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Enforcement Under the Food, Drug and Cosmetic Act— The Park Case in Perspective

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IN THE ABSENCE OF A PERFECT WORLD, in which all laws would be self-executing, we must recognize that no law can be effective without adequate and appropriate provisions for enforcement. One approach to enforcement of the Food, Drug and Cosmetic Act,[1] a complex regulatory statute, would be continuous government surveillance of production, packaging and shipping of all regulated goods. But in-plant inspection would require a very large expenditure of societal resources, particularly troubling in these inflationary times. In addition, experience demonstrates that it poses problems of its own.[2] We must rely, then, for the protection of the public against adulterated food, mislabeled drugs, and dangerous cosmetics, upon a combination of industry patrolling its own territory, appropriate incentives for industry to do that job well, and adequate sanctions for industry failures.

Some such incentives exist entirely independent of statute. An ever-strengthening incentive for industry is the prevention of direct financial liability for harm caused by one's products. Of course, one may insure against such losses and pass the cost on to the consumer. A

* The views expressed are solely those of the author.

[1] 21 U. S. C. Sec. 301 and following.

[2] See, for example, Schuck, "The Curious Case of the Indicted Meat Inspectors," 245 *Harper's* 81 (Nov. 1972).

related incentive is the avoidance of adverse publicity both from liability lawsuits and from direct consumer action. I trust no company is anxious these days to be charged with shortweighing or adulteration in a press conference called by a citizen or consumer group.

In addition to these self-imposed incentives, Congress has provided the Food and Drug Administration (FDA) with a panoply of legal deterrents and remedies to assure pure food and drugs. Ironically, the public hears the most about a "remedy" not actually provided in the law, the product recall, which the FDA cannot order but for which it can and does negotiate. The FDA's hand would be considerably strengthened by the formalization in law of its recall authority. When a recall is refused, the FDA must rely on its power to seize the offending products. But the necessity to locate and seize the offending item in each judicial district requires an unreasonable utilization of resources. The proposed detention authority for the FDA would at least assure that discovered items are not dispersed before seizure actions can be begun. The FDA also may seek injunctions, which may effectively terminate violations but without adequately dealing with the previously committed offense.

Legal Sanctions

The FDA also may turn to the use of legal sanctions, issuing warning letters or initiating criminal prosecutions against both companies and individuals who violate the Act. The FDA seems to be indifferent to adding civil money penalties to its enforcement armamentarium.[3] Such penalties surely should not be substituted for its other enforcement tools, but I see no reason to reject such power as an additional option to be used when appropriate. Subpoena and records inspection authority should also be granted the FDA, as they would immeasurably assist its performance of its duties by enabling the Agency to ferret out violations that now may be escaping detection. And a provision for citizen suits to enforce the Food, Drug and Cosmetic Act would provide a valuable protection for the public by assuring that someone is watching the watchman.

The FDA's power to initiate criminal prosecution is a matter of intense industry interest these days, not because of any changes

[3] Testimony of Alexander M. Schmidt, M. D., Commissioner of the FDA, Public Health Service, Department of Health, Education and Welfare, before the Subcommittee for Consumers and the Subcommittee on Health of the Committee on Labor and Public Welfare, United States Senate, 94th Congress, 1st Session, on S. B. 641 and S. B. 1168, "Food Safety and Labeling Legislation," Serial No. 94-25, p. 88 (June 4, 1975).

in the FDA's decision-making processes leading to prosecution,[4] but because John R. Park, chief executive officer of Acme Markets, Inc., chose to battle his criminal insanitation conviction all the way to the United States Supreme Court.[5]

Even if Congress were to increase, as it should, the maximum criminal fines which may be imposed under the Act to the $10,000 for the first, and $25,000 for later offenses that the FDA seeks, nevertheless money penalties alone no more than sting the mammoth corporations which prevail in the industries that the FDA regulates. "The criminal fine . . . is . . . little more than 'a reasonable license fee' for engaging in [prohibited] conduct."[6] Raising the "license fee" would undoubtedly modify the calculus, particularly for the small company, but without measurably increasing the threat to the financially powerful corporation. I am convinced that the FDA's most powerful deterrent is its existing criminal remedy against individuals. Why am I so certain? If it did not matter to John Park that he was convicted of five counts of a misdemeanor to which his corporation pled guilty, he would not have fought that conviction and its $250 fine—at a cost I conservatively estimate exceeded the fine by a factor of 250—all the way to the United States Supreme Court.

Individual Criminal Convictions

If corporate officials are so disturbed by convictions that they are willing to incur such great expense to fight them, they must also be concerned about avoiding individual criminal convictions in the first place. As Anita Johnson, co-director of the Health Research Group, observed in testimony on the pending Consumer Food Act, industry officials "don't want to be called criminals. . . . They are worried about it."[7] Worry leads to increased vigilance, and the greater the vigilance on the part of industry, the greater will be the protection consumers receive against threats to their lives, their health and their pocketbooks "which, in the circumstances of modern industrialism, are largely beyond self-protection."[8]

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[4] See generally 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, 25-30 (Jan. 1975).

[5] *United States v. Park*, — U. S. —, 95 S. Ct. 1903 (1975).

[6] Note, "Increasing Community Control over Corporate Crime—A Problem in the Law of Sanctions," 71 *Yale Law Journal* 280, 287 (1961).

[7] Hearings, *supra* note 3, p. 101 (June 4, 1975).

[8] *United States v. Dotterweich*, 320 U. S. 277, 280 (1943).

The standard of criminal liability under the Act has not changed for a very long time. Yet we have only recently heard it charged that the statute is unfair to top executives who cannot control all aspects of their far-flung operations from the plush comfort of their corporate suites. Now, Mr. Dotterweich may well have had a legitimate charge of unfairness to level, for, as the dissenters in his case stated, individuals should be given "clear and unmistakable warning as to their vicarious personal liability,"[9] and the dissenters felt the statute did not so warn. Even the dissenters in that case agreed, however, that Congress had the clear authority "to rest liability on an act in which the accused did not participate and of which he had no personal knowledge."[10] But, if Congress had not provided a "clear and unmistakable warning" to corporate officials in the Act, the *Dotterweich* decision certainly filled the lacuna. For the 32 years since *Dotterweich*, industry regulated under the Food, Drug and Cosmetic Act should have been aware of the high standard to which its executives would be held, so Mr. Park certainly could not claim surprise. And it is especially ironic that industry charges as unfair a standard of conduct upheld by a Supreme Court that could hardly be denominated "anti-business" and in an opinion written by Chief Justice Burger, not one of its more liberal members.

What would be unfair is the "solution" put forth by powerful industry backers, to predicate personal criminal liability solely on "willful and knowing" violations. The executive officers of small firms would be hard put to prove they did not know of or intend corporate actions which resulted in violations of the law, while government would find it virtually impossible to prove that a top executive of a vast multi-plant firm did have knowledge of the conditions leading to the lawbreaking. The same criticism would apply to a standard of personal negligence. Yet the top officials of the large firm, as well as the small, make policy and determine the company's level of commitment to following the mandates of any statute. Historically, the law has had difficulty "pinpointing criminal responsibility in the corporate hierarchy,"[11] finding out who formulated, rather than who implemented, a policy in violation of law. High-level executives could avoid the reach of the law by making certain they have no "knowledge" of illegal activities or failures to act, while creating the atmosphere and the conditions under which subordinates allow violations

[9] *Id.* at 289.
[10] *Id.* at 286.
[11] Note, *supra* note 6, at 293.

to occur or under which they are inevitable. For these policy-makers to escape the impact of the law would certainly be the height of unfairness.

Widespread Misinterpretation

In their unrelenting effort to demonstrate that the existing law is "bad" by concentrating on hard cases, industry spokesmen have repeatedly referred to the possibility of sabotage, and the unfairness of charging a corporate official with a crime when the mouse in the milk was put there by a dissident employee. I think that there has been widespread misinterpretation of the meaning of the *Park* case, whether occasioned by fear of its ramifications or by zeal to catch the ear of Congress with a grim portrayal, I would not venture to guess. Chief Justice Burger's opinion for the majority clearly states, "the Act, in its criminal aspect, does not require that which is objectively impossible . . . [and] permits a claim that a defendant was 'powerless' to prevent or correct the violation to 'be raised defensively at a trial on the merits.' "[12] A sabotage defense thus could be presented to the jury and, if credible, would lead to acquittal. The corporate executive is not *strictly* liable for all violations of the law, as it has been suggested, but he or (the rare) she is only responsible, and properly so, "to seek out and remedy violations when they occur . . . and . . . to implement measures that will insure that violations will not occur."[13] I find myself in complete agreement with the Chief Justice's reflection that

> "[t]he 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 supports them."[14]

The concern exhibited by executives of the industries regulated by the FDA is very healthy, and suggests the potent deterrent effect of the law in its present form. As to the charges of unfairness, I say that the *Park* conviction itself is not at all an example from the catalogue of horrors which industry spokesmen have put together to inveigh against the law. The Supreme Court's decision adequately protects corporate officials from conviction for violations of law which they were, in fact, powerless to prevent. Nor is there any evidence put forth that the FDA has abused its criminal enforcement powers. Even Edward Dunkelberger of Covington & Burling, counsel for the

[12] *United States v. Park*, *supra* note 5, 95 S. Ct. at 1912 (citations omitted).

[13] *Id.* at 1911.

[14] *Id.*

National Canners Association, has admitted that the criminal liability provisions of the Act "have . . . been around a long time and . . . really have not been abused by the agency."[15]

Possibility of Prison Term

Del Monte cannot go to jail. General Mills cannot go to jail. Pillsbury cannot go to jail. Acme Markets cannot go to jail. All four could absorb sizable fines; their financial losses, if any, are in any case borne by the stockholders rather than by the corporate officials who bear ultimate responsibility for the firm's compliance with laws written to protect the consumer.[16] But the fear of being branded a criminal—even though I doubt John Park is a social outcast because of his misdemeanor conviction—and the mere possibility, albeit remote, of a prison term,[17] strikes terror in executive hearts, creating a potent deterrent for which civil sanctions and criminal sanctions against the corporation alone cannot substitute. The mere existence of this sanction helps to create the desired behavior of full compliance with the Act.

I am not going to suggest that salmonella-laden foods would be released upon the market the minute this law were modified in accordance with industry desires. I am not going to accuse industry of lacking all social responsibility. But I do believe that there may be some firms which would let down their guard slightly if the law were modified; who might, for instance, choose to skimp on quality control expenditures in hopes of maintaining profitability, when their managers are personally less subject to criminal prosecution. In industries as vast as those regulated by the FDA, even a tiny percentage of diminished voluntary compliance in response to a lowered standard of individual responsibility could have serious, potentially tragic, consequences to the health and well-being of the public.

Key to Successful Enforcement

The key to successful enforcement under the Act, it seems to me, is a combination of a strong vigilant FDA capable of punishing violators, powerful deterrents to prevent violations from occurring, plus a citizenry with the ability to bring suit to assure that the system

[15] Testimony before the Subcommittee for Consumers of the Committee on Commerce, United States Senate, 93rd Congress, 2nd Session, on S. B. 2373 and Amendments 962 and 1053 and S. B. 3012, "Food Amendments of 1974," Serial No. 93-96, p. 144 (March 11, 1974).

[16] See generally Note, *supra* note 6.

[17] Green, *The Closed Enterprise System* (Bantam Books edition, 1972), pp. 167-69.

is functioning properly. If anything, the FDA has turned away from immediate punishment for violations to a greater reliance on issuance of warnings and negotiation of voluntary recalls. Industry should be the last to complain of this trend, on which consumers are casting a watchful, and somewhat wary, eye. The FDA must obtain and retain a wide variety of enforcement tools from which to choose judiciously to deal with the variety of circumstances it encounters. Congress should provide those tools not now available to the FDA and strengthen others, but without tampering with its existing sanctions which have proven themselves fair and fairly used during the long history of the Act. The consumer's confidence in the safety of food and drugs in this country could be seriously undermined by Congressional weakening of the FDA's enforcement powers. **[The End]**

Two Bills Propose Reorganization of the FDA

The Food and Drug Administration (FDA) would be divided into two separate administrations by two bills, S. B. 2696 and S. B. 2697, which were introduced by Senator Edward Kennedy on November 20. The bills would split the FDA into a Food and Cosmetics Administration and a Drugs and Devices Administration. The new Drugs and Devices Administration would handle prescription drugs by creating a scientific and an enforcement division. Under that Administration, the authority of the Secretary of the Department of Health, Education and Welfare would be expanded to allow the carefully controlled large-scale clinical distribution of a drug and the collection of data from a random statistical sampling of the prescribing doctors before final new drug application approval. A National Drug Review Board would be created which would be composed of outstanding scientists who would examine drug research. The Food and Cosmetics Administration would handle problems of food and cosmetics safety. Accompanying reform legislation has also been proposed for this administration. Because of the complexity of the issues involved, interested persons may submit analyses of the bills to the Health Subcommittee of the Committee on Labor and Public Welfare by March 31, 1976, in anticipation of hearings to be held by the subcommittee after April, 1976.

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