VOL. 30, NO. 12 DECEMBER 1975

Food·Drug·Cosmetic Law JOURNAL

Papers Presented at the 19th Annual Educational Conference of the Food and Drug Law Institute, Inc. and the Food and Drug Administration

A COMMERCE CLEARING HOUSE PUBLICATION
PUBLISHED IN ASSOCIATION WITH THE FOOD AND DRUG LAW INSTITUTE, INC.

THE EDITORIAL POLICY of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the higest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis contributions and comments are invited.

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: 1 year, $30; single copies, $3. Editorial and business offices, 4025 W. Peterson Ave., Chicago, Ill. 60646. Printed in United States of America.

December, 1975
Volume 30 • Number 12

Second-class postage paid at Chicago, Illinois and at additional mailing offices.

FOOD DRUG COSMETIC LAW JOURNAL

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TO THE READER

Nineteenth Annual Educational Conference of the FDLI and the FDA. The following papers were presented at the 19th Annual Educational Conference of the Food and Drug Law Institute and the Food and Drug Administration, which was held in Washington, D. C. on December 2nd and 3rd, 1975.

Marsha Cohen, Lecturer in Law at the University of California at Davis, argues for the continued use of criminal liability of corporate officials, first established in the *Dotterweich* case and recently reaffirmed in *Park*. In her article, "Enforcement Under the Food, Drug and Cosmetic Act—The *Park* Case in Perspective," she states her belief that there has been widespread misinterpretation of the *Park* decision and that, in fact, the judge's ruling permits a defense that the official was powerless to prevent the violation. The article begins on page 676.

The *Park* decision is also the subject of *Richard A. Merrill's* article on page 683. The Chief Counsel of the Food and Drug Administration defends the Supreme Court decision and reiterates the Agency's long-held belief in the importance and the legitimacy of strict criminal liability as an enforcement method for violation of the Federal Food, Drug and Cosmetic Act. He also outlines the Food and Drug Administration's criteria in deciding to recommend criminal prosecution of corporate officials. The article is titled "The *Park* Case."

In "The Food and Drug Administration's Enforcement Policy," beginning on page 687, *Alexander M. Schmidt* explains the various methods used by the Agency in fulfilling its mandate. Stressing that preventive activities are most important, the Commissioner of Food and Drugs of the Food and Drug Administration states that the Agency would like to set up a program of industry self-regulation, with the Agency acting only as overseer.

Peter Barton Hutt offers a perceptive insight into the mood of the nation and its effect on the Food and Drug Administration as a regulatory organization in "The Future of the Food and Drug Administration." Beginning on page 694, the article is a plea for continuance of the Agency as it is today but strengthened with more funds and greater communication between the government and the public. Mr. Hutt is a partner in the law firm of Covington & Burling.

Taylor M. Quinn, Director of the Division of Regulatory Guidance of the Bureau of Foods in the Food and Drug Administration, recaps recent changes and discusses future plans of the Agency concerning food labeling. The article, beginning on page 706 and titled "Labeling of Foods," includes information about nutritional quality guidelines, common or usual names, declaration of ingredients and flavors, and nutrition labeling.

"Enforcement Policy Objectives in the Changing Food Environment" discusses the Food and Drug Administration's inspection procedures. Written by *Robert Angelotti*, Associate Director for Compliance of the Bureau of Foods in the Food and Drug Administration, the article explains the Agency's hope to divide establishments into risk categories for more effective coverage and to share inspection responsibility with the states. The article begins on page 712.

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

By MARSHA COHEN *

Ms. Cohen Is Lecturer in Law at the University of California at Davis.

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.

CCH Food Drug Cosmetic Law Reports, No. 673

The Park Case

By RICHARD A. MERRILL

Mr. Merrill Is Chief Counsel of the Food and Drug Administration.

DISCUSSION OF THE *PARK* CASE[1] is an open invitation to hyperbole from both the critics and the defenders of Mr. Chief Justice Burger's decision. Representatives of the Food and Drug Administration (FDA) might be expected to call forth Justice Frankfurter's vivid statements of the high purposes of the Food and Drug Act. Advocates of acquittal, much in the nature of a second appeal to the jury, will invoke the "fundamental principles of Anglo-American jurisprudence" and the spirit of the founding fathers.

This discussion will be more useful, however, if its tone is more skeptical.

Let me begin in this vein by wondering, only half facetiously, why the *Park* decision has been made the focus of a panel on the FDA's enforcement policies. Not that the role of criminal prosecution in the enforcement of laws intended to protect consumers is not an important subject. But one may justifiably question how much the *Park* decision has to contribute to the topic.

People talk about the *Park* decision, in either hushed or angered tones, as if it had come as a surprise. Yet, since 1906, federal law has imposed strict liability on producers of food and drugs. That policy was consciously reasserted by Congress in 1938. And in the famous *Dotterweich* case in 1943,[2] the Supreme Court confirmed that Congress' judgment was both sensible and constitutional. Indeed, Chief Justice Burger himself spends a good portion of his opinion in *Park* explaining that criminal liability without proof of "awareness of some wrongdoing" is by no means novel.

[1] *U. S. v. Park*, 95 S. Ct. 1903 (1975). [2] *U. S. v. Dotterweich*, 320 U. S. 277 (1943).

Facts of the Case

Justice Burger's opinion, to be sure, contains some fine round words, but they do not account for the stir the *Park* decision has caused. Nor, I submit, do the facts of the case.

Very few people have seriously suggested that Mr. Park was unjustly convicted of a misdemeanor. Consider what the government was able to prove at the trial:

(1) FDA inspectors had, on three separate occasions, discovered serious sanitation violations in warehouses operated by Acme Supermarkets. It has never been suggested that no violations of law occurred.

(2) The last two inspections conducted by the FDA were of the same Baltimore warehouse . . . demonstrating either a persistent problem, or a persistent indifference to its solution.

(3) Mr. Park acknowledged that not only was warehouse sanitation one of the matters for which he accepted responsibility, but that he had specifically delegated to subordinates the job of solving the problem in Baltimore.

(4) Mr. Park was aware that the problem, discovered first in Philadelphia and subsequently in Baltimore, was not being solved or, at least, was continuing. He was, in short, on notice that his "system" was not working.

In the face of this evidence, under the standard announced in *Dotterweich,* it cannot be a surprise that the jury convicted or that the Supreme Court affirmed.

Strict Criminal Liability

I do not want to be understood as denigrating the efforts of the Supreme Court on our behalf. The *Park* opinion is a workmanlike product, and it reconfirms both the importance and the legitimacy of strict criminal liability for violations of the Federal Food, Drug and Cosmetic Act. But it is also an unsatisfactory decision in some ways, for it leaves troubling questions unanswered.

Two that come quickly to mind are: (1) the Court's failure to explain precisely what the government must show to establish that a defendant had a "reasonable relation" to the violations charged; and (2) the Court's cursory treatment of what is becoming known as the "impossibility" defense.

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Two cases now before the Ninth Circuit Court of Appeals, *Starr* and *Hata,* will soon speak to the latter issue. Therefore, I shall not explore it further.

On the former issue, which is really the heart of the matter, the Court says essentially that the facts proved by the government in *Park* clearly demonstrated such a relationship and that the jury instructions, though perhaps lacking in specificity, were adequate to focus the jury's attention on the facts before it.

It may not, however, be possible to do much better with this issue. We struggle very hard in reviewing proposed prosecutions to satisfy ourselves that the evidence of individual involvement—of opportunity to know and ability to prevent or correct—is adequate enough to justify prosecution. We are attempting to articulate and publish criteria for recommending prosecution, because we recognize that the uncertain scope of the *Park* decision—indeed, of the Act itself—imposes on us an obligation to deploy this ultimate sanction with great care.

Basic Ground Rules

The government's brief in the *Park* case identifies certain basic ground rules. First, we almost always will include one or more individuals as defendants; corporations alone do not commit crimes. At the same time, we will not include individuals who lack authority to prevent or correct violations or who could not be expected to have been aware of violations in the reasonable exercise of their corporate duties. And, even if investigation discloses the elements of liability, ordinarily we do not recommend prosecution unless the defendant, after learning of the violations, fails to correct them or to make changes to prevent their recurrence.

Our standards for reference of cases to the Department of Justice focus on continuing violations, on violations of an obvious and flagrant nature and on intentionally false or fraudulent violations.

These criteria may sound too flexible but, in practice, they produce a high degree of continuity and consistency in our recommendations. Moreover, it is important to recognize that the prosecutory function inevitably entails the exercise of judgment. The scope of our discretion under *Park* is not, I submit, notably different than that exercised by most local prosecutors.

This leaves the central issue of whether strict, though not absolute, criminal liability is an appropriate feature of a scheme for regu-

lating foods, pharmaceuticals, and medical equipment. In my view, the answer is self-evident. The other sanctions provided by the Act—*or providable by Congress*—would not by themselves assure the degree of punctilious concern for product integrity and safety to which consumers are entitled and too often fail to receive.

Testimony Before Congress

The point has since been more eloquently, but never more forcefully, stated than by Charles Wesley Dunn, who testified before Congress in 1948 *on behalf of* the Grocery Manufacturers of America, the American Pharmaceutical Manufacturers Association and the New York State Bar Association. The occasion was a hearing to consider a bill to amend the criminal liability provisions of the Act, a bill inspired by reaction to the *Dotterweich* decision. On that occasion, Mr. Dunn declared: "It has always been the situation under the Food and Drug Law . . . that intent is not an essential ingredient of the offense. If you make it so, you simply nullify, in effect, the practical value of these laws."

Congress wisely listened to Mr. Dunn then. The jury is still out on whether Congress will exhibit the same wisdom this time around.

The proposed Consumer Food Act, recently reported by the Senate Commerce Committee, includes a provision that would require the FDA to prove that a defendant charged with violating the food provisions of the Act did so knowingly, willfully or negligently. And it is widely rumored that the House Committee on Interstate and Foreign Commerce will be invited, and possibly persuaded, to amend the device bill so as to limit criminal liability to cases in which the FDA could prove that the defendant acted knowingly or willfully.

The latter of these proposals would, in Mr. Dunn's words, "simply nullify . . . the practical value" of the Federal Food, Drug and Cosmetic Act. The former, though less destructive of the Act's basic purposes, represents a fundamental shift in Congressional philosophy respecting consumer safety. And only Congress could then answer for the practical effect of its adoption on the willingness of individuals engaged in the production of food, drugs, devices and cosmetics to make the commitment necessary to guarantee that their products are safe.

[The End]

The Food and Drug Administration's Enforcement Policy

By ALEXANDER M. SCHMIDT, M.D.

Dr. Schmidt Is the Commissioner of Food and Drugs of the Food and Drug Administration.

I AM CONSTANTLY ATTENDING MEETINGS, the subject of which relates directly to the topic of this discussion. Some of the meetings involve only the Food and Drug Administration (FDA) staff while others are requested by industry officials. In addition, I have received, and am answering, no small amount of mail on the general subject.

In the process of this activity, I have learned a few things, have drawn certain conclusions and, as a result, have given specific instructions to the FDA staff.

It occurred to me, as I was preparing these remarks, that I really should say to you exactly what I have told my staff but go beyond a simple repetition of my statements to an explanation of why I have made them. At the very least, then, my contribution to this discussion should be timely and pertinent.

The meetings I have attended are of three general types. One kind has occurred when a company has wanted us to do something, or not do something—to take or not take a regulatory action, to adopt or not adopt a policy—and has come to us to present its case. At these meetings, I am invariably impressed by the statements of the top company official present, usually the president. The message I receive is this: "Now that we, the top corporate officials, know of the matter, appropriate and speedy action will be taken by us, and

the FDA need not have further concern." When a top corporate official makes such a statement, it almost always turns out to be true.

I have found top corporate officials to be superior persons, clearly in charge of their company. But I have been distressed by the number of times that the official has implied, or stated explicitly, that it was not until he learned of an injunction, or a seizure, or a recall, that he was even aware that he had a problem in his operation.

The same thing occurs again and again. We find a problem and we notify plant officials of the need to do something but nothing happens. Often, letters to corporate officials also achieve nothing. Then, as we bring a legal action, the responsible officials suddenly take charge, and things happen fast.

Personnel Changes

I have also been impressed by the number of times personnel changes in a company have occurred after one of our compliance actions. Such change has seemed to correlate well with the number of times that we have tried unsuccessfully to draw a company's attention to a matter needing correction.

And so I have been impressed by the capacity and the power of top corporate officials to cause good things to happen. As J. G. Holland once said, "Hand in hand with capacity and power walks responsibility."

In any case, this lesson is not lost on me, and I recall it during the second kind of meeting I have attended. These are in-house FDA-type staff meetings, often briefing me on an industry problem. I am told, "We've done this and this and that, and the problem remains. No one in the plant seems interested in correcting it. What should we do now?"

My response has been the following: "Find out who is in charge of that plant, or operation, or whatever it is, and send *his boss* a registered letter, and be certain that *that* boss knows he has a problem. We should then get a response. If we don't, we can then proceed logically and effectively."

The third type of meeting pertinent to this subject is a budget meeting or priority-setting session, at which we seek to trim fat out

of our budget, gain efficiency in our operation and do our job with a minimum expenditure of our all-too-scarce resources. At all these meetings we seek the best way to get compliance with the Act and our regulations.

Indignant Mail

My mail about the Agency's enforcement activities is often quite indignant, too much so to be either wise or credible. A good example recently reached my desk. It is from a division vice president, complaining because we had sent a regulatory letter to a manager of a plant in his division. Our regulatory letter began, "This letter is written to advise top management of inspectional findings which should be corrected." The letter then goes on to advise of a labeling infraction, and requests corrective action within a certain time.

I reviewed our letter, and find it entirely consistent with my instructions to the Agency to let company officials know, *early*, that a problem exists.

The division vice president, however, in letters he sent to Paul Rogers and other members of Congress, used the letter as an example of "unwarranted use of the *Park* type of regulatory letter," and an example of "an abuse of FDA regulatory power . . ." and so on. The suggestion is made that there should be better communication and cooperation between industry and the FDA.

I agree that we need better communication and cooperation with all those with whom we deal. But the issue seems to me to be better communication within a company. To me, the above-mentioned regulatory letter is fulfilling a responsibility we have to be certain that the most appropriate corporate official is notified of a violation of our law or a serious compliance problem. And our definition of "appropriate official" is no less than the boss of the person who is managing the plant or operation in question.

Lines of Communication

It is up to a company to look to its own lines of communication, but there is often a tendency within industry, as well as in parts of government, to maintain a sort of deniability of knowledge for top officials. This then allows them to "step in" when necessary.

We have discovered that corrections of serious deficiencies nearly always involve the administrative layer next above the manager of the plant or operation, if for no other purpose than to gain approval for the necessary expenditure of money.

We have also long noted a tendency for some companies to wait as long as they can before taking us seriously. They wait for an injunction or a seizure action and then come in and plead ignorance of the problem at the proper administrative level, even in the face of our repeated warnings to lesser plant officials, nominally in charge. The promise is then made to effect corrective action, which is carried out promptly. The promise is usually made by the company president.

Quick Action

What we have learned, then, is that it is top corporate officials who spend the money, who make the tough decisions and who get quick action when they know of a serious problem that must be solved. I have, therefore, instructed our staff to see that these officials know of serious problems, because they have demonstrated to us, over and over again, that they are, in fact and deed, responsible.

To me, the plea that responsibility has been delegated to lesser officials does not make sense. One can delegate authority, one can share power, but one is forever stuck with the responsibility. One of the best expressions of this I have encountered came in an off-the-cuff remark by Admiral Rickover at a Congressional hearing. He said,

"Responsibility is a unique concept; it can only reside and inhere in a single individual. You may share it with others, but your portion is not diminished. You may delegate it, but it is still with you. You may disclaim it but you cannot divest yourself of it. Even if you do not recognize it or admit its presence, you cannot escape it. If responsibility is rightfully yours, no evasion, or ignorance, or passing the blame can shift the burden to someone else."

What we have learned, then, simply by observing corporate behavior, is that to be effective, we should discover just who is most responsible, who can and will get the necessary job done, and then let that person know about the problem.

The purpose is not to set anyone up, but to get compliance with our requirements as quickly and efficiently as possible. The purpose of *that* is to prevent injury and protect the public health, our reasons for being.

It should surprise no one that I have mentioned our need to be more efficient, and to husband our resources. The FDA is expected by almost everyone to do more and more in an increasingly complex field of scientific regulation. Our resources are certainly not growing in proportion to our responsibilities, as defined by Congress and others. In addition, many questions are being asked about how we are carrying out our responsibilities, and even about the very purpose of regulation and regulatory agencies. So we are reassessing our activities, and how we conduct them.

Prevention of Injury

The primary activities of the Agency are preventive in nature, to prevent injury, sickness and death. Our regulatory activities are explicitly geared to the proposition that manufacturers must carry out their responsibility to market safe, effective products, properly labeled, and thereby prevent injury from occurring.

The prevention of injury, rather than its repair, is the only morally proper goal for us all. Also, prevention is efficient and conserves resources. Besides being an inefficient way to prevent injury, court actions are becoming increasingly ineffective as a means of establishing regulatory policy. Court actions, including prosecutions, will always play an important role in our total regulatory program. But after-the-fact court actions cannot substitute for a clear declaration, before the fact, of regulatory policy and requirements.

And so we are working hard at codifying our existing regulations and writing new ones. They will detail not only our procedural regulations but others that attempt to specify with fair precision what our regulatory requirements are, what we hold industry responsible for, what our policies, priorities, action levels or tolerances are and what we consider to be good manufacturing practices, practices that should prevent problems from occurring in the first place.

We are also trying to establish cooperative and at least semivoluntary programs of quality assurance, programs in which industry participants are capable of regulating themeselves, detecting and correcting their own deficiencies, overseen by the FDA.

Accrediting Bodies

The best analogy I can think of is how educational institutions are regulated by accrediting bodies. The FDA ought to be able to

accredit a firm to oversee its own practices and products in such a way that safety is assured, while the FDA acts as a guarantor.

If our regulatory requirements are spelled out in detail, and if we have agreed as to how the requirements best ought to be met, then all of our jobs ought to be a lot simpler, and it ought to be easier for corporate officials to know of deficiencies in their operations.

Recalls, seizures and injunctions will undoubtedly remain important regulatory tools, as will criminal prosecution for unattended serious violation of the law. I quite agree that no one should be prosecuted for trivial matters. Good judgment must be exercised by the Agency.

One point made in the previously mentioned letter from the division vice president was that the labeling violation, which he considered a minor violation of an obscure regulation, hardly justified a veiled threat to a corporate official. I do not consider our letter a threat at all, much less veiled. It is simply a declarative statement of fact. But I would agree that our enforcement tools must be used with great care. In particular, prosecution of individuals is an extremely serious business and, as Richard Merrill in mentioning our ground rules has outlined,[1] it is an option regarded very seriously by the Agency.

"Enforcement Regs"

I am anxious to have our enforcement policies and procedures clearly spelled out for all of our own employees, as well as for everyone else. We are now working hard at a new set of regulations, our "enforcement regs," as we call them, which will deal with recalls, injunctions, seizures and prosecution.

It is my hope that these regulations will inform and reassure everyone that we will not be arbitrary or capricious, thoughtless or incompetent, or anything else bad, in using our admittedly powerful enforcement tools.

Finally, I would note that we have discussed quite explicitly the idea that one can punish or threaten to punish, but one can also offer a reward.

Quite obviously, the withholding of punishment, when a reason to punish exists, can be a reward. I would also think that successful

[1] See article on page 683.

participation in a cooperative quality assurance program could be very rewarding in many different ways, not the least of which would be to have the confidence of positive knowledge of being in compliance with our requirements.

Reward System

We will continue to consider a reward system, and I would welcome any suggestions on this matter. As far as I've gotten in my own thinking is this: I would find it difficult to agree to a recommendation for prosecution of a corporate official who, immediately upon learning of a serious problem, corrected it.

This policy could be objected to on the grounds that it would encourage slow learning, but I do not agree with this. It does recommend to me the idea that we should, as I have said several times, help the learning process along with our notification of executives of their problems.

Any reward system will have to be built on the foundation of industry acceptance of its responsibilities. To me, responsibility is not a detachable burden, easily shifted to a subordinate. To bear responsibility connotes an active seeking of that knowledge necessary to carry out the trust. Neither the *Park* case nor any of the other enforcement programs of the FDA need alarm or disturb anyone who accepts responsibility seriously, and deals with us seriously and in good faith. This is not to say that we will not err, or be mistaken on occasion, but the more we do communicate and cooperate, the rarer that will happen. **[The End]**

PLAN FOR INCREASING "CONSUMER INPUT" IN FDA ACTIVITIES PROPOSED

Several recommendations aimed at increasing "consumer input" into the Food and Drug Administration's (FDA's) decision-making processes have been proposed by the Agency. The recommendations, which comprise the FDA's "consumer representation plan," were developed at the request of President Ford. Ford had requested such a plan from every agency of the Department of Health, Education and Welfare. Under the FDA's plan, the Agency would seek to interact with a broad, geographically representative group of consumers by means of *ad hoc* meetings, representation on advisory committees, emphasis on special groups and the mass media. Under the proposal, a system of Regional Consumer Representatives, composed of individuals from local consumer organizations, would also be established. The last day for filing comments on the proposal is February 24, 1976.

CCH Food Drug Cosmetic Law Reporter. ¶ 41,521

The Future of the Food and Drug Administration

By PETER BARTON HUTT

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SIXTEEN YEARS AGO, as a young Food Law Fellow at New York University School of Law, I took the train from New York to Washington to attend my first Food and Drug Law Institute-Food and Drug Administration (FDLI-FDA) annual educational conference. Although I am sure that none who attended the 1959 conference realized it at the time, that conference marked a sharp turning point for the FDA, a demarcation between the Agency and its predecessors as they had existed since 1906 and the Agency that we have come to know since 1960.

At that time, the allegations of conflicts of interest involving Dr. Henry Welch had recently been thoroughly explored in Congress and in the public press, the first time that the Agency had been accused of a public scandal. A few days before the 1959 conference, the Department of Health, Education and Welfare had released its still famous public statement about the potential danger of aminotriazole in cranberries, the first time that the Agency was embroiled in a major nationwide controversy about food safety. Congress was busy enacting major new laws to convert the Agency's regulatory responsibility from that of policing the industry to that of granting explicit approval of products before marketing.

The effects that those changes have had upon the FDA are very noticeable now, 16 years later. The greater public visibility caused by more vigorous enforcement action has engendered far greater public controversy about the Agency. The statutory requirements of premarket approval have stirred enormous criticism that the Agency is approving either too many—or too few—of the products that

must come before it and, thus, that it is either failing to protect the public adequately or failing to permit important new products to reach the market. Finally, and far more important, this new public prominence has necessarily caused both Congress and the public media to discover the FDA. Congressional committees and the General Accounting Office (GAO) have conducted more numerous, lengthy and detailed investigations of the Agency's daily work than of any other governmental agency of which I am aware. From a position of relative obscurity, the FDA has emerged as one of the leading subjects for daily national attention.

A New and Different Agency

For these reasons, the Agency that we knew 16 years ago no longer exists. It is a new and different Agency, and a new and different world in which it must function.

Moreover, the FDA that has emerged in the past 16 years now stands at the threshold of still another new era. The scope and structure of the Agency—even its name—are being questioned. My remarks, therefore, are addressed to the Agency's future, not to its past.

I start, as I have always started, from the premise that a strong and vigorous FDA is essential to the health and welfare of this country. This premise has guided much of my life for the past 16 years, and is likely to do so for as long as I live.

I think, moreover, that this premise is readily accepted by virtually all members of the public, including members of industry, consumer groups Congress, health and legal professions, and the media. It is simply an anomaly that segments of all of these groups, together with some in the FDA itself, are currently contributing to substantial impairment, or even destruction, of the Agency.

This phenomenon of public attack upon an important institution of our society is not unique to the FDA. We are witnessing it at every level of government. Commentators more experienced and perceptive than I have pointed out the deep public skepticism and emotional mistrust of government that pervades the country. Hostility and abuse are openly directed at our highest officials. Accusations are assumed true, and denials are regarded as attempted cover-ups. Many have warned about the similarities to the methods used by former Senator Joe McCarthy in the early 1950's.

Symbol of Distrust

The causes of this discontent are many and varied. I personally believe that Watergate is more the symbol of distrust than the cause. Many see a lack of leadership in Congress or in the White House, wholly apart from the issue of Watergate. We are all frustrated because the problems now faced by government do not permit simple solutions and often do not permit solutions at all. For the first time, we are realizing that our resources are indeed limited, and do not allow us to attack at once all of the problems we face. We are going through a period of self-reappraisal, a time when the nation must squarely face choices that it did not realize even existed before. The first idols to topple under these circumstances are quite naturally our governmental leaders, even though they may have little power to alter the events with which they are faced.

There is no point in bewailing our current national mood. It exists, and we must recognize that fact. But national moods are transitory, and I remain an incurable optimist. There is little doubt in my mind that, in time, this national despair and hostility will pass. Just as the student riots of the 1960's gave way to more reflective and just handling of disputes, I am sure that the hostility and abuse that prevail today in governmental affairs will give way, at some point in the future, to greater civility and restraint. My only concern is that, in the interim, our institutions of government in general, and the FDA in particular, do not suffer irreparable damage.

My thesis, therefore, is that we should hasten domestic detente by searching not for those things on which we disagree but, rather, for those goals which all of us can share in common. It is time to lay down our battle axes, to put aside our rhetoric and to settle our differences by more patient discourse.

Fundamental Issues

I would begin this search with very fundamental issues. I would hope, for example, that all segments of the public could reach substantial agreement on at least five basic principles, which I will now explore briefly.

First. There should be widespread agreement that the country does indeed need a governmental agency like the FDA, which, on the one hand, will protect the public from unsafe products and, on the other hand, will refrain from controlling industry like a public utility.

The FDA and its predecessors have been, since their inception in 1906, the country's most important consumer protection agencies. Let us at least join together in recognizing that the search for regulatory reform does not mean a return to the days of *caveat emptor,* any more than the need of the individual citizen for governmental protection against unsafe products means that the food and drug industry should be tightly controlled, in every minute detail of its enterprise, by rigid governmental requirements. There is a middle ground, which we must constantly seek, where private enterprise and governmental regulation can coexist.

Second. I would advance the proposition that the FDA, as an entity, should continue to exist in the future, and should be greatly strengthened, but should not be torn asunder. The present form of the Agency has existed since 1927. It has borne the same name since 1931.

Poll Results

Certainly, the Agency is widely known to the American people. A poll reported by Louis Harris in May 1975 showed that the FDA is known to 86 percent of the public, an extraordinary level of recognition of which even the President of the United States would be proud, and which far exceeds most other organizations.

That same poll showed that, in spite of the general public hostility to governmental agencies that prevails today, 61 percent of the public response was positive toward the FDA, an increase from 56 percent in 1971. Of 18 federal agencies included in the poll, the FDA was the only one to achieve a favorable rating of over 50 percent.

In contrast to this widespread respect for the Agency, the poll indicated that those who gave a positive response on Congress dropped from 42 percent to 16 percent; the executive branch, from 43 percent to 15 percent; and business, from 55 percent to 15 percent. Based on these statistics, one might conclude that a major reason for recent harsh attacks on the Agency is outright jealousy.

This poll obviously does not prove that the FDA has done, or is now doing, an adequate job. It does show, however, that the Agency and its work are well-known to the public. I believe that, now more than ever, the country needs and deserves governmental institutions that it recognizes and trusts. It would be years, if ever, before any new agency could generate the public recognition and respect that

the FDA now enjoys as a result of its work over the past 45 years. Public confidence, once achieved, should not be lightly discarded, especially at this point in history. Accordingly, absent compelling justification for breaking up the Agency, there are sound reasons for continuing it with the same name and in the basic form in which it now exists.

King Solomon's Judgment

Nor do I find reasons that are persuasive, much less compelling, for breaking the Agency apart. The FDA, like any other organization, is a living entity. I have never seen any living thing helped by dismemberment. We must remember that King Solomon's famous judgment is renowned only because he did *not* cut the baby in half.

I am in full agreement with Senator Edward Kennedy that the Agency needs and deserves substantial strengthening. But his recent proposal to split the FDA into two new organizations—a Drug and Devices Administration and a Food and Cosmetics Administration —would, I fear, have a counter-productive effect. The present components of the Agency are far more interdependent than some people outside it realize. Issues common to most or to all of these components arise every day. Separating them would further dilute the already scarce governmental resources now available to resolve these matters. This would tend to hinder, rather than increase, governmental efficiency and effectiveness. Interagency coordination can never be an adequate substitute for a close working relationship as part of the same agency.

The interdependence of the present components of the FDA can perhaps best be understood by a few current examples. The Bureau of Veterinary Medicine deals with the use of human drugs in animals, the products of which are in turn used for human food. Polyvinyl chloride has been used in containers for food, drugs, devices and cosmetics, and in making devices. Ethylene oxide is similarly used across product lines, as are color additives and many other chemicals too numerous to mention. The Bureau of Radiological Health makes important contributions to issues involving radioactive drugs, radiation sterilization of devices and radiation used in food processing. Numerous products regulated by the Agency fall within the jurisdiction of two or more bureaus. And the field force, which comprises about 50 percent of the Agency, serves all of these components, as do many of the administrative service personnel.

It does not appear to me that the present size, scope or structure of the FDA has been a major cause, or even a contributing cause, to whatever deficiencies presently exist in the Agency. Attempts at reorganization seem directed more toward the symptoms than the causes of current difficulties.

Statutory Reorganization

Thus, I find the statutory reorganization of the FDA which was adopted by Senator Kennedy in 1972 to be far more suited to his purpose of strengthening the Agency than his present proposal. In 1972, Senator Kennedy reported out the Food, Drug and Consumer Products Safety Act of 1972, which would have retained the FDA as an entity, with increased statutory authority and scope, while at the same time upgrading the entire Agency in the governmental structure. The new Agency would have been headed by an Administrator of Food and Drugs, under whom would serve a Commissioner of Food, a Commissioner of Drugs, a Commissioner of Veterinary Medicine, and so forth. The individual commissioners would have had immediate authority and responsibility for their areas of primary jurisdiction, just as they would have under the Senator's new proposal. Under the former proposal, however, the Administrator would have had overall authority to direct and coordinate Agency action to assure consistent protection of the public health with respect to the numerous overlapping issues that occur every day among these closely related product areas.

I thought Senator Kennedy's approach made good sense in 1972, and I still think it does. It would increase the scope of the Agency to eliminate duplicative regulation now performed by other agencies, as well as strengthen the Agency immeasurably by the new authority and positions granted. This would substantially increase the stature and morale of its employees at all levels and enhance existing public recognition and confidence in the Agency and its work.

Important Public Institution

I would hope that all interested members of the public could unite behind legislation along the lines proposed by Senator Kennedy in 1972, which would retain the FDA as an important public institution. It must be understood, however, that substantial further efforts would still be needed to make the Agency as strong and effective as it should be.

Third. As the first major step in strengthening the FDA, we must reach agreement on the need for an adequate budget for the Agency. All of us, either privately or in public forums, have admitted that, under the budgetary restrictions that currently exist, it is utterly impossible for the FDA to do even a small portion of what is now expected by the public. We all know that the usual small budget increases do not even keep up with inflation and the Agency's growing responsibilities. There must be a major budgetary increase in the near future if the Agency's job is to be done properly. Industry cannot expect its products to be reviewed responsibly, lawyers cannot expect matters to be handled expeditiously, health professionals cannot rely upon the FDA's decisions with confidence and consumers cannot be expected to trust the entire process unless the Agency is strengthened to a point where it is capable of handling its daily work load effectively.

Public Expectation

Public expectation of the FDA's performance has far outpaced provision of resources with which to meet those expectations. I am convinced that the public simply does not understand that the FDA must regulate products that account for roughly 25 to 30 cents out of every dollar spent by every consumer in the United States today, on a yearly budget of only 200 million dollars. It is as important that the public understand what the Agency *cannot* do with its present budget, as it is for them to realize what *is* being done.

No one today knows, or can even estimate, the budget needed to enforce the current provisions of the laws implemented by the FDA, largely because there is little agreement within Congress, the Executive Branch or the public at large, on what the Agency is expected to do in enforcing those provisions. I have pointed out many times that the Agency could spend all of its current resources just on enforcing the food adulteration provisions of the law, if it were to do so with the thoroughness demanded by some. The same is true of other provisions of the law. Even a modest step toward better enforcement of the current law would require a two fold increase in the Agency's present resources. But if one were to take seriously all of the demands made upon the FDA by the GAO reports, and by senators and representatives in the course of their Congressional investigations and reports during the past few years, one could easily forecast anywhere up to an immediate five fold budgetary increase.

It is therefore apparent that some agreement on the functions and priorities of the Agency is essential to its future. The public must begin to realize that a decision by Congress to appropriate specified amounts of money, and designate specified levels of employees, is as much a decision that the Agency will *not* do certain things as it is a decision that it *will* do certain things. Under our democratic process, that decision is made by elected representatives of the people, speaking on their behalf. It is therefore important that the public know the choices being made by Congress each year on their behalf, and that there be an opportunity for public exploration of the alternatives involved and the resulting realities of the choices that face the FDA now and in the future.

Administration Strictures

Current administration strictures preclude the Agency from conducting any such analyses or advocating any major increase in its budget. It is therefore incumbent on Congress and the private sector, on their own initiative, to analyze the current needs of the Agency and to speak out on its behalf. No reorganization or statutory change of any kind will have the slightest effect on the performance of the FDA without provision of adequate resources.

Fourth. The second major step that must be taken to strengthen the Agency is to push to completion its long-dormant plans for a unified campus in Beltsville, Maryland. I doubt that any of you can truly appreciate the frustration and inefficiency, much less the hindrance to public health, caused by the present split of the Agency's components throughout the Washington metropolitan area. Some departments are more than 20 miles apart. If it is important for the National Institutes of Health and the National Bureau of Standards to have a unified campus, surely it is far more critical for the FDA, where important health issues common to all of its components must be discussed and resolved on a daily basis.

Unified Campus

I believe that a large part of the morale problem that has been endemic among FDA scientists for over 20 years has been the result of extremely poor working conditions. A unified campus, with modern facilities, would make these positions far more attractive and prestigious. It would permit the Agency to make full use of its present

scientific resources without the logistical impediments that exist today. And it would allow the Agency to attract short-term visiting scientists under the program recently proposed by Senator Kennedy, which I hope all of us can enthusiastically support.

I do not believe that an FDA campus will be built without major public support. And I can see no reason why all of the diverse segments of the public interested in the Agency cannot agree on the need for this, and champion its cause in the Congress.

Fifth. In my judgment, the most important principle on which we need public agreement is recognition of the enormous difficulty (at times, impossibility) of the tasks that face the FDA today. There must be a much greater public appreciation of the inherent limitations of all FDA decisions, and of the fact that, in many situations, the Agency must act on the basis of incomplete and inadequate information.

Difficult Decisions

It is not sufficient, I submit, that people outside the Agency merely sympathize with those inside the Agency who must deal with these difficult decisions. Many of the issues posed to the Agency are utterly intractable, and defy the best of efforts. People must learn to accept the fact that government officials, like the family doctor, cannot always provide an adequate answer to every problem that arises.

It is well accepted in our society that organizations do not always make the right decisions. Businessmen market products that are rejected by the public. Congress writes laws that do not work and must be changed. Consumer groups take positions that are later proved to be wrong. The press makes errors in its reports: indeed, everyone makes mistakes in judgment at some point. In contrast, however, the FDA is expected to be right 100 percent of the time. The public simply cannot understand why, based on new information or a re-evaluation of old information, the Agency may reverse a decision that it made perhaps only a short while ago. Government officials are expected to be perfect, while all the rest of us are acknowledged to be ordinary mortals. Indeed, under these circumstances, government officials often make the fallacious assumption that they cannot even admit to mistakes that they know they have made.

When I first came to Washington, Paul Warnke warned me that the most frightening thing about this city is that you soon discover that those who govern our country are ordinary people, like you and me. I did not realize at the time what a profound truth that was. And with that mortality, of course, comes fallibility.

Slow-Moving Target

John Jennings is fond of pointing out that the FDA is a large, slow-moving target, easily hit, which bleeds profusely in public. I would add that, in contrast, the Agency's goal of product safety is an illusive target, only fleetingly glimpsed at a distance and very seldom fully attainable in the real world. The combination of these two facts of regulatory life constantly places the FDA in jeopardy of attack.

We can demand of our government officials integrity, hard work and the best judgment of which they are capable. We can also demand that they explain the reasons for any decision they make, and the basis for any action they take. We will always reserve the right to question scientific judgments through the well-established peer review system and to challenge the legality of governmental action through the courts.

However, we cannot allow ourselves to go beyond that. We cannot demand infallibility or decisions with which all of us agree. If our form of democratic government is to prevail, we must rise above the temptation to see each decision with which we personally disagree as a manifestation of some hidden conspiracy or the product of sheer incompetence. We simply cannot afford to delude ourselves into believing that there is only one side of any issue; namely, the side that we believe in, and that all other arguments are either foolish at best or venal at worst.

For years, Thomas Austern has reminded me that, although anyone can express an opinion with certitude, none can do so with certainty. I am not asking, however, for a wave of unnatural humility or cessation of disagreement. I ask only for recognition that disputes can be approached and resolved with calm dignity far more easily than with harsh invective.

Lest you go away with the wrong impression, let me state that I include in my remarks the FDA as well as those in Congress and

in the private sector. The FDA, including myself when I was there, has at times been a participant in the current escalation of confrontational politics. Conversely, there are some outside the Agency who have, in my judgment, done their best to avoid the level of antagonism that now prevails. My purpose is not to assign blame but, rather, to point out that we have a great need to avoid the excesses that now so often prevail in discussing food and drug issues. This can only be accomplished if we all work on it together.

If we are to achieve even the modest goal of agreement on some of the principles I have just set out, we must all exercise a much greater degree of self-restraint in both our public and private dealings than has been evident in the recent past. There must be recognition of higher goals, fundamental to the long-term stability of our government and, indeed, our entire society, which take precedence over our immediate individual concerns and needs.

Nor is it really enough to ask that all of us simply become less strident in tone and more civil in our relations. We also have an affirmative obligation to speak out publicly on the importance of the FDA and the functions it serves. Those of us who know more about the Agency and its daily service to the nation than other groups of people must speak out. If we do not support the Agency, I know of no one who will.

Unacceptable Alternatives

The alternatives, I believe, are wholly unacceptable. In my talk to the first National Academy of Sciences forum three years ago, I expressed concern about the specter of deciding safety issues through trial by combat, rather than through reasoned scientific discourse. In the intervening three years, that specter has become reality. Differences over scientific judgments and public policy have at times degenerated to gutter-level attacks on motives and personal integrity. Knowledgeable people have become afraid to participate and speak out, not for fear that others will disagree but, rather, for fear that they will be subject to similar hostility and abuse.

If permitted to continue, the demoralizing effect that this will have upon the FDA could be enormously damaging. Indeed, it has already led to the suggestion that the Agency be broken apart.

Certainly, the possibility that highly qualified people, willing and anxious to serve their government, will be either attracted to the

Agency or persuaded to remain with the Agency, will be severely diminished if this continues. No person of intelligence, no matter how much good will that person may entertain, can be expected to withstand for long the personal abuse that prevails today.

There will also be greater delay and slowness in any decision that presents difficult judgmental issues. Indeed, there may be attempts to avoid any controversial matter. No one enthusiastically tackles difficult decisions if he knows that the potential result will be character assassination. At a time when we all worry about a lack of initiative in government and a need for our governmental bodies to respond more quickly to the problems we all see in our country today, we must be deeply concerned about this cause of institutional paralysis.

Response to Raw Power

In this type of atmosphere, moreover, those decisions which are made are far more likely to be simply a response to raw power than the reasoned judgment of an independent mind made after a searching inquiry. Those who can potentially inflict the most harm on the Agency will have their way most often, regardless of the validity of their position.

The alternative to self-restraint, therefore, is a progressive deterioration of the Agency, which no legislation can prevent or cure. No individual or agency can long endure daily, vindictive attack from all sides, without bearing the scars of the wounds that are inflicted.

The FDA is a noble institution, with a proud heritage. It has served the public well for many years, and continues to serve it very well today. Like all institutions, it undoubtedly can and should be strengthened and improved. We must all work together on that task. But to destroy it, whether deliberately or through sheer carelessness, or even to inflict unnecesary harm on it, would be a major blunder that would severely undermine protection of the public health in this country. **[The End]**

Labeling of Foods

By TAYLOR M. QUINN

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FOR THE LAST FEW YEARS, the Food and Drug Administration (FDA) has published a number of regulations and proposed regulations in the food labeling area. These have caused many changes in labels and also a large amount of controversy. It is about this that I wish to talk. I would like to summarize some of what has been done recently and discuss what I think we may expect in the immediate future.

I will first consider the regulations in nutrition and related areas. In 1973, the FDA published a regulation entitled "Food Nutrition Labeling." This regulation sets forth the information to be provided and a format to be used when nutrition claims are made about foods or when vitamins, minerals or protein are added to foods. The regulation specifies that when nutrition information is required or is voluntarily provided, certain information must be given on a per-serving or per-portion basis. This information includes the caloric content, the protein content, the carbohydrate content, the fat content and the percentage of the U. S. recommended dietary allowance (U. S. RDA) of protein and seven vitamins and minerals. It also provides for the declaration of the U. S. RDA of a number of other vitamins and minerals, if the labeler of the product desires to do so. A fairly rigid format is called for so that all foods bearing nutrition labeling will furnish the information in essentially the same manner for ready comparison. The regulation also forbids a claim that a food is a significant source of a nutrient unless that nutrient is present in the food at a level equal to or in excess of ten percent of the U. S. RDA in a serving or portion. Further, no claim may be made that the food is nutritionally superior to another food unless it contains at least ten percent or more of the U. S. RDA of the claimed nutrient per serving or portion.

At about the same time, the FDA published a regulation concerning the labeling of foods with information on cholesterol and fatty acid composition. This labeling was entirely on a voluntary basis, but the regulation set forth some rules on what could be said and how it could be said. The regulation provides that the food in question must be labeled in accordance with the nutrition labeling regulation. If it is, it can also be labeled with the cholesterol content per serving and per 100 milligrams to the nearest 5 milligram increment. The regulation further provides that, if the food met certain criteria, the label could declare the percentage of calories from fat, and the grams per serving of polyunsaturated and saturated fatty acids. If this information is given on the label, it must be included with nutrition labeling, and the label must bear a statement that the information on the fat or cholesterol, or both, was furnished for individuals who, on the advice of a physician, were modifying their total dietary intake of fat or cholesterol.

Nutritional Quality Guidelines

The FDA has also published a procedure and general principles for the establishment of nutritional quality guidelines for foods. The general principles provide that a nutritional quality guideline would prescribe the minimum level or range of nutrient composition quality appropriate for a given class of food. It does not make the minimum level or range for the class of foods mandatory, but does specify that products complying with the requirements of the nutritional quality guideline may bear a label stating that the product furnishes nutrients in amounts appropriate for the class of food as determined by the United States government. The general principles also provide that, once a nutritional quality guideline is established for a given class of food and a nutrient not called for in the guideline is added to the food or a nutrient is added at a level that exceeds the established maximum, the food would be misbranded unless it bore a prominent and conspicuous statement that the addition of the nutrient at the level contained in the product had been determined by the United States government to be unnecessary and inappropriate, and did not increase the dietary value of the food. At the same time these general principles were published, the first nutritional quality guidelines for frozen heat-and-serve dinners were published. Several other nutritional quality guidelines are in various stages of preparation.

Four Principles

During the development of these regulations, it became apparent that there was a need to define and publish the principles governing the addition of vitamins, minerals and proteins to food. In June 1974, we published a proposal attempting to set forth what these principles should be. This regulation suggests four principles to be used in determining whether vitamins, minerals or proteins should be added to food. The first concerns the addition of vitamins, minerals and proteins to a food which is not a naturally significant source of such nutrients. The second deals with the addition of these substances to raise the nutritional quality of the food up to a level appropriate for that food. The third concerns the addition of these substances to a food to balance its caloric contribution. The fourth provides for the addition of these nutrients for the purpose of restoring those shown to be lost in measurable amounts by processing. This proposal also defines the terms "enriched," "fortified" and "restoration" in relation to the addition of vitamins, minerals and protein. As one would expect, we received a large number of comments on this proposal and are presently in the process of evaluating them and preparing a final regulation.

I would like to discuss common or usual names for foods and the application of the term "imitation." Under Section 403(c) of the Federal Food, Drug and Cosmetic Act, a food which is an imitation of another food is deemed to be misbranded unless its label bears the word "imitation" and immediately thereafter the name of the food imitated. The question is, of course, what causes a food to be an imitation. In 1973, we published a regulation stating what would cause a food to be an imitation of another food and what would not. This regulation states that a food is deemed to be an imitation (thus subject to the requirements of Section 403(c)) if it is a substitute for and resembles another food, but is nutritionally inferior to that food. The regulation also provides that the food is not considered an imitation if it is not nutritionally inferior to the food which it resembles and for which it substitutes and if its label bears a common or usual name that is not false and misleading. Nutritional inferiority is defined to include any reduction in the content of an essential nutrient that is present in a measurable amount, but does not include the reduction of caloric or fat content.

In order to avoid calling a food "imitation," the label of that food must bear a common or usual name. Thus, the food cannot be labeled with the name of the food it replaces. This leads into the next area of discussion—common or usual names for foods. The names of standardized foods are prescribed in the standard of identity. However, the names of nonstandardized foods have been decided, for the most part, by the sellers of the foods. These names have been informative in some instances but, in other instances, they have not been very informative. In some cases, they are downright deceptive. In an effort to bring some order into this area, the FDA published a regulation setting forth general principles for establishing common or usual names for nonstandardized foods. These principles provide that the common or usual name must accurately identify or describe, in simple and in as direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name must state in clear terms what it is that distinguishes it from other foods. The principles also provide that, when necessary to properly inform the consumer or to keep the consumer from being misled, the name must include either the percentage of any characterizing ingredient or components or a statement as to the presence or absence of a characterizing ingredient or component. The regulation also specifies the manner and the size for such statements to assure that they will be set forth uniformly and prominently. The FDA has published some regulations in this area and has a number of others in process.

Imitation Foods

I stated earlier that, in order to avoid being labeled "imitation," the food that is substituted for and resembles another food must be nutritionally equivalent to that food. Since some of the proposed common or usual names are for foods which substitute for and resemble other foods, we feel it is necessary to state what is considered nutritionally equivalent. In June 1974, we proposed such a common or usual name for plant protein products. We have received a large number of comments on this proposal, and a final regulation is being prepared for publication.

The next topic I would like to mention is ingredient labeling. The Federal Food, Drug and Cosmetic Act provides that all nonstandardized foods must bear a list of ingredients by their common or usual names, except for spices, flavorings and colorings which may be declared as such. The law does not provide for the declaration of mandatory ingredients in standardized foods and provides for a list-

ing of only those optional ingredients in standardized foods which the Commissioner decides is necessary. In the past, the FDA has not required the declaration of all optional ingredients in standardized foods. Recently, however, the Agency announced that it would so require in the future. A number of standards of identity have been changed already; others are in the process of change.

As we started working in this area, it became apparent that some clarifications and modifications were necessary in our regulations relating to declaration of ingredients in foods. The first of these concerned incidental additives. We had already promulgated a limited number of regulations exempting specific incidental additives from the requirement of Section 403(i)(2) of the Act. There remained, however, considerable question as to what were incidental additives. Therefore, in 1973, we published a regulation stating that incidental additives were exempt from compliance with the requirements of Section 403(i)(2) and stating what incidental additives were. Essentially, this provided that incidental additives were substances that were present in the food in insignificant levels and did not have any technical or functional effect in that food. We also decided it was necessary to make some revisions in our regulations. In June of 1974, we proposed a number of changes in this area. The most controversial was probably that concerning the declaration of fats or oils. We are very close to publishing a final order on this matter.

Declaration of Flavors

The next regulation I would like to summarize is the one concerning declaration of flavors. This is a very controversial area; we went through a proposal and two final orders before we came up with the present regulation. This regulation defines natural flavor and artificial flavor and also lays out the rules about how to declare the characterizing flavor of a food as part of the common or usual name of the food. The most important feature of this regulation is the provision which states that, if the food contains any artificial flavor which simulates or resembles or reinforces a characterizing flavor, the name of the characterizing flavor must be accompanied by the words "artificial" or "artifically flavored" in letters not less than one half the height of the letters in the name of the characterizing flavor.

Regulation 1.8b is my last area of discussion. This regulation provides that, except where there is insufficient room, the ingredient statement, the manufacturer's name and address and some other

information such as nutrition labeling must appear together on either the principal display panel or the information panel. The information panel is normally the panel immediately to the right of the principal display panel. There are some exceptions and they are set forth in the regulation.

Future Plans

What might you expect in the future in regard to labeling regulations? I think probably the most controversial rule you will see is the regulation on drained weight. We have just published a proposal in this area and we expect to receive a large number of comments. We must review all of these comments and then decide whether or not we wish to finalize the regulation and, if so, what it should say. In the near future, I hope you will also see the revision of regulation 125.6 concerning label statements relating to certain foods used in control of body weight or in dietary management with respect to disease. This also is very controversial and we have been working on it for a long time, but we hope to have something published soon. The third area for revision is ingredient labeling for alcoholic beverages. The Treasury Department recently announced that it was not going to proceed with its regulations to require ingredient labeling of these products. We will now proceed to handle them under the provisions of the Federal Food, Drug and Cosmetic Act.

Except for the above-mentioned three items, the finalization of the proposals that we already have out and publication of some more common or usual name and nutritional guideline regulations, I do not believe there will be a significant amount of new food labeling regulations proposed by the Agency. Of course, my crystal ball has always been pretty cloudy and I may be entirely wrong in this area. I hope, however, that I am right, because I think we all need a little time to digest and adjust to all the regulations that I have already mentioned. **[The End]**

Enforcement Policy Objectives in the Changing Food Environment

By ROBERT ANGELOTTI, Ph.D.

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IN THE PAST 50 YEARS the food industry of the United States has developed from a local, raw produce distribution system to a national processed food distribution system. During this period, the control of wholesomeness and safety of foods has moved from the individual homemaker to the processor, distributor and retailer of foods. Consumers can no longer effectively control the quality of the foods received and, additionally, are dependent upon numerous other people for their daily bread as it moves from raw agricultural product to processed, convenience commodity.

The increasing volume and sophistication in the types, production, packaging and marketing of foods have outstripped the ability of the Food and Drug Administration (FDA) and other federal and state regulatory agencies to guarantee perfect and continuous consumer protection against health hazards, economic cheats and nutritional inadequacies.

Though it may be argued that the consumer expects and is entitled to perfect and continuous protection of the food supply, the achievement of this ideal is doubtful because of the enormous effort and fiscal expenditure required. The recognition by the federal arm of government that it alone will never achieve the ideal dictates that a strategy be developed in which each affected party (regulator, processor, distributor, retailer, food service operator and individual consumer) recognizes his share of the responsibility and acts accordingly.

The acceptance of the concept of shared responsibility implies the acceptance of the concept of shared effort. It is generally recog-

nized, for example, that quality cannot be inspected into a product by either a regulatory agency or a processor. Consistent quality results when management recognizes the need for adequate quality assurance programs and insists that such programs be instituted and adhered to down the line. It is this type of responsible action and acceptance of shared effort that may be expected to consistently and most efficiently provide the consumer foods that are safe, wholesome and nutritious.

Shared Responsibility

To achieve shared responsibility and effort requires that the primary regulatory agency adopt a policy which admits to an inability to go it alone, to a lack of universality of knowledge. In short, we need a policy which states that the job we have to do cannot be done without help and cooperation from the industries we regulate, from our sister regulatory agencies of the federal and state governments, from educational institutions and from consumer advocacy groups.

The primary function of the FDA is to obtain compliance. Our research, educational efforts and standards development should be directed toward developing or offering information relative to the criteria that describe satisfactory compliance in terms of the safety, nutrition and wholesomeness of foods. We should strive to reduce intra-agency variation of what we consider acceptable compliance. Subjective value judgments should be replaced, where appropriate, by objective criteria as a means of achieving uniformity of interpretation and standardization of application. In addition to promulgation of regulations through the public rule-making procedure, we should make our compliance policies, practices and guidelines public. Where appropriate, they should be codified in the *Federal Register* with opportunity for public input.

A system should be developed in which the local and state food protection agencies, other federal agencies, the affected industries, educational institutions and consumers are led to accept their full share of the responsibility and the work load in cooperation with the FDA. Whenever possible, input should be sought from industry and industry associations, from federal, state and local health and food control agencies, from voluntary standards setting groups, from universities and from consumer advocacy groups, in the development of criteria, codes of practice and objective measurements of compliance.

Duplication of Effort

Without a central coordination point within the federal structure, the programs of the various federal, state and local food control agencies will continue to be applied on a self-interest basis that is conducive to duplication of effort and the causing of confusion through promulgation of ambiguous and oftentimes contradictory standards and criteria. This provides inequities in consumer protection among jurisdictional areas.

In moving toward a policy which solicits outside participation in the formulation and conduct of food control systems, it will be necessary to take certain departures from traditional FDA positions. Some of these departures already have been initiated while others remain to be accomplished.

To devise a compliance strategy that is more responsive to the sophisticated needs of today requires an identification of those things we need to do for ourselves and those things we need others to do for us. An example of shared work effort and responsibility lies in our new approach to food establishment inspections.

Domestic Food Establishment Inspections

Establishment inspections are a vital tool in the conduct of FDA responsibilities. They have been the mainstay of federal enforcement ever since the passage of the 1938 amendments to the Food and Drug Act of 1906.

Inspections provide opportunities to correct, on the spot, industry malpractices which could result in adulteration of food and, consequently, create a potential hazard to health. Inspections offer opportunities to measure both the compliance status of specific manufacturing plants, as well as the general compliance status of an industry segment. Inspections, through the interactions of FDA Consumer Safety Officers and plant personnel, provide an educational opportunity to the regulated industry which can result in the industry's better understanding of its responsibilities and obligations under the Federal Food, Drug and Cosmetic Act and FDA regulations. Inspections also serve as compliance motivators for the regulated industries. For example, many of the regulated industries attempt to achieve continual compliance rather than be subject to the punitive legal actions that can be and are directed against violative operators.

Over the years, inspectional activities within the FDA have varied in intensity and frequency depending upon leadership and Agency organization. Resource constraints, headquarters, regional and district experience, as well as the compliance history of a particular establishment or industry segment, have strongly influenced the decisions which have determined the type and frequency of inspections.

Sanitation Conditions

Until recently, inspections of the food industry have been directed primarily to sanitation considerations[1] and misbranding.[2] Earlier, following the passage of the 1906 Act and extending into the 1930's, the food processing industries were infamous for their insanitary conditions and deceptive labeling practices. It was appropriate that the predecessor agencies of the FDA pursued insanitation and misbranding violations to bring about corrections. Giant strides have been made in this direction and the vastly improved conditions of the food processing industry can be considered a direct result of the constant pressures which the FDA has exerted.

In the period after the passage of the 1938 amendments to the Food and Drug Act, technological developments accelerated, causing a dramatic impact on American society and industry. The advent of such innovations as blast freezing, freeze-drying, plastic packaging and the trend toward product diversification led to a complex of world trade in food commodities unimagined in the earlier years of the Federal Food, Drug and Cosmetic Act.

Because of the improved technology of many food processing lines, it is possible for a finished food to be in distribution—even in the home—before plant management recognizes that the product may deviate significantly from manufacturing specifications or may present a hazard to health.

Quality Assurance Systems

Recognizing this danger, enlightened industry members have instituted quality assurance systems that are designed to monitor and control critical stages in production processes. These systems are intended to provide early warnings of deviations at any point in a processing line (from raw ingredient specifications to finished product)

[1] Federal Food, Drug and Cosmetic Act, Sec. 402(a)(3), (a)(4).

[2] Federal Food, Drug and Cosmetic Act, Sec. 403.

that may adversely affect the wholesomeness, safety or nutritional quality of the processed foods. When operated properly, these systems prevent hazardous or below-standard foods from leaving the plant or getting out of corporate control. Built into these quality assurance systems is the application of basic knowledge in chemistry, microbiology, statistics, food technology and thermal, mechanical and chemical engineering.

Until 1973, the FDA's inspection program was oriented primarily to an in-depth review of the processing practices observed in a firm on a given day. This approach provided much in the way of corrective actions but, unfortunately, these types of inspections yielded little inferential information about the way business was conducted on the days the Consumer Safety Officer was not present. Furthermore, traditional inspections ordinarily did not consider the procedures employed by management to monitor and control their processes on a continuing basis. This inspectional approach limited the Agency's ability to assess industry conditions.

HACCP Inspections

The FDA now utilizes, on a limited basis, comprehensive inspectional techniques, such as the hazard analysis and critical control point inspection (HACCP) to obtain information about industry's continuous operations. The HACCP technique involves an intensive effort by trained investigators to document, evaluate and propose improvements in a plant's own quality assurance program. This approach stems from the Agency's belief that one of the best guarantees of the continuous production of safe food is the firm's internal capability to monitor and control its own manufacturing processes.

Despite resource increases in fiscal year 1973, the FDA is unable to inspect establishments as frequently as necessary. In addition, only a very small number of such inspections is directed toward reviewing the adequacy of the firm's quality control procedures. In fiscal year 1975, the FDA conducted only 420 HACCP inspections; 500 are planned for fiscal year 1976.

While we desire that more quality control inspections be performed, it does not follow that all inspections need to be in-depth quality control inspections nor that all inspections need to be performed with the same intensity or frequency. Thus, a logic is needed by which food establishments may be classified with respect to the

type and frequency of inspection that may be best suited to that type of establishment.

Since inspection can prevent or lower the probability that a health hazard will occur, it is reasonable to classify establishments according to the kind of health hazard involved. Certain potential health hazards associated with foods are universal; that is, they are applicable to foods generally and are not food or process specific. An example of a universal hazard is contamination with environmental contaminants such as heavy metals, industrial chemicals (PCB) or naturally occurring toxins. Another example is pesticide contamination that may result from misapplication at the farm. In addition to the universal hazards, some foods and/or some food processes present another potential health hazard that is related to microbiological contamination.

High Risk Potential

For example, certain establishments pose a greater potential health hazard than others because they process foods, such as custard and cream-filled goods, milk and dairy products, fish and fish products (including shellfish), meat and meat products, low-acid canned foods and infant and geriatric foods which, when improperly handled, support rapid microbial growth, or are such that they may be naturally or inadvertently contaminated with harmful or deleterious substances. These establishments are classified as having a high risk potential.

Commodity groups, such as soft drinks, bread and rolls, and bulk grains, while important with respect to sanitation, pose less of a potential health hazard with respect to prevention through inspection. Establishments processing these commodities are classified as having low risk potential.

In between the above two groups are food warehouses and storage facilities. They pose a potential health hazard because of the multiplicity of foods, including many foods which support rapid microbial growth if improperly stored. Additionally, these foods may be contaminated with harmful or deleterious substances through careless practices or improper storage. These hazards, while considerably more serious than the low risk establishments described above, are less probable than the hazards of the high risk establishments. Food warehouses and storage facilities are, therefore, classified as having medium risk potential.

Categorization Logic

Through application of this categorization logic, we determined the number of food establishments in our official inventory which fall into each risk category. We currently estimate that approximately 10,000 firms may be classified as high risk, 19,000 as medium risk, and 38,000 as low risk.

Establishments included in the high risk category should be inspected frequently because any poorly controlled process may pose a threat to health that is real, immediate and of huge proportions. Additionally, any changes in processes that occur between inspections may also create health hazards. Establishments which have little or no health hazard potential or for which insanitation is the principal factor of concern (low risk) should be inspected less frequently.

Moreover, it is also reasonable that variations in inspectional depth, complexity and intensity also should be applied to different risk category establishments, in addition to varying inspection frequencies. For example, the Agency experience with the comprehensive HACCP inspectional technique (an inspection which examines the manufacturer's quality control processes) in the low-acid canned food and frozen food industry segments has demonstrated its utility for: (1) identifying processing practices and conditions that are hazardous or potentially hazardous to health; and (2) bringing about corrections of these poor practices.

Process Controls

The full HACCP technique, however, is too costly in terms of inspectional time to be used for inspections of all establishments in the inventory. Moreover, as indicated above, only certain segments of the establishment inventory warrant full HACCP-type inspections. Most bakeries, for example, would not require a full HACCP inspection because their problems generally involve sanitation, not process controls.

In summary and based upon the logic, more frequent and more intense inspections should be conducted for those establishments that pose the greatest potential health risk.

In actual practice, however, two other factors also influence inspection frequency: (1) the compliance status of the last inspection; and (2) the lapse of time since the last inspection.

If an establishment is found out-of-compliance in the last inspection or has not been recently inspected, the priority of inspecting the firm should be increased. Similarly, these conditions demand a more intense inspection than firms frequently inspected or in-compliance. It is felt that a high priority for the FDA's inspectional resources should remain with the follow-up of known or indicated problem areas. Furthermore, it is felt that if an establishment, especially a high risk establishment, has not been inspected adequately in the recent past, it should be properly inspected as soon as possible and receive the next highest priority.

Initial Comprehensive Inspection

With the above in mind, it is concluded that even high risk establishments need not be continually inspected with the same intensity. It is felt that an "initial" comprehensive inspection (whether HACCP or other) would be of sufficient detail so that "subsequent" inspections could be abbreviated and still provide adequate information about the firm's operations (assuming that the establishment had no major changes in its process, and continued in-compliance). If, however, the establishment had undergone a major process change or was out-of-compliance, then a more comprehensive inspection would be needed again.

Using the rationale outlined above, it is our intention to implement the above plan in fiscal year 1977 with the purpose of conducting comprehensive inspections of high risk category establishments annually. Establishments in the remaining categories will be inspected with a lesser frequency and lesser comprehensiveness than those in the high risk category.

In order to achieve these objectives, it is necessary that the FDA request the state food control agencies to help us do this job. Our plans call for us to contract with the states to perform inspections in all three risk categories. Initially, most high risk category establishment inspections will be performed by the FDA. Through training, cooperation and input from appropriate persons at both the federal and state levels, effort between the FDA and the states can be such that the concept of shared work and shared responsibility will be a reality in the next decade. The state food control agencies will be sharing the inspectional load with the FDA for all three types of risk category establishments. **[The End]**

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Volume 30 1975

FOOD DRUG COSMETIC
LAW JOURNAL

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