respondent "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 which would "cause" the contamination of the foods."[24] The court concluded that Park's conviction must be reversed because the jury instruction "might well have left the jury with the erroneous impression that Park could be found guilty in the absence of 'wrongful action' on his part."[25]

In response to the contention that the requirement of such proof would make enforcement more difficult, the court stated: "Nevertheless, the requirements of due process are intended to favor fairness and justice over ease of enforcement. We perceive nothing harsh about requiring proof of personal wrongdoing before sanctioning the imposition of criminal penalties."[26]

The court also held that the evidence of the alleged prior violation in Philadelphia in 1970 not charged in the information should have been excluded as unduly prejudicial because, as the case was

(Footnote 23 continued.)
little about the factual setting in that case. Mr. Dotterweich was president and general manager of Buffalo Pharmacal Company, Inc. He was charged with three counts of violation of the Act. His company was small, employing only twenty-six persons, all of whom worked on one upper floor of the building. Mr. Dotterweich was responsible for "general overseeing" of the company operations; he was the direct supervisor of all employees. The trial transcript establishes that Mr. Dotterweich personally made every executive decision and had direct personal supervisory responsibility over the physical acts which resulted in the interstate shipment of misbranded and adulterated drugs. (These drugs were manufactured by another firm, then repackaged and sold by Buffalo Pharmacal Company.)

The jury in the original trial found Dotterweich individually guilty, but did not find the company guilty. Dotterweich had argued that he was not a "person" within the meaning of the act and that he had not had prior notice of potential liability. The Court of Appeals reversed the trial court's decision on this basis, because Dotterweich had not been derelict or perpetrated the wrong. But the Supreme Court ruled that Dotterweich could be held liable, thus setting a precedent for criminal responsibility of corporate officials as individuals, rather than any such liability's being limited (as previously) to the corporation as an entity.

[24] *United States v. John R. Park*, 499 F. 2d 839-842 (1974).

[25] Id. at 841-42.

[26] Id. at 842.

tried and submitted to the jury, "there was no actual need for the Philadelphia evidence."[27] The Court expressly allowed the district court on retrial "to determine the admissibility of this 'prior crime' evidence in light of developments."[28]

Judge Craven dissented on the ground that "this case is controlled by *United States v. Dotterweich,* (320 U. S. 277-1943)."[29] He explained:

"* * * Park was not just "remotely entangled" in the proscribed adulteration. Like Dotterweich he was president of the corporation with full power to control its operations and to take measures to prevent rat infestation of food. Although he had delegated the day-to-day supervision of sanitation to subordinates, Park retained both the power and responsibility to see that the system of rodent control was effective, and if it didn't work to change it."[30]

He noticed that the government had made "no effort to equate the presidency of the corporation with the responsibility. Instead the government argued that Mr. Park was responsible because he had established a system of rodent control that did not work in March, 1970, November, 1971 and March, 1972, and that even so, he made no effort to change or improve the system."[31] Finally, he stated that "if the FDA is required to show that Park 'acted wrongfully,' evidence of prior violations would clearly be admissible or the FDA could not possibly sustain its new burden of proof.[32]

Before The Supreme Court

In August, 1974, the United States filed a petition with the U. S. Supreme Court asking for a writ of certiorari against the Appeals Court's decision. The U. S. petition contended that in *Dotterweich,* the Court had cautioned that in construing Section 301 "(l)iteralism and evisceration are equally to be avoided" (320 U. S. at 184). Notwithstanding, the court of appeals gave an unduly rigid reading to Section 301(k). Furthermore, for thirty years, since *Dotterweich,* officials of business entities whose activities affect the public health have been subjected to the highest standards of public accountability. This standard has prevailed and has not been changed by Congress.[33]

In its brief, the U. S. argued that the 1938 Act made responsible officials criminally liable for failure to discover and correct unsanitary conditions because they have the power and responsibility to prevent such conditions, and have failed to do so. Further, the Act "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good, it puts the

[27] *United States v. John R. Park,* 499, F. 2d 843 (1974).
[28] Id.
[29] Id.
[30] Id. at 844.
[31] Id.
[32] Id. at 845.
[33] Supra note 8 at 8.

burden of acting at hazard upon a person otherwise innocent but standing in a responsible relation to a public danger."[34] The concept of responsible relation thus served to limit the application of the Act to those corporate officials who had the power and responsibility to prevent unsanitary conditions. By the same token, it allowed an apparently responsible corporate official to prove, as a matter of defense, that he was without power to affect the prohibited condition.[35] The holding of the Court of Appeals in the Park case would, therefore, substantially distort this statutory scheme.[36]

The standard of care and the criteria of criminal responsibility enunciated in *Dotterweich* and *Wiesenfeld* were those intended by Congress. The legislative history of the 1938 Act and subsequent action by Congress confirm this understanding.[37]

The 1938 Act contemplated reasonable exercise of prosecutorial discretion in the administration and enforcement of the Act. Further, that the prosecution of Park was reasonable and his conviction was supported by the evidence; and, the evidence of prior unsanitary conditions at another warehouse was admissible to rebut Parks' defense of good faith reliance on his subordinates.[38]

In his brief, Park contended that the appeals court was correct in reversing the district court's decision. In his charge to the jury, the district court twice instructed the jury that the main or only matter for their determination was whether the defendant, Park, held a position of authority and responsibility at Acme Markets. However, since Park was selected for prosecution because he was president and chief executive officer of Acme Markets, this position had already been established. This portion of the charge was therefore "contrary to the fundamental principle, 'that a judge may not direct a verdict of guilty no matter how conclusive the evidence.' *United Brotherhood of Carpenters v. United States*, 330 U. S. 395, 408."[39]

Respondent Park also contended that:

(a) The charge was contrary to the statute as construed by the Supreme Court in the *Dotterweich* decision.[40]

(b) The charge also failed to provide "appropriate guidance" or any other meaningful standard for the jury.[41]

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[34] *United States v. Balint*, 258 US 250, 281 (1922). See also Supra note 9 at 20.

[35] *United States v. Weisenfeld Warehouse Company*, 376 US 86 (1964). See also supra note 9 at 23.

[36] Supra note 8 at 23.

[37] Id. at 26.

[38] Id. at 30-42.

[39] Supra note 10 at 39.

[40] Id. at 17.

[41] Id. at 22.

(c) The criminal liability of an individual charged under the statute is never a vicarious liability for the conduct of others. The FDA has rarely, if ever, established criminal liability in cases which did not involve facts showing "their personal responsibility" which the Court of Appeals required be established on retrial in the present case. All the reported decisions relied upon in the Government's brief involved such facts as to the individuals named as defendants.[42]

(d) No impractical burden is imposed by requiring proof of acts of omission which cause the offenses charged because the government has always previously required evidence of such acts as a condition to prosecution of corporate officers.[43]

(e) Evidence of alleged prior crimes should have been excluded at the first trial and should be admissible at a subsequent trial only if the need for such evidence outweighs prejudicial effect.[44]

Amicus Curiae Briefs by Trade Associations

In view of the importance of the *Park* case and its potential implications for other companies and industries, a number of trade associations filed *Amicus Curiae* briefs before the Supreme Court. The associations filing briefs were, The National Association of Food Chains (NAFC), Grocery Manufacturers of America, Inc. (GMA), Synthetic Organic Chemical Manufacturers Association (SOCMA), The National Canners Association (NCA). There was no brief filed on behalf of the pharmaceutical industry, although it would appear that their stake in the outcome of the case would be quite important.

Summary of NAFC Briefs

The National Association of Food Chains, Inc. (NAFC) submitted its *Amicus Curiae* brief because of the concern of its members with the matter before the Court.[45] The members of the Association engaged in numerous activities subject to the Act, 21 USC 301 *et. seq.*, including warehousing and distributing food products to individual

[42] *United States v. John R. Park*, No. 74-215, at 31-32. Supra note 9 at 25-26. See also *United States v. H. B. Gregory Co.*, 502 F. 2d 700, petition for a writ of *Certiorari* pending, No. 74-142; *United States v. Shapiro*, 491 F. 2d 335-337 (CA-6); *Lelles v. United States*, 241 F. 2d 21, *certiorari* denied, 353 U. S. 974; *United States v. Cassaro Inc.* 443 F. 2d 600 (CA-7); *United States v. Parfait Powder Puff Co.*, 163 F. 2d 1008 (CA-7); *certiorari* denied, 332 U. S. 851; *United States v. Diamond State Poultry Co.*, 125 F. Supp. 617 (DC Del.).

[43] Supra note 10 at 32.

[44] Id. at 33.

[45] *United States v. John R. Park*, No. 74-215, on writ of Certiorari to the United States Court of Appeals for the Fourth Circuit, Brief *Amicus Curiae* of the National Association of Food Chains, Inc. (1974).

stores. NAFC members are also extensively engaged in food processing activities such as the operation of dairies, bakeries, coffee plants, and canneries.

NAFC's brief states that the case before the court concerns the responsibility of top-level management for warehouse sanitation. In order to provide guidance to its members in this important area, NAFC has recently taken responsibility for coordinating the efforts of seven trade associations and the FDA of the Department of Health, Education, and Welfare in the preparation and publication of Voluntary Industry Sanitation Guidelines for Food Distribution Centers and Warehouses.

The implications of this case, however, extend beyond the issue of warehouse sanitation and the application of Section 301(k), 21 USC 331(k). The decision in this case will have a direct impact on the extent of criminal prosecution for all offenses under the Act. As presented to the Court, the issue is whether or not an individual can be held criminally liable for a corporate violation of the Act where there is no evidence of his participation in the alleged violation.

The brief does not question whether an individual employee should be subject to criminal sanctions under the Act, where through some act or omission on his part, a food product was unlawfully adulterated or misbranded. Where, however, a corporate officer or other employee has diligently undertaken to establish and implement a comprehensive compliance program, neither the statute nor prior cases requires that he be convicted of a criminal offense. To the contrary, the underlying purpose of the Act, purity and accurate labeling of food, should encourage such comprehensive compliance. This purpose would be ill-served by a construction of the Act which would subject a company employee to criminal punishment for inadvertent, often unavoidable, violations without regard to the comprehensiveness of the compliance program which he has established or the diligence of his supervisory efforts.

NAFC's interest in this case, thus, derives from a basic conclusion that effective compliance with the Act will best be obtained by requiring a high standard of effort as evidenced in part, by its warehouse sanitation guidelines. The Government's advocacy of an absolute criminal liability rule based solely on an individual's corporate position adds nothing to an individual's corporate position, adds nothing to effective compliance, and, in fact, may detract from it.

The United States Court of Appeals for the Fourth Circuit established a correct, practical, and equitable standard which will result in better compliance with the Act.

Summary of the GMA Brief

The Grocery Manufacturers of America, Inc. (GMA) is a trade association of the leading manufacturers and processors of food and non-food products sold in retail grocery outlets throughout the United States. GMA represents the interests of its member companies in administrative, judicial, and legislative proceedings. The GMA brief states that the food industry shares with the FDA the goal of providing safe, wholesome, nutritious, and properly labeled foods.[46] To that end, GMA seeks to take a positive, constructive view of the roles and duties of its members in terms of compliance with the spirit as well as the letter of the law. For example, GMA in March, 1974, published "Guidelines for Product Recall," a comprehensive manual to assist companies in improving their procedures for undertaking voluntary product withdrawals for any reason. In 1974, GMA also joined the FDA and six other food trade associations in publishing "Voluntary Industry Sanitation Guidelines for Food Distribution Centers and Warehouses," and sponsored regional public seminars on warehouse sanitation for industry members.

The case at bar raises a vital issue regarding the definition and scope of potential criminal liability for corporate officers arising out of company violations of the Act. GMA's member companies have a direct, major interest in the resolution of this issue, since pertinent statutory provisions apply to all food processors.

The brief asserts that the Court of Appeals below provided strict but practical standards by requiring that individual criminal liability must rest on proof of the responsible individual's own "wrongful action," whether by deed or omission. By contrast, the Justice Department exploits the facts at bar to assert a vague "test of constructive participation" which would expose corporate officers to criminal prosecution at the bureaucratic discretion of enforcement officials without published "guidelines," "criteria," or "standards."

Such an authorization for harsh and arbitrary criminal prosecutions under the Act, based on corporate status rather than individual

[46] *United States v. John R. Park*, No. 74-215, on writ of Certiorari to the United States Court of Appeals for the Fourth Circuit, Brief *Amicus Curiae* for the Grocery Manufacturers of America, Inc. (1974).

"wrongful action" and shifting the burden of proving innocence to the accused, is offensive to established principles of fairness and justice and can serve no legitimate regulatory objective.

Summary of the SOCMA Brief

The Synthetic Organic Chemical Manufacturers Association (SOCMA) is an industry association of 72 member companies engaged in production of synthetic organic chemicals. A number of such chemicals constitute or are used in products subject to regulation under the provisions of the Act. SOCMA and its member companies thus have an interest in the interpretation accorded the Act, and in even-handed, non-discriminatory enforcement of its provisions.[47]

The brief contended that the Court of Appeals was right in separating the issue of vicarious liability from that of strict liability under the Act and correctly analyzed the decision of this Court in *Dotterweich* as requiring a factual nexus between the conduct of an officer of a company and the violation before holding the officer personally liable. *Dotterweich* interpreted the Act as dispensing with *mens rea* and thus imposed a strict liability for violations. However, the decision in that case made clear that to hold an officer liable, his conduct must bear a "responsible relation" to the offense.

The trial court accepted the Government's theory of vicarious responsibility and under its instruction, the jury could have found Park liable by reason of his position as president without any showing of factual nexus to the violation by conduct. The Government has now retreated minimally from its trial position of combining vicarious liability with strict liability and is asking the Court to endorse the unsound principle that the constitutional requirement that the Government prove its case beyond a reasonable doubt is satisfied by a showing of the title of an officer and the broad scope of his duties under company by-laws without any showing of personal acts or conduct which provide a factual nexus with the violation. It is up to the officer then, the Government proposes, to bear the burden of showing he was "powerless" in the situation.

The Court should reject the Government's attempt to misuse the phrase "responsible relation," which this Court used in *Dotterweich* to describe the requisite element of personal conduct or action,

[47] *United States v. John R. Park*, No. 74-215, on writ of Certiorari to the United States Court of Appeals for the Fourth Circuit, Brief *Amicus Curiae* for the Synthetic Organic Chemical Manufacturers Association (1974).

as a device for imposing vicarious responsibility. This case demonstrates the unsoundness of the Government's contention that the basic issue of vicarious criminal liability can be solved by trusting the discretion of the prosecutor.

Summary of the NCA Brief

The National Canners Association (NCA) is a nonprofit trade association of approximately six hundred members who have canning operations in forty-four states and the territories. Members of the Association pack eighty to ninety percent of the entire national production of canned fruits, vegetables, juices, specialties, meat, and fish. Many aspects of its members' operations are subject to the requirements of the Act and numerous comprehensive and technologically complicated regulations promulgated thereunder.

The brief states that this case involved the standard of individual criminal liability under the Act applicable to officers and employees of a corporation when violations of the Act and the extensive regulations under it occur in the course of the corporation's business.[48]

Nearly all of the Association's members are corporations whose officers and employees may be directly affected by the articulation of that standard by this Court. The Association believes that any penal standard must protect both consumers and the rights of the officers and employees of its members. Since, under the Act, individuals may be sentenced to prison (Sec. 303 (a)), and on second conviction are branded as felons (Sec. 303(b)), special considerations of justice and fair play must be taken into account in defining that standard. Since these considerations are largely inapplicable to corporations, the Association's view expressed here are limited to the question of individual criminal liability. Since *Dotterweich*, the country's economy has evolved to a point where most of the goods covered by the Act are produced and distributed by corporations having chains of management command which necessarily function by delegation. Many members of the Association have scores of packing plants and warehouses located throughout the nation and employing tens of thousands of employees. The management of these companies must necessarily function by delegating operational authority to subordinates, in large part, because of the physical separation between management, usually

[48] *United States v. John R. Park*, No. 74-215, on writ of Certiorari to the United States Court of Appeals for the Fourth Circuit, Brief *Amicus Curiae* for the National Canners Association, Washington, D. C. (1974).

located at a corporate headquarters, and the various processing operations, which must be located close to where different crops are grown.

Another factor which has led to an increased need for delegation of operational authority, particularly with respect to compliance with the Act, has been the increasingly complex technical requirements imposed by the FDA under the Act since *Dotterweich*. These now fill six volumes of the Code of Federal Regulations (CFR).[49] In the case of the canning industry, regulations prescribe virtually every step of the canning process and are so technical and complex that they are literally unintelligible to those who lack complete technological training in these areas.

One need merely examine, as an example, the regulations applicable to "Thermally Processed Low-Acid Food Packaged in Hermetically Sealed Containers (21 CFR Part 90 (1974); 21 CFR Part 128b (1974)), to comprehend that only a specially trained individual can be expected to understand and implement those requirements. Indeed, the regulations specifically provide that the processing be conducted:

". . . . under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction in report operations, processing systems operations, aseptic processing and packaging systems operations and container closure inspections, and has been identified by that school as having satisfactorily completed the prescribed course of instruction." 21 CFR 128b. 10.

Similarly detailed regulations, the interpretation of which may require medical, engineering, statistical and other forms of technical expertise, apply to the manufacturing and labeling of drugs, cosmetics and medical devices.[50]

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[49] 21 CFR 1-1401-73 (1974).

[50] See, e.g., the current labeling requirements for certain medical diagnostic devices. 21 CFR 328.10 (1974). Among the most detailed of the FDA's current labeling schemes, four pages of these regulation lists required labeling information including:

"Details of calibration: Identify reference material. Describe preparation of reference samples, use of blends, preparation of the standard curve, etc. The description of range of calibration should include the highest and the lowest values measurable by the procedure.

Expected values: State the ranges of expected values as obtained with the product from studies of various populations. Indicate how the ranges were established and identify the populations on which it was established.

Specific performance characteristics: Include as appropriate, information describing such things as accuracy, precision, specificity, and sensitivity. These shall be related to a generally accepted method using biological specimens from normal and abnormal populations. Include a statement summarizing the data upon which the specific performance characteristics are based." CFR 328.10 (b) (8) (v) (11) and (12) (1974). These requirements alone require expertise in medicine, chemistry, and statistics.

In some instances, these regulations are unrelated to any hazard to health and involve purely economic issues such as the proper type size and label format in stating net quantities of content in food packages.[51]

Since no company president can be expected to develop the requisite expertise in each of the fields needed to interpret and implement compliance with the bulk of the FDA's present regulations, he must rely on technically trained subordinates. Top management is equally dependent on these qualified personnel for information as to any problems which might arise with respect to compliance. While a layman may be in a position to detect grossly insanitary conditions which are apparent to the naked eye, if he has the opportunity personally to scrutinize every canning plant or warehouse, he must rely on the assurances of others on such questions as whether sufficient samples are being tested to support a statistically sound quality control program.

It is against this background, the brief states, that trial courts today must consider and charge juries as to the circumstances under which it is consistent with the intent of Congress and the purposes of the Act to impose absolute criminal sanctions, absent knowledge or intent, on chief executive officers and other management personnel for corporate violations, which may be used on a failure of a remote subordinate to conform to one of the massively detailed and technically-complex regulations which the FDA routinely and increasingly promulgates under the Act today.[52]

In the cases since *Dotterweich*, where individual defendants have denied having a "responsible share" in the transaction, the reported opinions of trial and appellate courts have generally justified a conviction with little more than a citation to or quotation from the rhetoric in *Dotterweich*. In those cases, it is clear that the individual defendants were intimately involved in and usually present on a day-to-day basis at the local site of the operations giving rise to the violations. Whatever may be said of the manner in which lower

[51] See, e.g., 21 CFR 1.8 b (1974).

[52] Criminal prosecution of individuals under the Act are a frequent, if not everyday occurrence. A recent study of the agency's enforcement activities reveals that in 1973, approximately 90 criminal cases were forwarded to United States attorneys for prosecution and in most, consistent with the FDA's policy, at least one responsible individual was charged. The United States Attorneys and the Department of Justice declined to prosecute only a very small precentage of these cases. See O'Keefe and Shapiro, *Personal Criminal Liability Under the Federal Food, Drug, and Cosmetic Act, The Dotterweich Doctrine*, 30 FOOD DRUG COSMETIC LAW JOURNAL 5, 27, (January 1975).

courts have dealt with that situation, as this case so clearly demonstrates, that approach is no longer adequate, in view of the changes in the regulated industries and the requirements under the Act since *Dotterweich*. One thing is clear. Some defined direction to lower courts is needed.

The difficulties inherent in applying a standard enunciated in a case involving a one-man operation with 26 employees to the realities of today's disparate mass production have prompted some commentators to ask:

". . . Who has, and under what conditions does he have, a responsible share in the furtherance of the transaction which the statute outlaws? When does he 'aid and abet' in the commission of the violative acts? When does he share responsibility in the business process resulting in unlawful distribution?

Sufficient time has elapsed since 1943, sufficient cases have been before the courts, and there is sufficient confusion on the point to warrant Supreme Court guidance. Hopefully, such guidance will be forthcoming from the Court, which has granted *certiorari* in the *Park* case."[53]

The Association believes that the opinion of the Court of Appeals offers both a realistic and just approach to this question and presents this Court with an opportunity to give the lower courts the wise guidance which they will require vigorously yet fairly to apply the criminal sanctions of the Act to individuals.

The Supreme Court Decision

In a six to three decision, the Supreme Court reversed the decision of the Court of Appeals and held that (1) criminal liability under the Act does not turn on awareness of some wrongdoing or conscious fraud and the act permits conviction of responsible corporate officials who have the power to prevent or correct violation, (2) viewed as a whole the jury instruction was adequate, and (3) the evidence that the president had previously been advised of insanitary conditions at the Philadelphia warehouse was admissible since it served to rebut the official's defense that he had justifiably relied upon subordinates to handle sanitation matters.[54]

The main elements of the Court's decision are as follows:

(1) The Court agreed with the prosecution's reading and interpretation of the Supreme Court's earlier decision in *United States v.*

[53] Daniel F. O'Keefe, Jr. and Marc H. Shapiro, "Personal Criminal Liability Under the Federal Food, Drug, and Cosmetic Act, The Dotterweich Doctrine," 30 FOOD DRUG COSMETIC LAW JOURNAL (January, 1975), p. 24.

[54] *United States v. John R. Park*, 421 U. S. 658, 44 L Ed 2d 489, 95 S. Ct. 1903 (1975), 489-490.

Dotterweich. Central to the Court's conclusion (in the *Dotterweich* case) "that individuals other than proprietors are subject to the criminal provisions of the Act "was the reality" that the only way in which a corporation can act is through the individuals who act on its behalf."[55] The Court also noted that corporate officers had been subjected to criminal liability under the Federal Food and Drugs Act of 1906, and it observed that a contrary result under the 1938 legislation would be incompatible with the expressed intent of Congress to "enlarge and stiffen the penal net" and to discourage a view of the Act's criminal penalties as a "license fee for the conduct of an illegitimate business." At the same time, however, the Court was aware of the concern that literal enforcement "might operate too harshly by sweeping within its condemnation any person however remotely entangled in the proscribed shipment." A limiting principle, in the form of "settled doctrines of criminal law" defining those who "are responsible for the commission of a misdemeanor," was available. In this context, the Court concluded, these doctrines dictated that the offense was committed by all who (have) a responsible share in the furtherance of the transaction which the statute outlaws.

The Court recognized that because the Act dispenses with the need to prove "consciousness of wrongdoing," it may result in hardship even as applied to those who share "responsibility in the business process resulting in" a violation. It regarded as "too treacherous" an attempt to define or even to indicate by way of illustration the class of employees which stands in such a responsible relation." The Court said that the Act "in its criminal aspect does not require that which is objectively impossible" and that the Act permitted a claim that a defendant was 'powerless' to prevent or correct the violations. The burden of proof in such cases, however, rested with the defendant.[56] The question of responsibility in such matters depended on the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries must be trusted.[57]

(2) The Court also stated that the rationale of the interpretation given the Act in *Dotterweich*, as holding criminally accountable the persons whose failure to exercise the authority and supervisory responsibility reposed in them by the business organization resulted in the violation complained of had been confirmed in its earlier cases. In order to make distributors of food the strictest censors of their

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[55] *United States v. John R. Park*, 421 U. S. 283. *United States v. Dotterweich*, 320 U. S. at 281 (1943).

[56] *United States v. Park*, 421 U. S. 658-673 (1975).

[57] Supra note 55 at 285.

merchandise, the Act punishes "neglect where the law requires care, or inaction where it imposes a duty." *Morissette v. United States,* 342 US, at 255, 96 L Ed 288, 72 S. Ct. 240. "The accused, if he does not will the violation, usually is in a position to prevent it with no more care than society might reasonably expect and no more exertion than it might reasonably exact from one who assumed his responsibilities."[58]

The Court observed that the Act imposed not only a positive duty to seek out and remedy violations when they occurred, but also, and primarily, a duty to implement measures that would insure that violations would not occur. The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that support them. Although the Act did not make criminal liability turn on "awareness of some wrongdoing" or "conscious fraud," the duty imposed by Congress on responsible corporate agents was one that required the highest standard of foresight and vigilance. The Act "in its criminal aspect," however, does not require that which is objectively impossible.

"The theory upon which responsible corporate agents are held criminally accountable for "causing" violations of the Act permits a claim that a defendant was "powerless" to prevent or correct the violation to "be raised defensively at a trial on the merits." *United States v. Wiesenfeld Warehouse Co.*, 376 US 86, 91 (1964). If such a claim is made, the defendant has the burden of coming forward with evidence, but this does not alter the Government's ultimate burden of proving beyond a reasonable doubt the defendant's guilt including his power, in light of the duty imposed by the Act, to prevent or correct the prohibited condition. 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, and the obligation of the courts is to give them effect so long as they do not violate the Constitution."[59]

The Court stated that although the concept of a "responsible relationship" to or a "responsible share" in, a violation of the Act, imparts some measure of blameworthiness, it is not incumbent upon a United States District Court in a prosecution of a corporate officer for violating Sec. 301(k) of the Act, to instruct the jury that the government has the burden of establishing "wrongful action." 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, respon-

[58] Supra note 56 at 671.

[59] Supra note 56 at 673.

sibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so. The failure thus to fulfill the duty imposed by the interaction of the corporate agent's authority and the statute furnishes a sufficient causal link.[60]

(3) Turning to the jury charge in the case, the Court stated that a simple instruction to the jury may not be judged in artificial isolation, but must be viewed in the context of the overall charge. The Court concluded that "viewed as a whole and in the context of the trial, the charge was not misleading and contained an adequate statement of the law to guide the jury's determination."[61]

(4) The Court also agreed with the Government that evidence of prior violations was relevant since it served to rebut respondent Park's defense that he had justifiably relied upon subordinates to handle sanitation matters. In light of the difficult task of the juries in prosecutions under the Act, the Court concluded that the relevance and persuasiveness of this evidence outweighed any prejudicial effect.[62]

Other Areas Of Expanding Personal Liability For Corporate Executives

The extension of the *Dotterweich* doctrine as enunciated in the *Park* case has since been reaffirmed and clarified in a number of other cases involving violations of the Act.[63] Recall that until the *Park* case, the application of *Dotterweich* had involved a close supervisory position for the defendant over the operation where the violation of the Act had occurred. Furthermore, no cases had involved senior corporate executives who were otherwise remote from the operations in which violations occurred.[64]

In the *Park* case, the Court stretched upward the hierarchical line of organizational authority by including in the definition of "responsible parties" any person who had, "by reason of his position in the corporation, responsibility and authority either to prevent in the

[60] Supra note 56 at 673-674.
[61] Supra note 56 at 675.
[62] Supra note 56 at 678.
[63] *United States v. Y. Hata & Co.*, 535 F. 2d 508 (CA-9), Cert. denied, 97 S. Ct. 87 (1976); *United States v. Starr*, 535 F. 2d 512 (CA-9 1976); *United States v. Acri Wholesale Grocery Co.*, 409 F. Supp. 529 (S. D. Iowa 1976); *United States v. Certified Grocers Coop.*, 546 F. 2d 1308 (CA-7 1976); and *United States v. Marcen Laboratories, Inc.* 416 F. Supp. 453 (S. D. N. Y. 1975). See also O'Keefe, "Criminal Liability: *Park* Update," 32 FOOD DRUG COSMETIC LAW JOURNAL 392 (September, 1977).
[64] O'Keefe in Supra note 63.

first instance, or promptly to correct, the violation complained of. . ."[65] The only escape provided was that of a situation where a defendant was "powerless" to prevent or correct the violations. However, the burden of proof was on the defendant. In subsequent cases, the Court held that the "powerless" defense could not apply where a defendant should have anticipated a problem of new arrival of materials[66] or non-followup of instructions[67] and should have taken corrective actions.

At present, a company cannot escape liability by maintaining that it had fulfilled the existing legal requirements. For example, in the case of prescription drugs, the courts have held that the mere compliance with regulations or directives as to warnings, such as those issued by the FDA in this case, may not be sufficient to immunize the manufacturer or supplier of the drug from liability. The warnings required by such agencies may be only minimal in nature, and when the manufacturer or supplier has reason to know of greater dangers not included in the warning, its duty to warn may not be fulfilled.[68] If one were to extend the notion of "person in a responsible position" to these situations, the implications for the marketing executives are indeed ominous.

In the *Park* case, the government made a significant point in its briefs that the president of the company had been aware of the violation of acts at another location some two years earlier. The implication was that if this had been the first violation by his company, there would not have been the seeking of sanctions against him. From this it could be extrapolated that the supervisor gets one free bite of the apple. From the *Acme Markets* case it would further appear clear that a geographic separation of the responsible official from the wrongdoing employee would be no defense whatsoever.

The demand for a greater degree of accountability and responsibility is not limited to the field of food, drugs and cosmetics. Indeed, recently enacted statutes, regulations and cases impose sanctions without fault. In the anti-trust areas, for example, the Justice

[65] *United States v. Park*, 421 U. S. 658, 673-74.

[66] *United States v. Y Hata & Co.*, 535 F. 2d 508 (CA-9). Cert. denied, 97 S. Ct. 87 (1976).

[67] *United States v. Starr*, 535 F. 2d 512 (CA-9 1976).

[68] See the case discussion of *Stevens v. Parke, Davis & Company, and A. J. Beland, M.D.* in S. Prakash Sethi, *Up Against the Corporate Wall*, 3rd Edition (Englewood Cliffs, N. J.: Prentice-Hall, 1977), p. 386. Also see *Love v. Wolf* (266 Cal. App. 2d, 226, 395-96); *Yarrows v. Sterling Drug Co.* (263 F. Supp. pp. 162-63); *Incollingo v. Ewing* ((Pa. 1971) 282 A. 2d 206, 220).

Department has not only broadened the area where criminal penalties will be sought[69] but has also campaigned for stiffer penalties and jail sentences for the violators in price-fixing cases.[70]

Product liability, while not an example of imputing liability to "higher ups" for negligence, does provide an example of imposing liability without fault. The concept of strict liability in tort, now the law in thirty-eight jurisdictions in the United States and the position of the Restatement of the Law of Torts (2d),[71] imposes liability for defective products upon the manufacturer even though there may be no negligence.[72] Common law requirement for a showing of negligence in tort action has been eliminated. It appears that a demise is in the offing for the requirement of a showing of knowledge and intent in a criminal action.

Another aspect of broadened personal liability for corporate officers is in the Occupational Safety and Health Act of 1970 (OSHA).[73] Pursuant to the OSHA provisions, sanctions, including fines, are assessable against individuals who are "responsible" for, though unknowledgeable about, safety infractions. The constitutionality of administrative assessment of civil penalties that are tantamount to criminal sanctions is the issue in a case presently before the U. S. Supreme Court.[74] If the Supreme Court affirms the Court of Appeals and upholds administrative assessment of civil penalties, which are frequently assessed against individuals who have no knowledge of the specific wrongdoing, there may well be a rush by other regulatory agencies to expand their penalty assessment authority.

Implications for Corporate Officers

The consequences of the *Acme Markets* case and other Supreme Court decisions are far-reaching for the corporate executives. If the pattern of expanding the scope of legal liability—civil and criminal—

[69] Baker, "To Indict or Not to Indict . . . A Question of Prosecutorial Discretion Under the Sherman Act." Remarks by Donald I. Baker, Assistant Attorney General, Anti-trust Division, Before the Anti-trust Law Briefing Conference, Arlington, Virginia, February 28, 1977.

[70] Schellhardt, Timothy D. "Justice Agency Bids for Stiffer Penalties, Including Jail, on Corporate Price-Fixers," *The Wall Street Journal*, October 20, 1976, 2.

[71] 402 a, adopted in 1966.

[72] "(2) The rule stated in Subsection (1) applies although (a) the seller has exercised *all possible care* in the preparation and sale of his product, and (emphasis supplied) . . ."

[73] 84 Stat. 1590; 29 U. S. C. 651.

[74] Frank C. Ivey, Jr., *Inv. v. OSHRC* pending before U. S. Supreme Court, argued November, 1976.

is sustained in future court decisions, which seems likely, it would cause significant changes in the organizational structures and decision-making processes of corporations that deal in consumer products. Every corporate supervisor, whether or not that supervisor is an officer or director, may under certain circumstances be held personally liable for the acts of his subordinates—regardless of whether that supervisor had any knowledge of or participation in the acts of the employees that have been determined to be wrongful or in violation of the law. This raises the very difficult question of what are the reasonable limitations of the executive.

Since it is virtually impossible for a corporate executive to be personally kept informed of all the corporate activities with potential for public injury, extreme care should be exercised by the law makers in extending the scope of such action for which a corporate executive may be held personally responsible. Since the notion for punishing the wrongdoer in the traditional sense is inappropriate here, the applicable criteria is that of social welfare or public interest to be derived from controlling corporate misconduct. However, it is not clear whether by imposing onerous responsibilities of supervision on the corporate executive, we would also sap his initiative for action and risk-taking in the market place. A careful balancing of competing interests is therefore in order and deserves social discussion. The companies, on their part, must initiate new procedures and develop new safeguards to ensure their economic survival and well-being as well as to protect their top executives from exposure to personal liability for good faith efforts made on a company's behalf during the normal course of business. [The End]

The Legality of the Administrative Restraint Provision of the Medical Device Amendments of 1976: Some Constitutional Considerations

By LOUIS SANTUCCI

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AS YOU KNOW the Medical Device Amendments of 1976 expanded the Food and Drug Administration's (FDA's) authority to regulate devices. The Device Amendments included a provision for the administrative restraint of devices.

Briefly stated, the Administrative Restraint provision of the device law[1] authorizes an officer or employee of the Secretary, while conducting an inspection, to order a medical device which he has reason to believe is adulterated or misbranded to be detained for a period of not more than 20 days. If the Secretary or his designee determines a greater period of time is necessary in order to institute an action to seize the product or obtain an injunction he may authorize a detention for an additional 10 days.[2]

[1] 21 USC 334(g).

[2] It is unclear whether the total detention period authorized under the law is 20 days plus 10 days or 20 days plus 30 days. An FDA official takes the position it is 20 days plus 30 additional days. See 31, FOOD DRUG COSMETIC LAW JOURNAL 427 (August 1976). The law provides that the Secretary may authorize a detention period of not to exceed 30 days.

The use of administrative restraint as another tool for government enforcement will undoubtedly receive increased attention by Congress in forthcoming legislative proposals.

For example, the DNA research bill introduced by Senator Kennedy (S. 1272) this spring, contains an administrative restraint provision. And you can be assured that if the FDA finds it an effective tool they will attempt to gain statutory authority for its use with drugs.

Before discussing the constitutional considerations of this provision, it might be of interest to note the background that led up to the inclusion of this requirement in the law.

The Government Accounting Office (GAO) issued a report in 1972[3] which recommended that the FDA be given authority to detain products suspected or known to be violative of the law. One of the chief reasons for their recommendation was that seizure actions by the FDA were too slow.

The GAO report concluded that detention authority was necessary to improve the FDA's ability to keep products suspected or known to be violative off the market. The legislative history of the device law indicates that the GAO recommendation was a motivating factor for the incorporation of this provision in the House Bill and later into the law.[4]

Pursuant to that authority, the Secretary is obligated to promulgate implementing regulations for the enforcement of this provision before the section can become operational. These regulations have not as yet been proposed.

While the administrative restraint provision is new to the device area, it is not new to the FDA. Detention authority for meat, poultry and eggs was added to the FDA's enforcement arsenal in 1967, 1968 and 1970 respectively.[5] Also, some states, California, for example, have such authority for drugs and devices.[6] Interestingly enough, there seems to be an absence of any case law challenging such statutes on constitutional grounds.

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[3] "GAO Report to Congress—Lack of Authority Limits Consumer Protection: Identifying and Removing from the Market Products Which Violate the Law". (B-164031(2))

[4] Report No. 94-853 "Medical Device Amendments Report by the Committee on Interstate and Foreign Commerce" (to accompany H. R. 11124) p. 47.

[5] 21 USC 679, 21 USC 467, 21 USC 1052.

[6] California Health and Safety Code Sec. 26830.

I would now like to offer three theories on how the federal administration restraint provision pertaining to devices might be challenged on various constitutional grounds.

Due Process

The first problem that one encounters in reading this provision is the lack of due process protection accorded the manufacturer. The Fifth Amendment states that an individual may not be deprived of property without due process of law. While the term "due process" is not precisely defined in the Constitution, there are certain principles that can be gleaned from various Supreme Court decisions that give one an operational framework from which to determine the level of due process to be accorded when there is a deprivation of property.

Due process rights are based on a concept of fairness. Courts have held that the government must follow a fair process in its decisions particularly when acting to deprive a person of property. Central to the concept of fairness is the right to adequate notice and the right to be heard. The Supreme Court has also held that "these rights must be granted at a meaningful time and in a meaningful manner."[7] So while the detention may only be brief it is well settled in the law that a temporary deprivation of property is nonetheless a deprivation for due process purposes.[8] Therefore, whether the restraint were for one or twenty days, for due process purposes it would still be a deprivation. Several recent landmark decisions of the Supreme Court have greatly expanded the concept of a constitutional right to due process prior to deprivation of a property right[9] and provide an outline of due process concepts which should be considered in light of the detention provision.

A very complete discussion of due process rights is contained in a 1972 case, *Fuentes v. Shevin*,[10] which offers a comprehensive insight into the high court's view on due process. The Court in *Fuentes* made clear that in most situations nothing short of prior notice and an opportunity for a prior hearing will satisfy the commands of due process where property rights are at stake. The Court in *Fuentes*

[7] *Armstrong v. Manzo*, 380 U. S. 545, 552 (1965).

[8] *Sniadach v. Family Finance Corp.*, 395 U. S. 337 (1969).

[9] *Bell v. Burson*, 402 U. S. 535 (1971); *Fuentes v. Shevin*, 407 U. S. 67 (1972); *Goldberg v. Kelly*, 397 U. S. 254 (1970); *Sniadach v. Family Finance*, 395 U. S. 337.

[10] *Fuentes v. Shevin*, 407 U. S. 67.

was considering two statutes that permitted repossession of personal property merely by obtaining a prejudgment writ of replevin through a summary process of ex parte application to a court clerk. At the same time as the individual received the complaint seeking repossession, the property was seized with no prior notice and no opportunity for a hearing. This is the same situation the manufacturer faces with the administrative restraint. For purposes of my argument I'm assuming the worst case where the manufacturer's first notice of the detention of the device will probably occur when the FDA inspector marks the goods with a detention sticker of some kind.

The Court held that a prior hearing must be held in these circumstances, because it is the only truly effective safeguard against arbitrary deprivation of property. The essential reason for the requirement of a prior hearing is to prevent unfair or mistaken deprivations of property.

The restraint statute does not provide for notice or an opportunity for a hearing prior to the detention of the device. Only after the detention of the device may the manufacturer appeal the detention. Within 5 days from the date of filing the appeal, the Secretary must provide an opportunity for a hearing and either confirm or revoke the detention. But since this is an after-the-fact determination, it would not satisfy due process requirements of prior notice.

It would appear, then, that without prior notice, the restraint action is violative of due process requirements. However, the Court in *Fuentes* and other cases has distinguished certain circumstances that may justify postponing notice and the opportunity for a hearing until after the deprivation has taken place. One such circumstance cited in this and other decisions relates to the seizure of a misbranded drug, upheld in the *Ewing v. Mytinger and Casselberry* case under the seizure power of the Act.[11]

Seizure Action

Just to refresh your memory, seizure actions do not require notice prior to the actual seizure and it is only after the seizure has occurred that the claimant of the property may appear and claim the seized goods. The court noted in the *Fuentes* case that the seizure of misbranded drugs and other situations are "extraordinary

[11] For example, both *Fuentes v. Shevin*, 407 U.S. 67, 92 and *Bell v. Burson*, 402 U.S. 535, 542 refer to *Ewing v. Mytinger and Casselberry*, 339 U.S. 594 (1950) upholding the constitutionality of a multiple drug seizure under the seizure provisions of the Act.

situations" justifying postponement of notice and the opportunity for a hearing. The court found that such "extraordinary situations" had three elements in common. If any of these three elements do not apply to the deprivation in question, then it would appear that under the *Fuentes* decision, due process protection in the form of prior notice would be extended prior to the deprivation. How then does the subject provision hold up against three elements?

The first element is that the seizure must be directly necessary to secure an important government or general public interest. In this case, the government or public interest in the face of the restraint provision would be to protect the public from devices thought to be adulterated or misbranded, clearly a sufficient interest. The need to protect the public health is a governmental or public interest of the highest magnitude. However, the Court has held in other cases that where the purpose, though legitimate and substantial, can be achieved through more narrow means, then, "[t]he breadth of legislative abridgment must be viewed in the light of less drastic means for achieving the same basic purpose."[12] Could not the governmental interest still be served by a more narrowly drawn statute or perhaps by giving the manufacturer notice of the contemplated action and an opportunity to discuss the problem with the inspector or the official who must approve the restraint order prior to it becoming effective? There may be a host of other less drastic means of achieving the public purpose.

If the end could be achieved less drastically, then a court could well find that the restraint provision is overbroad in its means of achieving the interest of protecting the public health.

The second element of the *Fuentes* case is that there must be a need for very prompt action. While there may be a need for prompt action in a restraint provision, the need for very prompt action would depend on the circumstances. In the seizure situation upheld by the Court, there was probable cause to believe that the drug was misbranded because of a booklet accompanying the drug. The need for very prompt action can be said to be more immediate where the standard is probable cause, than where it is such a nebulous standard as the "reason to believe" one found in the restraint provision.

In the seizure case the need for prompt action is apparent and therefore the "extraordinary situation" is based on positive factors.

[12] *Shelton v. Tucker*, 364 U.S. 479, 488 (1960).

The criterion for making the necessary findings therefore is stricter than that used for the administrative restraint provision.

The need for prompt action should be related to the potential harm that could result if the seizure is not very prompt. The need for very prompt action would appear to be less where the potential for harm is based only on supposition. In addition, since the restraint is not a court action a discussion of the inspector's intention to detain the product with the manufacturer prior to ordering it detained could not inhibit the promptness of the action to any extent.

The third qualifying element of *Fuentes* is that the person initiating the seizure is a government official responsible for determining, under the standards of a narrowly drawn statute, that it was necessary and justified in a particular instance.

The problem with the restraint provision in the device amendment is that it is not a narrowly drawn statute, because there are no standards written into the statute. The statute delineates no standards as to what constitutes a "reason to believe" a device is adulterated. The question of standards will be more fully discussed later. Since there are no standards for determining when the restraint is justified, the restraint provision should not qualify as an "extraordinary situation" under this test. Failure to meet any of these three tests which comprise the exception to the prior notice rule might be sufficient to invalidate the restraint provision.

Prior Notice of Restraint

The *Ewing* drug seizure case can shed additional light on the probability of a successful challenge.

In that case the Court held that there was not a right to prior notice and an opportunity to be heard on the "probable cause" determination that is made prior to instituting a multiple seizure action. However, the Court stated that after a "probable cause" determination was made by the FDA, the U.S. Attorney General's office then made a determination as to the sufficiency of that determination prior to instituting the seizure action. The Court, obviously, felt that an intermediate independent step of this type provides some safeguards where prior notice is not employed. This independent review by a different agency provides some protection against an arbitrary determination on behalf of FDA officials that probable cause existed to justify seizing the drug. No such intermediate and independent step exists in the device amendments. In the case of

restraint the inspector makes a recommendation, and while it must be approved by a designated official of the Secretary, perhaps a District Director, there is no determination independent of the FDA on the FDA employee's "reason to believe" a device is adulterated or misbranded. On this basis, perhaps a court would distinguish the restraint provision from the seizure action because of this lack of an independent determination and hold that prior notice of a restraint is necessary.

One other element of importance is that in the drug seizure case a hearing will be held in court if the party requests it. The restraint provision does not guarantee a hearing but only an opportunity for one. If the FDA chooses to read "opportunity for a hearing" when we feel one is required, then obviously a hearing is not guaranteed. Nor is there a provision for a subsequent hearing either judicially or otherwise, and situations could be envisioned in the case of radioactive diagnostic products with short useful lives where the product could be rendered useless in less than 20 days. The prospect of filing injunctive proceedings provides little comfort to a manufacturer who feels the FDA's action is unjustified. Therefore, the Court could distinguish the restraint provision as not an extraordinary situation because there is no guarantee of a hearing before the final administrative action becomes effective.

Other cases since *Fuentes* have reviewed various statutory schemes to determine the sufficiency of predetermination due process rights. These cases indicate that due process is a flexible concept and in my opinion would require prior notice and an opportunity to be heard prior to a determination to restrain a device.

Vagueness

Another approach to challenging the subject provision would be to argue that the statute is unconstitutionally vague. Such a challenge would be based on the lack of standards as to what will constitute a "reason to believe", on the part of the FDA officials, that a device is adulterated or misbranded. Without an explanation as to what are sufficient reasons to constitute a belief that a device is suspect, it would seem that a manufacturer would not be able to determine whether or not his conduct falls within the category subject to restraint.

In delegating the power to the FDA to restrain a device, Congress has failed to provide statutory standards regarding the "reason to believe" aspect of this provision.

Courts have struck down statutes under the vagueness doctrine where meaningful standards have not been incorporated into the law. However, as Davis, a leading administrative law writer, has declared, such an approach is unsatisfactory and courts are increasingly reluctant to base their determination that a statute is vague solely on the grounds that there is a lack of statutory standards.[13] One recent case held that the doctrine of vagueness can be used to declare a statute invalid where there is an absence of standards restricting the discretion of government authorities in enforcing the law.[14] In that case, the Supreme Court determined that when there are no standards governing the exercise of "the discretion granted by a statute," the scheme permits and encourages an arbitrary and discriminatory enforcement of the law,[15] and the result is that constitutional standards are not met. What the court is implying is that vagueness in the enforcement policy may be sufficient grounds for finding a statute void.

The statute regarding administrative restraint clearly does not contain any standards regarding when or how the "reason to believe" determination will be made. If the regulations that are to be proposed regarding this provision also fail to clarify the enforcement policy, it would appear that this statute could be declared void under a doctrine of vagueness. This is particularly true since the words "reason to believe" are open ended and to my knowledge have no established judicial or legal meaning such as a term like "probable cause" does. Obviously, one can imagine any number of circumstances where one person could have "reason to believe" that a set of circumstances could cause a device to be adulterated which another person faced with the same situation would not. Without such standards, a court could find that the statute permits arbitrary and discriminatory enforcement and is therefore void. But rather than declare the statute void on these grounds, the courts might exercise their power in a new direction. If such standards are not forthcoming via rulemaking, and because they are not contained in the statute, the courts could require the FDA to formulate such standards as are necessary to guide the exercise of the discretionary authority of the FDA officials.

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[13] Kenneth Culp Davis, *Administrative Law Supplement 1970*, Chapter 2 and *Administrative Law of the Seventies Supplementing Administrative Law Treaties*, Issued June 1976.

[14] *Papachristou v. City of Jacksonville*, 405 U.S. 156 (1972).

[15] Id at 170.

In two recent federal cases, for example, the courts have ordered the formulation of standards for the exercise of the discretionary functions of an agency where the court found no standards existed.[16]

Therefore, while a challenge of this provision might not be successful on the face of the statute, if standards are not forthcoming or are found deficient in that they do not adequately spell out the requirements for what constitutes a "reason to believe" a device is adulterated or misbranded, I feel a challenge could be successful. The court would then either declare the statute void or send the FDA back to the drawing boards to provide adequate standards.

Warrant Required for an Inspection

In order for an inspector to institute the administrative restraint provision, he must of course gain access to the device manufacturing plant. The statute provides that the imposition of the restraint can only occur during an inspection conducted pursuant to Section 704 if he finds a device he has reason to believe is adulterated or misbranded.

A possible challenge to this provision would be an assertion that the FDA, pursuant to the dictates of the Fourth Amendment, must obtain a search warrant prior to undertaking an inspection. If the court were to declare the FDA's present warrantless inspection authority as violative of the Fourth Amendment, then one would expect that access to facilities would be somewhat limited with a corresponding decrease in the frequency of implementation of administrative restraints. However, requiring a warrant before an inspection would not, in my opinion, limit the frequency of FDA inspections unless the court also determined that a strict probable cause standard for issuing the warrant applied. Under such a standard a warrant would be issued only where the inspector believed that a violation has occurred.

While this question of how the FDA's inspection authority, particularly with regard to devices, comports with the Fourth Amendment has not been expressly ruled upon by the Supreme Court, there are at present two lower court cases alleging in part that a warrant must be obtained prior to an FDA inspection.[17]

Regardless of the determination made in these two cases, in my opinion, it will be eventually necessary for the Supreme Court, at some time in the future to rule on the FDA's inspection authority.

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[16] *Environmental Defense Fund v. Ruckelshaus*, 439 F. 2d 584 (1971); *U. S. v. Bryant*, 439 F. 2d 642 (1971).

[17] *U.S. v. Sherwood Medical Industries, Inc.* Civil No. 77-0265-CU-W-2; *U.S. v. Becton Dickinson.*

The application of the Fourth Amendment right to be free from unreasonable searches and seizures in particular cases has been a task which has caused the courts a great degree of difficulty, particularly when the specific subject of review is the enforcement of warrantless inspection statute similar to Section 704 of the Federal Food, Drug, and Cosmetic Act.

The situation remains unsettled despite recent Supreme Court decisions on the general subject. And recent federal district court opinions which have attempted to apply the Supreme Court holdings to particular inspection authority provisions similar to the FDA's have only added to this state of uncertainty.

Present judicial authority regarding constitutional warrant requirements for administrative searches begins with the 1967 Supreme Court companion decisions. *Camara* and *See*.[18] These two decisions together stand for the proposition that administrative inspections of commercial premises require a search warrant and that issuance of a warrant must be based on satisfaction of a flexible probable cause standard which will vary on a case by case basis. Subsequent to these decisions, the Supreme Court has had two opportunities to review the reach of the Fourth Amendment with respect to two different federal regulatory statutes.[19] These two cases, *Biswell* and *Colonnade*, dealt with federal regulation of firearms and liquor, respectively.

In both these cases, the Court upheld statutory schemes authorizing warrantless inspections of licensed firearms dealers and liquor licensees, thus narrowing the scope of *Camara* and *See*.

Despite the different situations the Court faced in each of these four cases, I believe it is possible to derive a few principles that will be determinative in the Court's review of the FDA's device inspection authority.

Inspection Authority

First, warrantless inspections will not be considered violative of the Fourth Amendment unless they are "unreasonable". In determining the reasonableness of a particular inspection authority, three elements are considered. First, the enterprise sought to be inspected must be engaged in a pervasively regulated business. Second, the

[18] *Camara v. Municipal Court of the City and County of San Francisco*, 387 U.S. 523 and *See v. City of Seattle*, 387 U.S. 541.

[19] *United States v. Biswell*, 406 U.S. 311 (1972) and *Colonnade Catering Corp. v. U.S.*, 397 U.S. 72 (1970).

warrantless inspection must be a crucial part of the regulatory process designed to further an urgent federal interest and third, it must be authorized by statute and carefully limited as to time, place and scope. If any of these three elements is lacking, the Court would find that the inspection authority is "unreasonable" and therefore requires a warrant. Finally, if the Court agrees that a warrant is required, there must be "probable cause" to issue the warrant. The Court will make a second determination of reasonableness and if the inspection is reasonable, under certain factors then the Court will find that probable cause to issue the warrant exists.

In articulating the standards for determining whether a warrant should be required in the first place, the Court, in my view, has created a situation from which it will eventually have to retreat. Lower court decisions have discussed the FDA's inspection authority as well as similar inspection authority for the Occupational Safety and Health Administration. These decisions have placed the greatest weight on the "pervasiveness" factor, mentioned previously, in determining whether or not a warrant should be required for an inspection to occur.[20]

While such a distinction may in some circumstances be an easy one to draw, it obviously will create separate classes of business that will be treated differently for Fourth Amendment purposes.

Since *Camara* and *See* have not been overruled, I feel that eventually the Court will find that the drawing of distinctions on the standards previously discussed will create situations so unfair on their face that the Court will be obliged to extend Fourth Amendment protection to require a warrant prior to any regulatory inspection, regardless of the extent of regulatory control.

Until such time as my view is vindicated by the Court, perhaps the device industry will be able to differentiate itself as an industry that has not been subject to a pervasive regulatory atmosphere, thus requiring that any inspection of a device establishment to be pursuant to a warrant.

Devices have been subject to some regulatory control by the FDA since 1938. However, in 1976 devices were made subject to a much greater degree of regulatory control.

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[20] See for example, *U.S. v. Del Campo Baking Manufacturing Company*, 345 F. Supp. 1371 (1972); *Barlow's Inc. v. Usery*, 425 F. Supp. 437 (1976) cert. granted — U.S. — (1977); *Brennan v. Buckeye Industries*, 374 F. Supp. 1350 (1976); *Brennan v. Gibson's Products Inc. of Plano*, 407 F. Supp. 154 (1976).

In particular, with regard to inspection authority for devices, it was not until 1953 that mandatory inspection authority for device establishments was instituted. This inspection authority was limited to physical facilities, and pertinent equipment, finished and unfinished materials and labeling therein. The 1976 amendments extended this authority to expand the inspection authority for restricted devices only to include all things in a factory where a device is manufactured bearing on whether the device is adulterated or misbranded including records, files, processes controls or facilities.

If the measurement of the pervasiveness of control is the length of time the control has existed, then devices have only been subject to controls for less than 50 years. However, the *Colonnade* decision implies that it is the pervasiveness of control over the inspection authority itself that is of concern.[21]

In that decision the court pointed out that federal warrantless inspection authority for liquor existed as early as 1791. With device inspection authority less than 25 years old, the argument can be made that the device industry has not been long subject to such inspection authority. And with the inspection authority over restricted devices a little more than a year old, such authority would certainly not be pervasive.

Even though the Court might agree that a warrant is required in the case of all devices, or at least for restricted devices, the Court might find that the warrant will issue without a showing of cause to believe that a violation has occurred.

Reasonableness Factors

The Fourth Amendment provides that "no warrants shall issue but upon probable cause". However, the *Camara* decision articulated a different probable cause standard for issuing a warrant pursuant to regulatory inspection schemes. Probable cause for issuing a warrant will exist if the inspection scheme is reasonable. The Court in *Camara* listed several factors[22] that are relevant to a consideration of the reasonableness of the inspection scheme. While many of these factors do apply to the device inspection authority, at least two do not. Where these factors do not apply to a regulatory inspection system, such a system should be considered unreasonable.

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[21] *Colonnade*, 397 at 77.

[22] Other factors discussed by the Court were: long history of public and judicial acceptance; public interest demands that all dangerous conditions be prevented or abated; there are reasonable legislative or administrative standards for conducting the inspection. *Camara* at 535-539.

The first factor was that the inspection program was not aimed at the discovery of a crime nor was it impersonal in nature, and hence there is a limited invasion of the citizen's privacy.

However, under the Federal Food, Drug, and Cosmetic Act inspections are related to the discovery of evidence of a violation and may be aimed at discovering the identity of individuals who caused the occurrence of the violation, which, if found, can result in criminal fines and imprisonment. Hence, the potential for invasion of privacy is significant as the inspection can be personal in nature and aimed at the discovery of a crime.

The second factor relates to the purpose of the inspectional system. The purpose of the inspection program in *Biswell* was to control the distribution of guns. The inspection authority was a crucial part of the regulatory scheme to assure that weapons were distributed through regular channels, that they were traceable and that the sale to undesirable customers was prevented. The Court agreed that frequent unannounced inspections were essential to an effective inspection program.

The Court distinguished the gun control situation from the building code violation in the *Camara* and *See* cases by reasoning that building code violations were difficult to conceal or correct in a short time and warrants would provide little threat to the effectiveness of the program.

FDA inspections are also infrequent and for the most part involve violations that are not easily corrected or concealed in a short period of time. Therefore, it would seem that the threat to the FDA's inspection authority is equally minimal as that in *Camara* or *See*. Another factor to consider is that the FDA's regulatory system has the same concern as that in *Camara* and *See,* public health and safety.

It would appear that Agency inspection would not be considered reasonable under two major factors of the Court's multi-pronged test. Therefore, the applicable "probable cause" standard would be the traditional one, requiring personal knowledge or belief that a violation has occurred.

Finally, the Court determined that even if the inspection in question is reasonable under their tests, there must also be reasonable legislative or administrative standards for conducting the inspection.[23]

[23] *Camara* at 538.

The statute provides very general standards about inspections.[24] Perhaps the Court might find that the scope and limits of the inspection are not sufficiently defined and would require the FDA to promulgate more definitive rules.

While I have not considered all of the possible constitutional challenges to this provision, I would like to conclude with this comment: The major reason for the administrative restraint provision was that seizures were too slow. In that respect, I find a statement quoted in the *Barlow* opinion relevant. And that is that "Expediency is the argument of tyrants, it precedes the loss of every human liberty". While I would not argue that members of Congress or FDA officials are tyrants, I would say that expediency as a rationale for legislative enactments may be insufficient justification to support such enactments when challenged at some later date. **[The End]**

CURRENT PRACTICES FOR FLU VACCINE OUTLINED BY FDA

The influenza vaccine to be used during this year's flu season contains the prevalent A/Victoria and B/Hong Kong type viruses, according to a Food and Drug Administration summary of current Public Health Service recommendations on flu vaccine. Available in both "split-virus" and "whole-virus" preparations, adults and older children develop immunity with one shot of either vaccine. Two doses of the split-type vaccine are needed for children under age six. Because children and adolescents experience more side effects than adults, it was recommended that only the split type be given to those under 18 years.

Use of the vaccine was suggested for adults and children of all ages who have chronic diseases, and for older persons generally. It was noted that while use is not contraindicated for pregnant women, most physicians avoid prescribing unnecessary vaccines during pregnancy.

CCH Food Drug Cosmetic Law Reporter, ¶ 42,125

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[24] 21 USC 374.

Informed Consent and the Investigational Use of Medical Devices: A Comparison of Common Law Duties With Those Imposed on Researchers Under Section 520(g) of the Medical Device Amendments of 1976

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Introduction

WHEN THE FOOD AND DRUGS ACT OF 1906 was superseded by the Federal Food, Drug, and Cosmetic Act of 1938, medical devices (and cosmetics) were subject to regulatory control for the first time.[1] At least a major part of the pressure for passage of the 1938 Act was generated by the sulfanilamide disaster.[2] As a consequence of that disaster provisions were made that new drugs

[1] *See*, STAFF OF HOUSE SUBCOMM. ON PUBLIC HEALTH AND ENVIRONMENT OF THE COMM. ON INTERSTATE AND FOREIGN COMMERCE, 93d Cong., 2d Sess., A BRIEF LEGISLATIVE HISTORY OF THE FOOD, DRUG, AND COSMETIC ACT 4, (COMM. PRINT NO. 14, 1974), [hereinafter cited as LEGISLATIVE HISTORY].

[2] *Id.*, at 3.

could not be marketed unless they had first been shown to be safe for human use.[3]

While medical devices and drugs were lumped together for some purposes under the 1938 Act, devices were not subject to such preclearance. Nor, in 1962, when new drugs were subjected to even tighter control as a result of the thalidomide disaster,[4] were devices affected.[5] Not until later did a situation begin to emerge requiring a closer control of device marketing. In the late 1960's, thousands of deaths and injuries were attributed to faulty heart valves, pace makers and intrauterine devices.[6] Moreover, not only were there problems with the safety of devices, but the Food and Drug Administration (FDA) was also spending considerable resources to remove from the market useless devices being fraudulently palmed off on unwary consumers.[7] As a result of both of these developments, in 1969, the Department of Health, Education and Welfare (DHEW) convened a study group, known as the Cooper Committee, to study the problem and make recommendations as to how to deal with them.[8]

In 1970, the Cooper Committee filed its report, making specific legislative recommendations.[9] Among its suggestions was one that at least some kinds of devices be subjected to clinical tests prior to being marketed.[10] Shortly after receiving the report, the FDA convened expert panels to begin the important and time-consuming work of reviewing and classifying medical devices. By the end of 1973, when Congress began to hold hearings on proposed legislation, these panels had already classified over 3,000 devices according to risk and need for premarket testing.[11]

At least part of the reason that it took six or seven years from the time that the Cooper Committee began its work until passage

[3] Supra note 1 at 16, 18.

[4] *Id.*, at 15.

[5] *Id.*, at 18. *See* 21 USC Sec. 355 (1977).

[6] *Medical Devices: Hearings on H.R. 6073, 9981, 539 and 10061 Before the House Subcomm. on Public Health and Environment Comm. on Interstate and Foreign Commerce*, 93d Cong., 1st Sess., 154 (1973) [hereinafter cited as *House Hearings*].

[7] *Id.*, at 155. *See also* two cases coming to different conclusions about the authority of the FDA over devices used in the practice of a "religion": *Founding Church of Scientology v. U.S.*, 409 F. 2d 1146 (CA of DC 1969) and *Church of Scientology v. Richardson*, 437 F. 2d 214 (CA-9 1971). In addition to questions of safety and efficacy of medical devices, issues were beginning to develop concerning the distinction between drugs and devices: *see* Weitzman, *Drug, Device, Cosmetic?* 24 FOOD DRUG COSMETIC LAW JOURNAL 226, 320 (1969).

[8] *House Hearings*, note 7, *supra*, at 155.

[9] *Id.*

[10] *Id.*, at 156.

[11] *Id.*

of the Medical Device Amendments Act of 1976[12] was the difficulty of deciding which kinds of devices would be subject to what kinds of controls. Problems had arisen in regard to premarket clearance of new drugs, and there was no desire to repeat mistakes which had been made in regard to them.[13] Thus arose the need for the complex provisions setting forth the conditions under which new devices could be marketed without preclearance, and the need for time to draft and consider them.[14] Not only did the amendments set forth detailed provisions for exempting certain classes of devices from preclearance, but they also set forth conditions under which devices otherwise subject to preclearance could be used prior to such preclearance.[15] This paper will deal with the exemption granted for the investigational use of devices subject to premarket testing and, more particularly, it will deal with the obligation of an investigator seeking such exemption to secure an informed consent agreement from human subjects (or their representatives) under Section 520(g)(3)(D)[16] of the Act. It will also consider the relationship between that statutory obligation and that which might be imposed by the common law of negligence.

The Duty Under the Statute

It will be necessary to review, briefly, the overall organization of the Federal Food, Drug, and Cosmetic Act.[17] Only then can the full implications of the device amendments be understood. First, there is a section which defines words used in the Act: Section 201(h) defines a "device", with certain exceptions, to be an article which is:[18]

[12] Pub. L. No. 94-295, 90 Stat. 539 (May 28, 1976).

[13] *See generally, House Hearings*, at 364-97. *Also* at 331-35 and 360-61. *Cf. id.* at 196-204.

[14] *See generally*, Sec. 513(a)(1), 21 USC Sec. 360c(a)(1).

[15] Secs. 520(b) and (g), 21 USC Secs. 360: (b) and (g). Sec. 520(b) exempts custom devices ordered by a health care professional for a *named* patient. Sec. 520(g) exempts devices for investigational use with humans subject to application being made by "experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices." Sec. 520(g)(2)(A), 21 USC 360: (g)(2)(A).

[16] 21 USC 360j(g)(3)(D). This paragraph requires that the Secretary of DHEW promulgate regulations pursuant to paragraph (2)(A) requiring an assurance that, in the absence of extraordinary, life-threatening circumstances, informed consent will be obtained from the patient or his representative.

[17] 21 USC Secs. 321 *et seq.* (1977).

[18] *Id.* Sec. 321(h). For a discussion of the significance of this section as amended, *see, e.g.*, Weigel and Raubicheck, *How to Comply with the New Medical Device Law*, 31 FOOD DRUG COSMETIC LAW JOURNAL 312 (June 1976) or Geller, *The Medical Device Amendments of 1976—Major Features and Comparisons*, 31 FOOD DRUG COSMETIC LAW JOURNAL 424 (August, 1976).

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

There is also a lengthy section which sets forth "Prohibited Acts." These include the introduction into interstate commerce[19] or the receipt in interstate commerce[20] of an adulterated or misbranded device, as well as the failure to comply with the conditions of investigational exemption under Section 520(g) or the filing of a false or misleading report with respect to a device.[21] Lest someone seize upon the words "interstate commerce", it should also be noted that a provision buried in a rather unexpected place in the Act creates a presumption of interstate commerce. It is interesting that this presumption applies only to medical devices (as opposed to foods, drugs, or cosmetics). Further, this presumption of sufficient involvement with interstate commerce to enable federal regulatory jurisdiction would seem to have particular impact on the investigational use of medical devices.[22]

Consequences of Non-Compliance

One might wonder about the consequences of non-compliance with the Act or the doing of something prohibited under it. Sanctions are set forth in Sections 302—304[23] and include injunction,[24] criminal penalties,[25] and seizure of offending devices.[26] In regard to criminal penalties, it ought to be noted that it has been long held that *knowing* violation of the act is not necessary for prosecution.[27]

As noted above, traffic in adulterated or misbranded devices is prohibited. The conditions which cause a device to be adulterated

[19] 21 USC Sec. 331(a). *See also*, Geller note 18, *supra*, at 443.

[20] *Id.* Sec. 331(d).

[21] *Id.* Sec. 331(q).

[22] *Id.* Sec. 379a (Sec. 709 of the Act). *See* Geller, note 18, *supra*, at 426-7. It is expected that this provision could be especially significant with respect to 21 USC 331(q) and through it to Sec. 520(g) of the Act.

[23] 21 USC Secs. 332-4.

[24] *Id.* Sec. 332.

[25] *Id.* Sec. 333.

[26] *Id.* Sec. 334.

[27] *See, e.g., U. S. v. Park*, 421 U. S. 658 (1975).

or misbranded, respectively, are set forth in Sections 501 and 502 of the Act.[28] The former seems to be most relevant here, and Section 501(f) provides that a device subject to preclearance[29] (a Class III device) which has not been precleared and does not have an investigational exemption under Section 520(g), is adulterated.[30] Moreover, Section 501(i) provides that a device is adulterated if "any investigator who uses such device (under Section 520(g)) . . . fails to comply with a requirement . . . under such section."[31] One of those requirements is that the investigator secure informed consent from each human subject, and Section 520(g)(3)(D) requires the Secretary of DHEW (or his delegee, the FDA) to promulgate regulations governing the securing of such consent.[32] In this respect, it is interesting to note that in the bill which was passed by the Senate, detailed provisions were set forth governing this matter, but the House bill lacked them.[33] This discrepancy was taken up by the conference committee, and its report indicates why the specific provisions of the Senate bill were dropped from the conference bill.[34] The main reason seems to be that a blue ribbon panel has been convened to consider research on human subjects.[35] If specific provisions for informed consent had been in the Act, it would take Congressional action to modify them to be consistent with whatever the panel comes up with. If, on the contrary, it were left to the FDA to promulgate specific provisions, these could be more easily and quickly amended.

Thus the Act gave the FDA (Secretary of DHEW) 120 days from the date of passage of the amendments to promulgate rules covering informed consent and other conditions under which one might obtain an investigational exemption for doing clinical evaluation of a new Class III device.[36] Although the Act as passed appears to give the FDA considerable discretion, it is quite clear from the conference report that Congress intended the adoption of the specific provisions dropped from the Senate bill, pending the adoption of whatever recommendations which might come forth from the above mentioned study panel.[37] Since the 120 days are long past, one might

[28] 21 USC Secs. 351 or 352, respectively.

[29] *See generally* Sec. 515 of the Act, 21 USC Sec. 360e.

[30] 21 USC Sec. 351(f).

[31] *Id.* Sec. 351(i).

[32] 21 USC Sec. 360j(g)(3)(D).

[33] H. R. CONFERENCE REP. No. 94-1090, 94th Cong. 2d Sess., 64 (1976), *reprinted in* (1976) *U. S. Code Cong. & Ad. News* 1070, 1116.

[34] *Id.*

[35] *Id.* The National Commission on the Protection of Human Subjects of Biomedical and Behavioral Research.

[36] Sec. 520(g)(2)(A) of the Act, 21 USC Sec. 360j(g)(2)(A).

[37] Note 33, *supra.*

wonder what has become of the rules governing investigational exemptions. As of this writing none are in effect, but proposals were made quite some time ago, in August of 1976.[38] Interested parties were given until October 19, 1976, to provide written comments on them.[39] One is left to speculate on whether the delay has been caused by comments received or by the need to attend to more pressing business.

In spite of the fact that the rules are still only proposals, it is worthwhile to consider them in some detail. Prior to their publication, one writer suggested that:[40] "It would seem logical that the investigational device regulations would be patterned after . . . regulations . . . already promulgated (for similar regulated products)." However not only do the proposals go well beyond those in force, that is, in regard to new drugs,[41] but it is also likely that final regulations will do likewise.

Informed Consent

While regulations in effect for new drugs require investigators to certify that informed consent will be sought, they do not require, as do the device proposals, submission to the FDA of the form being used to obtain it.[42] Nor do the regulations in effect for new drugs set forth in detail what the contents of an agreement with a subject shall be.[43] Thus, not only do the device proposals go well beyond similar ones for other products, but it is also doubtful that they could differ much from their present form and be consistent with the legislative aims earlier noted.[44]

First, the proposals provide that each subject shall be given:[45]

(1) A full and fair explanation of procedures to be followed, including an identification of any which are experimental.

(2) A full explanation of the nature, expected duration and purpose of the administration of the investigational device.

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[38] 41 *FR* 35,282 (proposing 21 CFR Part 812). There were a number of specific rules implementing the provisions of Sec. 520(g), 21 USC 360j(g) generally. In regard to informed consent, specifically, elements which were to appear in an agreement with the patient or his representative appear at 41 *FR* 35,313 (proposing 21 CFR Sec. 812.130).

[39] 41 *FR* 35,313. Further action is expected shortly.

[40] Geller, note 18, *supra*, at 439, referring to previous regulations covering food additives, new drugs, and new animal drugs.

[41] 21 CFR Sec. 312.1(a)(12) and (13)(1977).

[42] 41 *FR* 35,288, discussing the impact of proposed 21 CFR Sec. 812.20 (b)(7). *See also* proposed 21 CFR Sec. 812.130(c), *id.*, at 35,313.

[43] Note 41, *supra; cf.* note 38, *supra.*

[44] *See* discussion corresponding to notes 33-37 *supra.*

[45] *Proposed* 21 CFR Sec. 812.130(a), note 42, *supra.*

(3) A description of any attendant discomforts and risks reasonably to be expected.

(4) An explanation of the likely results should the procedure fail.

(5) A description of any benefits reasonably to be expected.

(6) A disclosure of any appropriate alternative procedures that might be advantageous for the subject.

(7) A description of the scope of the investigation, including number of patients involved in the investigational study.

(8) An offer to answer any inquiries concerning the investigational study.

(9) An instruction that the subject, or his legal representative, is free to decline entrance into the investigational study or to withdraw his consent and to discontinue participation in the study at any time without prejudice to the subject.

(10) A statement that the investigational device is being used for research purposes.

Moreover, the proposals provide:[46]

(b) The agreement entered into by such person or his legal representative shall include no exculpatory language through which the subject is made to waive, or to appear to waive, any of his legal rights or to release the institution or its agents, or the sponsor, or the investigator from liability for negligence.

Finally, it is provided that the contents of the consent document be approved by an institutional review committee and that copies of the form be provided to the subject or his legal representative.[47]

In considering these requirements, one may wonder about the extent to which they change obligations which might already be imposed by the common law of negligence. That law obviously is enforced with sanctions considerably different from those noted above and applicable under the regulatory statute, but from the perspective of an investigator, their impact may be far more serious. This is because seizure or injunction is not likely to have much of an effect on an individual investigator (as contrasted with the sponsor).[48] Nor, if an effort is seriously made to comply with the law, is it likely that the criminal sanctions need to be considered as much of a threat to such a person.[49] Rather, the most significant implications seem to

[46] *Id.* Sec. 812.130(b).

[47] *Id.* Sec. 812.130(c).

[48] This is a matter of speculation. It just seems unlikely that the ordinary investigator is going to have enough of an economic investment for either of those to have much of an impact.

[49] No record of prosecutions of such a person has been found in the litera-

(Continued on next page.)

arise in regard to potential civil liability which might attach as a result of following the procedures for informed consent set forth in the proposed regulations. An effect on civil liability can only result if the proposals change the nature of the preexisting duty of research clinician to a human subject. For that reason, it is necessary to consider the common law and attempt to assess what that duty might be in the absence of regulatory alteration.

The Duty Under the Common Law

There are several things that need to be said at the outset of this discussion of the common law. Most important is that any such discussion must, of necessity, be general. There are 51 different jurisdictions, counting the District of Columbia, and each is free to develop and apply its own law of negligence. Another thing that should be noted is that the need for informed consent does not arise only in regard to experimental procedures. Rather, experimental procedures tend to involve more risk, and it seems safe to say that as the degree of risk goes up, the need to inform goes up. Also, it seems safe to say that if there is a traditional treatment available with a known risk and an experimental treatment with an unknown, and perhaps higher risk, the need to inform probably becomes absolute. Indeed, in the last situation, more than the law of negligence may be involved.[50] Finally, it may be useful to distinguish those situations where an injury results from an unavoidable risk in the procedure from those where the injury arises as a result of use of inadequate skill in the procedure. Both of those problems seem to be affected by the proposed regulations[51] and will be discussed here.

(Footnote 49 continued.)
ture, *but cf.* note 27, *supra*. A more likely sanction would be for the FDA to refuse to allow an investigational exemption where an investigator was proposed who had a record of misconduct. In FDA practice no record of such an action has been found, *but see Hamlin Testing Laboratories Inc. v. AEC*, 337 F. 2d 221 (CA-6, 1964) and *River Forest Pharmacy, Inc. v. Drug Enforcement Adm'n.*, 501 F. 2d 1202 (CA-7, 1974).

Also see Rheingold. *The Mer/29 Story —An Instance of Successful Mass Disaster Litigation*, 56 *Cal. L. Rev.* 116, 120-1 (1968), indicating that the Grand Jury returned indictments against the company and three scientists. All pleaded *nolo contendere*. The scientists received suspended sentences. Indictment was under 18 USC 1001 *not* 21 USC.

Also see O'Keefe, *Criminal Liability: Park Update* 32 FOOD DRUG COSMETIC LAW JOURNAL 392 (September 1977).

[50] *See, e.g., Canterbury v. Spence* 464 F. 2d 772, 783-5, (CA of DC, 1972).

[51] Note 38, *supra*.

Need to Inform of Unavoidable Risks

Let us first consider the question of need to inform as to unavoidable risks. Traditionally, the medical profession has been held to a somewhat subjective standard of care. In short, physicians tend to be held to the standard of conduct prevailing among physicians in the community. In the past this standard has been imposed not only in regard to the skill used in the treatment of a patient, but also to determine whether there was an obligation to inform a patient as to risks involved in a treatment.[52] Consider blood transfusions, for example. In every transfusion there is some unavoidable risk of serum hepatitis. Should the physician be liable if a patient contracts hepatitis when he has not been warned of the risk? It seems clear that no liability would attach if the transfusion were given in a life-threatening or other situation where a patient could be said to have no choice. What if the patient had a choice (or might have had a choice)? The traditional view has been that the physician is liable only if other physicians in the community would ordinarily warn a patient of such a risk.[53]

Some Court Observations

More recently, courts have come to apply a more objective standard. In a well written, leading case discussing the need to warn of the one percent risk of paralysis from a laminectomy, the D. C. Court of Appeals observed:[54]

"It is the settled rule that therapy not authorized by the patient may amount to a tort—a common law battery—by the physician. And it is evident that it is normally impossible to obtain a consent worthy of the name unless the physician first elucidates the options and the perils for the patient's edification. Thus, the physician has long borne a duty . . . to make adequate disclosure . . . The evolution of the obligation to communicate . . . has hardly involved an extraordinary restructuring of the law.

Duty to disclose has gained recognition in a large number of jurisdictions, but more largely on a different rationale. The majority of courts dealing with the problem have made the duty dependent on . . . custom . . . in the community . . . We agree that the physician's nonconformance with . . . custom . . . may give rise to liability . . . We do not agree that the patient's cause of action is dependent upon the existence and nonperformance of a relevant professional tradition.

There are, in our view, formidable obstacles to acceptance of the notion that the physician's obligation to disclose is either germinated or limited by medical practice. * * *

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[52] *See, e.g., Canterbury*, note 50, *supra*, at 783.

[53] *See, e.g., Fischer v. Wilmington Gen. Hospital*, 51 Del. 554, 149 A. 2d 749 (1959). Note that, in many jurisdictions this risk (blood transfusions) is regulated by statute. *See*, Frumer and Freidman 2 *Products Liability* Sec. 16.04[3][b] (Cum. Supp. 1976) listing states which have by statute eliminated liability. *Mass. Gen. Laws Ann.* Ch. 106 Sec. 2-316(5) (1965) is typical.

[54] *Canterbury*, note 50, *supra*, at 783-5. *Footnotes omitted.*

We hold that the standard measuring performance of that duty by physicians, as by others, is conduct which is reasonable under the circumstances."

In another leading case, decided in Rhode Island two years later, there was occasion to discuss what is "reasonable under the circumstances." There, the court observed:[55]

"It is not necessary that a physician tell the patient any and all of the possible risks and dangers of a proposed procedure. . . . As we noted earlier, materiality is to be the guide. . . . Materiality may be said to be the significance a reasonable person, in what the physician knows or should know is his patient's position, would attach to the disclosed risk or risks in deciding whether or not to submit to . . . treatment."

This was further refined in a pair of cases handed down by the Court of Appeals of Washington State in 1974.[56] In one of them, that court observed, after a lengthy discussion of exceptions to the doctrine of informed consent:[57]

"The precepts which have been discussed dictate that the elements which must exist to impose liability upon a physician under the informed consent doctrine are the existence of (a) a duty to inform, (b) a failure to inform, (c) evidence that, if informed, the patient would have chosen a different course of treatment, and (d) injury resulting from the treatment followed."

That last case is probably an adequate summary of the law of informed consent for present purposes. However, before considering what effect the proposed regulations have on the common law, it will be worthwhile to discuss the other aspect of liability noted above.

Inadequate Exercise of Skill

A question of an inadequate exercise of skill is as likely to arise as one of the duty to apprise a patient of hazards inherent in a therapy. Again, traditionally the standard of care was related to the skill prevailing in the community within which the physician practiced. However, this subjective requirement has also been superseded by a more objective one.[58]

Assuming that experimental evaluations are conducted in a teaching and research hospital, the question then becomes what is the standard of care in such an institution. Moreover, there is the question of what effect, if any, a waiver of liability would have in that

[55] *Wilkinson v. Vesey*, 295 A 2d 676, 689 (R. I. 1972).

[56] *Miller v. Kennedy*, 11 Wash. App. 272, 522 P. 2d 852 (1974), and *Holt v. Nelson*, 11 Wash. App. 230, 523 P. 2d 211 (1974).

[57] *Holt*, note 56, *supra*, at 219.

[58] *See, e.g., Canterbury*, at 785. There the D. C. Court notes that it has generally held that "Prevailing medical practice . . . does not itself define the standard." In general, *see* Louisell and Williams 1 *Med. Malpractice* ¶ 8.06 (Cum. Supp. 1976). For a decision perhaps indicating a contrary inclination, *see Holton v. Pfingst*, 534 S. W. 2d 786 (Ky. 1976).

setting. Both of these questions were addressed in a 1963 California decision.[59] After holding that a waiver of liability is of no effect in a tort suit by an injured patient for pressing reasons of public policy,[60] the court went on to state:[61]

> (D)efendant urges that . . . the funds of the research hospital may be deflected from the real objective of the extension of medical knowledge to the payment of claims for alleged negligence. Since a research hospital necessarily entails surgery and treatment in which fixed standards of care may not yet be evolved, defendant says the hospital should in this situation be excused from such care. But the answer lies in the fact that possible plaintiffs must *prove negligence;* the standards of care will themselves reflect the research nature of the treatment; the hospital will not become an insurer or guarantor of the patient's recovery. To exempt the hospital completely from any standard of due care is to grant it immunity by a contractual clause exacted of the patient. We cannot reconcile that technique with the (previous holdings of this court.)

Summary and Conclusions

It thus appears that, outside of a few jurisdictions,[62] the proposed investigational use regulations under Section 520(g)(3)(D) will have little effect on the tort liability of medical researchers. While the regulations *do* require informed consent and forbid the use of waivers, both of these appear to be consistent with the common law as presently developing in most jurisdictions. Moreover, as earlier discussed, while a failure to conform may give rise to possible statutory sanctions, the risk of these seems much lower than the risk of tort liability.[63] For that reason the proposals do not appear to present a basis for alarm, and indeed, may result in researchers being better informed than they might otherwise be of their obligations to human subjects. **[The End]**

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[59] *Tunkl v. Regents of U. Cal.*, 33 Cal. Rptr. 33, 383 P. 2d 441 (1963).

[60] *Id.*, at 447.

[61] *Id.*, at 448.

[62] Louisell and Williams, note 58, *supra*, at ¶¶ 17.07-57, for example, listing Oregon, Virginia, and West Virginia as currently recognizing a contract waiving a right to sue for negligence.

[63] *See* discussion corresponding to note 48, *supra*.

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MANDATORY WARNING LABELING PROPOSED FOR LIQUID PROTEIN DIETS

Label warnings on protein products intended for use in weight reduction or weight maintenance programs have been proposed by the Food and Drug Administration (FDA). The proposal would require labels on such produots to bear the statement: "Warning.—Very low calorie protein diets may cause serious illness or death. DO NOT USE FOR WEIGHT REDUCTION OR MAINTENANCE WITHOUT MEDICAL SUPERVISION. Do not use for any purpose without medical advice if you are taking medication. Not for use by infants, children, or pregnant or nursing women." The warning would apply to protein products sold in liquid or powdered form that are commonly used as a substitute for entire meals.

An additional warning was proposed for labeling on protein supplements that are not intended for use in weight reduction. The FDA believes that this warning is necessary because, even though protein supplements are not labeled for use in weight reduction, consumers often use these products for that purpose.

If the uniform, mandatory labeling program does not control the risk to health and life of consumers, the FDA warned that it will remove the products from the market. The agency also asked the medical community to supply any additional information on adverse reactions to the products. The few firms that responded to the FDA's November 9 request to voluntarily begin the use of a suggested label on the liquid diet products will be allowed a reasonable amount of time to adopt the exact language of the warning in the final regulation.

CCH Food Drug Cosmetic Law Reporter, ¶ 45,529

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