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Food Drug Cosmetic Law JOURNAL

Legal Issues in FTC Trade Regulation Rules

. . . . . CASWELL O. HOBBS

Consumer Nutrition Advocacy

. . . . . ESTHER PETERSON

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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 highest 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.

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TO THE READER

Dr. Donald Kennedy, Commissioner of Food and Drugs of the Food and Drug Administration, discusses what he believes to be the task confronting the FDA. In his article entitled, "Remarks of the Commissioner of Food and Drugs," he states that the FDA must devise ways to stimulate people to take a more active interest in their health. In discussing the FDA's reviewing process of new drugs, the author is quick to realize that it is a lengthy process but is firm in his conviction that it is better to do careful research than to make hasty decisions at the expense of the people's health. The article, which was presented before the Regional *Ad Hoc* Professional Meeting of the Food and Drug Administration in San Francisco, California on June 10, 1977, begins on page 384.

Pharmaceutical Update VI. The following papers were delivered at the Food and Drug Law Institute's Pharmaceutical Update VI held in New York City on May 25 and 26, 1977.

Daniel F. O'Keefe, Jr., a partner in the law firm of Wald, Harkrader & Ross, notes an increased concern on the part of drug company officials in being kept aware of their criminal liability. His article, "Criminal Liability: *Park* Update," which starts on page 392, is an attempt to trace the legal history of criminal liability, using the *Park* case as his main example. He warns that despite established guidelines in determining criminal liability there is a large amount of individual discretion involved. He concludes by offering suggestions to those who wish to protect themselves from liability.

The article by *Frank P. DiPrima,* "Some Partisan Musings on the OTC Review and the Advertising TRRs," starts with a brief description of the history of the development of the OTC Review. Noting the length of time between a request for information and the receipt of conclusions, Mr. DiPrima, who is Staff Vice President of Schering-Plough Corporation, suggests that the FDA redirect its approach to miscellaneous panels in order to obtain a more efficient outcome. The article begins on page 405.

The Magnuson-Moss guidelines for rulemaking procedures are not faithfully adhered to in the actual Federal Trade Commission proceedings. This point is made by *Caswell O. Hobbs* in his article "Legal Issues in FTC Trade Regulation Rules." The author discusses various problems in rulemaking procedures such as access to administrative records, and the rights of cross-examination and rebuttal of evidence. He also discusses the scope of the Commission's remedial powers, warning that they must be regarded with caution as they are capable of causing serious repercussions. Mr. Hobbs is an attorney with the law firm of Morgan, Lewis & Bockius. The article begins on page 414.

Food Update '77. The following paper was delivered at Food Update '77, sponsored by the Food and Drug Law Institute and held in Palm Beach, Florida on April 25 through April 27, 1977.

"Consumer Nutrition Advocacy" by *Esther Peterson,* is a discussion of the changing needs of consumers as they adjust to a changing food supply. Ms. Peterson, who is Special Assistant to the President for Consumer Affairs, discusses such topics as nutrition labeling, government regulation and the public interest. Her article begins on page 423.

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Remarks of the Commissioner of Food and Drugs

By DONALD KENNEDY, Ph.D.

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

OBVIOUSLY A NEW COMMISSIONER of the Food and Drug Administration (FDA), even if he does not come absolutely cold to the job, has a lot of learning to do. One of the most important elements in that process involves getting to know the FDA's several publics—their interests, their complaints, their points of view, and how the FDA might best respond to their needs.

In reviewing the record of earlier meetings I was struck by two facts. First, health professionals did not dance around; they wanted us to be talking about real issues, and responding to tough questions. The second was that many of these questions resulted from a certain degree of institutional failure, on the part of the FDA, to make sure that the reasons behind our actions or proposals were clear. We must not neglect the important function of advocating, clearly and forcefully, the things we feel strongly about. I believe these meetings offer us a chance to eliminate such sources of misunderstanding by a candid examination of several issues that concern you and the Agency.

Let me begin by eliminating one possible source of misunderstanding—my own background. For various motives, I have been given undeserved credit for two things I am *not*. First, I have been praised for being an outsider to the FDA, and therefore presumably untainted. That "compliment" I reject as a disservice to the thousands of dedicated, often abused people inside the Agency who devote themselves to the

misunderstood task of meshing science and law to protect the public health. And I discover from others that I possess another advantage. I am not a physician, nor a member of any other profession directly involved in the health delivery system.

I have just two things to say about that. First, I do not like to see lack of a particular kind of education made into a virtue. And second, as 17 years' worth of Stanford premedical and medical students could tell you, I do not come to this job without a long, and I trust mutually beneficial, contact with the concerns and attitudes of those who practice medicine.

Perhaps the most useful introduction will be a snapshot of the Carter Administration's health policy, as it provides a context for the FDA's particular responsibilities.

Some of you may have looked with considerable interest (not, I suppose, unmixed with concern) at the emergence of policies designed to slow the rate of inflation in hospital costs; of efforts to strengthen cost control of health expenditures; and at the general emphasis on preventive medicine reflected, for example, in Secretary Califano's commitment to a much more effective national immunization effort.

Role of the FDA

Where does the FDA fit in this emerging health policy? Well, we establish no cost ceilings, set no rates, track no costs, but we nevertheless play a legitimate role in minimizing the nation's public health expenditures. This legitimate role involves a more effective exercise of what has become the FDA's main function in our society: as a *technology transfer regulator.*

During most of the FDA's existence it acted primarily as a kind of detective, ferreting out transgressions, prosecuting the transgressors, and eliminating the fruits of their iniquity from the marketplace.

While we still stamp out quite a lot of sin, we increasingly have also become a major control point in regulating the movement of new health ideas and technology to the consumer. As such, it is incumbent upon us to conserve this limited store of creative ideas and new products by getting them swiftly into the hands of those who need them while, at the same time, assuring that those products are safe and—in the case of drugs—efficacious as well.

How does this technology transfer control function fit in with other policy efforts to increase the cost-effectiveness of our nation's

health expenditures? I want to employ two themes in the analysis; the first is the familiar one of health education. The most cursory glance at the statistics of health outcomes of cigarette smoking, obesity, lack of exercise, excessive alcohol consumption, non-compliance with prescription information, shows that our society, its government and all its health delivery modalities must find ways to help people accept a far greater degree of responsibility for their own health and well being. They must perceive the clear linkage between a particular style of living and a particular way of dying; to look at "health" not as something to be received passively from the hands of others, but rather as the end result of many factors—not the least of which are how one lives and what one does with the advice and assistance offered by health care professionals.

In an article that appeared in *Science* in 1971, Leon Kass, then executive secretary of the Committee on Life Sciences and Social Policy, National Research Council-National Academy of Science, explored the question of the new biology and the price being paid for what he called "relieving man's estate." Kass points to the slippage of autonomy under pressure of ever more complex medical technologies and the experts in command of such technologies.

He says, "With the growing complexity of the technologies, the technician gains in authority, since he alone can understand what he is doing. The patient's lack of knowledge makes him deferential and often inhibits him from speaking up when he feels threatened." The key words in that passage are "lack of knowledge." I am convinced of the connection between non-acceptance of responsibility, loss of autonomy, and lack of knowledge. And I believe that a regulatory agency can make a contribution toward dealing with this lack of knowledge, *without* heavy-handed intervention or large expenditure of public monies.

Patient Package Insert

One model that comes to mind is far greater use of the patient package insert. I know that many physicians are wary of this device, possibly because it is seen as a way by which a third party—the FDA—joins a conversation that should be restricted to two parties.

Let me say as clearly as I can that this is not the purpose of the insert, nor do I believe that this kind of intrusiveness will be its result. My own conversations with our internist at the Palo Alto Medical Clinic convinced me long ago that knowledge raises the quality of discourse between patient and physician, eliminates unfounded appre-

hension, increases compliance, and draws the patient into active participation in working to solve problems.

Of course, there is no reason for you to accept such anecdotal experience—particularly when it is the patient rather than the physician who is recounting it. But you should engage in the "willing suspension of disbelief," and look at patient labeling not as an intrusion, but as an educational *resource* for a particular drug—what it will accomplish, what it cannot accomplish, how to take it, what to avoid.

I will go further, and claim that it not only serves as a resource supporting efforts to increase patient education and, hence, responsibility, it has other virtues as well. Physicians within the FDA and those outside who wish to comment will help mold the insert into a form that reflects the highest standards of professional judgment. We intend to offer a vehicle for such input by launching patient package insert seminars sometime this fall. These will be designed to help health professionals learn more about the insert and help us learn more about how they are perceived by health professionals. We bring to this process no preconceived conclusions, other than the conviction that some way must be found to demystify the relationship between the physician and the patient. We are objective about the inserts, and we believe they will reflect that objectivity.

This should make them an oasis in a vast wasteland of medical communication having less objective purposes!

Physicians are now the target of some one-billion dollars' worth of drug promotional material a year, six times the entire federal expenditure for the nation's 114 medical schools—about $4,000 for every practicing U. S. physician. As was clearly shown in recent Congressional testimony, such promotional or marketing materials are molded by the most sophisticated communications techniques known to a nation that has brought advertising to a high art form. As a result, even physicians convinced of the importance of parsimony in prescribing drugs must find it difficult to resist a multitude of messages about the usefulness of this or that particular drug. While the patient package insert will not eliminate this kind of drug marketing, it will offer an educational resource of proven neutrality.

Laetrile

In regard to the need to demystify the relationship between physician and patient, I can think of no more disturbing object lesson than that provided by laetrile. The laetrile issue and all that it represents is

like a mushroom, requiring a very specific set of growth conditions, one of the most important of which is a kind of darkness, not only of ignorance, but of public distrust—distrust of government, distrust of science, distrust of physicians. We must do everything we can, all of us, to recapture public confidence, so as to avoid a destruction of the drug efficacy requirement, with all that entails in terms of the resurgence of quackery and exploitation. In some sense all of us in biomedical research have helped prepare the seedbed for this growth—by overpromising on the "cure" for cancer, by suggesting that it is a single disease with a single, magic-bullet solution, and above all by an argument heard too often in connection with new drug registration: that "clinical experience" or "the wisdom of practice" is an adequate substitute for carefully controlled clinical measurements of efficacy and safety. This is a case in which practitioners have to draw on their own scientific training and support the rigorous use of regulatory science.

Now let me turn to a different aspect of our function of technology transfer regulator. Everyone finds it easy to agree that diffusion can he too fast, so that it allows frankly dangerous or worthless innovations to flood the market—or too slow, so that it inhibits social progress by withholding valuable inventions. The question is, how can we identify the *best* diffusion rate?

Recently I had a chance to review what the Agency considers its greatest success stories over the past ten years or so. There was an impressive list submitted to a Congressional committee, all citing specific actions. In my view, however, the real success stories of the FDA involve actions that did *not* take place: the botulism that was not found in the food cans; the thalidomides that were prevented from joining the list of drugs you prescribe or use; the excess mortality that did not occur as a result of such disasters as faulty vaccines, carcinogens in food, excessive radiation, dangerous residues of animal drugs in edible tissue. These non-events are the Agency's real success stories, for they exemplify harm to consumers prevented, harm that would have seriously eroded the level of confidence that consumers have in the health care delivery system and in the safety of drugs and biologics.

Some critics of the Agency point to non-events of a less favorable nature; particularly to drugs that could have been on the market helping thousands had we been less dilatory or demanding. They point to other countries where the transfer of technology moves from laboratory to producer to physician to patient far more rapidly. The buzz-word for this kind of regulatory delay, itself a pharmaceutical innovation,

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is "drug lag." "While you in the FDA go on fiddling with them," we are told, "other more fortunate people in other nations are enjoying the benefits of important new drugs."

Beta Blockers

Because the situation regarding beta blockers has been so frequently served up as a kind of archetype of "drug lag," I have looked into this most carefully.

If the pattern is indeed archetypal, it hardly supports the drug lag argument. For example, since 1967, when the FDA approved propanolol, no attempt was made to market a beta blocker in the U. S. until mid-November 1976, when a new drug application (NDA) was submitted for metoprolol. A major reason for the delay was the suspicion that a number of beta blockers might be tumorigenic, and the resulting requirement that long-term animal studies be undertaken to investigate this possibility. Such studies have now been completed for eleven beta blockers. While five of them were cleared for initiation of long-term clinical studies, *two appear to be clearly carcinogenic;* two produced a statistically significant increase in benign lesions or tumors, the significance of which is yet unclear; and the data regarding the others are still being reviewed.

It thus appears that certain beta blockers are potential tumorigens and some of these cause frank carcinomas in test animals. Since beta blockers belong to a class of drugs intended for long-term use in a great many patients, the FDA's 1972 decision to require long-term carcinogenicity testing before clinical use has spared patients in the United States a potentially dangerous kind of exposure.

A similar history was traced by the birth control pills containing megestrol acetate. When the FDA refused to approve this drug after test animals developed breast nodules, several foreign countries, which had permitted marketing on the basis of less extensive testing, withdrew it.

I admit that by and large it *does* take longer here than in other advanced nations to approve a new drug, although we have taken a number of steps to speed this particular element of technology transfer. These include prior agreement about study design, sequential review and approval of data, and other steps aimed at eliminating unproductive and inflexible procedures. We also are supporting legislation to remove all scientific data related to the safety and effectiveness of drugs from concealment as trade secrets. Even with these

changes, accomplished and potential, the process of demonstrating safety and effectiveness prior to marketing may still move at a more deliberate pace than in certain other nations. This bothers me—just as it bothers *some* physicians, and *all* drug sponsors.

But the answer is not to close one regulatory eye, or in some other way reduce the quality of NDA review without also reducing the quality of the drug approved as a result of that review. The answer is to look for ways to gain speed without loss of quality. And there are only two points at which to get it—before marketing; or afterward. Except in rare cases where an "imminent hazard" is deemed to exist, it is easier for the FDA to do almost *anything* than to get a questionable drug off the market after it has been approved.

Because this is so, our only responsible course is to take extra care in the approval process. To the degree that such care entails a time penalty, that penalty could be eliminated by appropriate adjustments at the back end—at the point of removal.

The FDA has already taken the initiative in suggesting a mechanism to accomplish this—an additional phase in the approval process, during which a new drug would be limited in distribution, controlled in application, and susceptible to rapid pullback if anything disturbing is learned.

But we also ought to do much better about recognizing problems during the period of full clinical use. Some critics, pointing to the systems operating in Finland, Sweden, Great Britain and other nations, have cast us as a kind of underdeveloped nation in regard to drug experience reporting, particularly adverse reaction experience. Although this conclusion is somewhat exaggerated, there is no doubt that the process in other nations is formalized, routine, and effective. The fact that these nations have such systems *provides a key element in their system of rapid premarket approval.*

In my view, it is really unfair to criticize our rate of regulatory clearance without also stressing these special U. S. problems in drug experience reporting by doctors.

A drug shown to be safe and effective on 2,000 volunteers in a controlled clinical trial may present a different picture when used over a course of weeks or months by two-million or 20-million people. Thus, there is simply no adequate substitute for the observation and reporting of the reactions of your patients to the medications you administer. And yet, as I have indicated, this key element of post-market evalua-

tion is the least effective in our present system. As one reflection of that fact, the director of our office of biometrics was recently in England to analyze the experience reporting system in place there. He tells me that whereas in this country 15 percent of adverse reaction reports come from physicians and 63 percent from manufacturers, almost the mirror image of that situation exists in Great Britain.

I know that conditions differ there; and I know how overburdened you are. But lack of the kind of data we need about adverse reactions is one of the key reasons why we err, if at all, on the side of caution in approving a drug.

So, let me close by making a pledge to you who, I realize, are in the most exposed position regarding health care and who deal with reality rather than hopes or theories. I will do whatever I can to see that the fruits of technology—the devices, the drugs, the diagnostic products, the vaccines and all the rest—get into your hands as quickly as humanly possible without sacrificing that standard of safety and efficacy that you and your patients should take for granted. In this effort your understanding and cooperation will be of immeasurable help to me—not only in the limited sector described in the foregoing example, but more generally as well. **[The End]**

GRAS AFFIRMATION PROPOSED FOR ACONITIC ACID

Aconitic acid has been deemed generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) for direct use in human food, and the Agency has proposed affirmation of the GRAS status of the substance. Aconitic acid is also known as achilleic acid, citridic acid, and equisetic acid, depending upon its natural source. It can be isolated during the processing of sugar cane or synthesized from citric acid. Limited data indicates that aconitic acid is less toxic than citric acid, and its salt appears to be excreted readily by the kidneys. Based on an evaluation of all available information on aconitic acid, the FDA has concluded that the current GRAS status of the substance is justified. Comments on the proposal are due by October 31, 1977.

CCH Food Drug Cosmetic Law Reporter, ¶ 45,498

Criminal Liability: Park Update

By DANIEL F. O'KEEFE, JR.

Mr. O'Keefe Is a Partner in the Law Firm of Wald, Harkrader & Ross.

COURT ACTION in the *Park* case, legislative inaction in not amending the law, reported FDA activity in criminal prosecutions, and recent trade press coverage have all combined into a potion which apparently has increased the awareness of—and therefore interest in—criminal liability among those in the executive suites of major drug manufacturers. Until fairly recently, most Food and Drug Administration (FDA) actions and rumored actions on the criminal front have dealt primarily with rats in food warehouses. Sensing an increased interest among drug company officials in being kept up-to-date about criminal liability, I am presenting an update of the *Park* case.

I will first very briefly review the doctrine of criminal liability of drug companies and their executives, then I will talk about cases decided since *Park*, bring you up to date on FDA and Congressional activity, spend a moment or two on the criteria for criminal prosecution, and conclude with a few comments for those who want specific ideas about what to do and how to do it. I will not, for obvious reasons, comment on the several drug criminal matters either in court or rumored to be under consideration by the FDA or the Department of Justice.

The Doctrine

First, let's spend a moment on the governing legal doctrine itself. *United States v. Dotterweich*[1] held that responsible individuals can be criminally prosecuted for violations of the Federal Food, Drug, and Cosmetic Act (1) even though the defendant had no awareness of wrongdoing and (2) even though the defendant did not commit the violative act or know of its commission.

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

As to "responsibility," the Court said that the offense is committed by "all persons who aid and abet its commission," by all who share "responsibility in the business process resulting in unlawful distribution," and "by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws."[2] The Court, however, expressly refused to comment on the criteria for establishing which class of employees are considered responsible.[3]

In the intervening years from *Dotterweich* to *Park,* courts applied the *Dotterweich* doctrine in a wide variety of situations, thus establishing that the same principles apply to *any* violation of the Federal Food, Drug, and Cosmetic Act.[4] The *Dotterweich* doctrine has been applied to manufacturers, distributors, wholesalers, retailers, and warehouse operators.[5] Jail terms, terms of probation, and criminal fines have been imposed.[6] In one case, a jail sentence was imposed although the offense involved economic misbranding without risk to public health or safety. In that instance a wholesaler of dairy products repackaged butter and short-weighted the customer.[7] I certainly have no trouble with this case if the individual defendant knew what he was doing—but the court never reached that issue, as it was irrelevant under *Dotterweich.*

Until *Park,* however, close and immediate supervisory control by the defendant over the operation in which the violative act occurred had always been present when individuals had been held liable for acts which they neither committed nor of which they had actual knowledge.[8] And no cases had involved senior officers of large corporations, who may be remote from the operations in which violation occurred.[9]

In the famous *Park* case, the conviction of the president of a large supermarket chain for a warehouse sanitation violation was sustained. In reaffirming *Dotterweich,* the Court placed a high duty of care on officials of companies regulated under the Federal Food, Drug, and Cosmetic Act. The Court found that "the Act imposes not only a positive duty to seek out and remedy violations when they occur but

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[2] *United States v. Dotterweich,* 320 U. S. 284 (1943).

[3] *Id.* at 285.

[4] See O'Keefe, D. F., and Shapiro, M. H., "Personal Criminal Liability Under the Federal Food, Drug, and Cosmetic Act: The *Dotterweich* Doctrine," 30 FOOD DRUG COSMETIC LAW JOURNAL 5, 18 (Jan. 1975) (hereinafter cited as "Personal Criminal Liability").

[5] *Id.* at p. 18.

[6] *Id.*

[7] *United States v. H. Wool & Sons, Inc.,* 215 F. 2d 95 (CA-2 1954).

[8] See O'Keefe and Shapiro, "Personal Criminal Liability", *supra* note 4, at 20.

[9] *Id.*

also, *and primarily*, a duty to implement measures that will *insure* that violations will *not* occur."[10] The Court emphasized that the duty imposed by Congress is one that requires "the highest standard of foresight and vigilance."[11] Shedding some light on the question of who are the "responsible" parties for purposes of prosecution, the Court stated:

"The Government establishes a prima facie case when it introduces evidence sufficient to warrant a finding by the trier of the facts that the *defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation* complained of, and that he failed to do so."[12]

The Court also made it clear that an individual defendant in a criminal prosecution would be entitled to jury instructions on available defenses in some situations. The Court said that the Federal Food, Drug, and Cosmetic Act, "in its criminal aspect, does not require that which is objectively impossible"[13] and that the Act "permits a claim that a defendant was 'powerless' to prevent or correct the violation to 'be raised defensively at a trial on the merits'. If such a claim is made, the defendant has the burden of coming forward with evidence."[14] Thus, a legal defense is available. The circumstances in which a defendant would be entitled to a jury instruction on the defense, however, were not made clear.

Case Law Since *Park*

There have been five significant opinions since *Park*. The first, *United States v. Y. Hata & Co.*,[15] was an appeal to the Ninth Circuit from a jury conviction of a corporation and its president for holding food in a warehouse under conditions from which the food could have become contaminated in violation of the Act. Defendant's warehouse was found to be infested with birds. The case was tried prior to the Supreme Court's resolution of the *Park* case. On appeal, defendant argued that he was entitled to an instruction on "objective impossibility" since material for a wire cage system to keep the birds out of the warehouse had not arrived. The Court held that defendant was not entitled to such an instruction because, in the exercise of the high standard of care imposed by the Act, defendant should have

[10] *United States v. Park*, 421 U. S. 658, 672 (1975) (emphasis added). For a discussion of the *Park* case, see Burditt, "The *Park* Case in Perspective," 31 FOOD DRUG COSMETIC LAW JOURNAL 137 (March 1976); O'Keefe and Isley, "*Dotterweich* Revisited—Criminal Liability Under the Federal Food, Drug, and Cosmetic Act," 31 FOOD DRUG COSMETIC LAW JOURNAL 69 (Feb. 1976).

[11] *Id.* at 673. See also 672, 676.

[12] *Id.* at 673-74 (emphasis added).

[13] *Id.* at 673.

[14] *Id.* (Citation omitted.)

[15] 535 F. 2d 508 (CA-9), *cert. denied*, 97 S. Ct. 87 (1976).

recognized early that a cage system would have remedied the problem. A cage system, the court said, "is scarcely a novel preventive device."[16]

Significantly, the government contended that the "powerless" defense applied only when the officer "was in fact powerless to prevent or correct the violation, even by suspending the corporation's food warehousing activity if necessary."[17] The court expressly did not go that far, finding it unnecessary to do so. If the government's interpretation on the availability of the defense were to prevail, the defense would be totally meaningless. Presumably a violation could never occur where there is no operation. That's not "objective impossibility," that's absolute impossibility.

The second case after *Park* was also in the Ninth Circuit and was decided the same day as *Y. Hata*. It is *United States v. Starr*.[18] Here, a corporate official of a wholesale food distributorship was found guilty of holding food under unsanitary conditions—a mice-infested warehouse. This case too was tried prior to the final resolution of the *Park* case. On appeal, defendant argued that the mouse problem was caused by the plowing of a nearby field, causing mice in the field to scatter and invade the warehouse. The Court found that this phenomenon was foreseeable, that defendant should have prepared for it, and that defendant as a matter of law was not entitled to the "impossibility" defense on this ground. Defendant also argued that he had instructed his janitor to solve the mouse problem and that the janitor was a disloyal employee who intentionally sabotaged the company by not following instructions. Thus, defendant argued, he was entitled to a jury instruction on objective impossibility. Again the Court held that as a matter of law, defendant was not entitled to the instruction since he should have checked to be sure his instructions were followed.

While courts are not prone lightly to reverse verdicts on the ground that subsequent appellate court decisions have changed the law, these opinions do give the government room to argue that no instruction on the defense should be given except in the most extreme of circumstances. I expect that a considerable body of law eventually will evolve on when the instruction is to be given.

If strict criminal liability is to be the order of the day, the courts should at least be liberal in allowing an asserted defense to go to a jury with proper instructions. Indeed, the Court in *Dotterweich*, recognizing the "hardship" that might be caused by the doctrine, relied

[16] 535 F. 2d at 511.
[17] *Id.*
[18] 535 F. 2d 512 (CA-9 1976).

upon "the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries" to apply the doctrine fairly. As the *Dotterweich* Court put it, "Our system of criminal justice necessarily depends on 'conscience and circumspection in prosecuting officers.' "[19]

The third important case is *United States v. Acri Wholesale Grocery Co.*,[20] where a corporation operating a food warehouse and its two senior officers were convicted of permitting food to be held under unsanitary conditions—again, a rodent-infested warehouse.

There are three interesting features of this case. First, the Court upheld the admission of photographic evidence of warehouse conditions finding that it was not an "unreasonable" factory inspection practice for FDA inspectors to take such photographs in the circumstances of this case. Here the FDA inspectors were in the warehouse pursuant to lawful authority and following all lawful procedural requirements. Defendants fully consented to the inspection and the inspectors made no effort to conceal the fact that photographs were being taken. The Court also found that the photographs were "merely cumulative of the inspector's testimony."

Second, the Court held that defendants were not entitled to a *"Miranda"* warning from the FDA inspectors prior to the photographic activity. The Court found that defendants were not in "custody" or deprived of their freedom and that there was "no evidence of record that the focus of the Government's intent in inspecting the warehouse had, at any relevant time, shifted from a mere inspection to criminal investigation."[21]

Third, the Court found no error in the fact that defendants were not given portions of samples taken by the FDA inspectors or the results of the sample analysis until a few weeks prior to trial. Section 702(b) of the Federal Food, Drug, and Cosmetic Act entitled defendants to the sample *upon request* and they failed to request the samples. The Court also found that defendants were not prejudiced by the failure to be provided a copy of the results until a few weeks before trial.

United States v. Certified Grocers Co-op[22] was significant in that the government lost. This was a food-adulteration prosecution where the defendants were acquitted at trial before a judge. The District Judge said he was unable to conclude "beyond a reasonable doubt" that the adulterated product was not contaminated before the defendant

[19] See *United States v. Dotterweich*, 320 U. S. 277, 285 (1943).
[20] 409 F. Supp. 529 (DC Iowa 1976).
[21] *Id.* at 533.
[22] 546 F. 2d 1308 (CA-7 1976).

received it. The Seventh Circuit dismissed the Government's attempted appeal as barred by the double jeopardy clause of the Constitution.

The only significant opinion in a drug criminal case since *Park* was *United States v. Marcen Laboratories, Inc.*,[23] where defendants challenged the constitutional sufficiency of Section 201(p) of the Federal Food, Drug, and Cosmetic Act (the new drug definition), as too vague to permit a criminal charge. Defendants were charged with introducing a "new drug" into interstate commerce without an approved new drug application. The indictment was sustained on a finding that defendants had actual written knowledge before shipment that the FDA considered the drugs in question to be "new drugs."

Recent Activity Relating to Criminal Enforcement

Since this paper is characterized as an "update," it seems appropriate to update you on the progress of legislation intended to change the *Dotterweich* doctrine. You may recall that in the last session of Congress, a bill, S. 641 (the Consumer Food Act of 1976), would have amended the Federal Food, Drug, and Cosmetic Act by: (1) adding a civil penalty of not more than $10,000 per violation for offenses relating to food; (2) increasing the maximum criminal fine from $1,000 to $10,000 for any violation of Section 301; and (3) providing that criminal penalties do not apply with respect to individuals charged with violations related to food unless the individual acts knowingly, willfully, or "without the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent man acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of like character."[24] The only effect of the bill on drug executives would have been to increase the maximum criminal penalty. The language of the amendment, according to its legislative history was intended to codify the *Park* decision for food violations.[25] Presumably, drug violations would have been unaffected by the legislation and thus governed by the *Park* holding—the same effect. If so, why bother? In any event, S. 641, after passing the Senate, died in the House.

Thus far in the present session of Congress, no bills affecting the criminal liability provision of the Federal Food, Drug, and Cosmetic Act have even been introduced. So much for that!

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[23] 416 F. Supp. 453 (DC NY 1976).

[24] Secs. 308, 113 of S. 641, 94th Cong. 2d Sess., 122 *Cong. Rec.* 3844, 3846, 3848 (1976).

[25] See discussion at 122 *Cong. Rec.* 3833-3842.

Mary Halas, editor of *The Food & Drug Letter,* has scooped me on an analysis of enforcement trends. The April 1, 1977 issue of that publication predicts an increase in FDA criminal prosecutions in 1977. She suggests that the areas to watch are Good Manufacturing Practices and Good Laboratory Practices. There I agree. Those are the areas to watch. However, I am not convinced that the FDA's current interest in evaluating drug cases for possible criminal prosecution represents a policy shift toward increased use of criminal prosecution in drug matters. Some have drawn that inference. In 1976, three prosecutions were brought concerning human drugs, as opposed to one case in 1974 and one in 1975.[26] A review of the Weekly Enforcement Report reveals that no drug prosecutions have been filed through mid-April of 1977. One Section 305 hearing on a drug matter was held in 1976, up from zero in 1975.[27] Thus, while the trade press reports considerable FDA internal activity on the criminal front with regard to drugs, the trend—if there is a trend—has in fact been toward fewer rather than more criminal prosecutions.[28]

In any event, trend or no trend, when you're involved, you're hardly interested in the statistics. We have all been waiting with more than casual interest for the FDA to publish its regulations defining criteria for deciding who will be prosecuted, for what kinds of offenses, and for procedures for reaching decisions to prosecute.

No Mere Warning

All we have thus far been blessed with, however, is the Agency's regulations on Section 305 hearing procedures and public disclosure of records relating to such hearings.[29] A review of these regulations is in order because it has been plain for some time now that a Section 305 hearing no longer is viewed by the FDA as a mere warning. Now, when a decision is made to issue a Section 305 Notice of Hearing, the Agency has decided that prosecution is probably in order.[30]

The new regulations provide that an opportunity for a Section 305 hearing will be given to a person against whom criminal prosecution is contemplated, except in compelling circumstances. The purpose

[26] Information supplied by the Office of the Associate Commissioner for Compliance in the FDA.

[27] *Id.*

[28] See Hoffman, J. E., "Enforcement Trends Under the Federal Food, Drug, and Cosmetic Act—A View from Outside." 31 FOOD DRUG COSMETIC LAW JOURNAL 338, 340, 351 (June 1976). The total number of criminal cases reported in the Weekly List was 53 in 1974, 20 in 1975, 17 in 1976, and 2 for the first quarter of 1977.

[29] 42 *F. R.* 6803 (1977).

[30] See Fine, S. D., "The Philosophy of Enforcement." 31 FOOD DRUG COSMETIC LAW JOURNAL 324 (June 1976).

of the hearing is to give the prospective defendant an opportunity to present information and views to convince the Agency not to recommend criminal prosecution. The written Notice of Hearing (Form FD 466) will identify the products and shipments alleged to be in violation, and specify the time and place of the hearing. It is to be accompanied by a Charge Sheet (Form FD 1854) summarizing the "alleged" violations,[31] an Information Sheet (Form FD 466a) describing the purpose and procedure of the hearing, and a Legal Status Sheet (Form FD 454) which the prospective defendant is requested to fill out and return.

Separate hearings will be scheduled on request where more than one person is named in the Notice. Persons who receive a Notice are not under any legal obligation to appear or answer questions. Individuals may appear personally, with or without counsel, may designate a representative to appear for them, or may respond in writing.

The hearing will be conducted by an FDA employee designated as hearing officer. It is not open to the public. All persons present will be identified for the record. The hearing will be informal and the rules of evidence will not apply. The hearing officer will "briefly review the basis on which criminal prosecution is contemplated," but the FDA is under no obligation to present evidence or witnesses. The respondent may present any information he wishes bearing on why he should not be prosecuted.

The prospective defendant has a right to have the hearing transcribed at his expense, in which case a copy is to be provided to the FDA. Alternatively, the hearing officer may order the hearing transcribed at FDA expense, in which event a copy will be furnished to each prospective defendant. If the hearing is not transcribed, the hearing officer will dictate a written summary at its conclusion. The prospective defendant may remain present during the dictation and then offer additional comment or correction; in any event, a copy of the summary will subsequently be provided and additional written comment may be submitted. The prospective defendant may reopen the hearing if he has new information not reasonably available to him originally.

Generally the FDA will not release Section 305 records until consideration of criminal prosecution is closed, but the Commissioner reserves the right to make an earlier release in rare circumstances

[31] The regulation uses the word "apparent."

demonstrating "a compelling public interest." When consideration of criminal prosecution is closed, the records are available under the Freedom of Information Act, and the FDA's implementing regulations.[32] Generally, names and data identifying individuals not prosecuted will be deleted. Names of corporations, however, are available.

At the close of consideration of criminal prosecution, if no further criminal action is contemplated, persons subjected to a Section 305 hearing will be notified in writing. If one or more—but not all—are not to be further considered for criminal prosecution, those "off the hook" will be notified if the FDA concludes such notification will not prejudice the prosecution or any other person.

Perhaps I should briefly mention the proposed regulations on publicity[33] insofar as they pertain to criminal matters. Basically, they provide that the FDA should not issue publicity that may reasonably be expected to influence the outcome of a case. Generally, the FDA would release only descriptive information about the defendant, the substance of the charge, and the scope of the investigation. I would expect the Agency will be rather careful about publicizing criminal trials, although I found the statement in the preamble that the Commissioner will "risk dismissal of a prosecution because of the impact of publicity rather than fail to issue a warning that he believes is needed to protect the public."[34]

Criteria for Prosecution

While the criteria applied by the FDA in making criminal prosecution decisions have not been issued in the form of regulations, Agency officials have given us the thrust of what the regulations are likely to contain. At The Food and Drug Law Institute's Enforcement Work Session last year, Sam Fine, then the Assistant Commissioner for Compliance, identified factors considered by the FDA in matters of criminal prosecution:[35]

(1) The seriousness of the violation.

Is it a "gross" violation?—a filthy plant?

Is life or public health at risk? Is there a serious drug mixup? Sterility violation? Subpotency violation?

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[32] See particularly 21 CFR Sec. 4.60-4.84 (1976).

[33] 42 *F. R.* 12436 (1977).

[34] *Id.* at 12438.

[35] See Fine, "The Philosophy of Enforcement," *supra*, n. 30.

(2) Evidence of knowledge or intent.

Mr. Fine indicated that in most criminal cases, the FDA has evidence of actual knowledge on the part of named defendants.

Is the violation of a continuing nature?

Is there a deliberate attempt to circumvent the law? Submission of false data? Falsification of records? Substitution of cheap for expensive ingredients resulting in subpotency of a life saving drug?

Generally, the FDA and the Department of Justice,[36] favor including at least one "responsible" individual in criminal prosecutions.

(3) The probability that action will encourage future compliance by the firm in question as well as others similarly situated.

(4) The resources available to the FDA.

(5) The extent to which the action will benefit consumers in terms of preventing recurrences of the violation throughout the industry.

Mr. Fine also mentioned "consistency" within the FDA, together with "legal sufficiency" and "winability," as factors considered in reaching a collective judgment within the Agency.

Gene Pfeifer, Associate Chief Counsel for Enforcement, phrased the criteria somewhat differently. He identified eight criteria for criminal prosecution as follows:[37]

(1) A deliberate or intentional violation;

(2) A violation caused by gross negligence or reckless disregard for the law;

(3) Any violation which exposes the public to the risk of potentially dangerous conditions;

(4) Any violation which is obvious or easily detectable to experienced persons;

(5) Any uncorrected or recurrent violation;

(6) Any violation which results from any act of commission or omission and which could have been prevented, detected or

[36] See McConachie, C. R., "The Role of the Department of Justice in Enforcing the Federal Food, Drug, and Cosmetic Act," 31 Food Drug Cosmetic Law Journal 333, 334-35 (June 1976).

[37] Pfeifer, E. M., "Section 305 Hearings and Criminal Prosecutions," 31 Food Drug Cosmetic Law Journal 376 (July 1976).

corrected. Mr. Pfeifer indicated this factor may be the most important in many respects;

(7) Any violation which may result in significant economic damage to the public;

(8) In deciding *whom* to prosecute, the Agency looks for an individual who knew or should have known of the circumstances, conditions, or actions surrounding a violation, and who occupied a position with the power and/or authority to prevent, detect, or correct the violation, whether directly or indirectly.

Basically, that's what's now known about the FDA's current criminal prosecution criteria.

Discretion of U. S. Attorneys

The criteria applied by the Department of Justice are at least as important as those applied within the Agency, since the FDA's prosecution recommendations go to the Antitrust Division of the Department of Justice and to the U. S. Attorney in the District in which the action would be filed. Sometimes (about 10 percent of the time according to one study; one-third of the time according to another) Justice will not prosecute.[38] Unfortunately, the "criteria" applied at Justice are not expected to be published in the *Federal Register*. Generally, the primary responsibility for decisions on prosecutions rests with the U. S. Attorney in the district in which the case would be filed. The criteria applied by each of the 94 U. S. Attorneys will vary widely.

The Consumer Affairs Section of the Antitrust Division does perform a supervisory role in criminal prosecution[39] however, and former Antitrust Assistant Attorney General Donald Baker recently described in detail the Division's approach in exercising prosecutorial discretion in criminal cases.[40] This speech represents the Division's latest and most complete policy pronouncement on the subject and thus merits a moment of our time. Mr. Baker was speaking of criminal prosecutions under the antitrust laws, but because the Sherman Act is parallel to the Federal Food, Drug, and Cosmetic Act in that both have civil as well as criminal remedies, his remarks are significant for food and drug criminal matters. First, Mr. Baker endorsed the Anti-

[38] See O'Keefe and Shapiro, "Personal Criminal Liability," *supra*, note 4, at 27-28.

[39] See McConachie, C. R., "The Role of the Department of Justice," *supra*, note 36, at 334.

[40] Remarks by Assistant Attorney General Donald I. Baker, Antitrust Law Briefing Conference, February 28, 1977.

trust Division's statement of policy in 1967 that criminal prosecutions are sought only against willful violations of the law. Two alternative tests of willfulness are set forth: First, if the rules of law alleged to have been violated are clear and established—describing *per se* offenses —willfulness will be presumed. Second, if the acts of defendants show intentional violations—if through circumstantial evidence or direct testimony it appears that they knew they were violating the law or acting with flagrant disregard of it—willfulness will be presumed.[41]

No Criminal Prosecution

Mr. Baker identified four situations in which criminal prosecution would be unwarranted, even for price fixing. They are:

(1) Where there is legitimate confusion as to what the law is. For example, where the price fixing may arguably be under a regulatory umbrella the scope of which is not clear.

(2) Where there is a truly novel issue of law or fact. Such a case might be one where data is made public by several companies in such a way as to result in an alleged price fixing scheme.

(3) Where there is confusion because of prior prosecutorial action. For example, the Government would not proceed criminally to announce the fact that the Division no longer agreed with a previously expressed position.

(4) Where there is clear evidence that defendants did not appreciate the consequences of their actions—the naivete defense. For example, a group of small businessmen might publicly announce meetings to stabilize prices and eliminate price wars.

These policy statements are informative. If they are applied in the food and drug field, criminal actions will not be sought where the fact of violation is not patently clear. Criminal prosecution is not the place to decide the meaning of a law or regulation or otherwise to break new policy ground. As a practical matter, it is also important to know that the lawyers in the Department of Justice, like most lawyers, view criminal prosecution as a serious matter. These policy statements indicate a proper reluctance to prosecute where there is no moral culpability. And Justice can and does refuse to prosecute.

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[41] *Id.* at 9, quoting President's Commission on Law Enforcement & Administration of Justice, Task Force Report: Crime and Its Impact—An Assessment 110 (1967) (footnotes omitted).

Coping With the Possibility of Criminal Prosecution

We are now at the bottom line. What does one do about the risk of criminal liability?

Well, that's obvious. Run a tight ship. If you are in compliance with all the laws and regulations, you have little to fear. No matter how many times this has been said, it's no cliche. This is the best approach. In the brief time available, we can't get into detail, but a few generalizations may be helpful. (1) A careful inventory of all the relevant regulations, and an in-house audit of all operations and products cannot be beat. (2) Beyond this, careful record keeping and follow-up are important. The name of this tune is management. Be sure the system includes a reliable failsafe mechanism and that you are informed if anything goes wrong. (3) Some companies have placed a single person in charge of quality control for all the company's operations. Others have had management engineers review their systems. Many companies have internal financial auditors and management consultants—why not for quality control, too? The task is to really manage this problem to help assure that violations don't occur and to build a record of "objective impossibility" if a violation should occur.

What do you do if, in spite of all precautions, a plant inspection goes badly? Any adverse report or FDA problem should immediately be brought to the person in charge of handling these matters for the company. Company counsel generally should be consulted. The sooner the lawyers are aware, the better—if the matter turns out to be serious. Usually the best approach will be to handle the matter at the lowest possible level in the Agency, but counsel may see implications that would make self help inadvisable. If the violation appears serious, or if there are other signs that real trouble is afoot, you have no choice, you really have to go to your lwayer. **[The End]**

Some Partisan Musings on the OTC Review and the Advertising TRRs

By FRANK P. DiPRIMA

Mr. DiPrima Is Staff Vice President of the Schering-Plough Corporation.

LAWYERS ARE A MULISH LOT, not easily discouraged from following familiar pathways. This is especially so when they head for a symposium to share their visions of a future resulting from current legal issues.

Five years ago this month, at Pharmaceutical Update II, I was part of a panel that discussed what we thought would be the key issues for the future of the over-the-counter (OTC) Review. The Review had been formalized several days earlier by issuance of regulations defining the process. A fresh reading of papers given at Pharmaceutical Update II,[1] followed by a moment's reflection, will confirm that the issues then considered central to the future of the Review—the "substantive/interpretive" issue, the grandfather clauses, the ripeness of the regulations for a court challenge—have since all but disappeared from our consciousness.

So here we are again, five years later, another panel of lawyers trying to give the word on what's really critical for the future of the OTC Review and its offspring, the Advertising Trade Regulation Rule (TRR) proceedings.

The Trouble with Being a Seer

The trouble with being a seer is that problems never extend in the existential world to their logical conclusions. As Howard K.

[1] 27 FOOD DRUG COSMETIC LAW JOURNAL 532-540, 571-579 and 588-592 (Sept. 1972).

Smith recently observed, if the logical conclusion is bad enough, it is foreseen by people who set forces in motion to prevent it from eventuating.[2] The old problems are then replaced by new ones, some of which are caused by solutions to the old.

The OTC Review was itself an attempt to avoid carrying some propositions to their logical conclusion. In February, 1971, the Food and Drug Administration (FDA) proposed highly restrictive regulations on combination drugs,[3] intending to apply them to prescription and nonprescription drugs alike; and in the same month, the Agency published proposed regulations declaring that every existing drug product is legally a "new drug"[4] which must be the subject of a new drug application submitted by each manufacturer and supported by "adequate, well-controlled investigations." Carried to their logical conclusion, these regulations would have caused the abrupt end of most self-medication and would have resulted in an administrative burden unmanageable at the FDA even if the Agency were a hundred times its present size. Industry and government foresaw this, didn't like it, and after vigorous public comment and deliberation, the OTC Review was born.

The Review represented an abandonment of a licensing philosophy for the regulation of OTCs, and the adoption in its place of a standardization philosophy. It also represented the abandonment of several *per se* rules—such as the proposal declaring that everything is a new drug—*per se* rules that had nothing to commend them other than providing the illusion of a certainty which seemed to excuse prosecutors and judges from exercising judgment.

As the Review emerged, new fears replaced the old: on industry's side, fears that most panels would be dominated by academicians with anti-OTC bias, fears that empirical evidence and clinical experience would be ignored; on government's side, fears of a resistant and litigious industry refusing to develop and provide scientific support. These fears did not materialize, and as former Commissioner Schmidt recently observed, ". . . a process that could have degenerated into a hostile confrontation between adversaries became instead a cooperative enterprise in the public intreest."[5]

[2] Speech given at Annual Meeting of the Proprietary Association, White Sulphur Springs, West Virginia, May 16, 1977.

[3] 36 F. R. 3126 (Feb. 18, 1971).

[4] 36 F. R. 3372 (Feb. 23, 1971).

[5] Schmidt, *The Role of Self-Medication*, speech given at 4th General Assembly of the World Federation of Proprietary Medicine Manufacturers at World Health Organization, Geneva, Switzerland, March 22, 1977.

Dozens of serious problems have been and are being addressed by all sides. Both the FDA and industry realized that neither they nor the public health would benefit from an OTC Review that did not work. The point is that these fears failed to materialize, not because they were unrealistic, but because they were recognized, debated, deliberated and avoided.

In the same spirit, please expect me to be partisan as we consider three selected aspects of the Review and the Advertising TRRs —troubling issues that have neither been resolved nor sufficiently addressed. The first relates to the Miscellaneous Panels convened under the OTC Review. The second is the phantom issue of synonymy in the claims TRR proceeding, and the strange way the issue was joined. The third relates to procedural impartiality in the TRR proceedings.

The substance of the TRR that would require cautions to be recited in advertising is not part of my talk. My views on the Warnings TRR were given at the Food and Drug Law Institute (FDLI) Food and Drug Administration Education Conference in December of 1976 and have not changed.[6]

The Miscellaneous Panels

The OTC Review's claim to legal validity is based on the "new drug" definition at Section 201(p) of the Federal Food, Drug and Cosmetic Act. The Review is a massive attempt to determine which non-prescription drugs, under what conditions, are not "new drugs" —in the words of the statute, are "generally recognized" as safe and effective *"among experts qualified by scientific training and experience* to evaluate the safety and effectiveness of drugs. . ." Accordingly, the Review's legitimacy rests on the expertise of its panelists, whose joint views should be some indication of what is "generally recognized" within their relevant specialties.

Most of the panels have been formed with this requirement in mind, and are dominated by experts in the medical specialties pertinent to the therapeutic categories under their jurisdiction. This also contributes to the scientific quality of their work, and to the confidence with which their conclusions are viewed.

Since it would have been hard to assign every conceivable category to a specific panel, the FDA appointed two "catch-all" panels

[6] DiPrima, F. P. "Advertising of OTC Drugs; Proposed TRR on Warnings," 32 Food Drug Cosmetic Law Journal 96 (March 1977).

to ensure the comprehensiveness of the Review. This approach has two serious limitations. First, no panel can be expert in the many diverse categories caught up in the "Miscellaneous" panels; no one is an expert in miscellany. Second, the enormous breadth of their tasks will ensure to these panels a longevity rivaling Methuselah's. Even for panels with specific jurisdiction, it is now safe to project that the average elapsed time between call for data and final monograph will approach ten years. How much longer will miscellaneous panels last if each has dozens of unrelated categories?

Against this background, it is clearly counterproductive for the Miscellaneous Panels to re-review subject matter within the jurisdiction of other panels, or worse, to re-examine what has already been decided by other panels or by the FDA when the Agency is refining or finalizing panel action under established regulatory processes. Yet, this has happened or is happening in several instances —the safety of certain topical anaesthetics, the effectiveness of simethicone, warnings on calcium carbonate. Panels with a multi-year task are taking on redundant work. A body with more diffuse expertise is reviewing the work of a body with more specific expertise.

For example, the Antacid Panel was chosen for its gastroenterologic excellence and expertise in antacid therapy. Final orders resulting from its deliberations are being redeliberated by a body consisting no doubt of seven excellent professionals selflessly dedicated to their task, but not one of them is a gastroenterologist. The seven include two hematologists, an osteopath, a surgeon, a pharmacist, a G. P./pharmacologist and a nurse.

It is time the FDA questioned and redirected its entire approach to categories now assigned to Miscellaneous Panels. The alternative will be many years of waiting for reports which will be of doubtful validity because the very process ensures that the vital ingredient—relevant expertise—has been excluded.

The Phantom Issue of Synonymy

If you left the country after reading the proposed TRR on Advertising claims in November, 1975,[7] and returned during the hearings this past March, you would have had a hard time relating the hearings to the proposal. By its terms, the proposed TRR would ban the use in advertising of any claim for which a product has been deemed "unsafe or ineffective" (or "Category II") in a final order

[7] 40 F. R. 52631 (Nov. 11, 1975).

resulting from the OTC Review. Apart from its prospective effect on future monographs, the proposal was universally viewed as laudable.

So why did the hearings go on for five weeks, the testimony of fifty-odd witnesses spread over 14,000 pages of transcript, with five psycholinguists quibbling about whether any two words ever mean the same thing? Why are lawyers arguing about the First Amendment, about transagency redelegation, about notice?

Considering the effort and expense, the joining of the key issue in the hearings is one of the strangest episodes in the annals of administrative rulemaking.

It began December 3, 1975 when Richard Herzog, Federal Trade Commission (FTC) Staff's Assistant Director for National Advertising, spoke at an FDLI seminar and interpreted the proposal as permitting only the exact claims wording appearing in the final monograph and banning all other truthful language, even exact synonyms.[8] Thus, "short-term relief of constipation" would be fine, but "temporary constipation remedy" *per se* unlawful. "Antiflatulent," fine; "alleviates the symptoms of gas," fine; but "antigas," unfair or deceptive.

Incidentally, Herzog indicated that he wanted the FTC to occupy the same field in advertising as the FDA does in labeling. This always puzzled me, because I was never sure the FDA meant to ban, anywhere except on the statement of identity, truthful descriptive statements which are in accord with the monographs.[9] The FDA certainly never asked manufacturers to submit all possible truthful arrangements of words and never asked its panelists to review them.

Thus, the Herzog interpretation was made on an unofficial occasion, off the administrative record, and was prefaced with the comment that these views were his own and not necessarily anyone else's. The interpretation was unanticipated and could not have been inferred from the plain meaning of the proposal; Herzog indeed implicitly acknowledged this a year later when he referred to his December, 1975, speech as containing "dramatic new announcements

[8] Herzog, R. B., "The FTC's Proposed Rule on OTC Drug Advertising," speech given at Food and Drug Law Institute's Human Drug Workshop, December 3, 1975, published at 31 Food Drug Cosmetic Law Journal 147 (March 1976).

[9] See DiPrima, F. P., "The OTC Review and the Standardization of Symptom Nomenclature in Labeling," 32 Food Drug Cosmetic Law Journal 286 (June 1977).

or interpretations. . ."[10] Yet the opinion of one staffer (albeit a brilliant and earnest one), stated off the administrative record, intensified the debate, converting the rulemaking into an adversary proceeding which focused on semantics instead of safety and effectiveness.

Then, in March, 1976, Joan Z. Bernstein, then Acting Director of the FTC's Consumer Protection Bureau, appeared on a panel at an industry meeting and repudiated the Herzog interpretation.[11] She reminded her audience that she was Herzog's boss, and said: "My view of that is, that is his view."

The panel moderator observed: "I think what you are saying is: The TRR is not going to necessarily outlaw the use of synonyms."

She responded: "That is what I am saying."

But industry's relief was short-lived. Ms. Bernstein left the FTC a few months later.

This left Mr. Herzog and his interpretation, together with his understanding that he was paralleling a position taken at the FDA. The pre-hearing stage cranked on, and the hearings began early this year.

During literally every day of the hearings, the antigas/antiflatulent example was discussed and debated as illustrative of the synonymy question. Literally everyone involved thought that "antigas" in the statement of identity was, *in the FDA's view*, presently unacceptable in labeling. The preamble to the Final Monograph had stated: "The monograph allows only the use of the word 'antiflatulent' or the statement 'to alleviate the symptoms of gas.' Those are the only terms that can properly be used for OTC antiflatulent drugs."[12]

But on April 1, the last day of the hearings—hearings entirely on an individual interpretation based on what a staffer thought the FDA was doing—the last witnesses, Drs. Gardner and Gilbertson from the FDA, testified that the term "antigas" could be used now and until the Miscellaneous Internal Panel's action matures into a Final Monograph. For example, Robert Altman, counsel to Proprietary Association, asked:

"So what you are saying, that a manufacturer of an OTC product, antiflatulent product, should interpret the language we have read including the sentence,

[10] Herzog, R. B., "The Antacid Warning-Rulemaking at the FTC," 32 Food Drug Cosmetic Law Journal 76 (Feb. 1977).

[11] Reported at *FDC Reports—"The Pink Sheet"*, Vol. 38, No. 10, March 8, 1976 at A-5 *et seq.*

[12] 39 F. R. 19862 at 19872 (June 4, 1974).

'Those are the only terms that can properly be used for OTC antiflatulent drugs' to mean that other terms can be used?"

Dr. Gilbertson answered: "At this time."[13]

I think it pure coincidence that it was April Fool's Day.

This left only Mr. Herzog and his interpretation. Then, in the weeks following the hearings, word got out that Mr. Herzog is leaving the Commission to accept a promotional appointment elsewhere in government.

Let's see: an FTC rulemaking proposal appears noncontroversial; an FTC staffer offers a highly restrictive interpretation based on his perception of what the FDA is doing; the rulemaking proceeding heats up; his boss repudiates his interpretation; his boss quits; hearings deal exclusively with the interpretation; the FDA appears to back off; and then the staffer quits.

Where does all this leave us? The question may be academic because the recent commercial free speech cases make the interpretation clearly untenable as it relates to truthful claims.[14] But how could this have happened? It was the fault of the rest of us, and not of Mr. Herzog; he told us that the views expressed were his own and not anybody else's.

The TRR's and Procedural Impartiality

The power to make binding rules defining "unfair or deceptive acts or practices" is the broadest delegation of legislative authority in our history—broader than the National Recovery Act promulgating "codes of fair competition." This is the more terrifying because new penalties for violations of a TRR are more immediate, severe and numerous than for Section 5 violations before Magnuson-Moss. Three appointive officials—or perhaps two when a quorum of three Commissioners are present—can make laws with serious penal sanctions in an area no less broad than the economy itself, with the same legal effect as a law passed by 535 elected Congressmen and Senators.

Thus, Magnuson-Moss represents an awesome and unique grant of legislative power to the FTC. With it comes awesome and unique

[13] Transcript of Hearing on FTC's Proposed Trade Regulation Rule on OTC Drug Advertising, p. 5035 (April 1, 1977).

[14] *Bigelow v. Virginia*, 95 S. Ct. 2222 (1975); *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 96 S. Ct. 1817 (1976); *Beneficial Corporation v. FTC*, 542 F. 2d 611 (CA-3 1976) *cert. denied*.

responsibility. The responsibility should include a firm commitment to irreproachable procedural impartiality with an administrative analogue to separation of powers. That commitment is not manifest in the procedures followed in the making of TRR's.

The oddest aspect, and the one most offensive to a sense of elemental fairness, is that the Hearing Officer is a staff attorney, usually of the Bureau prosecuting the rule. This means at the end of the assignment he goes right back to the bureau to prosecute cases alleging violations of the rule. His work life, career chances, performance evaluations, selection of assignments, salary increases and perhaps job security are in the hands of the most avid champions of the proposed rule, the Bureau Director and his staff.

A less obvious problem, but one as defeating of procedural objectivity, is the way the Commissioners receive the reports of the record. No one expects the Commissioners to read tens of thousands of transcript pages. The Hearing Officer merely summarizes the record—he does not make recommendations on a proposed rule. The FTC staff proponents then analyze the record and the Hearing Officer's summary, and they, FTC staff proponents, make recommendations. As Washington lawyer Robert L. Wald[15] recently pointed out, the prosecuting staff's report is analogous to the Initial Decision in an FTC adjudicative proceeding.

Another problem is *ex parte* contacts. Though Commissioners and staffers will not hold off-the-record discussions of the TRR's with industry representatives, the prosecuting staff considers itself free to discuss the rulemaking *sub rosa* with Presiding Officers who are, after all, their once and future colleagues.

I want it to be very clear that I do not for a moment question the objectivity of individual Hearing Officers. I do not know them, but I assume they are fair people. The point is, they are being put in an unfair position by a procedure that is inherently inobjective.

I call to your attention to, and strongly endorse, the following procedural reforms which Bob Wald[16] proposed, and I will now summarize:

First, appoint independent Administrative Law Judges and not FTC staff attorneys to preside over the hearings. I fervently hope

[15] Wald, *After the Hearing is Over*, Remarks Before Conference on FTC Rulemaking Procedures and Practice, Practicing Law Institute, Washington, D. C., March 7-8, 1977.

[16] Id.

this obvious step can be adopted and implemented in time for the hearings on the Antacid Warnings TRR.

Second, have the presiding Administrative Law Judges analyze the record and make recommendations *after—not before*—the prosecuting staff and other interested parties make their comments; give each Administrative Law Judge a staff of at least one legal professional to help get this job done.

Third, prohibit all *ex parte* contacts on the TRR between FTC staff, on the one hand, and the Commissioners, the presiding Administrative Law Judge, and their personal staffs, on the other.[17]

These steps in my view are indispensable to a belief in the integrity of the process—belief by industry, by reviewing judges, and in its heart of hearts, by FTC staff.

* * *

So much for my three issues. How long will it be before they are somehow resolved, and they recede from consciousness?

I am sure only that new issues will take their place, and lawyers will meet again and again to try and see the future. We have got to keep doing it until we get it right. **[The End]**

[17] See *Home Box Office Inc. v. FCC*, 75-1280 (CA D of C) (March 25, 1977).

Legal Issues in FTC Trade Regulation Rules

By CASWELL O. HOBBS

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THE TOPIC I AM covering, legal issues in the Federal Trade Commission (FTC) trade regulation rules (TRRs), implicates a host of issues in a burgeoning area of administrative law, agency rulemaking. As always, time limitations force considerable selectivity.

As most of you know, the FTC first began to assert and exercise rulemaking powers in the 1960s. Generally, the Agency's early rules were unexceptional in scope and content and were relatively uncontroversial. In the 1970s, however, litigation[1] challenging the nature and scope of the FTC's rulemaking authority led to Congressional consideration of various legislative proposals to codify the Commission's rulemaking powers. The result was the enactment, on January 4, 1975, of the Magnuson-Moss Warranty-Federal Trade Commission Improvements Act.[2]

Section 202 of the Magnuson-Moss Act authorizes the FTC to prescribe "rules which define with specificity acts or practices which are unfair or deceptive." This section also expressly provides that such "rules may include requirements prescribed for the purpose of preventing such acts or practices."[3] The Act further provides specific procedures, supplementing those contained in the Administrative Procedure Act (APA), to govern FTC rulemaking proceedings.[4]

The FTC has not been at all reticent in exercising its newly conferred powers. It has initiated approximately 16 rulemaking proceedings. No final rule has yet been the subject of judicial review,

[1] *See, National Petroleum Refiners Ass'n v. FTC*, 482 F. 2d 675 (CA DofC 1973); *cert. denied*, 415 U. S. 951 (1974).

[2] Public Law No. 93-637, 88 Stat. 2183 (Jan. 4, 1975).

[3] 15 U. S. C. Sec. 57a(a)(1)(B).

[4] 15 U. S. C. Sec. 57a(b).

however, so this discussion is necessarily an exercise in legal speculation. The uncertainty inherent in such speculation is compounded both by the hybrid nature of the rulemaking procedures specified by the Magnuson-Moss Act, and by the increasingly closer judicial scrutiny being given to administrative rulemaking.[5] In addition, as you might expect, during this formative period in FTC rulemaking, the Commission staff is espousing aggressive and expansive positions in interpreting and exercising its rulemaking authority.

In my comments, I intend to generalize about some of the fundamental legal and policy issues presented by FTC rulemaking under the Magnuson-Moss Act. While this discussion will be relevant to the particular trade regulation rules the FTC has proposed for over-the-counter drugs, its intended focus is somewhat broader. If there is an underlying theme to my comments, it is that Magnuson-Moss rulemaking highlights the fundamental issue of whether FTC rulemaking should be viewed as "adjudicative" or "legislative" in character. The Commission itself appears to view its role in these rulemaking proceedings as essentially legislative—in other words, it sees itself as simply an extension of Congress, as a deliberative body whose obligation it is to listen to everyone's views and then to make policy judgments without particular emphasis placed on the traditional judicial function of weighing the evidence. And it may well be that this is the concept of administrative rulemaking that Congress had in mind when it granted explicit rulemaking powers to the FTC. As Professor Davis has pointed out,[6] however, there are some very fundamental differences between a body consisting of several hundred popularly elected officials, and a five-member administrative agency—particularly one with far-reaching prosecutorial powers such as are possessed by the FTC.

Role of the FTC

I think it is clear from the rulemaking proceedings conducted to date, however, that the FTC staff assigned to a particular role has come to view its role as that of being advocates in support of the rule which is under consideration. Implicit in the role of an advocate is the propensity to concentrate upon that evidence which most strongly supports his case, to contest the evidence opposed to his case, and to limit "premature" notice to his adversaries, to the

[5] Kestenbaum, "Rulemaking Beyond APA: Criteria for Trial-Type Procedures and the FTC Improvement Act" 44 *Geo. Wash. L. Rev.* 679, 685 (1976).

[6] K. Davis, Administrative Law, Secs. 6.05 and 6.06 (1958).

extent possible, of basic facts and theories of law underlying his case. The increasingly adversarial nature of the actual conduct of FTC rulemaking proceedings cannot be squared, in my opinion, with a simultaneous characterization of Magnuson-Moss Act rulemaking as open, quasi-legislative fact-finding to be conducted through informal rulemaking procedures. The legitimacy of the adversarial approach to fact-finding and decision-making rests on well-defined procedural safeguards and balanced adversarial powers which are currently lacking in the context of Magnuson-Moss rulemaking. Thus, in reviewing the specific legal issues which are evolving in FTC TRRs, this underlying legislative-adjudicative tension should be kept in mind.

In fact, this tension is emphasized by the "hybrid approach" to rulemaking established in the Magnuson-Moss Act. The APA[7] established a dichotomy between formal and informal rulemaking. Formal rulemaking accords many of the rights possessed by a defendant in an adjudicatory proceeding, including formal notice of a charge, a full evidentiary hearing, and a right to cross-examination. In contrast, informal notice and an opportunity to comment are the basic accoutrements necessary to informal rulemaking which thereby takes on a legislative cast. Magnuson-Moss rulemaking, however, while starting with the informal rulemaking/legislative model, includes some significant characteristics which evoke the adjudicative model of formal rulemaking. This "hybrid form" of rulemaking set forth by Magnuson-Moss, with its analogies to the adjudicatory model of agency action, emphasizes a variety of legal issues as to what ought to be the rights of parties involved in Magnuson-Moss rulemaking.

Legal Rights of Parties Involved

Rather than attempt to rank these issues in terms of seeming importance, I have decided to take them up more or less in the order in which they arise in a normal FTC (TRR) proceeding.

First, there is the issue of the adequacy of the initial notice of a proposed rule. In requiring that the Commission "publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule,"[8] the Magnuson-Moss Act requires a more detailed initial explanation of proposed action than is required for informal rulemaking under the APA. So far, the FTC's initial notices have stated the Commission's reason to believe the existence and preva-

[7] 5 U. S. C. Sec. 553 *et seq.*

[8] 15 U. S. C. Sec. 57a(b)(1).

lence of certain violations and have made reference to substantial material in the Commission's possession as the basis for this belief. These notices have not, however, provided any discussion or analysis of, or citation to, the specific evidentiary information which led the Commission to propose the rule. Whether such notice is sufficient to comply with the intent of Congress is an open question. Some commentators have suggested it is not. One concluded that:

"The notices thus have not required, and are not calculated to encourage the interested parties to examine the anticipated evidentiary conflicts or the practical need for oral direct or cross-examination. The Commission's presentation itself is in hypothetical terms and discloses no specific relation to whatever evidentiary bases may exist."[9]

A second commentator went further:

"There is in our view no justification for failure to fully disclose all relevant information concerning the Commission's proposed rulemaking as well as, with particularity, the basis for the proposed rule. Failure to provide this full disclosure can, and in the hearing aid rule we feel without a doubt did, seriously prejudice the ability of an industry to reasonably comment upon the need for a proposed rule and to reasonably challenge, where appropriate, the assumptions which form the foundation for the proposed rule."[10]

A second aspect of the Magnuson-Moss Act which raises a number of legal issues is the definition of the "rulemaking record." The contents of the rulemaking record are specified in the Act. They are: the initial notice; the hearing transcript; all written submissions; and "any other information which the Commission considers relevant. . . ."[11] That final phrase raises the issue of to what extent the FTC will be permitted to exercise its expertise or otherwise rely on matters outside the public record. Arguably, since interested persons are entitled to cross-examine and to present rebuttal submissions on all disputed issues of material fact,[12] the FTC should be circumscribed in any attempt to rely on matters as to which no opportunity for examination or rebuttal is presented.

The Rulemaking Record

In regard to the development and availability of the rulemaking record, the issue of adequate opportunity for comment by interested persons is highlighted by a number of practical problems. The Magnuson-Moss Act specifically requires the FTC to make publicly available all submissions by interested persons of written data, views, and

[9] Kestenbaum, at 697.

[10] T. Vakerics, Statement before the Subcommittee on Consumer Protection & Finance, House Interstate & Foreign Commerce Committee (March 16, 1977).

[11] 15 U. S. C. Sec. 57a(e)(1)(B).

[12] 15 U. S. C. Sec. 57a(c)(1)(B).

arguments.[13] In view of the enormous masses of materials being dumped into FTC rulemaking records, this requirement poses a considerable logistical problem. Anyone who has visited the public records room at the Commission in the hope of perusing the record in a rulemaking proceeding is well aware of the unpredictable outcome of such a venture. Very often several binders are not available purportedly because a prior request for copying has removed them to the xeroxing room. In at least one instance, one whole binder of industry comments disappeared completely.[14] Very often there is a considerable time lag between FTC receipt of documents and their public availability. In some instances, this delay results in volumes of material being dumped on the public record days before the commencement of hearings. On top of all of this, indexing of documents is often haphazard and confusing, and meaningful digests or analyses of documents are totally lacking. In short, for anyone not able to spend hours or days in Washington, D. C., a "record" maintained in this manner is simply meaningless.

Perhaps the best way to underscore this point is with the following quotation of J. Skelly Wright of the U. S. Court of Appeals for the District of Columbia.

"Considering the unpleasant remarks a number of courts have made recently about the state of administrative records, I suggest that the time is not far off when in some cases agency action will be vacated without judicial review because the record as kept by the agency is inadequate, confused, or incomplete."[15]

Legal issues are also raised by the roles of the various FTC staff personnel involved in rulemaking. The FTC has long been somewhat schizophrenic about its combined function as investigator, prosecutor, judge, and caretaker of the American economy. The exercise of these diverse functions by the FTC staff, the Presiding Officer, and the Commission itself are even more confused in the rulemaking context.

The Presiding Officer

For example, the Presiding Officer in an FTC rulemaking proceeding is not an administrative law judge, but rather an employee of the Bureau of Consumer Protection. This poses serious tensions between his responsibility to make a variety of legal rulings in a

[13] 15 U. S. C. Sec. 57a(b)(2).

[14] The volume of industry comments disappeared and had to be "reconstructed" in Proposed Trade Reg. Sec. 441, *Mobile Home Sales and Service* 40 F. R. 23334 (1975).

[15] Wright, "New Judicial Requisites for Informal Rulemaking: Implications for the Environmental Impact Statement Process" 29 *Admin. L. Rev.* 59, 61-62 (1977).

quasi-adversarial proceeding, and his responsibility to follow the directions of the Bureau Director who is effectively supporting adoption of the rule. More specifically, the Presiding Officer, who is granted a vast amout of discretion and authority in the conduct of the proceedings, is a staff attorney with the same status and stature as the FTC attorneys who are supporting the proposed trade regulation rule. It has been pointed out that:

"the Presiding Officer, who has discretion over such important items as (1) whether cross-examination will be permitted and the extent of cross-examination, (2) whether and to what extent rebuttal submissions will be permitted, (3) whether and to what extent discovery will be permitted and (4) whether appeal to the full Commission on procedural matters will be permitted, is an employee of the same Bureau that was responsible for (a) the investigation of the rule, (b) the determination that the rule should be recommended to the Commission, (c) supporting the proposed rule, during hearings and (d) recommending whether and to what extent a final rule should be adopted by the Commission."[16]

These tensions may well be found to have adverse impact on the Presiding Officer's ability to conduct a fair impartial hearing.

Consider also the Commission staff. As mentioned previously, they find themselves caught between a perceived obligation to use the rulemaking proceeding as a means to investigate impartially the need for and form of a rule, and, on the other hand, an obligation to use all forms of advocacy to defend a rule it has drafted. To the extent that the FTC staff adopts the advocacy role, can this be squared, for example, with their *ex parte* ability to communicate with the Commission at any time? The filing deadlines and limited opportunities to be heard which constrain outside parties simply do not exist for the FTC staff. Nor is there any way for other participants in a rule even to know of the existence of such *ex parte* communications.

And the Commission itself is not in an enviable posture. Realistically, the Commission cannot help being influenced by the considerable control and discretion the staff has over the shape of the rule as finally presented to the Commission. In addition, I seriously question whether the Commission—in view of the lack of anything resembling an impartial initial decision by an administrative law judge such as they have before them in an adjudicative case—is in a position to give any kind of adequate review to the enormous record amassed below. None of these situations is without due process implications.

[16] Vakerics, note 10, *supra*.

Cross-Examination

Two other areas of legal controversy were created by the Magnuson-Moss Act. First, there is the effect of the new procedural rights accorded to participants in the proceeding.[17] These rights are comprised basically of the right to conduct or have conducted cross-examination of other witnesses, the right to submit rebuttal evidence designed to contradict other evidence or testimony in the record, and the right to seek compulsory process to compel the attendance of witnesses. The way these quasi-adjudicatory rights are exercised, and the extent to which their use is curtailed by the Presiding Officers, are fertile areas for legal argument. Since these procedural rights are formally available only with regard to the "disputed issues of material fact" which have been designated by the Presiding Officer, the designation of such issues is in itself an event with legal significance. In this regard, it might be noted that attempts to limit cross-examination to "the designated issues of disputed fact" have proven to be simply unworkable. The Presiding Officers in FTC rulemaking proceedings have, however, adopted what many feel to be an equally unworkable alternative, that is, time limitations on cross-examination.

Similarly, while the Magnuson-Moss Act requires that the Commission permit the submission of rebuttal evidence, this right of rebuttal has been limited in actual practice. First, all rebuttal submissions must be made within 30 or 60 days after the close of the record, and this often does not permit adequate time to prepare rebuttal for a record of the size being developed in FTC rulemaking. A second serious problem arises from the fact that all interested parties, including FTC staff attorneys, are required to submit the rebuttal on the same day. This leaves open the opportunity for the FTC staff to place substantial amounts of new evidence into the record, with the comfortable knowledge that this new evidence cannot be subject to rebuttal by the industry to be regulated. This allegedly occurred in the hearing aid rulemaking proceeding when, on the last day the record was open, the FTC staff attorneys submitted approximately 2,000 pages of what industry lawyers characterize as new evidence.

Remedial Powers

In my opinion, however, the most significant legal issue in Magnuson-Moss rulemaking may turn out to be the scope of the Commission's remedial powers. In many of its proposed rules, the FTC

[17] 15 U. S. C. Sec. 57a(c).

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appears to be parlaying its essentially negative definitional authority to define and proscribe unfair and deceptive practices into an affirmative power to prescribe a particularized, mandatory, and often far-reaching code of fair conduct for an entire industry. It is true, as I noted earlier, that the Commission has been given power to prescribe requirements for the prevention of illegal practices.[18] But this only raises the question of what limits there are to this power. For instance, the Commission is specifically directed to consider the impact of its rules on consumers and on small businesses.[19] Detailed and inflexible remedial provisions can have severe impact in terms of raising the cost of products to the consumer, or driving the smaller operator's costs up to the point where he is competitively impaired. Repercussions such as these must bear upon the validity of the remedial provisions of a rule.

Moreover, it seems to me there ought to be some correlation between the FTC's showing of the prevalence of illegal or unfair practices in an industry and the strictness of the remedies it proposes. In other words, I do not think a court should uphold a rule which sets out detailed and complex compliance requirements for a whole industry to follow where only a minority of the industry was involved in the objectionable practices in the first place. Analogies to the adjudicative model are misleading in this instance. It is one thing to "fence-in" a single respondent who has been proven individually to have violated the FTC Act, and quite another thing to corral a whole industry via some guilt-by-association reasoning.

It can also be argued that the further the Commission moves from proscription of unfair or deceptive acts and practices to the mandating of numerous preventive remedial provisions, the greater is the quantum of record evidence required to support the rule.

Judicial Review

Lastly, at the same time that these issues will be resolved in the courts there will arise issues as to the standard and scope of judicial review itself. The Magnuson-Moss Act specifies that Commission rules be reviewed on a "substantial evidence" standard.[20] This represents a clear and intentional departure from the usual "arbitrary and capricious" standard for review of agency rules. As to the scope of judicial

[18] See, note 2, *supra*.
[19] 15 U. S. C. Sec. 57a(d)(1)(C).
[20] 15 U. S. C. Sec. 57a(e)(3)(A).

review, on the other hand, the Magnuson-Moss Act mystifyingly attempts to exempt the FTC's statement of basis and purpose from such review.[21]

I would like to close with a quotation from a recent law journal article which I think is directly applicable:

"The legal system is still struggling to adjust to the greatly increased importance of informal rulemaking. The old notions that such rules are scarcely subject to judicial review and that the right to a formal hearing must accompany any significant agency action have for all practical purposes been abandoned. Instead, agencies tend to use a number of carefully selected formal procedures in informal rulemaking itself. . . .

"To date, however, these procedures have not fully succeeded in creating an alternative structure for administrative action which can provide a satisfactory framework both for agency decisions and for judicial review."[22]

In short, there are many complex legal and practical issues to be resolved before the Magnuson-Moss Act will be found to have lived up to its title as the FTC "Improvements" Act. **[The End]**

EFFECTIVE DATE OF ESTROGEN LABELING RULE EXTENDED

The effective date of a rule requiring patient labeling for all prescription estrogenic drug products for general use has been extended by the Food and Drug Administration (FDA) from September 20 to October 18, 1977. The rule, which specifies the kind of information to be contained in the labeling and how it is to be made available to the patient, applies to manufacturers and suppliers who deferred preparing labeling of their product until publication of the final rule.

According to the FDA, the reason for the date change was that, after publication of the rule on July 22, the Agency received a petition from the Pharmaceutical Manufacturers Association and the American College of Obstetricians and Gynecology requesting a permanent stay. The FDA then agreed to delay the effective date of the regulation by as many days as it took to evaluate the petition. On September 1, the Agency rejected the petition and set the new effective date.

CCH Food Drug Cosmetic Law Reporter, No. 766

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[21] 15 U. S. C. Sec. 57a(e)(5)(C).

[22] W. F. Pedersen, Jr., "Formal Records and Informal Rulemaking," 85 *Yale L. J.* 38, 76 (1975).

Consumer Nutrition Advocacy

By ESTHER PETERSON

Ms. Peterson Is Special Assistant to the President for Consumer Affairs.

JUST WHAT IS IT consumers are after in the marketplace? I think consumers want to make informed decisions, intelligent choices. Perhaps that doesn't sound like much, but the truth is, especially in the food industry, the consumer is still a reactor rather than an actor. I have found, however, that having the consumer as an active participant tells one more about consumer needs and wants than a hundred expensive consumer surveys.

You are here to hear and discuss some thoughts on how to meet the changing needs of consumers, but I thought I would expand that to say ". . . as they try to adjust to our changing food supply and as they have to depend more on the food industry for vital consumer information . . . "

I would like to discuss today the evolution of nutrition labeling—a case history of consumer, industry and government joint action to reach a common goal.

In the late 1960's, consumer groups began advocating more information, both on food labels and at the point of purchase. Nutrition labeling became part of this drive. Nutrition labeling has grown from a rudimentary concept in the early 1970's to a widely accepted, if not always understood, component of most food labels today.

Initially, Giant Food in Washington, D. C., along with National Tea in Chicago, the Berkeley Food Co-op and other regional food retailers developed prototype nutrition labeling programs in 1971 and 1972.

After some hesitancy on the part of the Food and Drug Administration (FDA), these prototype labels were cleared. The tacit message in this governmental action was that providing nutrition information through labeling was reasonable, plausible and pragmatic, and furthermore, that the regulatory agencies were willing to develop the necessary standards and procedures. Therefore, the large national brand food

processors moved quickly to adopt nutrition labeling and to create the necessary technical support systems.

Significance of Nutrition Labeling

The significance of the evolution of nutrition labeling goes beyond the availability of a new set of useful data about the food we eat, however. We have at least learned the following about the participants in the process and the results of the actions taken by all of them:

(1) A fundamental change in the information available on food product labels has occurred without a specific mandate from either the Congress or the Executive.

(2) Consumer groups, by participating in an incremental decision process, implicitly acknowledge that food processors, within basic health safeguards, will still control the food products that reach the marketplace.

(3) The federal government, without clear legislative direction, can assume a positive role in food policy. Nutrition labeling requires dietary standards, and the FDA has developed the U. S. Recommended Daily Allowance to fill this need.

(4) The food label which once expressed the processors' view of the package contents now describes the product value from the consumers' or buyers' vantagepoint.

Nutrition labeling is still evolving, but we still face two major problems. First, there are no adequate data for meat and produce according to the FDA's requirements. The United States Department of Agriculture's (USDA's) Handbook Number 8 is not deemed adequate by the FDA. So, meat and produce retailers, manufacturers and growers are attempting to deal with this problem. Second, even if there were adequate data, we still face the problem of consumer understanding and use of nutrition labeling information. The problem here is primarily communication and label design.

The Public Interest

Nevertheless, nutrition labeling is a stunning achievement because it demonstrates what happens when consumers participate in a procedure that allows all segments of the food system to adjust together to product and information changes. When everyone participates, the result works to the benefit of each and to the whole.

We did find that there were problems, but we can learn from that. The government naturally believes that it can and must define the public interest. It has the legal power and the means to do so. Traditional political theory supports this role. In the case of nutrition labeling, however, government action focused on writing the regulations aimed at future compliance, rather than getting information to consumers.

The regulations are relatively stringent. Producers of basic agricultural products such as fruits, vegetables and meats had no data. They were not allowed to use the data from Agricultural Handbook 8 because the data are not specific enough to the product as sold. Admittedly, the data are old, but the producers had nothing better. They also were not organized with the technical back-up to produce such data.

As a result, the big food manufacturers have been able to nutrition label while the basic agricultural producers have not. This problem was partially recognized by the regulators, but their legal advisors convinced them that the only way to keep the industry honest was to be specific.

The poor consumers, not to mention the agricultural producers, were left out in the cold. Half of the products purchased could not be labeled. Consumer understanding of nutrition labeling was dealt a serious blow. Six years later we still do not have this labeling. What a pity it is since nutrition labeling could have been a basic educational tool if it included these products. Even the posters and pamphlets Giant Food produced had to go because they, too, were based on Handbook 8. And what a disappointment this has been for the teachers who repeatedly requested these materials for classroom use.

Government Regulations

Only recently, with the encouragement of consumers and retailers, especially Giant Food, have we started to try to get producers and the FDA together to discuss ways around these roadblocks. The government has found the nature of the regulations as detrimental to the program as the industry and the consumers, yet it has taken the work of all the groups to come up with solutions. I am hopeful we will see some results in the next year or so.

Thus, government regulation may end up making things worse rather than better. Regulators may have their own unique interests and may protect these interests rather than formulate the public interest

as a whole by their decisions. What emerges from this experience are at least two lessons:

(1) A working definition of the public interest recognizes that no one group can finally define it and that the public interest is the best combination of all specific interests; and

(2) If a proper means exists to insure that all segments of the public can participate in the decision, whether and in what form to have regulation, then everyone should benefit, consumers, industry and government.

I think these are the reasons why I have accepted President Carter's invitation to return to the White House and to work to secure passage of the Agency for Consumer Advocacy.

I know that effective consumer advocacy is to improve the way rules and regulations are made, the way they are carried out, and to question whether they may work at all. Effective consumer advocacy is not to impose arbitrary and capricious rules which prevent goods and services from reaching the consumer.

I am sure these points have escaped many of the critics of the advocacy agency. The agency offers the citizen an opportunity to restore responsive government and to eliminate those parts of our government which long ago ceased to perform any useful function.

Consumer Advocacy

My experience over the past eight years is that consumers are able to participate responsibly in the definition of the public interest, and that their efforts are beneficial in often very subtle ways.

This is not altogether surprising, if you consider some simple facts. There is but one food system and its troubles generally occur when one segment dominates the others, or when one segment is excluded from decisions which affect it.

Let me stress, the story is not over—consumers could have even better information and they will make even more informed decisions when the government listens more.

If the FDA and USDA listen to the meat and produce industries, we will be able to get more data on which to base labeling. If they listen to consumers, we may be able to devise a format which is more easily understood and, therefore, more quickly communicated.

If the Federal Trade Commission insists on sticking to its Food Advertising regulation, perhaps we can find a common ground where industry can talk meaningfully about nutrition without destroying the impact of the commercial.

Consumers often see problems as simpler than they are, but that has a refreshing directness. Consumers can help both government and industry look at the uncluttered issue of information before the distracting details that make it all seem too complicated to tackle.

[The End]

LOW-DOSE PENICILLIN ANTIBIOTICS FOUND NOT SAFE OR EFFECTIVE

Subtherapeutic use of penicillin-containing products in animal feed would be prohibited under a recent Food and Drug Administration (FDA) proposal. The proposal was based both on a general lack of evidence of safety and effectiveness and on the failure of the holders of new animal drug applications to submit reports of convincing studies justifying subtherapeutic use. Further, evidence has indicated that the use of penicillin and other antibiotics in animal feed has contributed to an increase in antibiotic-resistant strains of bacteria. Antibiotic resistance can be transferred from one strain of bacteria to another, thus increasing the probability of dangerous bacteria becoming immune to antibiotic treatment.

The proposed prohibition of subtherapeutic uses of penicillin, alone or in combination with other drugs, in medicated premixes is the first step in a program announced by the FDA in June to curb the threat of antibiotic-resistant bacteria posed by the use of penicillin and tetracycline in animal feed. The FDA has said that it will soon publish a similar proposal for withdrawal of approval for all tetracycline drugs for subtherapeutic use in feed. The issue has been under investigation by the Agency since the mid-1960s.

CCH Food Drug Cosmetic Law Reporter, ¶ 42,032

DATA SOUGHT ON NEED FOR NITRATES AND NITRITES IN POULTRY PRODUCTS

On the basis of a finding that nitrates and nitrites used as preservative or characterizing ingredients in the manufacture of poultry products are food additives or, in some instances, color additives, the Food and Drug Administration (FDA) is requesting information from manufacturers and others to be used in resolving safety questions raised by their new status. The FDA, which had considered such uses to be covered by prior sanctions issued by the U. S. Department of Agriculture and, therefore, not subject to the food additive provisions of the Federal Food, Drug, and Cosmetic Act, has since been informed otherwise by the USDA. In the absence of prior sanctions, the FDA must determine whether there is any legal basis for the use of nitrates and nitrites in poultry products.

Safety Questions

The FDA believes that the immediate objective of both the USDA and the FDA should be to eliminate all non-preservative uses of nitrates and nitrites for which substantial evidence of safety is lacking. The issues on which data and views are being requested include: whether nitrates or nitrites form cancer-causing nitrosamines in poultry products prior to ingestion by humans, the extent to which botulinal toxin is a genuine concern in such products, the extent to which nitrates and nitrites are effective in preventing the formation of botulinal toxin, and whether the substances are otherwise safe for human consumption.

Although the Agency has reached no final judgment about whether a regulation provisionally listing the substances for use as color additives or whether an interim food additive regulation covering even restricted use of the substances in poultry products would be appropriate, it will consider proposing such regulations if requested. Requests for issuance of interim food additive regulations authorizing the continued use of the substances or for provisional listing of the substances as color additives must be filed with the FDA by November 1, 1977, and must be accompanied by a commitment to conduct studies to resolve the safety questions.

CCH Food Drug Cosmetic Law Reporter, ¶ 42,033

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