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Industry and Government Cooperation— A Two-way Street

VINCENT A. KLEINFELD

Papers Presented at the American Bar Association Meeting on Food, Drug and Cosmetic Law

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

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TO THE READER

Industry and Government Cooperation.—*Vincent A. Kleinfeld* of Kleinfeld and Kaplan, Washington, D. C. attorneys, whose article begins on page 444, is the author of several other articles published in the JOURNAL which explore the major differences between and emphasize the common goals of the Food and Drug Administration and the drug industry. Mr. Kleinfeld, a former attorney with the United States Department of Justice, reveals the difficulties peculiar to the role of counsel in litigations wherein industry challenges FDA rulings.

1968 Joint Meeting of the Food and Drug Committee of the Administrative Law Section and the Division of Food, Drug and Cosmetic Law of the Corporation, Banking and Business Law Section of the A. B. A.—Three of the papers presented at the meeting are published in this issue of the JOURNAL. Additional papers read at this 91st annual meeting of the American Bar Association, which was held in Philadelphia on August 7, 1968, will appear in a later issue.

"Survey of Current Legal Problems in the Drug Area," the article by *Rodney R. Munsey* which begins on page 449, examines the legal problems that are currently prominent between the pharmaceutical industry and the FDA. The author discusses the controversial aspects of the issues involved, commenting on drug manufacturing, prescription drug advertising, and related drug regulation cases. Mr. Munsey is associated with the Pharmaceutical Manufacturers Association as Assistant General Counsel.

Walter E. Byerley discusses "Some Common and Uncommon Hearing Procedures Under the Federal Food, Drug and Cosmetic Act" in the article beginning on page 457. He reviews the hearing procedures governed by various sections of the Federal Food, Drug and Cosmetic Act. After outlining the circumstances under which hearings generally arise, commonly covered by Section 701(e), he presents a more careful analysis of less common procedures, urging his colleagues "to become familiar with the procedural oddities of each . . . so that substantive rights will not be sacrificed to procedural ignorance."

Joel E. Hoffman, a Washington, D. C. attorney with the firm of Wald, Harkrader & Rockefeller, offers "Some Suggestions for Improvements in the Hearing and Rulemaking Procedures of the Food and Drug Administration," beginning on page 465. Mr. Hoffman urges the need for equitable rules applicable to FDA hearings to permit prehearing discovery (knowledge of witnesses and evidence, and even of potentially relevant material not to be introduced in evidence) and compulsory process (the right of subpoena power to compel witnesses to testify).

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Food·Drug·Cosmetic Law
Journal

Industry and Government Cooperation— A Two-way Street

By VINCENT A. KLEINFELD

This Article Was Presented at a Meeting of the Drug and Allied Products Guild at Tamiment, Pennsylvania on June 5, 1968. Mr. Kleinfeld Is a Member of the District of Columbia Bar.

WE ARE ALL AWARE of the vast increase, during the last two or three decades, in the number of new drugs which have saved many thousands of lives and cured or relieved conditions which, in the past, had to be permitted merely to run their course. In almost every instance, however, there are side effects, and these, of course, must be weighed against the good which a drug is supposed to accomplish. I cannot quarrel with the concept that there should not be undue risks, particularly where the condition involved is not a serious one or where equally effective drugs, with definitely fewer side effects, are already available.

The drug industry has a right to be proud of what it has contributed to the welfare and well being of the American public. Of course it has made mistakes, and so has the government, but since the drug area is of such vital importance, the government must be in the position of being the arbiter with regard to the safety and efficacy of a new drug. Certainly every precaution must be taken to avoid an elixir sulfanilamide or thalidomide tragedy.

Reasonable Standards Essential

Undoubtedly the drug industry is aware of this. There is no question in my mind but that, at least as of 1968, the drug industry

would have no desire, even if it were possible, to do away with reasonable regulation. Industry has definitely accepted the concept that the consumer must be protected when it comes to the drugs which he takes. In addition, industry realizes that the consumer will be more likely to purchase and use drugs if he is confident of their safety and efficacy.

I have used the words "reasonable regulation." This should be important to any governmental agency which wishes to do an effective job. This is because a law on the books is one thing; the manner in which it is administered, enforced, and complied with is quite another thing. If a statute is so administered, or if the congressional intent is so distorted, that unnecessary and burdensome restrictions come into being, the result is inevitable. The reaction of any affected industry, in such a situation, is one of hostility and an increasing tendency to find some way to circumvent these restrictions. I believe that comprehensive legislation in the drug area is essential to this age and that the legislation should be forcefully and diligently administered. But I am also of the view that there is no necessity for indulging in unreasonable restrictions or in the issuance of regulations which go far beyond what Congress had contemplated. I have never felt that any end, no matter how good it may be, justifies any means, or that, in a democratic system, regulations should be issued predicated on the personal predilections of some official or officials.

It took 100 deaths, caused by an untested sulfanilamide product, to cause Congress to insert a new drug provision in the Federal Food, Drug, and Cosmetic Act in 1938. It is difficult to comprehend now what a far-reaching step that appeared to be thirty years ago. The thought that a drug product had to pass the scrutiny of a government agency before it was put on the market seemed to constitute a tremendous inroad upon private enterprise. That is probably why the new drug provision was sugar-coated by having it provide for the "making effective" of a new drug application rather than its "approval." The requirement that the safety of a new drug had to be demonstrated to the satisfaction of the Food and Drug Administration before it was marketed was, of course, a progressive rather than retrogressive step, but it would have been opposed violently, and probably would not have been enacted, if it had not been for the elixir sulfanilamide incident. The interesting thing is that as far as the drug industry as a whole is concerned, profits have certainly increased rather than diminished. It would be a most unusual industry

representative who would advocate the marketing of new drugs without prior governmental sanction or, at least, without the sanction of some highly qualified and reputable scientific body.

The reaction to the passage of the Drug Amendments of 1962 was similar in many respects to that which occurred after the enactment of the 1938 Act. Many in industry threw up their hands in horror at what they believed to be unnecessary and costly restrictions. The trouble is that some of these complaints were justified in both instances. This is because of what appears to be inherent in the nature of a government agency—the insistence upon the promulgation of regulations which amount to new legislation, inevitably resulting in continued confusion and inordinate delays. I believe, however, that the delays are not as prolonged now as they were a couple of years ago, and that a minor miracle may be occurring in that some officials may be saying "yes" instead of "no" in some instances and may even be taking the position that some drug which one wishes to market is not a new drug. In addition, and this would appear to be of some minor importance, my guess is that the balance sheets of many companies have not suffered appreciably. This may be despite the government, but prayerfully, I feel otherwise.

A Common Goal

I have always indulged in the fond belief that, as in industry, there are many dedicated and reasonable people in the government who possess that rare talent, intellectual integrity. I cannot believe that all government people are zealously endeavoring to emasculate all those in industry, or that every official in industry seeks to put untested, useless, and possibly dangerous drugs on the market.

Part of this is due to the fact that what the government and industry are attempting to do is not necessarily dissimilar in purpose. There are plenty of reasonable persons in the government who will not keep a drug off the market merely because some newspaper writer or congressional committee, by a process of hindsight after unforeseen side effects have occurred, will criticize the official or officials who approved the new drug application. These governmental officials will not say "no" because a drug which is not marketed cannot cause side effects, and therefore the officials will never be subjected to criticism. I will even say, with some temerity, that not every government official feels that "profits" is a nasty word.

Thus, I believe that there is and must be industry and government cooperation. This helps both and, more important, redounds to the benefit of the consuming public. But this cooperation must be a two-way street. The proper approach is one of mutual respect and understanding of the other's problems. I cannot go along with the occasional doctrinaire government official who (1) believes that every member of the drug industry is a scoundrel, and (2) seeks to impose more and more controls, legally or extra-legally, and by means which are sometimes suspect, because of the power which these straitjacket controls will give him.

On the other hand, the drug industry should not indulge (and in my opinion only a few have so indulged) in the misleading and exaggerated promotion of drugs. These products are too vital to permit competitive games and hyperbole. Those who do wish to go as close to the legal line as possible must expect to be forcefully told by the government, occasionally, that they have stepped over that often tenuous line and must pay the piper. Recently, a member of the Federal Trade Commission adverted to a statement by the late Mr. Justice Brandeis:

> Now, I do not believe . . . that the difficulty for the businessman is nearly as great as he imagines it to be. * * * If you ask me how near you can walk to the edge of a precipice without going over, I can't tell you, for you may walk on the edge, and all of a sudden you may step on a smooth stone, or strike against a little bit of a root sticking out, and you may go over that precipice. But if you ask me, how near you can go to that precipice and still be safe, I can tell you, and I can guarantee that whatever mishap comes to you, you will not fall over that precipice. * * * You must not expect that you can go to the verge of [the] law without running any risks. Why should you? You do not in any other relation of life that I know of.

This is something to be well borne in mind by industry.

The Herculean Task

What is a member of industry to do, however, when it appears clear to him and to his attorney that the government is taking a position which is not based upon law? This is indeed a difficult situation when the area involved is that of foods and drugs. When he is not dealing with these commodities, the lawyer's role is reasonably clear. What he must do is deliberate and then furnish an opinion to his client based on the statute and pertinent cases. This may take considerable time, but the attorney can inform his client whether the client may or may not do what he wishes to do. But the task of the

unfortunate food and drug lawyer, chastened and somewhat befuddled by positions which have been taken in the past by the FDA and frequently accepted by the courts, is a different and much more difficult one. The food and drug specialist must do everything which the specialist in other areas of law must perform. But he must necessarily do something else, and this is where his alleged expertise comes into play. He must say to himself that he is now required to come to the more difficult and ubiquitous question. Regardless of the legal conclusion he may have come to, he must now turn to another problem. This is with regard to the position the FDA may take, bottomed on what the agency believes will afford the consumer greater protection (and the government greater power). And will the courts sustain the government because of the tremendous yearning of most judges to accept virtually any position which the FDA takes, regardless of the law? In addition, there is the high cost of litigation and the damaging and adverse publicity which frequently ensues at the institution of a law suit in the food and drug field.

To repeat, therefore, what should a drug company do when his lawyer has come to the firm conclusion that his client is right and the FDA is wrong? He can decide, of course, as so many do, not to market his product or make the claim in question. His only alternative, although it is by no means a perfect one, is to litigate. Now, litigating with the FDA reminds me of one of the exploits of Hercules. Antaeus, a giant and a mighty wrestler was invincible as long as he could touch the earth. If thrown to the ground, he sprang up with renewed vigor. If the FDA, by some miracle, loses an important case, it can go all the way to the Supreme Court and can always turn to Congress if all the courts hold against it. Hercules solved his problem by lifting Antaeus into the air and strangling him. But even though many may wish to do this with the FDA, it is a somewhat difficult undertaking. Nevertheless, somewhere along the line, a member of industry may wish to stand upright and say that "I am right and I am willing to face the consequences (which in many instances may not occur) of a seizure action or even of a Draconic prosecution." There are cases where a brave manufacturer has done this and has prevailed in the courts. If manufacturers never follow this course of conduct, under any circumstances, the inevitable tendency on the part of some government officials will be to take unwarranted and extra-legal positions which never even occurred to the Congress which passed the law.

[The End]

Survey of Current Legal Problems in the Drug Area

By RODNEY R. MUNSEY

The Following Article Was Presented at the Joint Meeting of the Food and Drug Committee of the Administrative Law Section, and the Food, Drug and Cosmetic Law Division of the Corporation, Banking and Business Law Section, American Bar Association, held in Philadelphia on August 7, 1968. Mr. Munsey Is Assistant General Counsel of the Pharmaceutical Manufacturers Association. The Succeeding Articles in This Issue Were Presented at the Same Meeting.

I SUPPOSE IT WOULD BE MOST SURPRISING IF ANY SURVEY of current drug industry legal problems didn't begin with at least a cursory treatment of some of the legal issues involved in Pharmaceutical Manufacturers Association's (PMA) recent submission to the Department of Health, Education and Welfare's Hearing Clerk on the advertising regulations. The Food and Drug Administration (FDA) proposed broad changes in its regulations governing advertising and labeling in May of 1967[1] and published final orders relating to advertising only on June 27 of this year.[2] The usual 30-day time period was allowed for the filing of objections and requests for public hearing. We filed our objections and requested a hearing on July 26.

The basic statutory requirement relating to prescription drug advertisements is brief. It reads "A drug . . . shall be deemed to be misbranded in the case of any prescription drug . . . unless the manufacturer . . . includes in all advertisements and other descriptive printed matter . . . a true statement of . . . such . . . information in brief sum-

[1] 32 Fed. Reg. 7533.

[2] 33 Fed. Reg. 9393.

mary relating to side effects, contraindications and effectiveness as shall be required in regulations . . ."[3]

The May 1967 proposals issued under this provision seemingly required extensive interweaving throughout journal ads of information on possible adverse effects of a drug with information on effectiveness. 34 so-called *per se* violations were listed in the proposal. An ad in violation of any one of these, according to FDA officials, would automatically be in violation of Section 502(n) of the Federal Food, Drug and Cosmetic Act. The proposal also contained a requirement that a brief summary of adverse information, comparable in length and detail to discussions of such information in "full disclosure" labeling appear in longer ads, and in ads containing dosage information. The proposal reasserted FDA's position that section 502(n) gave it jurisdiction over the entire ad and over ads for bulk drugs and prescription chemicals. Radio, television and telephone promotions were classified as prescription drug advertisements within the coverage of section 502(n). The concept of fair balance was retained and expanded. The proposal also categorized sound recordings and other audio matter as labeling, and categorically included such items as films and letters as labeling, apparently whether or not such items "accompany" a drug within the meaning of the definition of labeling contained in section 201(m) of the Act.

After the proposals were issued, the FDA and the PMA appointed working committees to study the proposals and to ascertain whether a mutually acceptable set of regulations could be devised. The committees worked hard and considerable progress was made.

The final regulations were modified in several respects. Interweaving requirements were cut back and clarified. The 34 *per se* violations were divided into 22 *per ses* and 12 *may bes* and were clarified and/or made more specific in many respects. The final order made it clear that in some circumstances adverse information could appear in a distinct part of an advertisement. There was some uncertainty as to whether so-called veterinary prescription drugs were covered by the proposed regulations. The final regulations are worded so that they would apply to these drugs.

After the final regulations were issued, meetings were held with member company representatives to determine what PMA action, if any, should be taken on them. A substantial majority of our members

[3] Section 502(n), Federal Food, Drug and Cosmetic Act. 21 USC 352(n).

believed that the final regulations represented a considerable improvement over the proposals but that compliance was still impracticable. Accordingly, objections were filed and a public hearing requested.

Legal Issues

I would like to pinpoint some of the legal issues involved in the regulations. The legislative history of section 502(n) makes it clear that the purpose of the section is to regulate advertisements to physicians. Thus, it is questionable whether FDA has the authority to regulate ads for bulk-sale drugs or ads for prescription chemicals. One of the provisions of the final regulation states, "Each feature and theme of the advertisement that would be misleading by reason of the omission of appropriate qualification or pertinent information shall include the appropriate qualification or pertinent information which may be concise. . . ." Each feature and theme, viewed in isolation, must not be misleading. There is a serious question as to whether the statute permits a test based upon whether a particular statement, feature or theme of an ad, viewed in artificial isolation is misleading. It is impossible to give a fully balanced picture in any one statement. There are many who maintain that the proper test is whether a particular statement, feature or theme renders the brief summary information misleading independently of whether a particular feature or theme would, by itself, be regarded as potentially misleading under this section by reason of omission of appropriate on-the-spot qualification.

The final order continues the requirement of a brief summary comparable to "full disclosure" discussion of adverse information in certain ads. Since section 502(n) requires only a true statement in brief summary of such information, it is arguable that as long as an ad contains such a true brief summary, there is no authority to go beyond this and require additional information. Several of the *per se* provisions in the final order prohibit specific claims, statements and representations unless such statements are supported by "substantial evidence or substantial clinical experience." The statute is couched in terms of truth. Thus, it can be argued that the regulations may only prohibit untrue statements in the sense that the statements cannot be false or misleading. The regulations cannot impose requirements on manufacturers that such statements be supported by specified quantum or type of evidence. Some of the *per se* rules seem to prescribe conduct that would not in all cases render the ad untrue or

false or misleading. Such rules may, therefore, be objectionable on the ground that statutory authority has been exceeded. At this stage, of course, it is impossible to predict the final outcome of the industry-FDA dispute on the regulations.

Good Manufacturing Practice

Those of you who were here this morning are aware of some of the legal problems created by FDA's rule of summary suspension of antibiotic certification procedures.[4] You will recall that one of the grounds for suspension is the failure of a manufacturer to adhere to FDA's current good manufacturing practice regulations. The Drug Amendments of 1962 amended section 502(a)(2)(B)[5] to read "a drug . . . shall be deemed to be adulterated . . . if . . . the methods used in, or the facilities or controls used for, its manufacture, . . . do not conform to . . . current good manufacturing practice . . ." This provision does not authorize the promulgation of substantive regulations setting forth current good manufacturing practice. The original Kefauver proposed amendment had empowered the Food and Drug Administration to determine, subjectively, what was good manufacturing practice and to suspend the entire operation of a licensed manufacturer if the standards were breached.[6] While the revision to the statute was pending in 1961, consideration was given to revising section 501(a) to provide that a drug is adulterated if not manufactured in accordance with FDA regulations prescribing good manufacturing practice.[7] On August 23, 1962, the final Senate version of the amendment to section 501 was passed without any regulation-promulgating authority.[8] Various amendments giving FDA the power to regulate manufacturing had been rejected. The House bill introduced on May 23, 1962, by Congressman Oren Harris, had also contained a provision giving FDA regulation-making authority in this area.[9] This provision was also deleted. Commenting on the final form of the amendment, Senator Kefauver noted that the provision for regulations by the Secretary of Health, Education and Welfare had been deleted.[10] The FDA did promulgate interpretive regulations on manufacturing practices, however, and by making violation of these interpretive regulations a ground for summary suspension

[4] 21 CFR Part 146.

[5] Section 501(a)(2)(B), Federal Food, Drug and Cosmetic Act. 21 USC 351-(a)(2)(B).

[6] S. 1552. April 12, 1961.

[7] Cong. Rec. p. 14680. August 4, 1962.

[8] See Cong. Rec. pp. 16304, 16307, August 21, 1962.

[9] See Cong. Rec. p. 19895, September 22, 1962.

[10] Cong. Rec. p. 22501, September 30, 1962.

of all antibiotic certification services, the Agency has, in effect, in direct contravention of the will of Congress, attempted to give these regulations substantive effect.

While we are on the subject of current good manufacturing practices, another FDA deviation from Congressional intent should be pointed out. Senator Eastland, in describing the intent of the Judiciary Committee in framing the amendment to be 501(a) stated, "Since the competitive position of responsible manufacturers depends ... on the confidence of the medical profession and the public, it will be to their own interest to maintain high standards of current good manufacturing practice *which will provide a readily determinable basis for enforcement proceedings against any substandard operator.*"[11] Congressman Schenck, in discussing the purpose of the amendment stated, ". . . The purpose of this provision is to enable the Secretary to require all companies producing drugs to observe the high standards that are now followed by the better manufacturers."[12] Not only was FDA not authorized to promulgate substantive regulations setting forth good manufacturing practices; the Agency was not to innovate new standards or require the regulated companies to comply with any standard other than that already followed by the better companies. FDA has never followed this mandate.

Interpretive v. Substantive Orders

Some of the problems involving interpretive versus substantive regulations were discussed this morning. The intermingling of substantive and interpretive orders in the same regulation is becoming an increasing problem. A good example was contained in the proposed drug fair packaging regulations.[13] The Fair Packaging and Labeling Act exempts prescription drugs from its application. Yet the August 1967 proposed regulations were a combination of substantive orders applicable to over-the-counter (OTC) drugs promulgated pursuant to the Fair Packaging and Labeling Act and interpretive regulations applicable to prescription drugs proposed pursuant to 701(a) of the Federal Food, Drug and Cosmetic Act. Interpretive regulations involving OTC's issued under both the Fair Packaging and the Food and Drug statute were thrown in for good measure. The special dietary food supplement regulations[14] currently the subject of extensive hearings contain many provisions which are interpretive only. The third sentence of section 125.2(a) of the order is concerned with FDA

[11] Cong. Rec. p. 16304, August 21, 1962.

[12] See footnote 9.

[13] 32 Fed. Reg. 12060 ff.

[14] 31 Fed. Reg. 8521 ff, 31 FR 15730 ff.

opinion as to types of label statements on special dietary food supplements which would be misleading within the meaning of sections 201(n) and 402(a) of the Federal Food, Drug and Cosmetic Act. There is no substantive regulation promulgating authority for this opinion. The definition of "special dietary use" in section 125.1(a) is likewise an interpretive order and inappropriate for hearing. It is hornbook law that an administrative definition of a statutory term is merely advisory to the courts, and that the authority to determine that scope cannot be delegated to an administrative agency. The 6th Circuit reaffirmed this principle last March in *U.S. v. Bacto-Unidisk*.[15] The advertising regulations likewise contain many interpretive provisions.[16]

Substantive regulations, e.g., regulations issued pursuant to section 701(e) and requiring compliance with comment and hearing procedures spelled out in the section have the force of law. It has been held that a court may not, when a violation of such a regulation is alleged, reconsider evidence on which the regulation is based. Interpretive regulations, on the other hand, issued pursuant to section 701(a) consist of FDA opinions of the meanings of various sections of the Act, and opinions as to the impact of those sections on particular fact situations. They have advisory effect only. That is, they tell private parties what the FDA position will be in an enforcement proceeding. But in that proceeding, the court must consider, on a full evidentiary showing, whether the particular conduct challenged by the FDA pursuant to its announced enforcement policy is a violation of the Act. It should be noted that substantive regulations not only must be based on substantial evidence of record, but also are subject to judicial review in a United States Court of Appeals to determine legal questions and whether the order is in fact based on "substantial evidence." No such review is provided for interpretive regulations. Does FDA's intermingling of the two types of regulations represent efforts to raise interpretive orders to the level of substantive ones? We have noted one example of this kind of thinking in the purported application of current good manufacturing practice regulations to antibiotics.

A survey of current legal problems, of course, would not be complete without noting PMA's pending case in the U. S. District Court for the District of Delaware on the reporting regulations case.[17] In that case, we have challenged FDA's authority to require record-

[15] *United States v. An Article of Drug * * * Bacto-Unidisk * * **, CCH Food Drug Cosmetic Law Reports ¶ 80,194, 392 F. 2d 21 (CA-6 1968).

[16] See footnote 2.

[17] *Abbott v. Celebrezze*, CA 2884, U. S. Dist. Ct., D. Del.

keeping and periodic reporting for drugs which were once new drugs but which have become "old drugs." They have become "old drugs" either because they are now generally recognized as safe and effective, and have been used to a material extent and for a material time or because they had become generally recognized as safe prior to October 10, 1962 and are currently being marketed for the same conditions of use. That case has been pending for some time. Originally, it was delayed because many of the procedural issues involved were the same as those involved in the generic name case. More recently, further proceedings in the case have been held in abeyance pending further reports from the National Academy of Sciences-National Research Council effectiveness review teams on drugs clearing new drug procedures prior to passage of the Drug Amendments of 1962. The court is of the view that factual determination of effectiveness of some of the drugs involved might simplify some of the issues in the case. There has been one recent development relating to that case. On May 28 of this year, FDA published in the *Federal Register*, as a proposed interpretive regulation, a procedure under which the Agency would formally publish its opinion of examples of circumstances under which particular drugs, which were once new drugs, would become old drugs.[18] The proposed order would require that the New Drug Application (NDA) holder of a "no longer new drug" would still be required to maintain records and file some of the reports required by the new drug reporting regulations.[19] The pendency of PMA's suit was apparently ignored. If this proposed order is made effective, however, it should help in pinpointing the issues involved in that case.

Other Controversies

Many legal problems are, of course, inherent in FDA's implementation of the National Academy of Sciences' effectiveness review teams. The Agency, of course, takes the position that all drugs that ever cleared new drug procedures prior to October 10, 1962 and all drugs that were marketed prior to that date without effective new drug applications because they were substantively the same as cleared drugs which had become old drugs will be directly affected by FDA orders revoking approved NDA's as a result of the review teams' findings. It can be anticipated, I believe, that some manufacturers will take the position that drugs which cleared NDA procedures prior to 1962 but which had become old drugs by the time the Drug Amendments

[18] 33 Fed. Reg. 7758, 7762 ff.

[19] 21 CFR Sections 130.13 and 130.35.

of 1962 became law, cannot be affected by the review. Others will take the position that regardless of any possible applicability of NDA revocation proceedings to drugs once clearing NDA procedure, such revocation cannot affect drugs which were never the specific subject of NDA's.

There is one outstanding "legal" problem that has existed for some time that indirectly affects domestic drug manufacturers and directly affects the public. Section 510(i) of the Act directs the Food and Drug Administration to issue regulations permitting foreign drug manufacturers to register with the Food and Drug Administration. Any regulations issued would include provisions making the registration conditional upon the existence of adequate and effective means for determining whether drugs manufactured by the registrant should be denied admission into the country. Section 801(d) provides that samples of all drugs shipped into this country by foreign firms not so registered would then be required to be submitted to FDA for inspection. For reasons best known to FDA, such regulations have never been promulgated. Consequently, the only protection to the American public from any improperly manufactured "old drugs" in foreign countries is the spot sampling procedure utilized by FDA on imports. It would seem that the public deserves better protection.

Summary

I have only covered the highlights of some of the existing legal problems between FDA and the pharmaceutical industry. I think enough has been covered, however, to indicate that we are in no danger of becoming additions to the 3% unemployed in this country.

[The End]

NEW NATIONAL MICROBIOLOGICAL TESTING CENTER IN OPERATION

Frozen pies and cooked shrimp will be the first products tested for possible contamination by harmful bacteria at the Food and Drug Administration's newly designated National Microbiological Testing Center. The Center, located in the Minneapolis district laboratory, will allow the FDA to analyze a broader range of products than can be analyzed at any of its 17 district laboratories. Prepared or dried foods, imported and domestic cheeses, and a variety of skin preparations supplied to hospitals for both medical and cosmetic use will be among the other products tested for Salmonella and other bacterial contaminants during the four-month pilot program that began September 15, 1968.

Some Common and Uncommon Hearing Procedures Under the Federal Food, Drug and Cosmetic Act

By WALTER E. BYERLEY

Mr. Byerley Is a Member of the Washington D. C. Law Firm of Markel & Hill.

ALL OF YOU WHO ARE LAWYERS for one or more of the industries regulated by the Food and Drug Administration (FDA) run the risk of, sooner or later, getting involved in one of their hearings. It makes no difference whether your client is involved with New Drugs, food additives, or standardized foods — sooner or later, you are going to find yourself enmeshed in what is termed, at least in polite society, "The Administrative Process." And, ultimately, this process will grind you and your client into a hearing. It is my purpose today to try to describe for you what happens then.

In general, FDA hearings arise under one of the following sets of circumstances:

1. There is a proposal to list a drug as one having a potential for abuse, under Section 201(v);

2. There is a proposal to standardize a food, under Section 401;

3. There is a proposal to require certain information to appear on the label of a special dietary food, under Section 403(j);

4. There is a necessity for the issuance of emergency permits, under Section 404(a);

5. There is a proposal to establish tolerances for poisonous ingredients in food, under Section 406;

6. There is a proposal to establish tolerances for pesticide chemicals on a raw agricultural commodity, under Section 408(a);

7. There is a petition to issue a regulation establishing the safe usage of food additives, under Section 409;

8. There is a proposal to establish tests and methods of assay for drugs described in official compendia, under Section 501(b);

9. There is a proposal to designate a drug as habit-forming, under Section 502(d);

10. There is a proposal to establish packaging regulations for drugs liable to deterioration, under Section 502(h);

11. There is a proposal to establish requirements for prescription drug advertisements, under Section 502(n);

12. A New Drug applicant avails himself of the opportunity for a hearing, under Section 505;

13. There is a proposal to establish regulations providing for the certification of insulin-containing drugs, under Section 506;

14. There is a proposal to establish regulations providing for certification of antibiotics, under Section 507;

15. There is a proposal to provide for the listing and certification of a color additive, under Section 706;

16. There is a proposal to establish Fair Packaging and Labeling requirements, under Section 4 of the Fair Packaging and Labeling Act; or

17. There is a proposal to designate a substance as a hazardous substance, under Section 3 of the Federal Hazardous Substances Act.

In nearly all of these situations, the hearing procedures are governed by Section 701(e) of the Federal Food, Drug and Cosmetic Act. The exceptions are those regulations issued under Sections 408, 409, 505 and 507. I assume that most of you are fairly familiar with the procedures under Section 701(e) of the Act, so I will only briefly review these procedures, and devote the majority of my time to discussion of the procedures under these other sections, which are less well-known.

I. Procedures In a 701(e) Hearing

The procedures to be followed in a Section 701(e) hearing are spelled out in some detail in that section itself. These procedures are further detailed in the Code of Federal Regulations, 21 CFR 2.48 through 2.104.

Section 701(e) itself provides for the giving of notice of the hearing, the scope of the hearing, who may be heard and the effect of the hearing. The regulations, in the main, outline the procedural guidelines for fulfilling the law's requirements.

I will not go into the provisions of each section of the regulations. I will, however, touch upon some of the salient points which you will need to know if you are going into one of these hearings.

The first step, of course, is getting the Commissioner to grant you a hearing. This is not simply a matter of objecting to the Commissioner's order and demanding a hearing. The law requires that you must:

1. Show that you have *standing* to object; that is, that you will be adversely affected by the order;

2. Specify with *particularity* the provisions of the order which you find objectionable;

3. State the *grounds* for finding those provisions objectionable;

4. Request a hearing.

Assuming that you, or someone, has stated sufficient grounds for a hearing, a notice to that effect will appear in the Federal Register. This notice may also delineate the issues to be resolved by the hearing. Simultaneously, or later, there will be a notice designating a hearing examiner for the hearing and setting dates for the hearing and pre-hearing conference.

After the pre-hearing conference, or conferences, are out of the way, the hearing itself begins. The hearing is usually conducted in a manner much like a trial, with the hearing examiner sitting as judge. There are these important differences.

1. There is no subpoena power available.

2. The examination of witnesses, both direct and cross, is directed toward building a record, since the ultimate finder of fact is not present.

3. The rules of admissibility of evidence are somewhat relaxed; hearing examiners are notoriously inclined to "let it in for what it's worth."

The burden of proof in a 701(e) hearing is always on the *proponent* of the proposed order. If the Commissioner of Food and Drugs initiated the proceedings, then his staff and counsel must go forward with the presentation of evidence. Those who oppose the order are then given the opportunity to rebut the direct evidence.

On the other hand, if the original proposal was by an outside party—a segment of industry, perhaps—then the burden of proof is on that party, and the FDA, if it so desires, can offer rebuttal evidence.

Once the evidence is all in, the hearing examiner usually requests all parties to the hearing to submit to him briefs, proposed findings of fact and conclusions of law, and a proposed order. The findings

of fact, of course, must be grounded on substantial evidence of record, and should contain complete record references. The conclusion of law should be based on the findings of fact, and should follow from the findings in accordance with accepted rules of law. The proposed order should make final disposition of every issue raised.

Once these documents are before the hearing examiner, he utilizes all of them, together with the record, to prepare his report to the Commissioner. This report usually takes the form of the hearing examiner's proposed findings of fact, conclusions of law, and order. These, together with the record of the hearing, are certified to the Commissioner by the hearing examiner.

The Commissioner, "as soon as practicable thereafter" prepares and publishes in the Federal Register *his* findings of fact, conclusions of law, and tentative order. This order may be the same as the one which originally gave rise to the hearing, or it may be modified to reflect the changes made necessary by the evidence which was introduced at the hearing.

The Commissioner's tentative order will specify a period of time —usually sixty days—within which any party to the hearing may file exceptions to the order. These exceptions must be specific and supported by record references, and may be supported by a brief. Oral argument can be requested; the Commissioner has discretion to grant it or not.

After time for filing exceptions is past, the Commissioner publishes his final order, again with the conclusions of law and findings of fact. This order goes into effect on the effective date specified in the order, usually ninety days, unless some party to the proceeding appeals to the Court of Appeals. Such an appeal, which is provided for under Section 701(f), may be taken at any time within ninety days after the publication of the order in the Federal Register.

This appeal is not for the purpose of trying the issues *de novo*, although there is a provision whereby the Circuit Court may order additional evidence to be taken by the Commissioner. The function of the Court of Appeals is that of review, applying the well-known rules of administrative law. If the court finds that the order is supported by substantial evidence of record, and adequately disposes of the dissenting party's contentions, the order will be affirmed.

Disappointed parties do, of course, have final recourse to the Supreme Court.

This, then, is a brief review of 701(e) procedures. Let us now look at some of the others.

II. Hearing Procedures Under Other Sections of the Act

A. Petitions to Establish Tolerances or Exemptions for Pesticide Chemicals Under Section 408 of the Act

There are three steps involved in initiating a pesticide petition—and, oddly enough, two of those steps involve not the FDA, but the United States Department of Agriculture (USDA). The petitioner first applies to USDA for registration of his pesticide as an economic poison. The petitioner then files with FDA a petition for a tolerance or exemption, whichever is appropriate. A copy of this petition is sent to the USDA, with a request that that department certify the usefulness of the pesticide.

At some point thereafter, the Secretary of Agriculture certifies that the pesticide is useful—or he refuses to so certify, in which case you're dead. Assuming such certification, the FDA then has ninety days to do one of three things:

1. Establish a tolerance for the pesticide.
2. Exempt the pesticide from the requirements of a tolerance.
3. Refer the petition to an advisory committee.

If the petition is referred to an advisory committee, then, after the committee makes its report, the Commissioner must either:

1. Establish a tolerance; or
2. Exempt the pesticide.

You will note, that at no point is the Commissioner given the option of flatly denying the petition. He must, either on his own or after the report of the advisory committee, establish a tolerance for the pesticide or exempt it. That is why there are pesticides which have been approved with a tolerance of zero.

After the Commissioner's order is published, *any person who will be adversely affected* by the regulation may object to it and request a hearing. These objections, like those in a 701(e) hearing, must:

1. Show that the objecting party does, in fact, have standing to object;
2. Specify with particularity that part of the regulation to which objection is taken;
3. State reasonable factual grounds for the objection.

Note that anyone can object, not just the petitioner. If someone other than the petitioner files objection, the petitioner is so notified, and given two weeks to answer.

Assuming the objections are proper, a hearing is held. It is presided over by a Food and Drug hearing examiner. The rules of conduct are set forth in 21 CFR parts 120.15 through 120.28. The hearing is conducted in a manner quite similar to hearings under 701 (e). As in 701(e) hearings, the examiner has power to administer oaths, rule upon offers of evidence, receive evidence, examine witnesses, and generally regulate the conduct of the hearing. He does not have subpoena power.

An interesting twist in these hearings, and one area in which they differ from the 701(e) hearings, is the placing of the burden of proof.

The person whose objections raised the issues to be determined at the hearing has the burden of proof. This is not necessarily the petitioner.

Another deviation from the 701(e) procedure is the provision that parties to the hearing may be allowed to file written arguments, with record references, but are not invited to submit proposed findings of fact and conclusions of law.

After the arguments are filed, the hearing examiner certifies the record, exhibits, and arguments to the Commissioner, who then publishes his findings of fact, conclusions of law, rulings on objections and tentative order. From this point, the procedure for exceptions, oral argument, final order and appeal are identical to the 701(e) hearing, except that time for appeal to the Court of Appeals is sixty days instead of ninety days.

B. Petitions to Establish Safety of Food Additives Under Section 409

The procedure to be followed in these petitions is quite similar to the procedure just described with reference to pesticide tolerance petitions, except that the Secretary of Agriculture is not involved here. Also, there is provision under the food additive law for absolute denial of the petition.

The procedural regulations governing these hearings are set forth in 21 CFR 121.55 through 121.73.

Again, after the Commissioner has published his order ruling on the petition, any person adversely affected may object to the order and request a hearing. He must make the same showings of standing, damage, specificity, and reasonable grounds. And, as with the pesticide petition, the objector has the burden of proof.

The presiding officer is given the same powers, and the invitation is extended to submit arguments, with record references. Provision for publication of the tentative order, exceptions to it, publication of the final order and judicial review are all similar to the pesticide petition and 701(e) provisions.

C. *New Drug Petitions Under Section 505*

Hearing procedures under the New Drug provisions of the Act have some unusual aspects.

When a New Drug Application (NDA) is filed, the Commissioner has two choices: He may either approve the application, or he may give the applicant an opportunity for a hearing. Although this notice of hearing is published in the Federal Register, and the hearing itself is open to the public, there is no provision for interested persons to comment or for adversely affected parties to intervene, as there are in most other situations. Theoretically, at least, interests other than those of the applicant and the FDA might be involved, but, if so, there is no way to protect these interests.

If the applicant avails himself of the opportunity, then a hearing is held "on the question whether such application is approvable." Nothing in the law, or in the procedural regulations (21 CFR 130.14 through 130.31) delineates who has the burden of proof on this question. In the abstract, it seems clear that the applicant should have the burden of showing that his application is approvable, but in one recent New Drug hearing, the office of General Counsel assumed the burden of proof and came forward first with evidence that the application was *not* approvable.

Another unusual aspect of New Drug hearing is the statutory delineation of the issues to be tried. The statute outlines six grounds for denial, and provides that if the Commissioner finds that none of these grounds exist, he shall approve the application. Obviously, then, all hearings on New Drugs will be restricted to one or more of these six basic issues.

There is also provision, under 505(e), for withdrawal of approval of an NDA. The grounds for withdrawal are a little different from the grounds for refusal to approve, but the procedural moves are the same. Notice is given of the Commissioner's intention to withdraw approval, and opportunity for a hearing is offered. Again, there is no delineation of who has the burden of proof, but in this case it seems more logical that the FDA should have it.

In either type of hearing, however, the powers of the hearing examiner are identical to those in a 701(e) hearing, as are the provisions for submission of oral and written arguments by the parties. However, a 505 hearing differs from all others in that here the hearing examiner, not the Commissioner, prepares the findings of fact and a tentative order, which he serves upon both the applicant and the FDA. If neither takes exception, this tentative order becomes final in twenty days. If either party takes exception, then the exceptions, with supporting briefs, are filed with the hearing examiner. There is also provision for oral argument, although it is not clear whether this is before the Commissioner or the hearing examiner. At any rate, if exceptions are filed or oral argument is heard, the Commissioner then issues the final order. There are the usual provisions for judicial review which must be taken in sixty days.

D. Antibiotic Certification Petitions Under Section 507

Under the provisions of Section 507(f), "any interested person" may petition for the issuance of a regulation establishing certification procedures, or exemption from certification, of antibiotics.

The petition should include, in general terms, the proposed regulation, and reasonable grounds therefor. Notice of the proposal is published in the Federal Register, and all interested persons are invited to submit their views. After such opportunity, the Commissioner acts upon the proposal, and publishes his decision. At this point, again, "any interested person" may object and request a hearing. Notice that here, unlike all the other sections, "any interested person" may object; he does not have to be an "adversely affected" person.

If such a hearing is requested, the Commissioner is directed to hold such a hearing. There are no statutes, or regulations which lay down the guidelines for such a hearing. After such a hearing, the review provisions of 701(f) are available.

Conclusion

These, then, are some of the more uncommon types of hearings provided for under the Federal Food, Drug and Cosmetic Act. I submit that it behooves each of us, who may at one time or another find ourselves with a client who has an interest in one or more of these areas, to become familiar with the procedural oddities of each of these types of hearings, so that substantive rights will not be sacrificed to procedural ignorance. **[The End]**

Some Suggestions for Improvements in the Hearing and Rulemaking Procedures of the Food and Drug Administration

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NEXT TO SWAPPING HORROR STORIES about how arbitrarily and illegally the Food and Drug Administration (FDA) treated their most recent clients, the favorite indoor sport of practitioners before that agency is suggesting improvements in its administrative processes. But many of these suggestions obviously spring from the heart, and their proponents advance them with utmost seriousness. Thus, when the Chairman of the Administrative Law Section's Food and Drug Committee called for such improvement proposals last spring, in the course of planning the Committee's activities for the coming year, the intensity with which views were expressed—as well as the striking similarity of many of the suggestions —made clear that the bar regards procedural reform at FDA as a matter of major importance and even urgency.[1]

Besides the multitude of detailed suggestions others have made, there are a number of fundamental matters which any serious reform effort should consider. For example, there is the two-pronged matter

[1] Other recent criticism is reported in Levine, "Separation of Functions in FDA Administrative Proceedings," 23 FOOD DRUG COSMETIC LAW JOURNAL 132 (June, 1968); Austern, "Is Government by Exhortation Desirable?" 22 FOOD DRUG COSMETIC LAW JOURNAL 647 (December, 1967); Spiker & Stafford, "A Look at FDA's New Rules of Practice — And Problems Still Unresolved," 21 *The Business Lawyer* 1069, 1074 (1966).

of prehearing discovery and compulsory process. Because it cuts across the whole range of adjudicatory and rulemaking hearings held before FDA, this subject warrants close attention.

Traditionally infrequent (if only because the "lifted eyebrow" regulatory technique is so effective),[2] adjudicatory hearings are threatening to become increasingly common in FDA practice. The National Academy of Sciences-National Research Council efficacy review has already resulted in proceedings to revoke New Drug Applications for a whole class of allegedly ineffective products,[3] and former Commissioner Goddard predicted before he left office that many more such cases may be instituted.[4] Sharply-contested rulemaking proceedings are similarly on the upswing. As Selma Levine and others have pointed out, many of these proceedings—particularly those conducted under the "rulemaking-on-a-record" provisions of Section 701(e) of the Food, Drug and Cosmetic Act—bear most if not all the hallmarks of adjudication.[5]

The Federal courts have long since learned that the conduct of adversary hearings is expedited, and the facts made more accessible to the deciding authority, by the liberal use of interrogatories, depositions, production of documents for inspection, and admissions.[6] Even the criminal law, with its delicate problems of self-incrimination, has seen the development of a limited prehearing discovery procedure.[7]

Yet prehearing discovery is unavailable in proceedings before many if not most federal administrative agencies. As John Frank put it at the American Bar Association's 1967 National Institute on Federal Administrative Practice, "discovery in an administrative agency is roughly at the stage of the pre-1912 equity rules of the Federal Courts".[8] And it goes without saying that FDA is not exactly in the vanguard of reform.

Thus, in adjudicatory proceedings to deny or revoke approval of new drug applications, discovery by private parties under FDA's

[2] See 1 Davis, *Administrative Law Treatise*, 233 and following (1958).

[3] *Drugs for Human Use Containing Rutin, et al.*, HEW Dkt. No. FDC-D-112.

[4] *FDA Reports* (The Pink Sheet), Jan. 8, 1968, p. 15.

[5] Levine, cited at footnote 1.

[6] Federal Rules of Civil Procedure, 26-37. See also Committee on Rules of Practice and Procedure, *Preliminary Draft of Proposed Amendments to Rules of Civil Procedure for the United States District Courts Relating to Depositions and Discovery* (1967).

[7] Federal Rules of Criminal Procedure, 16. See dissenting statement of Douglas, J. 384 U. S. 1089, 1091-92 (1966). See also *Brady v. Maryland*, 373 U. S. 83 (1963); *Giles v. Maryland*, 386 U. S. 66 (1967).

[8] "Pre-Trial Discovery and Preparation for Trial," 20 *Administrative Law Review* 59, 96 (1967).

Rules of Practice is limited to advance notice of the documentary evidence to be offered at the hearing.[9] A slightly broader discovery is provided in the Rules of Practice for on-the-record rulemaking proceedings, which require advance notice not only of documentary evidence[10] but also of witnesses,[11] and which further authorize the Hearing Examiner to "require parties to state their position with respect to the various issues in the proceeding."[12] In neither adjudicatory nor rulemaking proceedings, however, has FDA explicitly provided for prehearing discovery of relevant matter or leads thereto which may be in the hands of another party (including the agency staff) but which is not intended by that party to be introduced into evidence. Nor is there explicit provision for discovery against non-parties who may possess relevant matter or leads to relevant matter.

Closely related to prehearing discovery against non-parties is the right to compel their testimony at a hearing. Indeed, the administrative subpoena is even more clearly necessary in administrative hearings than is discovery, since the hearing is the vehicle for bringing to the deciding authority the facts upon which decision must be based; if the parties are disabled from presenting relevant facts, the hearing process becomes something less than reliable. Section 6 of the Administrative Procedure Act[13] confers upon parties to agency proceedings the right to utilize the agency's subpoena power. But if the agency has no subpoena power, there is nothing for the private party to utilize. And the Food and Drug Administration is not authorized by any statute to issue subpoenas.

Lack of Progress

The need for prehearing discovery and compulsory process in administrative proceedings has been studied and reported on for years. The principal work is that of the Administrative Conference of the United States appointed by President Kennedy in 1961. In Recommendation No. 30 of its Final Report, the Conference "approve[d] the principle of discovery in adjudicatory proceedings and recommende[d] that each agency adopt rules providing for discovery to the extent and in the manner appropriate to its proceedings." The Report of the Conference's Committee on Compliance and Enforcement Proceedings in support of Recommendation No. 30[14] reviewed

[9] 21 C. F. R. § 130.19.

[10] 21 C. F. R. § 2.74(e).

[11] 21 C. F. R. § 2.74(d).

[12] 21 C. F. R. § 2.73(c).

[13] 5 U. S. C. § 555(d).

[14] *Selected Reports of the Administrative Conference of the United States*, S. Doc. No. 24, 88th Cong., 1st Sess. 115, 122-33 (1963).

the rationale and benefits of discovery in administrative practice, and found the arguments in its favor compelling.

Five years after the Administrative Conference did its work, however, the analogy to 1912 quoted earlier was still apt. What progress has been made since the Conference Report? Regrettably, almost no progress at all. In fact, the courts have contributed a major handicap to agency efforts in this area, in the *Anglo-Canadian* case, by denying the authority of the Federal Maritime Commission to include in its rules of practice a provision for production and inspection of documents, on the ground that explicit Congressional sanction for such provisions was required.[15] Subsequently, a district court hinted that the Federal Trade Commission might similarly be restricted in its ability to promulgate discovery rules for proceedings before it.[16]

Reforming Discovery Procedure

There are two avenues by which the Food and Drug Administration could bring its procedures further along towards the goal of fully adequate preparation by counsel and the full exposition of relevant facts for the benefit of the deciding authority. One is the promulgation of discovery rules despite the *Anglo-Canadian* decision, which has persuasively been shown to be untenable as a matter of law as well as policy.[17] This could be done pursuant to FDA's authority to promulgate regulations "for the efficient enforcement of the [Food, Drug and Cosmetic] Act."[18]

The rulemaking power granted in Section 701(a) is extremely broad, extending to any regulations as to which "a substantial showing" cannot be made "that they are plainly inconsistent with the statute."[19] There should be no doubt today, *Anglo-Canadian* notwithstanding, that administrative agencies are "free to fashion their own rules of procedure and to pursue methods of inquiry capable of per-

[15] *FMC v. Anglo-Canadian Shipping Co.*, 335 F. 2d 255 (9th Cir. 1964).

[16] *Union Bag-Camp Paper Corp. v. FTC*, 233 F. Supp. 660, 667 (S. D. N. Y., 1964). The FTC's discovery rules were thoroughly reviewed in Mezines & Parker, "Discovery Before the Federal Trade Commission," 18 *Administrative Law Review* 55 (1966). Other articles in the same journal examined discovery practice at the National Labor Relations Board, the Securities and Exchange Commission, the Civil Aeronautics Board and the Federal Power Commission.

[17] See remarks of George M. Galland in "Pre-Trial Discovery and Preparation for Trial," 20 *Administrative Law Review* 57, 59-60 (1967).

[18] Section 701(a), 21 U. S. C. § 371 (a).

[19] *Toilet Goods Ass'n v. Gardner*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 40,285, 278 F. Supp. 788, 789 (S. D. N. Y. 1968).

mitting them to discharge their multitudinous duties."[20] And the Supreme Court has confirmed that FDA's rulemaking power under Section 701(a) is as broad as the powers of other agencies under comparable grants.[21]

The other promising vehicle for reforming discovery procedure in cases before FDA, at least with respect to matter in the agency's hands, is the recently-enacted Freedom of Information Act.[22] Agencies are now required to make "identifiable records * * * promptly available to any person" requesting them unless one of the specific exemptions set forth in the statute is applicable.

The plain purpose of the Act was to increase the availability of agency information to the public at large. Numerous agencies have modified formerly restrictive practices to comply with Congress' new policy.[23]

FDA does not seem to be among the leaders here either, however. When Senator Long surveyed the Federal establishment to evaluate compliance with the law, FDA replied that "most, if not all" of the materials it now makes available "are types of material available upon request prior to enactment of the Freedom of Information Act."[24] The list of items which the agency has refused to produce since the new law became effective is lengthy, varied, and strongly suggestive of a general indisposition to disclose.[25]

The Freedom of Information Act authorizes suits in the federal district courts to compel the production of information which an agency improperly withholds.[26] At least one such suit has already been filed challenging FDA's refusal to disclose information in its possession (or readily obtainable) underlying the bioflavonoids NDA revocation proceeding.[27]

Whether litigants before FDA will press the Information Act as a discovery device remains to be seen. The propriety of its use for this purpose is suggested, however, by two of the new law's exemptions from the general disclosure requirement.

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[20] *FCC v. Pottsville Broadcasting Co.*, 309 U. S. 134, 143 (1940); *FCC v. Schreiber*, 381 U. S. 279, 289-90 (1965).

[21] *Toilet Goods Ass'n v. Gardner*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 40,260, 387 U. S. 158, 163-4 (1967).

[22] 5 U. S. C. § 553.

[23] See Sky, "Agency Implementation of the Freedom of Information Act," 20 *Administrative Law Review* 445 (1968).

[24] Letter from Robert C. Wilderell to Sen. Long, in Subcommittee on Administrative Practice, Senate Judiciary Committee, *The Freedom of Information Act* (Ten Months Review), 90th Cong., 2d Sess. 130 (Comm. Print 1968).

[25] See footnote 24, 131—134.

[26] 5 U. S. C. § 522(a)(3).

[27] *Matonis v. FDA*, Civ. No. 479-68 (D. D. C.).

Agencies are entitled to withhold "memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency,"[28] and "investigatory files compiled for law enforcement purposes except to the extent available by law to a party other than an agency."[29] It might well be argued that material which could be obtained in pretrial discovery under the Federal Rules of Civil Procedure in litigation with the agency is material "available by law" in the literal sense and thus available as of right under the Information Act. If so, parties to FDA administrative proceedings would have the benefit of prehearing discovery as full as that available to litigants in the federal courts.

Compulsory Process Requirements

In contrast to discovery, however, there may be little FDA can do about compulsory process for parties before it in the absence of new legislation. A committee of the Administrative Conference noted six years ago that "only a few of the major regulatory agencies lack the subpoena power altogether"[30] and listed FDA as one of the two "most important cases in which no such power has been granted."[31] The traditional view has been that due process does not require compulsory process in behalf of private parties in regulatory proceedings, at least in the absence of demonstrated prejudice.[32] Evolving conceptions of fairness might, however, come to include the necessity of compulsory process. Professor Davis has characterized the older cases as "somewhat lacking in strength and clarity."[33]

Alternative methods of investigation have long been employed by FDA, of course, Chief among these is the power of entry for inspection, backed with sanctions for wrongful refusal.[34] There is no reported instance of a private party in proceedings before FDA seeking the exercise of the "factory inspection" power in his own behalf. But Section 6 of the Administrative Procedure Act provides that "agency subpoenas authorized by law shall be issued to a party on request * * *"[35] This was intended to "assure private parties the same

[28] 5 U. S. C. § 552(b)(5).

[29] 5 U. S. C. § 552(b)(7).

[30] "Report of the Committee on Compliance and Enforcement Proceedings in Support of Recommendation No. 13," *Selected Reports of the Administrative Conference of the United States;* see footnote 14, p. 207, at 213.

[31] See footnote 14, p. 215. The other was the Post Office Department.

[32] *Reetz v. Michigan*, 188 U. S. 505 (1903); *Brown v. Macy*, 222 F. Supp. 639 (E. D. La. 1963), *aff'd*, 340 F. 2d 115 (5th Cir. 1964).

[33] 1 Davis, *Administrative Law Treatise*, at 584.

[34] Food, Drug and Cosmetic Act, § 704, as amended, 21 U. S. C. § 374.

[35] 5 U. S. C. § 555(d).

access to subpoenas as that available to the representatives of agencies."[36] The same considerations of equity would seem applicable to all investigatory methods, and an expansive construction of Section 6 might well be found not inconsistent with the statutory purpose.

A district court has firmly rejected this possibility, finding that "the language and meaning of the statute are clear" and refusing to "create an ambiguity where none exists, * * * [or to] legislate for the benefit of a litigant."[37] But it was not so clear even to that court that the equal-protection element of due process is satisfied when agency powers of investigation can be used to assemble evidence against but not for a private party. Rather, the court suggested that the Constitution might prohibit any such distinctions if the effect were for lack of alternative methods, to deny a party "the right to present its evidence and summon the witnesses of its choice."[38]

Not only the factory-inspection power but the authority of FDA to require reports from drug manufacturers and others can plainly be, and no doubt are, used to assemble evidence suitable for use in subsequent adversary hearings. Either the Administrative Procedure Act or due process of law might thus arguably require the agency to exercise these powers at the behest of parties to administrative proceedings, particularly if there is no other way information can be obtained adequate to rebut the evidence presented by the agency staff. Resort to such an approach may well be necessary in future FDA proceedings, if the agency's promise of vigorous regulation and enforcement is kept.

Conclusion

Perhaps reform in these or other areas is not likely immediately to come from inside FDA itself, unassisted and unencouraged. But an unusual opportunity for demonstrating the compatibility of drug regulation in the public interest with fair and modern administrative procedures is provided by the recent transfer of the Bureau of Drug Abuse Control (BDAC) to the Department of Justice. The Department has for many years been a leading exponent of administrative procedural reform. Practice before BDAC could become a model for other agencies, particularly FDA with its closely allied fields of interest. The food and drug bar should make every effort to ensure that this opportunity is not allowed to slip away unrealized. **[The End]**

[36] S. Rep. No. 752, 79th Cong. at Sess. 20 (1945), in *Administrative Procedure Act—Legislative History*, S. Doc. 246, 79th Cong. 2d Sess. 206 (1946).

[37] *Union Bag-Camp Paper Corp. v. FTC*, 233 F. Supp. at 665 (S. D. N. Y., 1964).

[38] See footnote 37, at 666.

TASK FORCE ON PRESCRIPTION DRUGS ISSUES SECOND REPORT

The Task Force on Prescription Drugs studying a wide range of such drugs issued its second interim report September 13, 1968. The government task force was set up by former Secretary of Health, Education and Welfare, John W. Gardner in 1967.

Of interest to manufacturers and packagers are the following recommendations of the task force affecting the purity, standards, packaging and labeling of drugs:

(1) a study to develop a registration and licensing system under which no drug product would be permitted in interstate commerce unless produced under quality control standards set by HEW,

(2) acquisition of adequate financial support for FDA to determine what quality control methods can be instituted and properly maintained in all drug manufacturing and packaging establishments,

(3) a study to determine the feasibility of limiting free drug samples to those specifically requested by prescribers,

(4) enactment of legislation requiring containers of all dispensed prescription drugs to be labeled with the identity, strength and quality of the product,

(5) encouraging the wider use of prepackage dispension of prescription drugs to promote efficiency and minimize errors, and

(6) enactment of legislation to require use of an identifying code number as part of all drug labels, package inserts, catalogs and advertising.

In its first interim report delivered to the HEW Secretary on March 7, 1968, the task force recommended the establishment of a federal drug compendium.

The task force is under the chairmanship of Dr. Philip R. Lee, Assistant Secretary for Health and Scientific Affairs. Head of the professional staff is Dr. Milton Silverman, a special assistant to Dr. Lee. The material accumulated during the study will be published as a series of background volumes, Dr. Lee said. The task force must submit its final report by December 31.

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