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ood Drug Cosmetic Law JOURNAL

Papers Presented at the Food and Drug Law Institute's Work Session on Enforcement

How to Comply With the New Medical Device Law

. . WILLIAM F. WEIGEL and CHARLES J. RAUBICHECK

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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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FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . June, 1976

Volume 31 Number 6

FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

The JOURNAL'S first article is a timely presentation concerning the recently enacted Medical Device Amendments of 1976. The authors, *William F. Weigel* and *Charles J. Raubicheck*, examine the premarket provisions of the new legislation and explain the designation and requirements of the three classification categories. Both Mr. Weigel and Mr. Raubicheck are members of the law firm of Rogers, Hoge & Hills. "How to Comply With the New Medical Device Law" begins on page 312.

Work Session on Enforcement. The following papers were presented at the Work Session on Enforcement sponsored by the Food and Drug Law Institute in Washington, D. C. on March 17—19, 1976.

"The Philosophy of Enforcement" by *Sam D. Fine* discusses the decision-making process of the FDA in its determination of when to prosecute violations of the Federal Food, Drug and Cosmetic Act. Written by the Associate Commissioner for Compliance in the Food and Drug Administration, the article, beginning on page 324, details the criteria and the review procedure used by the Agency in the prosecution process.

Prosecution under the Federal Food, Drug and Cosmetic Act is also the subject of *Charles R. McConachie's* article, which begins on page 333. Mr. McConachie, Acting Chief of the Consumers Affairs Section of the Antitrust Division in the Department of Justice, explains the relationship of the Justice Department and the FDA in litigation involving violations of the Act. Mr. McConachie's article is titled, "The Role of the Department of Justice in Enforcing the Federal Food, Drug and Cosmetic Act."

In "Enforcement Trends Under the Federal Food, Drug and Cosmetic Act," beginning on page 338, *Joel E. Hoffman* analyzes the enforcement actions of the FDA, the reasons for some of the different types of sanctions and the ways in which industry can blunt their effect. Mr. Hoffman is a member of the law firm of Wald, Harkrader & Ross.

As Deputy Assistant Commissioner for Public Affairs of the Food and Drug Administration, *Wayne L. Pines* discusses the specific Agency enforcement mechanisms of regulatory letters, publicity and recalls. In his article beginning on page 352, he relates the FDA's latest views on these sanctions and its reasons for using—or not using—each one. The article is titled "Regulatory Letters, Publicity and Recalls."

Eugene I. Lambert also covers regulatory letters, publicity and recalls but from a different viewpoint. Mr. Lambert, a partner in the law firm of Covington & Burling, identifies the statutory derivation of the enforcement techniques and presents some of the legal issues which arise from their use. "Recalls, Regulatory Letters and Publicity—Quasi-Statutory Remedies" begins on page 360.

"Handling FDA Injunction Actions" is *Richard S. Morey's* discussion of the use of injunctions by the FDA and the methods of settlement available to a company. Mr. Morey, whose article begins on page 366, is a member of the law firm of Kleinfeld, Kaplan and Becker.

Vol. 31, No. 6 June, 1976

Food·Drug·Cosmetic Law
Journal

How to Comply With the New Medical Device Law

By WILLIAM F. WEIGEL and CHARLES J. RAUBICHECK

Mr. Weigel and Mr. Raubicheck Are Members of the Law Firm of Rogers, Hoge & Hills.

ON MAY 28, 1976, President Ford signed into law the Medical Device Amendments of 1976[1] to the Federal Food, Drug and Cosmetic Act.[2] These new statutory provisions create, *inter alia,* a regulatory scheme of premarket clearance for medical devices similar to that in the existing Act for food additives and new drugs. Basically, this scheme will require a substantial number of manufacturers of medical devices to establish the safety and effectiveness of their products to the satisfaction of the Food and Drug Administration (FDA) prior to marketing. However, the legislation contains certain premarket clearance requirements that are unique to devices. This article examines the premarketing provisions of the new device law as they will affect the many manufacturers of devices throughout the nation who must now comply with these federal regulatory standards.

Coverage

The threshold question a device manufacturer must answer in determining compliance is, "Is my product covered by the new law?" The legislation defines a device as an

[1] P. L. 94-295.

[2] Hereafter referred to as "the Act."

"instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part, or accessary, which is—

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

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

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes."[3]

The last clause is an important addition to the definition in the existing Act in that it distinguishes devices from drugs. Products which meet either of the first three criteria but which are not dependent upon chemical action and not dependent upon being metabolized are to be regulated under the provisions of the new legislation and not, as were some devices prior to the amendments, under the drug provisions of the Act.[4] Examples of products classified as devices under the definition are cardiac pacemakers, intrauterine devices, kidney dialysis machines, defibrillators, cardiac and renal catheters, surgical implants, artificial vessels and heart valves, intensive care monitoring units and contact lenses. Obviously, there is a wide spectrum of products governed by the legislation. It should be noted that, although the definition speaks of animal devices as well as those intended for human use, Congress has determined that the new premarket clearance provisions apply only to devices intended for human use, since the legislation was developed primarily as a response to an incidence of injuries to humans from unsafe or ineffective devices.[5]

[3] Sec. 201(h) of the Act.

[4] Under the rulings in *United States v. An Article of Drug * * * Bacto-Unidisk*, 394 U. S. 784 (1969) and *AMP, Inc. v. Gardner*, 389 F. 2d 825 (CA-2 1968), cert. denied *sub nom. AMP, Inc. v. Cohen*, 393 U. S. 825 (1968) which approved the procedure, the FDA regulated certain products that fell within the statutory definitions of both "drug" and "device" as drugs in order to bring them within the premarket clearance controls of the existing Act because of the Agency's concern that such controls were needed for public health reasons. Among these products were an antibiotic diagnostic disk, a nylon surgical ligature and certain types of hard contact lenses. The new definition of "device" removes the confusion that resulted from the FDA's exercise of premarket jurisdiction over products that were clearly devices, but questionably drugs.

[5] Report by the Committee on Interstate and Foreign Commerce to accompany H. R. 11124, H. R. Rep. No. 94-853, 94th Congress, 2nd Session 14 (1976).

Classification of Devices

The mechanism of the new law by which the FDA will determine the nature and the scope of the premarket clearance procedure applicable to a particular device or class of devices is an innovative classification process. Indeed, by means of this process, the Agency will decide whether a device has to undergo premarket clearance at all, or whether it may be marketed subject only to the general controls of the Act governing all devices on the market.

The classification process, set forth in new Section 513 of the Act, establishes three categories into which every medical device intended for human use must be classified by the FDA, depending upon the degree of regulation necessary in the Agency's judgment to provide reasonable assurance of the product's safety and effectiveness. The three categories are: (1) Class I—General Controls; (2) Class II—Performance Standards; and (3) Class III—Premarket Approval.

A device will be classified in Class I if the general controls of the Act governing medical devices—the sections on adulterated devices; misbranded devices; registration of device manufacturers; banned devices; notification and repair, replacement or refund; records and reports on devices; and good manufacturing practices—are in the FDA's view sufficient to provide reasonable assurance of the safety and effectiveness of the device.[6] The significance of classification as a Class I device is that the product will not have to be tested at all prior to marketing. A manufacturer of a Class I device, however, will have to make sure that the device is in compliance with the above regulatory controls. In essence, a Class I device will be regulated in much the same way as devices were regulated prior to the enactment of the new law.[7]

A device will be classified into Class II if:

(1) it cannot be classified into Class I because the FDA decides that the above general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device; and

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[6] Sec. 513(a)(1)(A).

[7] Manufacturers of Class I devices should be aware that the FDA may, upon classifying their products into Class I, exempt them from requirements of registration, records and reports, and good manufacturing practices if the Agency determines that the devices do not require extensive regulation to assure protection of the public. H. R. Rep. No. 94-853, 94th Congress, 2nd Session 35 (1976).

(2) there is sufficient information to establish a performance standard to provide such assurance.[8]

Such a device will be subject to a performance standard promulgated as described below. A Class II device will be subject to general controls as well as to a performance standard unless the necessity for such controls, from the standpoint of safety and effectiveness, is negated by compliance with the standard.[9]

A device will be classified into Class III if:

(1) the FDA determines that it cannot be classified into Class I or Class II because insufficient information exists to determine the adequacy of general controls or of a performance standard to provide reasonable assurance of safety and effectiveness; and

(2) either it is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury.[10] A device classified in Class III is subject to the premarket approval application requirements described hereafter.

Advisory Panels

How will the classification process work? First, the FDA will establish expert advisory panels according to various medical and scientific specialties. The expert panels are to review devices already on the market before passage of the new law, as well as those to be marketed in the future, and are to make recommendations to the Agency on the classification of such devices. For each type of device,

[8] Sec. 513(a)(1)(B).

[9] H. R. Rep. No. 94-853, 94th Congress, 2nd Session 35 (1976).

[10] Sec. 513(a)(1)(C). Congress intended the clause "use in supporting or sustaining human life or . . . use which is of substantial importance in preventing impairment of human health" to be construed broadly where the FDA deems necessary, stating that such uses as prevention of pregnancy, application to the body of energy and substitution of a device for a major body function are uses of substantial importance that would justify a device's classification into Class III. With respect to the clause "presents an unreasonable risk of illness or injury," Congress indicated that the requirement of an unreasonable risk encompasses a balancing of the possibility of illness or injury against the benefits from use of the device, and that the risk need only be a potential risk, which can be demonstrated by foreseeability as well as by reported injuries. H. R. Rep. No. 94-853, 94th Congress, 2nd Session 35, 36 (1976).

the FDA will review the panel recommendations and publish a notice in the *Federal Register* classifying the device into Class I, II or III and inviting public comment. Upon consideration of the comments received, the Agency will publish a final regulation of classification.

The manufacturer and any other person who has an interest in the classification of a particular device has the opportunity to participate directly in the classification process by making a presentation at the meetings of the appropriate expert panel, as well as by filing comments on the proposed notice of classification. A personal appearance before an expert panel can be of considerable significance in the panel's ultimate classification decision, since these expert panels on devices, unlike any other FDA advisory panels, are specifically authorized by the Act to be an integral part of the classification process. The Agency is expected to lend great weight to their recommendations.

In anticipation of the new law while it was still before Congress, the FDA established 15 expert panels for devices in the following categories:

(1) orthopedics;
(2) cardiovascular diseases;
(3) dentistry;
(4) anesthesiology;
(5) obstetrics and gynecology;
(6) gastroenterology;
(7) urology;
(8) radiology;
(9) neurology;
(10) ear, nose and throat disorders;
(11) ophthalmology;
(12) plastic and general surgery;
(13) physical medicine;
(14) clinical pathology; and
(15) general and personal use.

These panels already have made recommendations to the FDA on the classification of many of the devices on the market today. However, the new legislation requires that each of the panels now reconvene to reconsider its previous recommendations in light of the classification criteria of the law as finally enacted. Each panel will render a new classification recommendation to the Agency prior to the notice and comment procedure described above.

Panel Recommendations

How long will the classification process take? The legislation requires that all expert panels present their classification recommendations to the FDA for devices already on the market no later than one year after funds are first appropriated for implementation of the classification process. Since the Agency anticipates an appropriation of such funds as a supplement to the FDA's 1977 budget, panel recommendations are expected to be made by some point in the second half of 1977 or in early 1978.

Manufacturers, however, cannot sit back and wait until this date. The FDA expects to begin publishing notices of proposed classification of devices within three to four months after the enactment of the new law (beginning approximately in September of 1976). This means that certain panels will submit their new classification decisions to the Agency during the summer of 1976. For these devices, a final regulation of classification after the notice and comment procedure will be published, most likely in mid-1977.

The date when a final regulation of classification is published is important to a manufacturer of a device already on the market. Until then, the manufacturer may distribute the device commercially. Thereafter, if the device is classified into Class I, he may continue to market the product subject only to general controls. If the device is classified into Class II or Class III, he has limited time frames, explained below, within which to comply with premarket clearance requirements relating to performance standards or premarket approval.

Performance Standards

Medical devices classified into Class II will be required to conform to a new type of premarket clearance under Section 514 of the Act—performance standards. A performance standard is a measurement designed to provide reasonable assurance of the safety and effectiveness of a device and must include provisions for:

(1) the construction, components, ingredients and properties of the device and its compatibility with power systems and connections to such systems;

(2) the testing of the device on a sample or an individual basis;

(3) the measurement of the performance characteristics of the device; and

(4) where appropriate, a requirement for the use of labeling for the proper installation, maintenance, operation and use of the device, including a prescription of the form and content of such labeling.[11]

Testing of a device under a performance standard will include both clinical testing and testing relevant to technical characteristics.[12]

Performance standards will be established by regulation, after invitation by the FDA in the *Federal Register* for submission of existing standards already developed by public entities or private standard-setting organizations or for offers by such groups or other qualified persons to develop standards. The FDA has the authority to accept or reject the submission of an existing standard or an offer to develop a standard. Once the Agency accepts a standard, it will initiate a notice and comment rule-making proceeding, during which it may refer proposed standards to expert advisory committees (which must have different memberships than the classification panels) for recommendations.[13] Thereafter, the standard will be codified in a final regulation covering all Class II devices for which it was developed. Should no standard acceptable to the FDA be submitted by private industry, the Agency itself is authorized to develop an appropriate standard and publish it for notice and comment rule-making.

Once a performance standard is promulgated as a final regulation, all Class II devices to which it is applicable must comply with the standard to enter or, in the case of devices already marketed, to continue on the market. This form of clearance is similar to that involved in the FDA's over-the-counter drug review. Since compliance with a standard, in many instances, will involve testing and may therefore take some time, the legislation provides that a final regulation establishing a standard will not take effect until one year after the regulation is published in the *Federal Register*.[14] While this time

[11] Sec. 514(a)(2).

[12] H. R. Rep. No. 94-853, 94th Congress, 2nd Session 26 (1976).

[13] It should be noted that at the outset of any such proceeding, a manufacturer can petition the FDA to reclassify his product into Class I on the basis of new information since classification of the device into Class II. Sec. 514(b)(1). The FDA must act on the petition, after consultation with the appropriate expert panel, within 60 days. Congress enacted this provision in the recognition that a manufacturer should not have to await the outcome of a performance standard proceeding when there is information warranting Class I classification arising during the considerable period of time that may elapse between classification of a device into Class II and development of a performance standard for it. H. R. Rep. No. 94-853, 94th Congress, 2nd Session 27 (1976).

[14] Sec. 514(g)(3)(B).

frame for compliance with a performance standard appears reasonable, manufacturers of Class II devices are advised to follow closely and, if possible, participate actively in the proceeding for the development of the standard applicable to their devices from the moment the products are classified into Class II.

Premarket Approval

To be lawfully marketed, a medical device classified into Class III is required, under new Section 515 of the Act, to have approval of an application for premarket approval similar to the procedure governing a new drug application (NDA) under existing law. Devices classified into Class III will be of three types:

(1) devices on the market before the date of enactment of the legislation ("old" devices);

(2) "new" devices, that is, devices which are not on the market prior to enactment and are not substantially equivalent to a device which is on the market as of enactment;[15]

(3) products which have been regulated by the FDA as drugs prior to enactment but which come within the new statutory definition of "device."[16]

"Old" devices will be placed in Class III via the classification process. "New" devices and products formerly regulated as drugs are automatically classified into Class III. In addition, devices which are intended to be implanted in the human body for more than a period of 30 days, such as cardiac pacemakers, intrauterine devices and intraocular lenses, are automatically classified into Class III unless the FDA makes a specific finding, including reasons therefor, that Class III classification is not necessary to provide reasonable assurance of the safety and effectiveness of the device.[17]

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[15] Sec. 513(f)(1). Congress intended the term "substantially equivalent" not to be so narrow so as to refer only to devices that are identical to devices already marketed nor so broad so as to refer to devices which are intended to be used for the same purposes as marketed products. H. R. Rep. No. 94-853, 94th Congress, 2nd Session 36 (1976). Devices deemed "substantially equivalent" to marketed devices are akin to so-called "me-too" drugs and are not automatically classified into Class III.

[16] See note 4, *supra*.

[17] Sec. 513(c)(2)(C). Congress enacted this automatic Class III status for implantable devices because of the considerable testimony it received concerning death or injury associated with the use of implants. H. R. Rep. No. 94-853, 94th Congress, 2nd Session 37 (1976).

An application for premarket approval must contain:

(1) full reports of all information on investigations known or which should reasonably be known to the applicant to determine the safety and effectiveness of the device;

(2) a statement of the components, ingredients and properties and of the principle(s) of operation of the device;

(3) a description of manufacturing methods, facilities and controls;

(4) information showing compliance with a performance standard which would be applicable if the device were a Class II device;

(5) samples of the device, if practicable; and

(6) specimens of proposed labeling.[18]

The FDA must act on the application within 180 days after filing, unless the applicant and the Agency agree on a greater period of time.[19]

Testing of Effectiveness

The most significant feature in the premarket clearance procedure for Class III medical devices, as well as the most significant departure from the law governing premarket clearance for new drugs, is the requirement in Section 515 on testing of effectiveness. Efficacy tests submitted in an application for premarket approval of a device must show that there is a "reasonable assurance that such device is effective" under the conditions of use prescribed, recommended or suggested in its labeling.[20] While the legislation contains a general rule that effectiveness must be established by well-controlled investigations, including clinical investigations "where appropriate," Congress explicitly spelled out its intention that the FDA accept meaningful data developed under less rigorous methodology than the adequate and well-controlled clinical investigations required for approval of an NDA.[21] Such less rigorous methodology for devices is authorized in instances in which well-documented case histories that establish effectiveness

[18] Sec. 515(c)(1).

[19] This is a requirement that Congress specifically intends be observed by the FDA, unlike the present practice regarding new drugs whereby the Agency's review of an application often takes several years. H. R. Rep. No. 94-853, 94th Congress, 2nd Session 32 (1976).

[20] Secs. 513(a)(1)(C) and 515(d)(2)(B).

[21] Sec. 513(a)(1)(C). H. R. Rep. No. 94-853, 94th Congress, 2nd Session, 17 (1976). It should be noted that, as with the provisions of the Act governing new drugs, the legislation does not require safety to be proved by adequate and well-controlled clinical investigations.

assure protection of the public health or in instances in which well-controlled investigations would present undue risks to patients.[22] Congress adopted this standard in recognition of the fact that devices vary widely in type, mode of operation and in the scope of testing and experience they have undergone.[23]

The less stringent testing requirement for devices will mean that it is possible for the manufacturer of a Class III device to establish the effectiveness of his product in less time and at less expense than is involved in the testing of new drugs. Although the FDA is certain to examine with great care case histories and other relevant efficacy data submitted in an application for premarket approval, it appears that if these data and the safety data are sound, the product should receive relatively expeditious clearance for marketing. In addition to aiding clearance of Class III devices already on the market, the broader efficacy testing standard should also foster the development of new medical devices.

Application for Premarket Approval

A new device—that is, one not on the market as of the enactment date of the legislation—must receive approval of an application before it can be distributed commercially. A device on the market before enactment which is classified into Class III has a 30-month period from the date it is so classified during which its manufacturer has the opportunity to develop data and file an application for premarket approval.[24] Until the FDA acts on the application, such an "old" Class III device is subject to the general controls applicable to all devices. For each "old" device requiring an approved application for premarket approval, the FDA must publish, in addition to the regulation classifying the device into Class III, a separate regulation stating that the product requires such approval.[25] A manufacturer must file his application for premarket approval within 90

[22] H. R. Rep. No. 94-853, 94th Congress, 2nd Session 17 (1976).

[23] *Id.*

[24] H. R. Rep. No. 94-853, 94th Congress, 2nd Session 42 (1976). This is the only "grandfather" provision of the legislation and, unlike the grandfather clauses applicable to new drugs, does not afford a complete exemption from premarket application requirements.

[25] As with regulations for performance standards, such a regulation must afford an affected manufacturer the opportunity to petition for reclassification of his product. Sec. 515(b)(2)(B). Manufacturers of new devices automatically receiving Class III status may petition for reclassification *sua sponte*. Sec. 513(f)(2).

days of the publication of this regulation or within the aforementioned 30 months from the date of classification, whichever is later.[26]

The legislation also contains a section governing the withdrawal of approval of an application for premarket approval, similar to that in existing law on withdrawal of approval of an NDA.[27] The principal ground for withdrawing approval is the availability of new information which creates, in the FDA's view, a lack of reasonable assurance that the device covered by the application is safe or effective. Such new information may be based on a re-evaluation of data that enables experts to identify a problem with a product that previously had not been known to exist.[28] The affected manufacturer has the opportunity to contest the proposed withdrawal.

Investigational Use Exemption

As in the existing law for drugs, the new legislation provides that Class III medical devices may receive an exemption from the requirement of an approved premarket approval application which will allow limited distribution of the device for the purpose of developing investigational data. Under new Section 520(g) of the Act, the FDA is authorized to promulgate regulations specifying the procedures and conditions under which devices will receive such an exemption. In many cases, the investigational use exemption will be the way in which a manufacturer will develop the data submitted in his application for premarket approval.

Akin to this procedure is a novel provision of the new law whereby the investigation of a Class III device and the development of data necessary for its approval are merged into a single mechanism called a "product development protocol" (PDP).[29] Under this mechanism, a manufacturer will submit a PDP to the FDA containing a description of the preclinical or clinical trials to be conducted on the device involved. If the FDA approves the protocol, the next step is for the manufacturer to submit a notice of completion of the protocol containing the results of the tests conducted. Approval of the notice of completion has the same effect as approval of an application for premarket approval.

The investigational use exemption and the PDP are methods intended by Congress to encourage the discovery and the develop-

[26] H. R. Rep. No. 94-853, 94th Congress. 2nd Session 42 (1976).
[27] Sec. 515(e).
[28] H. R. Rep. No. 94-853. 94th Congress, 2nd Session 32 (1976).
[29] Sec. 515(f).

ment of new devices under the regulatory controls of the legislation.[30] They undoubtedly will receive frequent use by both manufacturers and scientific investigators.

Judicial Review

The new legislation contains a specific provision authorizing review by the U. S. Court of Appeals for the circuit wherein a manufacturer resides or has his principal place of business, or by the Court of Appeals for the District of Columbia, of any FDA regulation concerning classification of a device, promulgation of a performance standard, requirement of an application for premarket approval or withdrawal of approval of an application for premarket approval.[31] The standard for judicial review is that the FDA's regulation must be supported by "substantial evidence on the record taken as a whole." The record will include the recommendations of the expert advisory panel involved as well as the comments of interested persons. A manufacturer may obtain a stay of effectiveness of the regulation until the court rules on the validity of the regulation.

This outline of the provisions of the new device law governing premarket clearance should provide manufacturers with a basic view of the legal requirements ahead for the continued marketing of their products. The FDA's future actions in implementing the legislation will provide additions, interpretations and refinements respecting these regulatory controls that will be essential knowledge for the device manufacturer. The industry is urged to become familiar with these basic provisions and to follow closely the practical development of the new law. **[The End]**

[30] H. R. Rep. No. 94-853, 94th Congress, 2nd Session 32, 42 (1976).

[31] Sec. 517.

The Philosophy of Enforcement

By SAM D. FINE

Mr. Fine Is Associate Commissioner for Compliance in the Food and Drug Administration.

WHEN I JOINED THE FOOD AND DRUG ADMINISTRATION (FDA) in 1939, I realized I had become a member of a consumer protection agency. As part of my indoctrination, I was directed to read the following books:

(1) "The Jungle" by Upton Sinclair;

(2) "The American Chamber of Horrors" by Ruth de Forest Lamb; and

(3) "100,000,000 Guinea Pigs" by Kallet and Schlink.

I was impressed by the facts reported by those early consumer advocates, and became convinced in my first year of service of the need for a strong FDA enforcement policy. That year formed the basis for my philosophy of enforcement, which has been evolving ever since.

In my first two years, I took part in a nationwide recall of a drug to the medicine cabinet level in order to prevent further loss of life from a serious manufacturing error by a major drug firm. I also learned by performing that inspection-type work that professionally trained individuals would lie to a government inspector if it might serve their purpose. I have never forgotten that experience, for it meant redoing an investigation in southwestern Iowa.

My first exercise of judgment in recommending prosecution came in 1948, while I was still a bench chemist in the FDA's Cincinnati District Laboratory. For training purposes, the District Chief had me participate in Section 305 hearings and prepare Summaries and Recommendations. The training was invaluable, for when I became Chief Chemist in the Denver District in 1950, I soon found myself holding about 90 percent of the Section 305 hearings.

Today I find myself sometimes described as the FDA's "Chief Cop." The title brings to mind a line from a Gilbert and Sullivan operetta—"A policeman's lot is not a happy one." Let me assure you that since Dr. Edwards asked me to become the Associate Commissioner for Compliance in December of 1969, I have discussed many times with three Commissioners and three Chief Counsels the appropriateness of various kinds of enforcement actions necessary to protect consumers.

All of you are aware that the FDA, of necessity, must depend upon the entire regulated industry for a great amount of self-regulation. With its limited resources, the Agency can never hope to monitor completely the massive industries subject to its legislative mandates. Effective regulation is an impossibility without the willingness and the ability of the vast majority of the regulated to comply with the various laws enforced.

Enforcement by Self-Regulation

Can all of the FDA's enforcement be by self-regulation? I believe we can all agree that the answer is no. There is a very real need for all of the legal sanctions set forth in the Federal Food, Drug and Cosmetic Act. Seizures were recognized as essential when the Department of Agriculture started enforcement of the 1906 Food and Drug Act. The first Chief Inspector, Walter G. Campbell, an

pliance, we prosecuted. Two of the responsible individuals received 30-day jail sentences, to be served. The effect on the rest of the Texas pecan shellers was dramatic. It was brought home to me most vividly when the president of an El Paso firm came to see me in Dallas and stated, "Tell me what I have to do, Mr. Fine—I don't want to go to jail." Our senior microbiologist joined the conference and we made a series of suggestions to the visitor, which he promptly carried out. Having the attention of the pecan-shelling industry in the Southwest, we proceeded to hold a workshop in Muskogee, Oklahoma, in cooperation with a local firm and State and local officials. The firm in Muskogee became an early entrant into what is now called our Cooperative Quality Assurance Program. To the best of my knowledge, the pecan-shelling industry in the Southwest today is a far better industry as a result of the judicious use of both criminal prosecution and an educational program.

How are decisions made to prosecute? The process involves several stages of review, each of which serves as a check to assure that existing policy guidelines, requiring fair, impartial and uniform treatment, are followed. There is a growing consensus as to the criteria for prosecution among the individuals responsible for review.

Prosecution Recommendations

Virtually all prosecution recommendations are initiated by District managers, following a hearing. The initial step is the decision to issue a Notice of Hearing under Section 305. Such a decision is carefully and deliberately arrived at because we no longer use—and have not used for the last eight to ten years—such notices for the purpose of warning, as was done earlier. When the decision is made to issue a Notice of Hearing, we have decided that prosecution is probably in order. We have delegated to our field managers direct reference authority to issue such notices for a total of 88 specific type violations. Sixty-one involve food adulteration, such as insect and rodent filth in spices, decomposition in fish and shellfish, pesticide residues in raw agricultural commodities, etc. Direct reference authority on drugs includes potency violations, sterility violations, content uniformity violations and tablet disintegration violations. While there is no requirement that the firm and individuals respond to the Notice of Hearing, in my view, failure to answer the charges is a grave error. This represents the last good chance for the prospective defendants to forestall prosecution.

Once the decision to prosecute has been reached by the District Office, and has received the concurrence of the Regional Food and Drug Director, the Record of Hearing is sent forward as part of the Summary and Recommendation package for headquarters' review. The proposed case also contains an explanation of the kind and the significance of the violations encountered, the names of individuals and/or firms deemed to be responsible for the violations, and any other pertinent facts, together with a detailed statement outlining why prosecution is considered appropriate. This package is usually referred to one of the bureaus (for example, Foods, Drugs, Devices, etc.) for initial review. After approval at the bureau level, it is then forwarded to my Regulatory Management Staff for additional review. Reviews at these two levels are designed to ensure that:

(1) the agreed upon criteria for prosecution are met;

(2) there is uniform application of the criteria throughout the ten regions of the nation;

(3) all cases are prepared as precisely and accurately as possible to withstand careful legal review, first in the office of our Chief Counsel and later by the appropriate offices of the Department of Justice.

Final Review

If prosecution is still considered appropriate, the recommendation is forwarded to our Chief Counsel for a final review before transmittal to the Department of Justice. The review by the Chief Counsel covers:

(1) legal sufficiency;

(2) consistency;

(3) "winnability."

There is only one type of case where recommendations for prosecution may be forwarded by the Regional Food and Drug Director directly to the Regulatory Management Staff without going through preliminary review by the cognizant bureau. It involves sanitary conditions in food warehouses. Direct referral in this type of case requires that all of the following conditions are met:

"1. The inspection or inspections on which the prosecution is based shows substantial insect, rodent or bird infestation of the warehouse or storage area

and

2. Samples of lots from at least two different interstate shippers are found to contain insects, bird excreta, rodent gnawed food, rodent excreta, or rodent urine in the food itself. This does not mean one insect infested lot and one rodent infested lot. If the area is rodent infested there must be two rodent infested lots; if bird infested, two bird infested lots; or if insect infested, two insect infested lots. On insect infested lots, there must be insects of the same species in both lots

and

3. At least one responsible individual is included in the prosecution

and

4. There is substantial evidence to show that all individuals included in the prosecution have authority to correct the violative conditions found

and

5. There is a background showing warning by letter, citation, or prosecution of the firm and all individuals included in the prosecution for similar insanitary conditions, which warning issued prior to the inspection or inspections on which the prosecution is based."

Interrelating Factors

In deciding whether to recommend prosecution in particular cases, we consider several interrelating factors, including:

(1) the seriousness of the violation;

(2) evidence of knowledge or intent;

(3) the probability of effecting future compliance by the firm in question as well as others similarly situated as a result of the present action;

(4) the resources available to conduct investigations necessary to consummate the case successfully; and (underlying all of these)

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

We have not found it possible to assign fixed weights to these factors or to establish a formula for decision that will automatically produce a decision in each and every case. The Agency relies on the collective judgment of its regional and headquarters managers—and their cadre of compliance officers—to assure that these criteria, which are not quantifiable or precise, are assessed accurately.

There are, however, certain general guidelines which are observed by all persons involved in the prosecution process. These guide-

lines are not used as a substitute for judgment on the part of individual decision-makers, but they do channel decision-making to assure useful, uniform and fair practices.

One of the first factors to be considered in deciding whether to initiate or to forward a prosecution action is the inspectional and/or analytical evidence that substantial violations of the Act have occurred. The Agency makes frequent use of its authority under the Act to deal with minor violations without utilizing the sanctions of seizure or injunction, much less prosecution. One feature of the FDA's prosecution review mechanism is to assure that the Agency does not bring criminal actions on technical violations when such violations can be corrected by less stringent means.

Documentation

A second consideration involves documentation that the individuals and/or firms charged were, in fact, responsible for the alleged violation. The general Agency posture is to consider that individuals acting for and within the corporation are responsible for violations of the law, rather than to consider the corporation as acting alone. Therefore, as a rule, the FDA does not recommend criminal prosecution against a corporation without including charges against responsible individuals as well.

The law allows the FDA to charge individuals who *have no knowledge* of a violation, if they hold a responsible position and, by virtue of the position held, *should have known* of the violative condition. We believe this is a reasonable position and the Supreme Court has so held. We insist, however, that our prosecution recommendations include a factual record which demonstrates that every individual charged either knew or should have known of the violative conditions set forth, and was in a position to do something about those conditions but failed to do so. In most cases, we have evidence that actual knowledge does exist on the part of the named individuals.

In considering whether or not prosecution action should be forwarded to the next reviewing authority, and eventually to a United States Attorney, one or more of the following general conditions must exist. In most cases, more than one of the conditions does exist.

(1) The violations ordinarily are shown to be of a continuing nature; that is, previous inspections or documented incidents indicate man-

agement of the firm is aware of the problem and has failed to take steps to correct the violations. This situation requires a showing of awareness.

An example of such a situation is an actual case in which insects were found in a firm's processing equipment during two consecutive FDA inspections. A regulatory letter was issued following the first inspection, and a Notice of Hearing under Section 305 was issued after the second. During the hearing, the responsible officials promised immediate correction and reported that they thought that the necessary improvements had been made prior to that second inspection. Because the violation was not obvious and management appeared to have a positive attitude, a third inspection was made two weeks following the hearing. When insects were found once again, the FDA brought a criminal action. The firm was fined a total of $2,500 after pleading guilty to five counts, and the responsible individuals were fined $500 each after *nolo contendere* pleas to one count.

Gross Violation

(2) The violation is so gross that any reasonable person would conclude management must have known of the conditions. Examples include a heavily insect- or rodent-infested warehouse or au obvious fraud.

A case which was brought following a single inspection by the FDA involved a heavy mouse infestation at a food salvage operation. Hundreds of live and dead mice were observed throughout both the retail and the storage areas. Nests containing live baby mice were found in food containers both in the wholesale and the retail areas. Live mice were observed and photographed running on overhead pipes, in and through food containers, etc. Spilled foods and filth up to one-half inch thick were noted on some floors, and the odor in one area was very offensive. Mouse excreta pellets far too numerous to count were seen both on foods and in the environment. Seizures of the foods were made both at the main storage facility and at a retail store after management failed to hold and recondition them properly. The prosecution resulted in the corporation being fined a total of $1,000 on two counts and the individual being fined $800 on one count and being placed on probation for two years.

(3) The violations are such that it is obvious that normal attention by management could have prevented them; for example, those situations where violations develop because management delegates

authority and does not exercise normal care. This situation may be demonstrated by either or both of the examples previously given. An obvious violation could be one which was brought to management's attention by the FDA or one which was so gross that any reasonable person would have known about the violation. Many FDA criminal cases have charged top level managers who, although they have delegated varying amounts of authority to others, should have been aware of the violations. The *Park* decision by the Supreme Court speaks to these circumstances.

Life-Threatening Violations

(4) The violations are such that they are life-threatening or injuries have occurred; for example, botulism in improperly prepared products or serious drug mix-ups.

One such case developed after two FDA District Offices began receiving complaints that a canned food was causing illnesses. In a one-week period, over 200 food poisonings were reported. The inspection of the processor revealed that it had inadequate controls and that it had failed to remove a natural poison from the raw product. The offending lots were removed from commerce by a recall. The firm and responsible officials were subsequently charged—in a criminal case—with the distribution of an article which contained a poisonous or deleterious substance and which was unfit for food. Following guilty pleas, the corporation and responsible individuals were fined a total of $4,000 and the individuals were placed on probation.

(5) The violations are deliberate attempts to circumvent the law; for instance, submission of false data, falsification of records, or deliberate short weight or subpotency.

An example of this condition is a prosecution for the substitution of a cheaper ingredient for an expensive drug ingredient. The scheme inflated the dollar value of the finished product 60 times. Although the normal analytical method did not differentiate between the two ingredients, the effectiveness of the life-saving drug component was reduced or eliminated by the substitution. In the resulting criminal prosecution, which charged intent to defraud or mislead, the corporation was fined $10,000 and the responsible individual was fined $10,000 and placed on probation for two years.

What this means is that continuation or repetition of violations over a period of time, or a single gross or deliberate violation, generally will trigger consideration for prosecution.

Recalls, seizures and injunctions are usually the alternatives of choice when we are seeking immediate corrective action of serious violations. We are using both recalls and injunctions far more today than in the past. Multiple sanctions are indicated in some instances. Examples that come to mind are multiple seizures, followed by prosecution. Some injunction actions have included provisions for recall of violative products. As a consumer protection agency, we believe that we must prevent the distribution of defective products, if at all possible. If such products have been distributed, we must remove them from consumer channels in as expeditious a manner as possible. To accomplish this mission, we will utilize all of the measures provided by the legislation we enforce. **[The End]**

THE FDA SETS FORTH PROCEDURES FOR IMPLEMENTING NEW MEDICAL DEVICE LAW

The procedures which the Food and Drug Administration (FDA) and its Bureau of Medical Devices and Diagnostic Products will follow in implementing the Medical Device Amendments of 1976 (Public Law 94-295) are discussed in an Agency notice dated May 28, the date of the legislation's enactment. Most provisions of the new law become effective upon enactment, although many of these will not become enforceable regulatory requirements until regulations promulgated by the FDA take effect. The FDA said notices and proposals will be published concerning implementation of the device amendments. They will set forth the requirements applicable to device establishment and product registration, new product notification, premarket approval, defect reporting and other record keeping/reporting requirements, classification, performance standards and exemptions for investigational use.

The requirements imposed directly by the amendments, which will be further defined by future notices and proposed regulations, include the duty to: (1) notify the FDA 90 days prior to introduction into interstate commerce of a device for human use; (2) submit an application for premarket approval for any device (other than those covered by general controls or performance standards) marketed after enactment of the amendments that is not substantially equivalent to a device in commercial distribution prior to enactment; (3) comply with special transitional provisions applicable to products formerly considered drugs that are now classified as devices; (4) comply with the new disclosure requirements for advertising restricted devices; and (5) permit FDA representatives to inspect records concerning restricted devices.

CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 41,649

The Role of the Department of Justice in Enforcing the Federal Food, Drug and Cosmetic Act

By CHARLES R. McCONACHIE

Mr. McConachie Is Acting Chief of the Consumer Affairs Section of the Antitrust Division in the Department of Justice.

IT IS MY PLEASURE to discuss the Department of Justice's function in the government's enforcement of the Federal Food, Drug and Cosmetic Act.

Congress has charged the Food and Drug Administration (FDA) to protect the public health and safety by keeping interstate commerce free from specified adulterated and misbranded articles subject to regulation under the Act.[1] To meet these responsibilities, the Act provides for several methods to effectuate compliance with its provisions. Because the responsibilities of the Department of Justice are limited to enforcement activities under the Federal Food, Drug and Cosmetic Act involving litigation in federal courts, my remarks will not encompass two very important enforcement tools, written warnings[2] and publicity.[3]

Simply put, the function of the Department of Justice in enforcing the Federal Food, Drug and Cosmetic Act is to review recommendations of the FDA and, where appropriate, institute civil seizures,[4] bring actions for injunctive relief[5] or institute criminal actions

[1] *U. S. v. Sullivan*, 332 U. S. 689 (1948); *U. S. v. Lexington Mills*, 232 U. S. 399 (1914).
[2] 21 U. S. C. 336.
[3] 21 U. S. C. 375.
[4] 21 U. S. C. 334.
[5] 21 U. S. C. 332.

for apparent violations of the Act.[6] Thus, the balance of my remarks will be in this area.

While perhaps elementary, it should be noted that the Department of Justice is a law enforcement agency with a statutory basis for the responsibilities it has in conducting litigation to enforce the Food, Drug, and Cosmetic Act.[7] In this same context, the Department of Justice also functions as trial counsel to the FDA in what may be termed defensive-enforcement litigation, situations where the Agency is sued to preclude some enforcement activity[8] or where a petition for judicial review is filed following final Agency action in connection with its enforcement efforts.[9]

Within the Department of Justice, these litigation responsibilities are borne in the main by the various United States Attorneys and the Consumer Affairs Section of the Antitrust Division. The primary responsibility for litigation rests in the more than 90 United States Attorneys' offices located wherever United States District Courts are situated. The Consumer Affairs Section performs three functions in the enforcement process: (1) secondary litigation responsibilities; (2) supervision of litigation being conducted or contemplated; and (3) coordination and communications between the FDA and the Department of Justice.

Enforcement Action

In almost every instance resulting in an enforcement action in a federal court, the FDA has conducted an investigation in the field and ultimately recommended prosecution.

Typically, the appropriate United States Attorney and the Consumer Affairs Section review the proposed action to determine that prosecution is appropriate. This exercise of prosecutorial discretion is designed to ensure, as is usually the case, that a case can be made in court, that the relief sought is appropriate and timely and that, in criminal prosecution recommendations, the proposed defendant or defendants are, under the circumstances, proper.

As I believe is true with the FDA, the Department of Justice is of the strong view that, in criminal prosecutions, the responsible

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[6] 21 U. S. C. 333.

[7] See 28 U. S. C. 516, 519.

[8] For example, *Certified Color Manufacturers Assn. et al. v. Mathews et al.*, Civil Action No. 76-153, (DC DofC Feb. 6, 1976), appeal docketed, No. 76-1120 (CA DofC).

[9] 21 U. S. C. 346a, 348(g), 355(h), 360b(b), 371.

individual or individuals should be charged together with the inevitable corporation.[10] Simply stated, our continuing view is that, regarding regulatory statutes, such as the Federal Food, Drug and Cosmetic Act, corporations do not violate the law in a vacuum. There is a responsible individual who, in most instances, should be prosecuted.

In the context of civil enforcement litigation, the bulk of civil seizure litigation recommended by the FDA is carried on by Assistant United States Attorneys. Because timing in these seizure actions can be so important, the better practice is for the appropriate United States Attorney to file the seizure complaint quickly and seek the arrest of the goods in section before shipment or consumption.

Expeditious Handling

As is true in all litigation arising under the Federal Food, Drug and Cosmetic Act, occasions often do arise when, because of a heavy caseload or other reason, the United States Attorney in whose district an FDA case is pending requests the Consumer Affairs Section to take the prime responsibility for conduct of litigation. This is a typical function of most Justice Department offices, and it serves to ensure that necessary and proper enforcement litigation receives expeditious handling by the Department of Justice.

I should like to point out at this point that attorneys from the Department of Justice act, as closely as possible, in partnership with attorneys from the FDA. Thus, in almost every instance, an attorney from the Department of Justice and an attorney from the Chief Counsel's Office will prepare for and go to trial in partnership. In my view, it is a very sound procedure that results in the government's case being prosecuted in the best possible way.

Another Justice Department function performed by the Consumer Affairs Section is the handling, in a supervisory sense, of Form 900 recommendations. Under Department of Justice regulations, no government attorney (United States Attorney or Consumer Affairs Section attorney) is permitted to dismiss a criminal case without the prior approval of the Assistant Attorney General of the Antitrust Division. A Form 900 is nothing more than a paper vehicle by which the government attorney makes a request and, if acceptable, the Department of Justice approves it. Part of the Form 900 process is obtaining, if possible, the views of the agency referring the prosecution, in this case, the FDA. This fact-finding procedure is performed by the Consumer

[10] *U. S. v. Park*, 421 U. S. 658 (1975).

Affairs Section. While the final decision to dismiss remains with the Department of Justice, as does the decision on whether to prosecute, the views of the FDA in food and drug criminal cases are always considered seriously and, where possible, adhered to.

As is true in any advocacy situation, there are instances, although decreasing in number in recent times, where the FDA disagrees with the decision of the Department of Justice on a particular dismissal or prosecutorial decision. Because of the close working relationships between the FDA and the Department of Justice, these situations, in our view, are not a threat to the fundamental process. Indeed, they are probably helpful to ensure a reasonable outcome to reach justice.

Plea Bargaining

Because the Department of Justice controls the dismissal of any criminal defendant sought by trial counsel, including attorneys in the Consumer Affairs Section, it quite naturally takes an active role in any plea bargaining which may occur in criminal cases. In such situations, it is also the policy of the Department of Justice to obtain the views of the FDA prior to reaching any bargain with defense counsel.

Our experience has shown that the greater the communication between the FDA and the Department of Justice before and during the bargaining process, the less chance of error or some part of the government misspeaking through a lack of communication. In this context, it is the view of the Department of Justice that a bargain where the corporate defendant agrees to plead guilty to a certain number of counts of the criminal information in return for the government's dismissal of the individual defendants is *not* acceptable.

On the other side of the coin, there are any number of instances where private interests seek to affect FDA enforcement activities by suing the Agency—or, more specifically, its officials—for declaratory relief, review under the Administrative Procedure Act or for review in the courts of appeal where provided for in the Act.[11] In these instances, the Department of Justice normally acts as trial counsel to the FDA defendants. In this context, the Department solicits the views of the FDA on virtually every aspect of the case just as any one of you would with a corporate or individual client. Again the preparation, discovery and trial are handled in a sort of partnership between the Department of Justice attorneys and attorneys of the Chief Counsel's Office. As with the other types of enforcement litigation, the coordination

[11] See Note 8, *supra*.

and blending of expertise has proven to be quite successful in the results achieved.

Appeals

The final FDA enforcement litigation I want to discuss briefly is appeals. As you know, one may appeal an adverse final judgment from a federal district court to a court of appeals, or appeal to a court of appeals final action taken by the FDA. For a number of years the Department of Justice and the FDA have worked very closely together on all appellate cases arising under the Federal Food, Drug and Cosmetic Act. In most instances, once an appeal is docketed, an attorney in the Chief Counsel's Office prepares a draft brief setting forth the position of the FDA in the particular case. This draft is reviewed and edited by an attorney in the Consumer Affairs Section and the two attorneys spend whatever time is necessary polishing the brief until ultimately the Department of Justice files the brief in preparation for argument.

In closing, I want to thank the Food and Drug Law Institute for the opportunity to present this discussion on the Department of Justice's role in enforcing the Federal Food, Drug and Cosmetic Act.

The better understanding you have of the enforcement process, the less chance the government will find it necessary to take action against you or your products for violations of the Federal Food, Drug and Cosmetic Act. **[The End]**

STANDARDS FOR DRESSINGS FOR FOOD REVISED

The standards of identity for mayonnaise, French dressing and salad dressing have been amended by the Food and Drug Administration (FDA) to require label declaration of ingredients and to allow the use of functional classes of safe and suitable ingredients that will not modify the fundamental characteristics of the foods. The FDA rejected comments, submitted in response to the proposed amendments, which urged the Agency to amend the standards to permit the use of artificial flavors, to permit the non-specific label declaration of vegetable oils, and to permit the use of any safe and suitable thickening agent. The revised standards are effective as to all products initially introduced into interstate commerce on or after January 1, 1978, but compliance may begin July 26, 1976.

CCH Food Drug Cosmetic Law Reporter, ¶ 41,643

Enforcement Trends Under the Federal Food, Drug and Cosmetic Act— A View from Outside

By JOEL E. HOFFMAN

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THE ROLE OF A PRIVATE LAWYER in a symposium on enforcement trends is far from obvious. The private lawyer has access only to past trends, even though the audience would much rather hear about future trends.

The two are not unrelated, however. And the lessons of experience have their value. Still worth heeding is the motto of a well-known former enforcement official: "Watch what we do and not what we say." This, coupled with that other old motto, "The past is prologue," will be the theme of the remarks which follow.

Quantitative Trends

The first job of any analyst of trends is to look at the numbers. Unfortunately, the available data base for enforcement activities of the Food and Drug Administration (FDA) is too imprecisely broken down to permit findings of statistical significance.[1] The num-

[1] For example, multiple seizures of a single product should not be considered the equivalent of an identical number of unrelated enforcement actions. Multi-defendant criminal prosecutions are not the same, for analytical purposes, as separate prosecutions of an equal number of defendants for unrelated crimes. Moreover, the only data available from the FDA for all but the most recent years apparently include in actions "instituted" or "initiated" all actions recommended by a

(Continued on the following page.)

bers do confirm, however, the impressions one would glean from the day-to-day practice of food and drug law.

Looking at the years since 1965,[2] the number of enforcement actions initiated each year rose steadily until 1968, when it dropped almost 50 percent and then fell another 40 percent in 1969.[3] A new upward trend began in 1970 and continued until 1974, when the number of enforcement actions initiated fell almost 60 percent to approximately the present levels with only a modest increase in 1975.

One component of the 1974 cutback has been widely and candidly discussed—the moratorium on over-the-counter (OTC) drug enforcement pending completion of the OTC Review and the publication of monographs for broad classes of products.[4] The numbers also show, however, that the number of food seizures in 1974 was only half that of the preceding three years and that the number in 1975—while rising—was still far below previous levels. An official explanation for this has yet to be forthcoming.

Perhaps the most striking statistic of all is the number of criminal prosecutions in 1975 compared to previous years. In fiscal 1975, the year of *Park*,[5] only 40 to 60 percent as many criminal prosecutions were initiated as in any of the preceding three years. The 1975 figure is approximately the same as for each of the three years before

(Footnote 1 continued.)
bureau within the Agency, whether or not the action was ultimately filed in court or even approved at the highest levels of the FDA. Declinations by the Department of Justice to file actions recommended by the Agency are discussed on pages 347—350 *infra*.

[2] See Table I on page 351.

[3] The sharp drop-off resulted in large part from the transfer, during 1968, of criminal enforcement responsibility under the Drug Abuse Control Amendments (since superseded by the Controlled Substances Act) to the Bureau of Narcotics and Dangerous Drugs in the Department of Justice. But Table I also shows a 40 percent reduction in food seizures in 1968 compared to previous consistent levels, followed by a further 40 percent reduction in 1969 with no substantial increase until the number almost doubled in 1971. Drug seizures showed a comparable decline in 1968 and 1969, and have never since reached the former levels. The FDA Annual Report for 1968 attributes that year's fall-off to "greater emphasis on voluntary compliance, changing priorities, and the policy of using court procedure as a last resort." Department of Health, Education and Welfare 1968 *Annual Report* 318.

[4] H. R. Rep. No. 94-787, 94th Congress, 2nd Session 9 (1976); Hearings on the Use of Advisory Committees by the Food and Drug Administration Before a Subcomm. of the House Comm. on Government Operations, Part 2, 94th Congress, 1st Session 77 (1975) (testimony of Chief Counsel Hutt).

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

that (1969—1971).[6] The number of criminal cases reported in the Weekly List as filed in court during calendar year 1975 was a mere 20, compared with 53 the previous year, the fall-off actually having begun in mid-1974 and accelerated in the first half of 1975. Whether the 1972—1974 period was aberrationally high, or whether, in 1975, the FDA was simply awaiting reversal of the Court of Appeals decision in *Park* before resuming its effort, remains to be seen.

The Changing Role of the Section 305 Hearing

Another trend worth noting is the elimination of the Section 305 citation hearing as an independent sanction.[7] Until 1975, there were far more Section 305 hearings than criminal prosecutions.[8] It was well known that Section 305 was used to provide a kind of warning that continued or repeated violations would be treated more severely than with mere civil sanctions, but that immediate repentance and improvement might well mean the end of the matter.

This is no longer the case. The number of Section 305 hearings has fallen to some 25 percent of the pre-1975 figures.[9] It appears that anyone summoned to a Section 305 hearing should give substantially more consideration than previously given to its character as a prefiling discovery device primarily benefiting the U. S. Attorney.[10]

Regulatory Letters

Systematic analysis of regulatory letters has been possible only since January of 1975, when the FDA began its practice of placing all such letters on display in the Office of the Hearing Clerk.[11] It is debatable whether anything called a trend can be discerned from a study of such short duration, but here too the numbers are thought-provoking.

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[6] In 1968 and earlier years, prosecutions under the now superseded Drug Abuse Control Amendments resulted in substantially higher total figures. See note 3, *supra*.

[7] 21 U. S. C. Sec. 335, giving prospective defendants the opportunity to present facts and arguments in defense or mitigation. But see *United States v. Dotterweich*, 320 U. S. 277 (1943), holding that failure to provide a Sec. 305 hearing does not vitiate a prosecution.

[8] Compare Table I with Table II.

[9] See Table II.

[10] The 1975 amendments to Rule 16 of the Federal Rules of Criminal Procedure may give the government some of this advantage in any event.

[11] The number of regulatory letters was first reported by the FDA in its 1974 Annual Report, which notes less than 1200 sent in fiscal 1974. Approximately 1800 are on file for fiscal 1975.

The regulatory letters on file confirm Commissioner Schmidt's recent statement to the Food and Drug Law Institute (FDLI) that he is uninhibited about writing to the chief executive officers of regulated companies.[12] More than 175 heads of companies have been so notified thus far in fiscal 1976. The alleged violations ranged from classic problems of rodent infestation of food warehouses to technically esoteric problems under the labeling provisions of the Federal Food, Drug and Cosmetic Act and the Fair Packaging and Labeling Act. Recipients ranged from presidents of large corporations to the husband-and-wife president and vice-president of a family firm, and from Chairmen of the Board to the Chairman of an Indian Tribal Council.

It is apparent from the letters on file, moreover, that others beside the chief executive officer may receive regulatory letters. When the FDA appears to take the violation particularly seriously, separately addressed letters are sent to all individuals deemed to have some responsibility for the alleged violation. The chief executive officer is invariably included. In the case of one large company, such letters were sent to seven different individuals, including quality control personnel and the company's government liaison.

In about 30 percent of the cases, the chief executive officer was not cited at all. In some of these, various other individuals were targeted, such as the director of quality control, the director of regulatory affairs, the director of grocery processing, secretary-treasurers, executive vice-presidents and plain vice-presidents. No reason appears from the letters why these individuals alone were singled out, although it seems that when drug advertising is at issue, the individual in charge of medical communications can expect a letter.[13]

There are some classes of letters, however, which typically seem to be sent to the company only. For example, failure to list under the Drug Listing Act is handled in this manner. The same is true of follow-ups to the withdrawal of approval of new drug applications and of letters alleging that products such as the soft contact

[12] Remarks by Alexander M. Schmidt, M. D., Commissioner of Food and Drugs, at the 19th Annual FDLI/FDA Educational Conference. December 2, 1975, pp. 5-6. See Schmidt, Alexander M., "The Food and Drug Administration's Enforcement Policy," 30 Food Drug Cosmetic Law Journal 687 (Dec. 1975).

[13] Lawyers as such have yet to be addressed, but the canning consultant for one food packing establishment was conspicuously carbon-copied on one regulatory letter.

lens or N-2 dental paste are new drugs. These account for 80 percent of the letters in which the chief executive officer is not the addressee.

The foregoing survey disregards the figures for blood plasma facilities and for methadone treatment programs. As a class, blood facilities receive by far the largest number of regulatory letters. Likewise, many letters have been sent to drug treatment facilities using methadone. The recipients in both these classes include governmental bodies, such as the District of Columbia Department of Human Resources and its Director with two methadone regulatory letters,[14] and well-recognized charitable institutions, such as the American Red Cross, recipient of enough letters to paper the walls of its national headquarters.

Comparative Trends

The food and drug laws are not the only business-regulatory statutes enforced through civil and criminal court litigation. Examination of the broader context may provide both a perspective for viewing the present situation of companies regulated by the FDA, and a hint of where such companies may be headed.

For a number of years the proportion of criminal prosecutions to total enforcement actions initiated by the FDA has been ten percent or less.[15] In contrast, under the securities laws, the proportion typically has been 20 to 30 percent.[16] And almost 50 percent of antitrust enforcement actions filed in the last two years have been criminal, more than ever before in recent years.[17] Moreover, the Department of Justice is currently taking pains to stress that a record number of price-fixing cases are now under grand jury investigation.[18] This suggests that criminal enforcement now plays a unique-

[14] Query: Does the third go to the Mayor?

[15] See Table I.

[16] Derived from Securities and Exchange Commission (SEC) *Annual Reports* 1970—1974. Information for 1975 was supplied by the Commission.

[17] Derived from U. S. Department of Justice *Annual Reports* 1970—1974. Information for 1975 was supplied by the Department.

[18] Address by Joseph Sims, Deputy Assistant Attorney General, Antitrust Division, U. S. Department of Justice, before the Board of Directors Conference, School of Business Administration, Southern Methodist University, Dallas, Texas, Feb. 26, 1976, p. 17; Statement of Thomas E. Kauper, Assistant Attorney General, Antitrust Division, U. S. Department of Justice, before Subcommittee on Monopolies and Commercial Law, House Committee on the Judiciary, March 4, 1976, p. 3.

ly limited role in food and drug enforcement, but that the wave of the future may be otherwise.

Quantitatively, however, the SEC initiates well under 200 civil cases a year compared to the FDA's current 550. Prior to 1970, the figure was usually less than 100.[19] Antitrust actions are even fewer—only about 60 to 70 in almost every year since 1970 and fewer than that in earlier years.[20] Yet the number of companies subject to the securities and antitrust laws is far greater than the number regulated by the FDA—many, if not most, of which are covered by all three sets of statutory prohibitions.

The proportionately greater level of enforcement activity under the food and drug laws may not reflect a higher frequency of violation. But it would be difficult to deny the special importance evidently attached by the government to protecting the consumer's health and safety as opposed to protecting his pocketbook.

Influences on Future Trends

In addition to the numbers, a trend analyst should consider qualitative factors affecting the events studied. Two such factors in today's regulatory context are readily identifiable. They can be called "consciousness-raising" and "government in the sunshine."

Consciousness-Raising by the Supreme Court and the Withering Away of Enforcement

Nothing in the modern enforcement history of the food and drug laws has stirred so widespread, so impassioned and so inconclusive, if not pointless, debate among lawyers and businessmen alike, as has the Supreme Court's decision in *United States v. Park*.[21] It is not the function of this discussion to enlighten you on what the Court held, or on what it really held, or even on what it must have meant to hold. Suffice it to say that just as in our culture the medium frequently is the message, so also the debate over the *Park* decision may have its own enforcement consequences.

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[19] Derived from SEC *Annual Reports* 1963—1974. Information for 1975 was supplied by the Commission. Most cases involve multiple defendants, but these are usually individuals.

[20] Derived from U. S. Department of Justice *Annual Reports* 1965—1974. Information for 1975 was supplied by the Department.

[21] 421 U. S. 658 (1975).

It has always been true that when a food and drug lawyer mentions the possibility of jail to a client, perhaps in a last desperate attack on recalcitrance, the lawyer most likely will provoke an entirely new order of response. Ever since the *Park* decision, however, executives have been responding in this way without the external stimulus of counsel. The decision and the well-publicized ensuing debate have seemingly led to an expanded awareness on the part of senior corporate officials, both as to the requirements imposed by law (at least as interpreted by the FDA) and as to their own role in meeting those requirements.

It may not be overly optimistic to think that the *Park* decision may serve the public-protection function intended by the Court primarily in this way, rather than as a guide for future judges and juries. Perhaps, therefore, the result of *Park* will not be more enforcement, but less.

Government in the Sunshine—The Decline of Prosecutorial Discretion v. the Decline of Selective Prosecution

If the law is a seamless web, as Oliver Wendell Holmes once wrote, then so is the web of statutes and regulatory policies governing the FDA. Freedom of information and its corollaries—collectively known in the 1970's as "government in the sunshine"—may well have a subtle but profound effect on enforcement policies and practices as well as on informational activities. Together with this, there should also be considered the growing pressure for increased accountability of regulatory bodies to Congress.

The realities of a prosecutor's office are such that not every prospective defendant who deserves to be prosecuted can be, and that not every prospective defendant who can be prosecuted should be. In addition to straightforward shortages of funds and manpower, our system allows for play in the joints, for intuitive prosecutorial judgments in good faith that are not easy to articulate, much less justify, under formally stated legal criteria.

It is not insensitive to the need for accountability and public confidence to suggest that unremitting pressure to explain and to justify prosecutorial judgments may lead in the end to mindless "playing it by the book"—when "the book" was written with the understanding that something else would be forthcoming. The Su-

preme Court in *Dotterweich* made clear that, under its extraordinary permissive standard for prosecution, much was intended to be left to "the good sense of prosecutors."[22] Competent prosecutors with integrity should be chosen and they should be allowed to exercise the good intuition for which they were selected, free from paranoid demands to express the inexpressible. Failing this, we will have prosecutors in the worst bureaucratic tradition, governmental or corporate, for whom the decisive question is, "What will people say when they read this in *The Washington Post*?" And we will deserve them.

The same pressures which may make it increasingly difficult for prosecutors to implement their good sense also may inhibit the unfair treatment of similarly situated companies in different ways, whether for reasons of prejudice and retribution or for innocent budgetary reasons. The company that can show it has been singled out, to its competitive disadvantage, has a powerful moral, if not strictly legal, argument against a contemplated enforcement action. And "government in the sunshine," with its freely available Establishment Inspection Reports and the like, can provide the ammunition for such an argument.

This is only one reason why one can respectfully disagree with the distinguished industry official who was reported as urging his colleagues, at a recent educational seminar, to refrain from seeking out their competitors' regulatory records.[23] "Government in the sunshine," in other words, can and should be a two-edged sword.

Bucking the Trends

Generalities do not decide concrete cases, and a company faced with the possibility of enforcement action need not merely sit back to await the worst. It is sometimes possible to reshape the situation so as to turn away or blunt the anticipated enforcement thrust.

"The Decree Goes Against the Mushrooms"

When a regulated company discovers or is informed by the FDA that violative goods are on its premises, and seizure is feared, there is one course of action that almost always commends itself:

[22] *United States v. Dotterweich*, 320 U. S. 277, 285 (1943).

[23] *M-D-D-I Reports*, pp. 12—13 (March 1, 1976).

destroy the goods immediately. This serves both the purposes of the statute and the interests of the company.[24]

Since the statutory objective is to remove offending goods from the channels of trade, their prompt and voluntary removal obviates legal action to remove them. From the FDA's viewpoint, one would hope, compliance has been achieved. The company also has demonstrated its commitment to protection of the public.

It is sometimes possible, however, that the FDA would prefer the dramatic impact of a seizure as a means of impressing its seriousness of purpose on both the company involved and the trade generally. Here, too, the company's interests are well-served by prompt destruction of the offending goods. For the seizure action is an *in rem* proceeding, that is, it is a suit against the goods themselves. And if there are no goods, there can be no suit.

The classic expression of this principle is found in a case involving the destruction of seized goods by court order during the pendency of an appeal. This was held to require termination of the proceeding. As the Court of Appeals held in that case, "The decree . . . goes against the mushrooms."[25]

The Bird in the Hand v. the Bird in the Bush—The Executive as Hostage

It appears that enforcement action can sometimes be averted by frank recognition of the problem involved and the placing of at least one head on the block for future removal. When a manufacturing plant of Travenol Laboratories was threatened last year with the filing of a suit for injunction to close down the plant, suit was avoided through a series of commitments made by Travenol and its Chairman of the Board. The commitment letter is noteworthy in that it includes a statement by the Board Chairman "recogniz[ing] that the Chairman of the Board of Travenol has a responsible relationship to the performance of the commitments and agreements set forth herein."[26]

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[24] Wholly different considerations may apply if the company has reason to believe that a criminal proceeding is contemplated by the FDA. Such a situation might present questions of obstruction of justice through the destruction of evidence. Such questions are beyond the scope of this paper.

[25] *United States v. 3 Unlabeled 25-Pound Bags* * * *, 157 F. 2d 722, 723 (CA-7 1946).

[26] Letter to Alexander M. Schmidt, M. D., Commissioner of Food and Drugs, from William B. Graham, Chairman of the Board, Travenol Labs., Inc., dated June 30, 1975, p. 1.

The file memorandum prepared on this incident by the FDA's Chief Counsel highlights the important role of the Board Chairman's statement in the Agency decision not to sue. The Chief Counsel explained that the commitment letter "is an appropriate resolution of the matter and fully protects the public interest" for the following reason, among others: If conditions at the plant do not improve, then, in light of the Board Chairman's statement, "criminal prosecution of all of the individuals who share responsibility for the . . . operation would seem not only appropriate, but comparatively straightforward."[27]

Thus, the FDA was persuaded not to initiate proceedings for an injunction *now* by providing the Agency with, among other things, a future criminal defendant in the event proceedings were found to be warranted *later*. The company was successful in avoiding present enforcement action, even though action in the future was made easier if the promised compliance effort were to fail.

The human sacrificial offering in this case presumably went along with the program because he perceived an identity of interest between himself and his company. However, other individuals, particularly those below the level of chief executive officer, may not be so ready to volunteer as hostage. This method of turning enforcement action aside, therefore, may not be of widespread utility, at least in publicly held companies.

Persuading the Prosecutor

Enforcement actions under the food and drug laws are filed and conducted in the name of the United States, almost all of whose litigation is controlled by the Department of Justice. The Department's concurrence and authorization must be obtained by the FDA. In some cases, where efforts to convince the FDA have failed, the Justice Department can be persuaded by the prospective defendant that action should not be taken or that civil, rather than criminal, proceedings should be initiated.

A company or individual against whom the FDA contemplates recommending enforcement action should therefore carefully consider

[27] Memorandum to the File from Richard A. Merril (GCF-1), re Travenol Laboratories Small-Volume IV Problem, dated July 2, 1975, pp. 1—2. See also the report of a similar exchange of personal correspondence between the Commissioner and a Board Chairman in *Washington Drug & Device Letter*, p. 6. (March 15, 1976).

requesting a meeting with the Justice Department in Washington or with the U. S. Attorney in the district in which the action would be filed. The purpose of such a meeting is to present facts and arguments about why the initiation of proceedings would be unfair, unnecessary or contrary to the public interest.

The record shows that efforts of this kind can be successful. Testimony before the Rogers Subcommittee in 1972 disclosed that more than ten percent of the seizure actions recommended by the FDA over a 4½-year period either were turned down by the Justice Department at the outset or were dismissed after filing, usually because the product was no longer available.[28] The record is even more striking in criminal cases. Out of 253 criminal cases recommended by the FDA, 37 were declined, 8 were dismissed after filing, and 101 individual defendants in 39 cases were dropped before or after filing.[29]

It is difficult to generalize on the showing which must be made to obtain a "declination." A review of recently published interagency correspondence in a series of prescription drug advertising cases recommended by the FDA for criminal prosecution and declined by the Department of Justice reveals four recurring factors:

(1) reliance by the FDA upon a strained or at least unobvious interpretation of the statute or regulations;

(2) the possibility of a difference of opinion among physicians as to the meaning of the advertisement in question;

(3) the inconsistency of the FDA's criticisms with prior Agency action approving the labeling of the drug in question; and

(4) the passage of substantial time between the offense charged and the request for prosecution.[30]

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[28] Hearings on H. R. 15315 (Food and Drug Administration Act) Before the Subcomm. on Public Health and Environment of the House Comm. on Interstate and Foreign Commerce, 92nd Congress, 2nd Session 38 (1972).

[29] *Ibid.* More recently, the Justice Department has testified that "over the years, almost 90 percent of the agency's recommendations have been filed." Hearings on H. R. 5361 and H. R. 6107 (Consumer Product Safety Act Amendments) Before the Subcomm. on Consumer Protection and Finance of the House Comm. on Interstate and Foreign Commerce, 94th Congress, 1st Session 161 (1975).

[30] Hearings on Present Status of Competition in the Pharmaceutical Industry (Competitive Problems in the Drug Industry) Before the Subcomm. on Monopoly of the Senate Select Comm. on Small Business, 94th Congress, 1st Session, Pt. 28 (Oral Hypoglycemic Drugs [continued]), pp. 13568—13619 (1975).

The Department of Justice recently has presented Congressional testimony, with reference to prosecutions under the Federal Hazardous Substances Act recommended by the Consumer Product Safety Commission, describing factors which lead to declination. These include:

(1) the age of the case, with the passage of a year between offense and recommendation apparently raising problems;

(2) the *de minimis* nature of the violations;

(3) "prompt and willing corrective action" by the proposed defendants;

(4) confiscation of the contraband goods through seizure;

(5) the defendant's abandonment of prohibited activities;

(6) lack of evidence that a proposed individual defendant stood in a responsible relationship to the alleged violation as required by *Dotterweich;* and (perhaps most important)

(7) the inadequacy of the facts and circumstances "to convince judge and jury that the defendant's misconduct warrants redress by the extreme criminal sanction, and that lesser civil remedies will not adequately deter future violations."[31]

Meetings with the Department of Justice on pending or proposed criminal matters tend to resemble not so much dialogues as oral argument before an incommunicative and inscrutable court. A few questions may be asked by the Justice Department lawyers but forthright and specific statements of what aspects of the facts they deem dispositive are difficult to obtain. Nonetheless, no one but the proposed defendant can be counted upon to pull together the facts in a way which focuses the rationale for nonprosecution. Certainly none but the defendant will do so with the convincing ring of good advocacy.

Similar considerations apply when the government has tried an enforcement action and lost in a district court. All proposed appeals by the government to the Court of Appeals, civil or criminal, must be reviewed by a new set of Justice Department lawyers and approved by the Solicitor General. Because they have had no prior involvement in the case, the appellate lawyers are capable of taking a fresh

[31] Hearings on H. R. 5361 and 6107 (Consumer Product Safety Act Amendments), note 29, *supra*, pp. 161—163.

look at the facts and the legal theory asserted by the government's trial counsel, in light of the record made below.

At this stage too, reasons can be presented why no further proceedings should be taken. Or a settlement proposal can be advanced which may have been unacceptable to the government prior to its defeat in the district court.

Conclusion

"Watch what we do and not what we say." The foregoing review of the facts of FDA enforcement suggests two things. First, industry does not appear to be swept by a campaign of terror, forcing board meetings to be held in the exercise yards of the more elegant federal correctional institutions. Nor is such a regime foreseeable on the basis of present indications.

Second, no company or individual with an enforcement problem need view itself as a mere statistic in a trend. Much can be done in the context of a particular case to mitigate the impact of the FDA's considerable enforcement powers.

Above all, however, the best way to solve enforcement problems is to operate at all times in good-faith compliance with the law as reasonably interpreted. This will minimize the prospect of enforcement problems arising, and maximize your chances of prevailing if they do.

TABLE I

Seizures, Prosecutions and Injunctions Under the Federal Food, Drug and Cosmetic Act[1]

	1975	1974	1973	1972	1971	1970	1969	1968	1967	1966	1965
Seizures:[2]											
Foods	348	272	515	547	510	267	232	384	657	566	522
Drugs	72	72	195	153	164	169	151	235	434	397	298
Devices	36	66	430	23	49	116	29	56			
Cosmetics	60	7	8	42	8	4	4	9	14	14	1
Subtotal	516	417	1148	765	731	556	416	684	1105	977	821
Prosecutions:											
Foods	43	92	96	65	47	33	45	70	77	59	67
Drugs	1	1	16	11	4	8	11	9	330	231	222
Devices	1	0	0	0	0	1	0	1			
Cosmetics	0	0	0	0	0	0	0	0	0	0	0
Subtotal	45	93	112	76	51	42	56	80	407	290	289
Injunctions:											
Foods	15	7	8	10	11	23	5	3	10	4	11
Drugs	13	5	8	8	2	1	7	4	14	2	8
Devices	3	0	0	0	0	0	0	2			
Cosmetics	1	1	0	0	0	0	0	0	0	0	0
Subtotal	32	13	16	18	13	24	12	9	24	6	19
Grand Total	593	523	1276	859	795	622	484	773	1536	1273	1129

TABLE II

Citation Hearings Under Section 305[3]

Year	Number of Hearings
1969	315
1970	305
1971	278
1972	345
1973	307
1974	130
1975	84

[The End]

[1] Derived from FDA *Annual Reports* 1965—1974 and tentative information for 1975 supplied by the Office of the Associate Commissioner for Compliance in the FDA.

[2] Particular figures may reflect large-scale multiple seizures of the same product.

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

Regulatory Letters, Publicity and Recalls

By WAYNE L. PINES

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I ALWAYS WELCOME AN OPPORTUNITY to attend and participate in Food and Drug Law Institute sessions like this one. I have been involved with communications in the food and drug field in one capacity or another for more than seven years, and it never fails to surprise me how many things are going on, and how difficult it is for people to keep up with everything. Conferences like this help bring us all up to date.

The subjects of this session are regulatory letters, publicity and recalls. These are broad topics. Each would be worthy of a separate seminar. What I am going to do is to relate the latest thinking at the Food and Drug Administration (FDA) on these three subjects.

Let me start with regulatory letters—the subject I know least about. When I think of a regulatory letter, my mind goes back to a Congressional hearing I attended a few years ago when I was reporting for "The Pink Sheet." The subject was drug advertising and one of the witnesses was John Jennings, then Director of the Bureau of Medicine. It seems that the files uncovered by the committee showed that a minor advertising violation had come to the attention of the Bureau of Medicine, and someone had sent a memo to Dr. Jennings asking what to do. One would have expected to get from Dr. Jennings a lengthy memo setting forth a regulatory course of action. Instead, Dr. Jennings wrote six words in the margin of that incoming memo, words that summed up the very heart and soul of the regulatory letter concept. Those words were , "Tell them to knock it off."

"Tell them to knock it off." This rough and ready phrase contains the essence of what the regulatory letter is all about—a communication issued to a company by the FDA pointing out a violation which the Agency expects will be corrected without any need for legal action. The purpose is to bring that violation to the attention of the company's management in the expectation that they will "knock it off."

No Immediate Risk

When the FDA decides to send a regulatory letter, it means the Agency has reason to believe the company will move quickly to correct the violation, and that no immediate risk to consumer safety exists. It also means, and is intended to convey, a specific message—if the violation is not corrected within a reasonable amount of time, the FDA is prepared to take legal action.

Regulatory letters usually are signed by a regional or district director, after approval by headquarters. The letter does not come in a disguise borrowed from the Central Intelligence Agency. It identifies itself as a regulatory letter and asks for a response within a certain time period, usually ten days.

The rationale behind the use by the FDA of regulatory letters is quite simple. The Agency feels that many violations are not flagrant or intentional or do not reflect a pattern of poor compliance, and that its limited resources must be reserved for instances in which a violation should be brought to court. Regulatory letters provide a company with an opportunity to correct a violation with a minimum of expenditure of time and money by the government.

Regulatory letters are not classified documents. They are, and should be, public information as soon as they are sent out. The response from the company also is public information. This means that anyone who requests a copy of a letter can have one. The FDA maintains a file of regulatory letters in its Public Records and Documents Center in Rockville, Maryland.

Public Information

This is how members of the public and the press find out about them. However, we do not ring a fire bell when one is dispatched. That, I believe, would be an unfair flexing of our public information muscle. Indeed, I know of no instance in which the FDA has en-

couraged publicity about a regulatory letter. So when you read about one in the trade press, it means the reporter has sought out the letter through the Public Records and Documents Center.

This thought provides a bridge to the second topic of this session, namely publicity. This is the subject I know most about.

The FDA is one of the few agencies in government which is specifically required and authorized by law to use publicity. I am referring, of course, to Section 705 of the Federal Food, Drug and Cosmetic Act.

Many of you, especially those who live in Washington and read *The Washington Post* and *The Evening Star,* read about the FDA often, sometimes several times a week. You may get the impression that our public affairs mechanism is really churning out the publicity. Actually, while we all work hard, the vast majority of stories you read about the FDA in the trade press or in the daily press are not generated by the Agency.

Publicity Mechanism

This point seems rather elementary, but it is central to an understanding of how the FDA's publicity mechanism works. The FDA actually seeks publicity—that is, seeks to have a story in the newspapers—fewer than 50 times a year, when we issue a press release. The remainder of the stories—and there have been many, especially lately—are initiated through other sources, perhaps by a Congressional hearing, or information sought by someone under the Freedom of Information procedures or in response to a question from a member of the news media. The reason that there are so many stories about the FDA or the products it regulates is not because we seek it but because there is an enormous public interest in what we do.

There are several reasons why we try to restrict the number of times we seek publicity about something. The most basic one is that we want to reserve our efforts for those situations in which we really believe something should be brought to the public's attention. We know what happened to the boy who cried "adulterated" too often. He got himself and his message "adulterated." So, the issuance of too many public warnings would simply lessen the impact of a public warning about a serious health hazard.

The point I want to leave with you is that we use judiciously our authority to issue information for the purpose of seeking publicity,

and relatively few of the stories you read about the FDA or about the products we regulate are generated by us.

This distinction becomes especially important when it comes to the third subject of this session—recalls. Those who follow the FDA closely know that each week a story appears about some item or another that was recalled or is being recalled. These stories are based on our recall list, which is issued by the Office of Public Affairs every Wednesday. The list contains all the recalls which have come to the FDA's attention, as well as other actions such as seizures, injunctions and prosecutions.

Cheddar Cheese Recall

Just a few weeks ago we received a complaint from a supermarket chain which had recalled some cheddar cheese. The recall appeared on our list nearly a month after it took place. The stories in the press did not reflect this fact and implied that the recall was still being conducted. The chain was very concerned about the publicity that resulted. We have had other similar complaints about the issuance of the recall list and the publicity it generates.

We do not issue the list for the purpose of having stories appear in the news media. We issue the list because the public has expressed an interest in recalls and wants to know what products have been or are being recalled. Reporters who ask for the list receive copies of it, as do thousands of other people who have asked to be put on our mailing list. This is why the news stories appear. I want you all to understand, though, that we do not intend to seek publicity about any of these recalls. If we wanted to warn the public about a recalled item, for example, when there is public danger, we would issue a press release. In the past year we have issued only one press release about an item being recalled. In that case, an ear product had caused injuries to seven people on the West Coast and we wanted consumers to return the drops to the store.

Even though we do not seek publicity for the weekly list of recalls, we know that it can and usually does attract publicity. The media's coverage reflects the great public interest in the products regulated by the FDA and in the safety of our environment in general. Quite frankly, I and other members of the Public Affairs staff are very concerned about the indiscriminate publicity given to recalls. The weekly stories that are now appearing tend to lessen the impact

of a real public warning. We also recognize that by the time the recalls appear on our list, very often the recall has been completed by the manufacturer. Publicity at that juncture therefore tends to confuse the public by implicating good products that now are on the shelves. Consumers also get mad at us because, by the time the list is issued, most of the products already have been consumed.

We all recognize that the public is interested in recall information and we have to learn to live with this publicity. The fact is that recalls are going to get publicity whether we seek it or not. The recall of any product is a matter of public concern.

Time Lag

We are working very hard to improve our recall list by reducing the lag between the time we learn about a recall and the time it gets on our list. The aim is to make the list as current as possible. The time lag now averages close to six weeks. I would agree that this is too long.

But I think we must also recognize that part of the problem—and much of the solution—rests with industry. Often, we learn about a recall only after it is well under way or completed. This increases the chance that it will appear on the recall list long after it is completed. I would urge all of you who work for industry to report to the FDA as soon as your company becomes aware of a potential recall or actually starts one. This will speed its eventual appearance on the recall list.

Part of the problem for the time lag rests with the FDA itself, and we have a responsibility to do something about it. Our internal procedures need to be streamlined so that we can list a recall earlier. Before a situation is classified as a recall and processed to our office for inclusion on the weekly list, the field investigator and the bureau have to evaluate the health hazard, assign a classification number, develop a strategy for handling the recall, and make many other decisions. In the case of the cheddar cheese recall, for example, the company quickly completed the recovery of stock from its store but the FDA still needed to investigate the cause of the problem, decide whether any health hazard was posed to consumers who had the cheese in their homes, and evaluate whether the company had acted properly. Only after all these considerations are studied is a notice sent to our office for inclusion on the recall list.

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No Simple Solution

So, while I can assure you that we are trying to streamline the procedure to make the recall list more current, I am sure that none of you would want the FDA to react to a recall situation precipitously without a full evaluation of all the facts. There are no simple solutions. The lag time in the present recall list is a serious problem that we need to look at and that we are looking at.

I can tell you that the solution will not be to cut back the recall list. Information about recalls cannot and will not be withheld from the public. None of us likes to learn about recalls. They are bad news. They reflect a failure by someone to manufacture or to label a product correctly. But they do occur. And just as the FDA cannot shirk from its obligation to make information about recalls public, you in industry also cannot shirk your own responsibilities. You cannot withdraw into your corporate shell when you are recalling a product and then complain about the stories which come when the FDA makes the information public through the recall list.

It is entirely appropriate, and indeed wise, from a public relations standpoint for a company to give public notice of a recall situation in certain circumstances. The companies that explain to the public what the problem is and what they are doing about it present a positive image compared to a company that conducts a recall which the public learns about through a list issued several weeks later by the government.

We certainly are not opposed to the idea of a company issuing its own recall publicity. We want to be consulted, however. Recall situations are made much more difficult when a company issues information that fails to address the regulatory problem or that is blatantly self-serving.

Life-Saving Products

There has been some confusion about one aspect of our policy on recall publicity, and that is about recalls of life-saving products such as implanted pacemakers or implants. Publicity about these products could cause unnecessary anxiety in some patients. Our policy is that if identifiable patients should be and can be informed by a health professional of a hazard, then the FDA will delay publication of a recall on the recall list until this can be accomplished. This presumes

that all patients at risk can be identified and notified. Once the patients have been informed, the recall will be placed on the recall list. If we are queried about such a recall prematurely, we have to respond fully and factually but we will not initiate any publicity.

Some people have misinterpreted this policy. They think that we often delay publication of a recall. This is not true. The current lag time in processing recalls has made it unnecessary for us to delay the publication of any recall. Quite to the contrary, we usually try to speed up the publication of recall information so that the recall list can be current. I mention the delaying policy because it has gotten some visibility, primarily because people have either misunderstood or misinterpreted it. To repeat, we would delay publication of a recall only if necessary but, as a practical matter, we do not have to. In fact, we are trying to speed recalls into publication.

The Agency's policies in all three of these areas—namely, regulatory letters, publicity and recalls—will be spelled out in formal language through three separate regulations which are being written.

Regulations

The regulation covering regulatory letters, for example, will set forth the criteria the FDA uses in issuing one, and explain what a regulatory letter means for a company receiving it. The regulation on publicity will discuss why the Agency issues information for the purpose of seeking publicity, what special precautions apply when the FDA is issuing information that could result in adverse publicity about a company, an individual or a product, and how the Agency handles publicity about court proceedings. The third regulation, on recalls, will describe in detail FDA policy and procedures for recalls. It will set forth, for example, industry's responsibilities in this area. Of course, all three regulations will be published in the *Federal Register* with an opportunity for public comment.

An inkling of what will be contained in the recall regulation was provided in a document made public earlier this year. This document is a revision of the FDA's internal procedures for handling recalls. Several important changes were made. Probably the most significant is that the FDA no longer will be bound to require that a recall be conducted in a particular way simply because of the class to which it is assigned. The FDA will handle each recall on an individual basis,

depending on the circumstances, by developing a specific strategy. The strategy will address the extent of the checks needed to determine the recall's effectiveness, the depth to which the recall is to extend, and whether a press release will be issued. Another part of the revised internal procedures document contains new definitions for Class I, Class II and Class III recalls. These are the categories in which all recalls are placed, depending on the level of hazard. A copy of this document can be obtained from the Public Records and Documents Center.

The key point to remember about all these procedures and regulations is that, while they set forth how the FDA operates and what its policies are, they will preserve the Agency's flexibility in dealing with each individual case. The concept of flexibility is important to industry and to consumers because the FDA must be able to deal with circumstances individually if it is to carry out its basic mission of consumer protection. So the regulations will set forth general policy while still preserving the flexibility needed by the Agency to deal with cases individually, in the interest of the public health and safety.

[The End]

THE FDA PROPOSES DISCLOSURE OF EXEMPT MATERIAL TO CONTRACTORS

The public information regulations of the Food and Drug Administration (FDA) would be amended to provide for the disclosure of exempt material to contractors, under a proposal issued by the Agency. The proposed amendments reflect changes made in the Federal Food, Drug and Cosmetic Act by the Medical Device Amendments of 1976. The Amendments added a new section 708, which authorizes the FDA to provide contractors with information relating to trade secrets, commercial and financial data, and other information that is privileged or confidential. Section 301(j) was amended to provide that contractors may not use such data and information to their own advantage or reveal it outside the Department of Health, Education and Welfare. Section 520(i) was added to provide that transcripts be made and maintained of the proceedings of advisory panels dealing with medical devices.

The proposed amendments to the public information regulations provide for such disclosures, specify that contractors and their employees are subject to the same restrictions and penalties against unauthorized disclosure as FDA employees, set forth eight basic security precautions, and exempt such disclosures from the general disclosure obligation, which provides that any FDA record disclosed in an authorized manner to any member of the public must thereafter be made available to all members of the public.

The Agency found that the proposed regulations do not require an environmental impact statement and that they would have no major inflationary impact. Interested persons have until July 7, 1976 to comment on the proposal.

CCH Food Drug Cosmetic Law Reporter, ¶ 45,374

Recalls, Regulatory Letters and Publicity— Quasi-Statutory Remedies

By EUGENE I. LAMBERT

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THE TOPICS COVERED IN MY PRESENTATION fall into a gray area of statutory authority. While they are not explicitly dealt with in the statute, in many instances their existence can either be implied or has been derived from the statute. The purpose of my discussion will be to identify the statutory heritage of each of these enforcement techniques and to suggest some of the legal issues presented in their use.

I. Recalls

Recalls perhaps can be characterized as do-it-yourself seizure actions. In many ways, they are much more efficient and comprehensive than even multiple seizures because they utilize resources far greater than the government can ordinarily command in a short period of time to remove violative products from the market. It is for this reason that the Food and Drug Administration (FDA) itself states that a "recall is the action of choice . . . where there is a definite threat or potential threat to life or where a significant number of injuries are known, or where gross consumer fraud requires extensive removal of a faulty product from the market."

Based upon my review of the Freedom of Information log for the last week, I am confident that virtually everyone at this session has requested and perhaps by now has received from the FDA its revised Compliance Policy Guide on recalls, market withdrawals and stock recoveries, together with the recall procedures chapter of the Regula-

tory Procedures Manual. These documents set out the FDA's current, even if interim, definitions of recalls and procedures for supervising these actions being carried out.

From a legal standpoint, the important consideration is that it is the FDA's position that a "recall" exists only where a violation of the Federal Food, Drug and Cosmetic Act has been found by the Agency. Where there is no violation of the Act, the action by the manufacturer is not a "recall," it is a "market withdrawal." A decision by a manufacturer to retrieve a product from the market, therefore, always must include a judgment by that manufacturer as to whether he is engaged in a recall or in a market withdrawal. Engaging in a recall is an admission that a violation of the Act has taken place but a market withdrawal is a retrieval of a product for commercial reasons unrelated to statutory proscriptions.

A determination by a manufacturer, or by the FDA, that a recall exists or should take place necessarily carries with it other subsidiary legal determinations. First, the FDA (or the manufacturer) will have determined that there is sufficient evidence for the Agency to demonstrate in court that a violation of the Act has taken place.

Admission Against Interest

Second, the manufacturer, in conducting a recall or in denominating his action a "recall" or in acquiescing in the FDA denominating his action a "recall," may be making what amounts to an admission against interest that the Act has been violated. This can have consequences in product liability actions if the legal status of the product, that is, its conformity with the Act, were to be an asserted basis for liability. Third, both the FDA and the manufacturer will be under a public obligation to pursue the recall and be subject to subsequent scrutiny with respect to its adequacy because it involves a "violative" product.

Thus, it can be seen that the decision to undertake the retrieval of goods and to denominate such a retrieval as a "recall" is not one that should be undertaken lightly either by the FDA or by a manufacturer. Rather, it is one that must be undertaken after a careful examination of the facts, and the consequences to both past and future production by the firm must be borne in mind.

If there is any substantial legal problem with recall procedures at the present time, it is the lack of any reasonable means of challenging either the FDA denomination of a retrieval as a "recall" or an

FDA suggestion that a recall is necessary. The ultimate way to challenge an FDA position is to refuse to recall and thus set up a situation where the Agency must prove its case in court. Taking an adamant position, however, can lead to the FDA's use of multiple sanctions, including much more striking publicity than would otherwise occur.

It is, however, this ultimate availability of a forum for making factual and legal determinations on an impartial basis that has led me to object to proposals to establish statutory recall authority. In my view, it would not be desirable to vest in an administrator the authority to command, without a forum for impartial factual determinations, the retrieval of a product from the market, with its attendant substantial economic dislocation.

II. Regulatory Letters

If recalls represent do-it-yourself seizures and are carried out under the implicit threat of formal enforcement action for failure to comply, regulatory letters appear to have at least a tenuous connection with Section 306 of the Federal Food, Drug and Cosmetic Act. For those who have generally stopped reading at Section 305 and have quivered at the threat implicit in precriminal hearings, Section 306[1] appears to bring some relief because it provides that there is no requirement that the Secretary report for prosecution or other judicial proceedings "minor violations of this Act whenever he believes that the public interest will be adequately served by a suitable written notice or warning."

Regulatory letters were instituted as a means of implementing that statutory provision and they call to the attention of a firm a specific, clearly defined violation of the Act that the FDA believes must be corrected. The format of the letter is very specific. It is headed a "regulatory letter" and it identifies the article, the statutory provision involved and the specific manner in which the statute has been violated, in the Agency's view. It also often states the corrective action that is indicated in order to achieve compliance.

It normally requests (or, perhaps, more correctly, requires) a response within ten days to the FDA Office (usually a district office) that has issued the regulatory letter. It inevitably closes with the solemn warning that one ignores the regulatory letter at his peril since the FDA is fully prepared to invoke all the formal judicial sanctions of the Act in order to achieve compliance.

[1] 21 U. S. C. Sec. 336.

As in the case of FDA-initiated recalls, the issuance of a regulatory letter indicates a decision by the Agency that it has adequate legal grounds to initiate formal court proceedings. It thus normally represents a firm decision by the Agency. The principal issue posed for the person receiving the letter is the manner of compliance rather than the fact of violation. While it is certainly permissible to go to the FDA, either at the district level or in an informal appeal to the Washington headquarters, to argue the fact of violation, my experience has been that the Agency feels itself in a strong legal position in any regulatory letter and is perfectly willing to have its position tested through a court proceeding should the respondent be intransigent in its position.

Lack of Public Hazard

On the other hand, the use of the regulatory letter procedure often is indicative of flexibility with respect to compliance programs on the part of the respondent. There is a notable lack of public hazard involved, and there is often an FDA recognition that compliance may take either significant funds or time or both. Thus, there is an ability to work with the Agency in a compliance program and, unlike the situation in a seizure or a recall, one normally is not faced with an immediate and significant economic dislocation through the use of this compliance mechanism.

An information letter is a subspecies of regulatory letter. In many ways, it may be viewed as akin to a court order to show cause. It normally will describe an article and question the legality of some aspect of the product's marketing without coming to a firm conclusion that the Act has been violated. It commonly provides for a period of 30 days within which to respond to the FDA and either explain or substantiate the firm's activities, or indicate what steps are being taken to avoid the legal problem that the Agency has outlined.

Even more than in the case of regulatory letters, there is a great deal of flexibility in the FDA's response when a firm which received an information letter comes to the Agency. The FDA, in this case, has not made a firm decision that the Act has been violated, and is amenable to substantiating information. It often will be willing to work with a firm on what would constitute substantiating data and to review revisions in labeling or packaging that might be required under the FDA's view of the law.

III. Publicity

The uses and abuses of publicity are, as everyone knows, a widespread topic of discussion. There are numerous ways in which the Agency may use publicity. The FDA's output includes formal news conferences, briefings, releases, talk papers, *FDA Consumer*, and leaks. The legal test for each of them is how the use can be squared with the statutory provisions on publicity.[2]

The first paragraph of this statutory provision is quite straightforward, directing the Secretary to publish reports summarizing judgments, decrees and orders. These are the familiar Notices of Judgment, which used to be published as separate pamphlets and which are now incorporated into the final pages of each issue of *FDA Consumer*. Controversy necessarily arises under paragraph (b) of Section 705 that permits:

". . . the Secretary . . . to . . . disseminate information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department."

One must reasonably wonder whether the first sentence is necessary in light of the second, or whether the second grants any authority in important cases that is withheld by the first. In any event, taken together, the two sentences suggest authority to deal with the following situations:

(1) a press release concerning a situation believed by the FDA to pose an imminent danger to health, even where no regulatory action has been taken;

(2) the publication of the weekly recall list;

(3) the issuance of press releases in connection with regular enforcement actions, including administrative actions relating to the approval, denial of approval or withdrawal of approval of food additives, color additives and human and veterinary drugs; and

(4) the issuance of periodic reports concerning factory inspection findings for selected segments of industry.

A firm's principal legal concern is normally the use of publicity by the FDA in conjunction with some other regulatory activity. This may be the press release issued announcing the Agency's monitoring

[2] Sec. 705, 21 U. S. C. Sec. 375.

of a recall undertaken by a firm. It may be the press release issued in connection with a proposed administrative action to withdraw approval of an existing marketed product. In all of these cases, the firm involved often will be trying to catch up with the original FDA release if it is not prepared with its own resources to go to the press simultaneously or in advance of the FDA action. Often in the case of the recall, where the firm does have the first knowledge and often the only firsthand knowledge of the facts, it is in a unique position to make its position known independently of any FDA-generated publicity.

There are relatively few instances where publicity can be limited by industry. Perhaps only in cases involving FDA publicity during the pendency of court proceedings is it likely that a court will intervene to protect either its own procedures or to chastise the FDA's extra-judicial attempt to achieve what it has not obtained in court proceedings. A recent article by Richard Morey[3] gives the details in one of the rare instances where this occurred and I commend this discussion in depth to you.

To summarize, each of these "informal" enforcement techniques is grounded either in the existence of a statutory provision or on the threat of using a statutory provision. Because they are "informal," they do not provide the depth of procedural safeguards that one can achieve when the FDA is forced into formal judicial enforcement proceedings. Conversely, in many instances, one can devise compliance programs with the Agency based on the facts that would not be applicable in court relating to resources, existing inventories of noncomplying materials, and overall risk to the public health. Before a company enters into active resistance of any of the informal enforcement proceedings and thus forces the FDA's hand with respect to formal proceedings, it must evaluate not only its likelihood of success in court but the consequences of an adverse court ruling with respect to future compliance with the Act. **[The End]**

[3] Morey, Richard S., "Publicity as a Regulatory Tool," 30 FOOD DRUG COSMETIC LAW JOURNAL 469, 474—476 (Aug. 1975).

Handling FDA Injunction Actions

By RICHARD S. MOREY

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I HAVE LIMITED MY DISCUSSION to the subject of handling Food and Drug Administration (FDA) injunction actions, that is, actions in which the FDA seeks to enjoin alleged violations of the Federal Food, Drug and Cosmetic Act. I think this is appropriate because this particular type of legal action is unique in several respects, which I will discuss in a moment, and its handling deserves separate consideration from other FDA litigation.

I will deal first with the applicable legal rules concerning injunction actions brought by the FDA. This is relatively settled law and is indeed the least complex element involved in handling these actions. Injunction proceedings are based on Section 302(a) of the Federal Food, Drug and Cosmetic Act. This provision, with certain minor exceptions, gives to the federal courts jurisdiction "for cause shown, . . . to restrain violations . . ." of the Act. Thus, theoretically, the FDA might seek to enjoin any of the myriad of minor transgressions which could be said to constitute adulteration, misbranding or otherwise violate the Act. In fact, however, the Agency only rarely uses this remedy and then normally only in cases in which it contends that there are potentially serious violations of a continuing nature.

As to the circumstances under which a court can and should grant an injunction, it is established, both generally and in FDA cases, that an injunction may be granted even if the violations of law which the Agency is complaining about already have been corrected. On the other hand, it is equally well settled that the court need not grant an injunction even though all such violations have not been corrected. Basically, the rule is that it is left to the sound discretion of the court when an injunction should be issued.

Mandatory Injunction

The one legal question which appears to be a matter of controversy at this time is whether a court may issue an injunction which is mandatory rather than prohibitory in nature. This issue has arisen mainly in terms of whether a court has the authority to order defendants to recall violative products which already have been distributed in interstate commerce. The District Court for the Northern District of Illinois in the *C. E. B. Products* case held that it did not have such authority. The Court's scholarly and well-reasoned opinion in this case, after a careful examination of the legislative history of Section 302(a), concludes that: "The section [referring to Section 302(a)] appears to contemplate only negative injunctions prohibiting statutory violations rather than any sort of mandatory or affirmative relief." This is the only decided case on this precise issue and the government did not pursue it on appeal. However, the prayers for relief in recently filed injunction cases still include provisions seeking affirmative relief. The FDA clearly has not acquiesced in this ruling in *C. E. B. Products.*

I would like to go through a typical pattern of an FDA injunction action in chronological order. Most of these cases—at least recently—have involved what the FDA considered to be undesirable practices during the manufacturing process of products subject to the Act. The Agency has alleged that these practices were violations of current good manufacturing practice (GMP) or, where there was no statutory requirement as to GMPs, that they violated explicit or implicit label claims that the products were carefully manufactured.

The primary sign that an injunction action of this type may be forthcoming is a pattern of FDA inspections increasing in frequency and in the number and the severity of the observations made as to manufacturing practices. This is particularly a problem when observations are repeated on successive inspections and there is little indication that the firm is responding to the Agency's concerns. Frequently, this pattern is coupled with severe communication problems between firm personnel and the Agency. Indeed, from examining inspection reports from firms which have been the subject of injunction actions and those which have not, it would appear that this is a critical factor since the nature and the severity of the observations often seem to be very much equivalent between firms which are sued and those which are not. Firms which are in serious danger of being the subject of injunction action usually also receive a

regulatory letter from the Agency and are often the subject of one or more product recalls, usually initiated by the FDA.

Part of my assignment in discussing injunction actions concerns how to settle them. Actually, this is something of a mystery to me. The primary point to be made is that, once the Agency makes a determination to seek an injunction, it virtually seems to be impossible to settle on any basis short of complete capitulation. Before the Agency reaches this decision, however, while the pattern of bad inspection reports, bad communications, a regulatory letter and recalls is just coming into focus, it is possible not to settle but to avoid an injunction action by taking immediate and drastic steps to improve the situation, to correct the defects discovered by the Agency and to improve communication and indicate the responsiveness of the firm to the Agency's concerns.

Settlement

In terms of settlement, the only specific matter about which I would like to comment is the so-called Baxter-Travenol situation. This was a case in which the FDA apparently was on the verge of filing a suit for injunction. It agreed to forgo this action in exchange for responsible company officials committing themselves in essence to abide by the terms which would have been in the injunction if the FDA had obtained one from the court. The only real advantage of this approach over agreeing to a consent decree of injunction, or of litigating and losing, is that the firm also obtained from the Agency a commitment that there would be no criminal prosecution based on the conduct at issue, assuming that the firm honors the commitment to close down its plant until its operations meet FDA approval.

In trying an FDA injunction action, several basic differences between this type of action and other actions under the Federal Food, Drug and Cosmetic Act must be kept in mind. In a sense, injunction action is the most severe remedy available to the Agency. It is true, of course, that a criminal action can have a more severe personal impact on individuals responsible for alleged violations of the Act. But only an injunction action has an immediate and catastrophic effect on an enterprise which may employ hundreds or thousands of people and which literally could be wiped out overnight by the issuance of the prayed-for injunction.

Because the basic question is the survival of an ongoing enterprise, the real issue in an injunction action is, in my opinion, *what*

is happening right now and what is likely to happen in the future. Alleged past violations are of much lesser consequence. This is a critical distinction. It is entirely different from a seizure action, which basically deals with the status of a specific lot of goods no longer under the control of the manufacturer. It is also different from a criminal action which inevitably must focus on specific past conduct. It is also different from a typical declaratory judgment action which may deal with the present or the future but largely in a hypothetical sense.

Because the basic issue in an injunction action is what is happening now and in the future, a contested case is basically fought in two separate arenas. First, there is obviously a contest in court. Second, and equally important, there must be continuing work being done by the defendants at their facilities throughout the course of litigation to correct and to change any conditions which must be modified to sustain the firm's position in court.

In dealing with specific observations made by the FDA investigators, there are several different approaches depending on the nature of the observations. Obviously, any observations of conditions which are in fact wrong must be corrected as soon as possible, giving priority to those items most likely to affect the product adversely. On the other hand, there are usually some observations as to which the FDA investigator was in error, either in understanding the firm's present practice or in understanding the consequences of the procedure which the observation suggests. If changes in response to an observation would lead to conditions detrimental to the product or to conditions which would have little or no favorable effect on the product and are very expensive or impractical, the procedure suggested by the FDA can reasonably be opposed. Many FDA observations, however, seem to fall into a middle ground in which the procedure suggested by the FDA offers little discernible benefit but can be instituted with only minor inconvenience to the firm. In these instances, we recommend that the procedure suggested by the FDA be adopted without further argument. It simply is not worthwhile to oppose such suggestions, particularly during the course of litigation, when they can be instituted readily. While some observations may reasonably be opposed, contesting too many of them, particularly when they involve only minor inconvenience, gives an unfortunate impression of noncooperation and nonresponsiveness to the FDA's concerns.

Desirable Changes

A question always arises as to whether making changes casts doubt on the status of products produced prior to the institution of the changes. This is a matter of serious concern but, generally speaking, this is not a sufficient reason to stop the institution of desirable changes. It is often the case, and can be demonstrated to the court, that although the new practices are superior to the existing ones, the prior practices nonetheless were adequate to assure the safety and the reliability of the product.

The basic overall effort of the defendants in an injunction suit is to show the court that: (1) the existing enterprise and its products are essentially sound and in good order; and (2) the desirable changes in the present situation which will satisfy the concerns expressed by the FDA are being and will be made.

I might point out that, due to the basic position I have just indicated, it is often the case that, in injunction actions, unlike other litigation with the FDA, evidentiary and legal issues which might be raised properly by the defendants are not relied upon. Particularly because the basic issue concerns the present and future status of an enterprise rather than past conduct, it is important to show to the court that conditions, in fact, are satisfactory. It is not an adequate substitute under these circumstances to show that the FDA has no legal authority to require a procedure or to inspect records relevant to its concerns. The effort must be made to show that the firm is producing a good product and thus should be allowed to continue to do so.

Temporary Restraining Order

Procedurally, the trial of a contested FDA injunction action in which there is no court order halting plant operations is usually broken down into a series of separate hearings, often with intervening FDA inspections of the firm's facilities. The Agency may or may not commence the proceedings by seeking a temporary restraining order (TRO). In general, it would appear that a motion for a TRO is likely to be successful only if the Agency can show that immediate and irreparable injury is likely to occur. This is the standard set forth in Rule 65 of Federal Rules of Civil Procedures for the issuance of a TRO without notice to the adverse party. Except in these circumstances, the courts are understandably reluctant to issue such an order to close down, even temporarily, an ongoing enterprise without allowing an opportunity for hearing. The most likely result, except where there is a threat of immediate or irreparable

injury, is that the TRO will be denied with a hearing on the government's motion for preliminary injunction scheduled on an expedited basis.

Since it is often the position of defendants at such a hearing that they have made the necessary changes in their operations since the FDA's last inspection, a possible result of such a hearing is a failure to grant a preliminary injunction with an order or suggestion to the FDA that the establishment be reinspected.

Assuming that no order is issued which would interrupt the defendant's operations, the course of proceedings from here on seems to be a series of inspections by the FDA with intervening hearings before the court. During these inspections, the Agency seeks both to show that its prior observations were not corrected and to find any new deficiencies which it can. The defendant's efforts in the plant must continue with new FDA observations being responded to as soon as the firm becomes aware of them.

Expert Witnesses

Generally, the FDA presents its evidence at these hearings by presenting its investigators as witnesses testifying as to the observations which they made at the defendant's establishment. The Agency usually has one or more expert witnesses who testify that the observations made by the inspector in their opinion constitute violations of current GMPs or whatever the prevailing standard may be. As the FDA promulgates more specific GMP regulations, the need for such expert witnesses may decrease but, at present, they are an integral part of the government's mode of presentation.

Typically, the defendant presents its case through both company witnesses and experts. Company personnel obviously testify as to the specific observations made by the FDA investigators, attempt to put them in context, and indicate the response which the firm has made or is making to each observation. It is also often appropriate for company witnesses to testify on a broader scope indicating the positive features of the firm's operations. This is often necessary because the FDA observations are very specific and focused on adverse conditions in the plant. These adverse conditions often can be put into perspective by presenting an integral picture of the entire nature and scope of the manufacturing operations involved. The defendants also usually present expert witnesses. These include experts on GMPs who will counter the FDA experts. The defense experts usually will comment on the significance of the FDA obser-

vations based on actual observation of the conditions in the plant. This is in contrast to the FDA experts who typically testify on the observations of the FDA investigators without having personally observed the particular conditions at issue. Defendants also may wish to offer expert testimony describing the nature and the value of the product involved. This is particularly useful in the case of a new or innovative type product which may offer advantages to the user compared with other available products used for the same general purpose.

Avoiding Court Order

I would like to close by discussing what seems to me to be a major problem with contested FDA injunction actions. This concerns actions which are litigated over a substantial period of time without the issuance of any court order which substantially interferes with defendant's operations. In these circumstances, the firm typically has been successful in avoiding such a court order because it has made, and is making, substantial progress in meeting FDA concerns. Thus, in the larger sense, the FDA has clearly succeeded in carrying out its mission although it may have failed to obtain favorable court rulings.

The difficulty seems to be that once battle is joined in one of these actions, it is hard to end. Due to the improvements being made by the defendant, the Agency finds it increasingly difficult to come up with evidence of conditions which would support the issuance of an injunction. It must go to court with observations of a nature on which it is hard to believe that it would ever have sought an injunction initially. It just appears to be very difficult for the Agency to abandon a contested legal action. This is in spite of the fact that the Agency has accomplished its purpose and also is in no way precluded from making further inspections and going back to court if further problems should arise.

Unfortunately, as in the *International Medication Systems* case which I was involved in several years ago, a hostile adversary atmosphere can prevail which prevents any resolution even when ultimate denial of the injunction, as occurred in the *IMS* case, seems inevitable.

I will close by urging that the Agency review its policy as to this situation and consider agreeing to the dismissal of these cases when the Agency's main purpose of protecting the public has been achieved or is obviously on the way to fulfillment. **[The End]**

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