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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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REPORTS

TO THE READER

The increased awareness of consumer groups and their desire to be involved in decision-making processes, has subjected the FDA to new and mounting pressures. This is one of the themes in *Donald P. Rothschild's* article, "The FDA's Regulations—A Model for the Future?" He discusses the informal hearings as an innovative response to those pressures, and predicts that other agencies will also initiate alternate forms of decision-making. The author, a Professor of Law at the George Washington University National Law Center, believes that the informal hearings facilitate greater participation and can also better "accommodate the nature of the dispute." The article begins on page 344.

Subpart F of the FDA's new procedural regulations is the subject of *Ronald J. Greene's* article, "Informal FDA Hearings." He discusses two forms of decision-making, adjudicatory and bureaucratic, presenting Subpart F as an attempt to combine the important aspects of each. He points out nine areas in which a Subpart F hearing may be used and also discusses the procedures surrounding a hearing. An attorney with the law firm of Wilmer, Cutler and Pickering, Mr. Greene suggests that the presiding officers at the Subpart F hearings must remain open-minded in order for them to be successful. The article begins on page 354.

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

The article "Property Rights in the Color and Shape of Capsules," by *Houston L. Swenson,* is a discussion of trademark registration and the problem of look-alike drugs. The author, who is Trademark Counsel for Eli Lilly and Company, describes various court cases to illustrate the criteria used in determining if trademark privileges have been infringed. He also discusses the problems caused by what he terms unfair competition laws. The article is found on page 361.

The promulgation of Trade Regulation Rules as a form of administrative rulemaking was authorized by the Magnuson-Moss—Federal Trade Commission Improvements Act. *Paul M. Hyman,* in his article, "Participating in a TRR," gives a detailed description of this process, pointing out, however, that there is not much evidence as to its efficiency or effectiveness. In the article, which begins on page 369, he describes the process as a legislative hearing rather than a rulemaking procedure. He then discusses the elements involved in making a TRR public such as cross-examination, and group representation. Mr. Hyman is a member of the law firm of Rogers, Hoge & Hills.

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The FDA's Regulations— A Model for the Future?

By DONALD P. ROTHSCHILD

Mr. Rothschild Is a Professor of Law at the George Washington University National Law Center.

A LITTLE OVER A YEAR AGO, two former law students of Richard Merrill suggested in a law review article[1] that the Federal Trade Commission (FTC) and the Federal Communications Commission, among other federal agencies, should pay more attention to the interplay of substance, procedure and efficiency in administrative proceedings, and what the Food and Drug Administration (FDA) is doing in this respect. A three-part *New York Times* article about the FDA[2] indicated that others were also impressed with the Agency's efforts, especially on behalf of consumers. Certainly, in a quantitative sense during the past few years since the FDA extricated itself from the quagmire of the vitamin and peanut butter hearings[3] and since the landmark 1973 Supreme Court decisions,[4]

[1] Ames and McCracken, "Framing Regulatory Standards to Avoid Formal Adjudication: The FDA As a Case Study," 64 *California Law Review* 14 (1976).

[2] *The New York Times*, "FDA Is Caught Between Demand For New Goods and Public Safety" March 12, 1977; "Demoralization Plagues FDA; Some Top Jobs Unfilled," March 13, 1977; and "FDA May Be Ultimate Challenge to Carter's Pledge on Reorganization and Consumer Aid," March 14, 1977 by Richard D. Lyons.

[3] See, *e.g.*, Hamilton, "Rulemaking on a Record by the Food and Drug Administration," 50 *Texas Law Review* 1132 (1972).

[4] *Weinberger v. Hynson, Westcott and Dunning, Inc.*, 412 U. S. 609 (1973); *CIBA Corp. v. Weinberger*, 412 U. S. 640 (1973); *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645 (1973); and *USV Pharmaceutical Corp. v. Weinberger*, 412 U. S. 655 (1973).

the Agency's informal rulemaking has been prodigious by any standard. The subject matter of this conference is obeisance to just a small part of the FDA's notice and comment rulemaking during the past two years. I will attempt to show that the FDA has been very innovative, as well as active, in its informal rulemaking capacity.

However, during this time frame, its activities have also drawn the attention of other branches of the federal government that have been studying these actions. The Agency has been the subject of over 100 Congressional investigations, of which the saccharin hearings are but another bittersweet example. The General Accounting Office (GAO) has issued some 50 critical reports, and external and internal study commissions have been formed to scrutinize FDA procedures. The motivation for this attention is not to consider the Agency's suitability as a model for the future, but rather to consider it as a candidate for reform.

Innovative Administration

In fairness, it is difficult to evaluate the interplay of substance, procedure and efficiency in the FDA's administrative procedures by analyzing its recent activities. Some have been in the traditional Interstate Commerce Commission mold of a federal agency established to regulate a specific industry, with the related concern of promoting the well-being of that industry. Other activity has been in the new mold of spearheading regulatory efforts on behalf of consumers. Still others are probably just a response to what the American Enterprise Institute for Public Policy Research considers to be the pressures of conflict among regulatory agencies caused by overlapping jurisdiction, uncontrolled power and downright inefficiency.[5] The fact is that the FDA has responded to all of these pressures. The purpose of my remarks, however, is not to evaluate the Agency's performance, but rather to present another perspective of the FDA's new procedures as a model for the future.

My assigned topic requires more than analysis, in that it suggests prediction. However, candor requires me to admit that my association with law professors has never impressed me with our prophetic abilities. More in point, there is nothing in my background that indicates such talent. Casper Weinberger, who was fond of

[5] M. L. Weidenbaum, "The New Wave of Government Regulation of Business," *Business and Society Review*, Fall 1975, reprinted in American Enterprise Institute, Reprint No. 39 (Feb. 1976).

appointing panels and commissions, appointed me to an external advisory council in May of 1970, to help the FTC rewrite their Rules of Practice & Procedure, along with some bona fide experts in the field. Yet, after two years of considerable effort, our major proposal, which was an acknowledgement of a significant regulatory trend toward informal rulemaking, was voted down by the FTC Commissioners. So much for my predictive abilities. Interestingly, our recommendations then were more in line with the new FDA regulations now than they are with the new FTC regulations. I hope that the Weinberger-appointed Health, Education and Welfare (HEW) Review Panel on New Drug Regulations, which is supposed to issue a report next month, will be more on point than ours was.

Merrill's two law students, whom I mentioned earlier, suggested that the FDA is uniquely qualified as a source of administrative innovation, because of the Agency's specialized jurisdiction, the volume of products it regulates, and its tradition of limited judicial review. I do not disagree with this assessment. In fact, it may be that because the courts have deferred to its expertise under the doctrine of primary jurisdiction, the FDA has turned from the formal evidentiary public type of hearings to the more appealing informal procedures in order to facilitate greater activity.

Alternate Proceedings

Although there has been much scholarly outpouring on how to improve formal evidentiary hearings, I agree with Robert Anderson's statement in the March 1976 issue of the CCH Food Drug Cosmetic Law Journal[6] that the underlying premise of the new FDA regulations is to avoid, rather than improve on, formal hearings. I also agree with him that they will be granted in the future only in situations where there is an unwaived statutory right to obtain them. My opinion was reinforced when I went through Subpart B, the new regulations on Formal Evidentiary Public Hearings, for my class in Administrative Practice & Procedure. Despite the Agency's attempts to streamline the procedures, they still allow for interminable proceedings. This means that for all intents and purposes the FDA's new model is based on informal alternatives to formal evidentiary hearings.

[6] Anderson, R. N., "An Overview of Recent Regulatory Development—The Case for Evidentiary Hearings," 31 Food Drug Cosmetic Law Journal 159 (March 1976).

Despite the fact that the new regulations provide for a number of procedures,[7] I would suggest that there are basically three models which the FDA will use: (1) Informal Rulemaking, by which I mean notice and comment rulemaking; (2) Fact Finding by Specialists, such as the Public Advisory Committees; and (3) Informal Dispute Settlement like the Public Board of Inquiry.

Informal Rulemaking

Since notice and comment rulemaking has been an integral part of the Agency's procedures for some time, it is important to my thesis to sort out the usage I am referring to as informal rulemaking. For example, notice and comment procedures can arise in the traditional manner by citizen petition or the Commissioner's direction as an alternative to formal evidentiary public hearings. As a summary procedure, it will take one of three possible forms. The first type will arise when the FDA issues precise regulations which are sufficient in themselves to provide adequate notice of the standards promulgated to affected persons.[8] The second model will arise when the FDA states a *prima facie* case for its action in a proposed regulation.[9] And, the third type of procedure will arise when the FDA chooses to proceed on a case-by-case basis, but posits the issues involved in the case and the type of evidence the Agency will consider in the proceeding.[10] In these alternatives to formal evidentiary hearings, the amount of comment solicited from interested parties will vary according to the type of procedure used. The point is that since each of these models has been considered in judicial proceedings and approved, the FDA considers it to have ample precedent to support their usage.

In addition, however, to these more traditional alternatives to formal adjudicatory types of hearings, there is now ample evidence that the FDA will use its general administrative statutory au-

[7] Alternatives to 21 CFR Sec. 2.100 (Formal Evidentiary Public Hearings) are listed in 2. CFR Sec. 2.117(a)(2) Public Board of Inquiry pursuant to Subpart C; 2 CFR Sec. 2.117(a)(2) Public Advisory Committee pursuant to Subpart D; and 21 CFR Sec. 2.117(a)(3) Public Hearing Before Commissioner pursuant to Subpart E.

On Tuesday, March 22, 1977, the FDA recodified the procedural regulations (42 *F. R.* 15553). 2.100 is 12.1 and 2.117 is 12.32.

[8] The Supreme Court upheld this type procedure in *Weinberger v. Hynson, Westcott and Dunning, Inc.*, note 4, *supra.*

[9] *Ciba-Geigy Corp. v. Richardson*, 446, F. 2d 466 (CA-2 1971); *Cf. Hess and Clark, Division of Rhodia, Inc. v. FDA*, 495 F. 2d 975 (CA DofC 1974) (dicta).

[10] *Cosmetic, Toiletry and Fragrance Association, Inc. v. Schmidt*, 409 F. Supp. 57 (1976); *Cf. Cooper Laboratories Inc. v. Commissioner, FDA*, 501 F. 2d 772 (CA DofC 1974).

thority[11] to promulgate regulations for the efficient enforcement of the Federal Food, Drug, and Cosmetic Act much in the same fashion that it published the new regulations by notice and comment rulemaking.[12] When, for example, the Agency published its proposed rule on nutrition labeling[13] and asked for comment under its general administrative authority, it was engaging in another form of informal rulemaking. I predict that this "legislative" model of notice and comment rulemaking will substantially increase under the new regulations. There is administrative precedent for such action. The FTC has recently utilized notice and comment rulemaking under the Magnuson-Moss Warranty Act to regulate tie-in warranties. The Consumer Product Safety Commission has been publishing State petitions for exemptions from federal safety standards for the purpose of soliciting comments prior to its ruling. The Department of Transportation's air bag hearings, and the Occupational Safety and Health Administration noise level hearings are other examples of notice and comment rulemaking where, even though the notice given and the comment solicited vary considerably, they are held to meet due process standards in administrative proceedings. In every case they are less than what is required in a judicial setting, and also in formal evidentiary public hearings.

Fact Finding

Fact finding by external specialists, the second model to be utilized by the FDA, antedates their new regulations. Dr. Philip Handler, President of the National Academy of Sciences (NAS), stated the rationale for this form of procedure in an NAS forum on "How Safe is Safe—The Design of Policy on Drugs and Food Additives."[14] He explained that "government regulation of technical products must rest on a rational and sufficient scientific base." Further, in his opinion, "products involving hazards must, as a minimum rest on detailed appraisals of the nature and magnitude of those risks, of the monetary and other costs of measures intended to reduce the severity of each risk, and of the nature and magnitude of the benefits involved in the process or product under consideration." The efficacy studies

[11] 21 U. S. C. 371(a), Sec. 701 (1975 Supp.).

[12] *See, e.g.*, McNamara, S. H., "The New Age of FDA Rule-Making," 31 FOOD DRUG COSMETIC LAW JOURNAL 393 (July 1976).

[13] 21 CFR Sec. 1.17, Food: Nutrition Labeling (April 1, 1976).

[14] Speech reprinted in 43 George Washington University Law Review 791, 794 (1975). *See also* Handler, "A Rebuttal: The Need for a Sufficient Scientific Base for Government Regulation," 43 *George Washington University Law Review* 803 (1975).

mandated by the 1962 amendments to the Federal Food, Drug, and Cosmetic Act made by the National Academy of Science—National Research Council (NAS-NRC) panels are an example of this policy, and the use of these studies to set up scientific guidelines for summary procedures was validated by the Supreme Court.

Public Board of Inquiry

A third, but to date untested alternative model proposed by the FDA is the Public Board of Inquiry, which is an informal dispute settlement model analogous to arbitration. Although the FDA has not utilized this device, it has substantial precedent in the labor field where arbitration is the bedrock of industrial dispute settlement. The National Labor Relations Board ruled in the *Collyer Insulated Wire* case that where an informal proceeding can resolve both a labor dispute and an alleged violation of federal statute in a manner compatible with the Act, it would defer to private (as distinguished from Agency) resolution of both the dispute and the violation of statute. In a long progeny of cases, the Supreme Court has validated the use of informal dispute settlement as part of the administrative process when the parties have voluntarily accepted its usage. The key is voluntary acceptance of the procedure.

Although the three models included in the new regulations have judicial and administrative precedent for use as informal rulemaking, there still is an open question as to whether there is significant pressure to utilize these procedures afforded by the FDA, as well as by other regulatory agencies. I think it is very important to point out that the FTC is currently struggling with the reality that its Informal Dispute Settlement Mechanism, established under Rule 703 and promulgated by notice and comment rulemaking under the Magnuson-Moss FTC Improvement Act, has not been adopted by a single manufacturer. The mere fact that an agency has created a procedural model does not insure its use. This is particularly true where the participants must waive other rights in order to use the new procedures.

Pressures on the FDA

The preamble to the new rules is replete with carefully thought through statements indicating the rationale for establishing the new procedures. However, I would like to discuss three practical, but unmentioned, pressures for use of these procedures that are political in nature.

"Anti-Washington sentiment" is a generic, catchy phrase fashioned by the media to describe the "outsider phenomenon" of the last election. Yet, in my opinion it has implications about the demand for the new procedures promulgated by the FDA. *The New York Times* March 12th article describing how the Agency is caught in the middle of demand for new goods and public safety, points out that the American public is now far more educated and sophisticated than ever before. The result is that citizens assert their rights to be heard and informed about government decisions that affect their lives. The article uses as an example the current demand by women's organizations to know what over-the-counter and prescribed drugs will do to their minds and bodies. This is just one of the many examples of pressure that is being exerted by "outsiders" to the administrative process on the FDA in order to become part of the decision-making procedures.

The second type of pressure exerted on the FDA involves the current schism between law and science which was expressed eloquently by my colleague Harold Green when he responded to Dr. Handler's views in a *George Washington Law Review* article.[15] In response to the suggestion that where the ultimate administrative decision turns upon scientific questions, scientific fact should dictate the ultimate decision, or at the very least, should define the factual predicates on the basis of which value conflicts are resolved, Professor Green distinguished the scientific from the legal approach. He argued that while to the scientist, truth, objectivity and accuracy are the ultimate desiderata, to the lawyer, the ultimate goal of public policy decision-making is the optimum resolution of conflict, such as in the current saccharin dispute. While this sounds like an academic dispute, I predict that the argument over the respective roles of the scientist and the lawyer in administrative decision-making will be one of the major debates of this decade.

The third political pressure toward utilization of the new FDA regulations arises from the fact of regulatory reform. I think that it is now too late in the day to deny that administrative reorganization is a reality. The only open question is what form it will take. Without claiming any insider knowledge, let me suggest at least two ascertainable pressures. I have already alluded to the demand by citizen/consumers to become part of the decision-making process. A recent and very interesting study about consumer organizations' expecta-

[15] See Green, "The Risk-Benefit Calculus in Safety Determinations," 43 *George Washington University Law Review* 791 (1975).

tions about the FDA has just been published by the Agency's Office of Professional and Consumer Affairs.[16] It involves a survey of consumer organizations, the National Advisory Food & Drug Committee (the only policy advisory committee appointed by the FDA thus far), the Commissioner's staff, and personnel from the FDA field offices who were asked to prioritize their concepts of "risk," "public interest," and "ease of correcting problems" involved in the Agency's actions. Not surprisingly, the study indicates a considerable variation as to these priorities, for example, in the area of food additives. What is surprising is the extent to which this variation exists both within and from without the Agency. As *The New York Times* articles rightly conclude, the FDA is caught in the middle of these conflicting demands. I believe that the pressure of regulatory reform will cause the Agency to respond by increasing access, rather than by any attempt to redirect priorities.

Cost of Reforms

Opening access to administrative procedures, however, will increase costs for many obvious reasons. For example, to me it is quite clear that the Agency or some other arm of government will be forced to provide funds for consumer group representation, if such representation is to be fair and meaningful. Public opinion will coerce meaningful, as distinguished from illusory access, and the federal government will pay the cost, at least in the first instance. However, because of the populist nature of this Administration, I also believe that increased access will be allowed only after a careful cost-benefit analysis whereunder just the most cost-effective procedures will survive this scrutiny. My analysis is that although regulatory reform will provide increased access to the decision-making process, it will be limited to those procedures which are flexible, speedy and relatively inexpensive. Put simply, I believe that reorganization will be carried out only after a careful cost-benefit analysis of administrative practices and procedures.

Insofar as the FDA is concerned, I predict that the anti-Washington sentiment will put pressure on the Agency to utilize its informal rulemaking model to the fullest extent feasible in order to provide maximum access by the greatest number of citizens at the lowest cost. Since significant action by all regulatory agencies is now newsworthy, it will be brought to the attention of our citizenry by the media. The

[16] *Discussion of Priorities*—Consumer Organizations and Other Participating Groups, Fiscal Year 1979 FDA Planning Process (Feb. 1977).

proposed saccharin ban is a dramatic example of this phenomenon, and the resulting public pressure that it can generate.

Such pressure also has significance in prompting an Agency to utilize an "escape valve" mechanism where it has procedures that utilize outside experts to resolve disputes. For example, in the new regulations, a Standing Advisory Committee was established to advise on policy matters as they relate to the statutory mission of the Agency.[17] Where the issue is "adversarial" in nature, the FDA's Public Board of Inquiry might be an appropriate alternative forum, especially where the issue has broad public policy implications such as the saccharin ban.

The law-science dichotomy raised by these issues is probably responsible for what Jim Turner characterizes as the FDA's schizophrenic choice of informal forums to resolve the same type of dispute. He considers the Public Advisory Committee's role to be antithetical to that of the Public Board of Inquiry's role. I would argue that they are supplementary, and both desirable. Although it is not clear from the comments, I believe the Public Advisory Committee should be utilized to make risk-benefit calculations when scientists are important participants in the process, because safety calculations are involved. On the other hand, it does not follow that scientists have the same qualifications for acting in representational roles. Nor do I think that scientists are more qualified than others in making general policy decisions. In the latter case, I would prefer to use generalists, rather than specialists, to make such decisions, because they will better reflect public opinion. In such cases, I would use the Public Policy Advisory Committee or the Public Board of Inquiry with plain old specialists as an alternative form of rulemaking procedure.

As I have indicated, the pressure of regulatory reform is going to force the FDA to utilize cost effective procedures. In my opinion, this requires alternative forms of rulemaking. For example, where a petition poses a question that affects a large number of people and involves legal/policy issues, a "legislative" type of form, such as informal rulemaking, is undeniably the most cost effective administrative procedure to utilize. Using an adjudication model for such purposes would promote interminable delays, appeals and increased fees for representation. On the other hand, where a petition involves questions affecting a smaller number of persons and the issues are factual, informal dispute resolution models are less costly. The point is that alternative

[17] 21 CFR Sec. 2.340 proposed in 40 *F. R.* 40753 (Sept. 3, 1975).

forms of rulemaking have the advantage of being able to accommodate the nature of the dispute in the least costly manner, because they allow the Agency to recognize the necessary interplay of substance, procedure and efficiency.

Conclusion

The reason I used the political pressures generated by anti-Washington sentiment, the law-science dichotomy, and regulatory reform is because they are general in nature and national in scope, and they have important social implications for the new FDA regulations. They also apply with equal force to other federal agencies, particularly where product safety is an important factor. My prediction, therefore, is that other agencies will adopt procedures that utilize alternative forms of resolving disputes. The procedures they adopt will also be those that are flexible, speedy and cost effective. Because of this requirement, I would not be surprised to discover that informal rulemaking, informal dispute settlement and external advisory committee models are part of such procedures.

However, I will temper my prediction that the innovative spirit at the FDA is going to spread to other agencies with the caveat that before this occurs, the Agency is going to have to establish some definitive guidelines for the use of each of these models. I think the FDA's Commissioner will soon come to realize that the discretion provided him under the new regulations so that he can act on an *ad hoc* basis depending on the problem that he is confronted with is not a blessing in disguise. A colleague of mine, a fine labor lawyer, called attention to the practicing labor bar many years ago that providing alternative forums to resolve disputes can have profound implications on the parties involved.[18] Such procedures require careful analysis, especially as to procedural safeguards that are necessary to protect all of the participants involved. Those of us who are administrative lawyers have an obligation to point out that discretionary justice is fraught with examples of past, present and future dangers about which we should be particularly sensitive. **[The End]**

[18] Dunau, "Contractual Prohibition of Unfair Labor Practices: Jurisdictional Problems," 57 *Columbia Law Review* 52 (1957).

Informal FDA Hearings

By RONALD J. GREENE

Mr. Greene Is with the Law Firm of Wilmer, Cutler and Pickering.

THE FOOD AND DRUG LAW INSTITUTE has asked me to speak about Subpart F[1] of the Food and Drug Administration's (FDA's) new procedural regulations. Before I begin, I have a confession to make. I am not a food and drug lawyer. In fact, I have participated in only one proceeding at the FDA.

I do, however, have one advantage in speaking to you about Subpart F. My one and only FDA proceeding happens to be the first—and perhaps the only—proceeding ever conducted under Subpart F. It involved some microwave ovens which were the subject of a series of related proceedings before the Bureau of Radiological Health. Those proceedings, which took place prior to the effective date of Subpart F, were nevertheless conducted in accordance with its provisions by agreement of the parties.

Background

Let me begin my discussion of these new regulations by being a bit professorial. At the risk of oversimplifying, I would say that governmental decisions are ordinarily reached either through what could be called "bureaucratic" procedures or through "adjudicatory" procedures. "Bureaucratic" actions would include most typical government decisions, including everything from a decision by the President about whether to sign a bill, to the selection of a janitor to clean out the basement of a government building. Such decisions are made by government officials on the basis of information that they compile by whatever procedures are most appropriate in the circumstances. Even some more formal actions would probably fall into this category. For example, so-called "informal" rulemaking

[1] On Tuesday, March 22, 1977, the FDA recodified the procedural regulations (42 *F.R.* 15553). Subpart F is now Part 16.

under the Administrative Procedure Act is essentially a bureaucratic process. The relevant officials ask for the submission of outside opinions, but they then make up their minds based upon all the facts they consider to be relevant.

In contrast, adjudicatory decision-making is patterned upon the judicial process. Here, the materials upon which a decision will be based are developed by an adversary process, and the decision-maker is (to a large extent) restricted to those materials when he makes his decision.

Obviously, the bureaucratic approach to decision-making is much simpler and more flexible than the adjudicatory method. But, from the standpoint of the private party who may be affected by a government decision, the adjudicatory model offers much greater promise of protecting his rights and of allowing him to assure that all relevant factors (and no irrelevant factors) are properly placed before the decision-maker.

Subpart F represents an attempt to combine some important aspects of both the bureaucratic model and the adjudicatory model. It was designed to apply in a wide variety of contexts in which FDA decisions had previously been made solely in accordance with the bureaucratic model. These include cases where private parties apply for some type of administrative relief, and FDA action must be taken on the application. They also include situations in which the FDA on its own motion seeks to impose certain sanctions or makes certain findings which could adversely affect private parties. In both situations, previous regulations provided very limited procedural safeguards. The appropriate FDA official could simply make a decision on the basis of whatever information he felt was relevant, and even where an opportunity for a hearing was provided, the procedures governing such a hearing were not articulated.

Obviously, where individuals may be adversely affected by such decisions, there is a possibility that judicial review of the administrative decision will be sought. If such review were sought in a context in which no procedural safeguards had been available to the affected private party at the administrative level, the cases indicate that the reviewing court might well require the Agency to prove its case anew in court. In short, the court would offer the protection of a trial *de novo* as a substitute for the procedural protections denied at the administrative level.

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Subpart F was devised to avoid such a result, while maintaining the flexibility of the bureaucratic decision-making model. It allows the decision-making process to go forward much as it always has—that is, without any substantial procedural guarantees for affected private parties. However, if the affected party is dissatisfied with the initial decision, he may request a hearing under Subpart F. In certain special cases, as set forth in the regulation, such a hearing could also be scheduled at the initiative of the FDA. Thus, flexibility of the initial bureaucratic decision-making model is retained, and adjudicatory procedures are to be made available only to those parties who show some sign of wishing to challenge the bureaucratic decision.

Before describing the manner in which Subpart F has been designed to work, I should briefly describe the circumstances as set forth in the regulation in which these provisions would apply. The regulations provide that a Subpart F hearing will be available in nine general areas supervised by the FDA. These nine areas include regulations governing color additives, food, prescription drug advertising, treatment of animals with experimental drugs, new drugs for investigational use, certification services, electronic product radiation standards, permits under the Federal Import Milk Act, and a multitude of exemptions dealing with antibiotic drugs. In every case, the hearing is held after the Commissioner, or one of the bureaus to whom he has delegated authority, has made an initial determination. Sometimes that determination results in immediate administrative action, and sometimes the actual effectiveness of the determination is postponed pending the hearing. There is no clear pattern in the regulations on this question; obviously an attempt was made to accommodate previous procedures and to apply Subpart F procedures in a manner which would least disrupt established practices.

For example, a hearing is provided after the commissioner has suspended certification, or has refused to grant authorization, for use of food containing a new color additive. In the area of prescription drug advertising, a hearing is granted after the Commissioner has decided that advance approval is needed to distribute a particular advertisement or after he has disapproved a particular advertisement.

Even when a Subpart F hearing is provided prior to a final determination, the responsible decision-maker has come to a tentative conclusion without affording the affected party an opportunity to

know what information the decision-maker is considering and without an opportunity to confront his accusers. Thus, even though a hearing is provided, and even though the regulations may provide that the agency involved has the burden of proof or the burden of persuasion, in practice the individual affected by the decision may well have a heavy burden to carry in order to dissuade the decision-maker from his initial conclusion.

Pre-Hearing Procedures

Under Subpart F, a party is ordinarily notified of his right to request a hearing by receipt of a notice from the appropriate FDA official. Although the regulations do not specifically say so, this notice will, as a practical matter, ordinarily be included with the initial decision which has been made by what I have called "bureaucratic" procedures. The notice must specify the facts which are to be the subject for any hearing and must include other procedural details, like the name and address of the hearing officer.

Within three days after receipt of a notice, a request for a hearing must be "filed." In the absence of such a filing, the hearing will be deemed to have been waived. Although the Commissioner, in promulgating the regulations, refused to change the three day period to ten days, as some persons requested, the regulations do provide for extensions of time, and it may in some cases be possible to obtain them.

The regulations provide that the Commissioner shall designate a presiding officer if a hearing has been requested. As a practical matter, the designation will probably have been made before the notice of an opportunity for hearing is mailed. In any event, scheduling of further procedural steps will be under the control of the presiding officer. He and the person requesting the hearing are required to agree upon a time for the hearing, but if no agreement can be reached, the presiding officer may set the hearing date as early as two days after the receipt of the request for a hearing.

The regulations provide that almost any FDA employee may be a presiding officer. The only limitations are that the presiding officer shall not have participated in the action that is the subject of the hearing, and that he not be subordinate to any such person. Since most of the decisions that will be the subject of Subpart F hearings will have been reached by the director of a bureau, this provision in effect means that an FDA employee with no special

expertise or knowledge of the subject matter, will ordinarily preside at the hearing. In the microwave oven proceeding, the job was given to an official in the office of the Assistant Commissioner for Compliance. He obviously had no background or experience in radiation matters. Although such a person may be, as the regulations require, free from "bias or prejudice," he obviously will be reluctant to overrule the supposed experts whose decision he is asked to review.

Rules for Discovery

The rules contain no general provision for discovery, either by the FDA or by the private party. This may well prejudice the private party more than the FDA since the Agency presumably will have obtained much information through its normal regulatory operations or during the period when it was making its initial decision. All that the regulations do contain are two requirements apparently designed to avoid the introduction of "surprise evidence" at a hearing. Prior to the hearing, the private party must be given "reasonable notice of the matters to be considered at the hearing," including a general summary of the information that will be introduced by the FDA at the hearing. The term "reasonable" is not defined, but in the microwave oven case we objected to receiving notice of surprise evidence on a Thursday night before a Tuesday hearing, and the presiding officer agreed to adjourn the hearings to give us additional time to investigate. In addition, if either side wishes to introduce published articles or written information at the hearings, a copy must be provided to the other side at least one day before the hearing.

Obviously, these limited discovery provisions do not provide either side with a very thorough understanding of the evidence which will be presented by the other parties. In addition, there is no opportunity for the use of third party subpoenas or other discovery techniques to gather evidence. But since the time frames set forth in the regulations are so short, it is doubtful whether much discovery could be completed before a hearing, even if the procedures provided the tools to obtain the information.

Hearing Procedures

When the hearing convenes, the regulations provide that it will be conducted in the most informal manner. The rules of evidence will not apply, no motions or objections relating to the admissibility of evidence will be received, and almost any type of information,

oral or written, may be introduced. The regulations purport to allow parties the right to reasonable cross-examination of any person who makes a statement at the hearing, but since written evidence is fully admissible, this right is, as a practical matter, meaningless. No one has yet invented the technique for cross-examining a document. In practice, the documents introduced to support the initial decision will almost certainly have been created by the usual bureaucratic procedures under which dozens of people take part in drafting the document and no one will take responsibility for it. In the microwave oven case, this approach made it impossible to conduct any meaningful inquiry into the basis behind the statements contained in the documents introduced by the Bureau of Radiological Health.

The purported right of cross-examination set forth in the regulations also has one other peculiarity. The regulations do not state whether cross-examination must be conducted by an attorney, or whether the parties can use one expert to cross-examine another. This peculiar situation in fact arose during the microwave oven proceeding, and resulted in an absurd situation in which a totally confused hearing officer was forced to listen to two engineers exchanging totally incomprehensible views about a totally irrelevant subject. The parties certainly should plan their presentations to avoid such a result.

The rules also contain one other strange provision. Unless the hearing is ordered closed to the public because certain types of sensitive information will be discussed, the public may attend and may participate by presenting evidence. Apparently, public participants are not allowed to cross-examine the parties, although they are subject to cross-examination themselves. However, no provision is made for advance notice concerning the content of the presentations to be made by public participants, and accordingly the parties will not know if, and how, members of the public intend to expand the scope of a proceeding before the day of the hearing.

Decision

After the close of the hearing, the presiding officer is required to put together a record. It consists of the written data submitted, the transcript, any additional information the presiding officer agrees to receive, and a report which the presiding officer is required to

prepare. The parties are supposed to have an opportunity to comment on the presiding officer's report, although the regulations provide that this right may be withdrawn if the need for rapid decision so requires. The report also must contain findings on the credibility of witnesses and a recommended decision, unless the Commissioner has previously directed that the report not contain such items. The report is then forwarded to the office responsible for making a final decision, and the final decision is then made, presumably by endorsement on the presiding officer's report. This final decision is supposed to be based on the record developed by the presiding officer.

Reconsideration, Stay, and Judicial Review

The regulations categorize the decision reached after a Subpart F hearing as "final Agency action," but they also provide that the Commissioner may be asked to reconsider or to stay the decision. Presumably, if judicial review is to be sought, the stay provision should be utilized, although bypassing it might not be fatal.

The success of the Subpart F experiment will not be known until someone seeks to exercise this right to obtain judicial review. As I have already indicated, the main purpose of the Subpart F experiment was to avoid trials *de novo* in the district courts. I would suspect that some private party some day will claim that the procedural safeguards supposedly provided by Subpart F are inadequate, and that he is nevertheless entitled to a trial *de novo* notwithstanding the availability of the Subpart F procedures.

I would not want to hazard a guess at this early stage about how the courts will treat such a claim. Presumably, their willingness to permit a trial *de novo* will depend upon the particular facts of the case before them, and most importantly upon the ability of the petitioner to show that he was injured by certain inadequacies in the procedures. I would think that the short time deadlines, the lack of any opportunity for discovery, the meaningless nature of the cross-examination right, and any inadequacies in the notices provided to the affected private parties will be the most crucial factors in a court's mind.

Only further experience will demonstrate how these matters will be handled in practice. If presiding officers are fair and open-minded, Subpart F may have a chance to succeed. In any event, it is an interesting experiment, and one which is worth watching.

[The End]

Property Rights in the Color and Shape of Capsules

By HOUSTON L. SWENSON

Mr. Swenson Is Trademark Counsel for Eli Lilly and Company.

WITH MY BACKGROUND in trademarks, you may have surmised that I am going to be dealing with the problem of look-alike tablets and capsules on a trademark basis. This is not quite the whole picture for I'm going to center my comments on the larger scope of unfair competition that embodies the law of trademarks.

Trademark registrations have occasionally been granted on a particular type of a capsule or tablet. These have been fairly well limited, though, to rather unique appearing arrangements. Registrations have been granted for the band about the middle of the Parke Davis capsules. A registration has also been granted for the truncated conical ends on the SKF capsule. Likewise, a trademark registration has been granted for the parabolic end of the Lilly capsule. However, to the best of my knowledge, no U. S. trademark registration has been granted for a capsule having one half colored, for example, yellow and the other half colored green. Likewise, I am unaware of any registration granted for a conventionally shaped tablet that has two colored sections. However, it should be pointed out that if a particular color design of a distinctive nature such as concentric circles is placed on a tablet or capsule a trademark registration might be possible. But in general the look-alikes that we're concerned about today do not involve features of this type.

The practice of copying another's goods in order to achieve a greater amount of commercial success dates back centuries. To some degree this has been controlled by our patent and copyright laws. But it is our unfair competition laws, based primarily on common law rights, which are most relevant to us. Although this field of law pertaining to look-alikes in the pharmaceutical industry follows the

general doctrines laid out in other industries, I think there are some rather distinct twists that occur which have troubled the courts. There are three, not two, parties involved in the retail sale of a prescription drug. Which party is in the best position to know if there is a deception? The patient is not necessarily knowledgeable about the drug that is being dispensed. He may not even know the manufacturer's name. The physician, whose instructions may barely be legible, is not in a position to see that they are carried out. The patient rarely shows the physician the item dispensed by the pharmacist. It is this triangular arrangement that has caused some intricate criteria to be added to the law of unfair competition dealing with look-alikes in pharmaceuticals that I am going to concentrate on here.

Court Decisions

Can an imitator lawfully duplicate a liquid form of quinine, even to the extent of using chocolate to give it the same color and flavor as the original product? The U. S. Supreme Court in 1924 stated that Eli Lilly and Company could not enjoin the William R. Warner Company from duplicating a chocolate flavored quinine product.[1] However, certain conditions were set forth by the Supreme Court. In this case, Lilly had been marketing a quinine product and found that to make it palatable, chocolate should be added. This caused the product to become colored brown as well as carrying the chocolate flavor. Several years after the introduction of this product, the William R. Warner Company introduced its product that was prepared in a similar manner. Lilly attempted to enjoin this practice on the basis of unfair competition.

The Court found that the chocolate ingredient was not a nonfunctional item and in fact not only imparted a distinctive color and flavor but also served as a medium to suspend the quinine and prevent its precipitation. Consequently, the Court ruled that the color brown did not serve as an identifying mark for plaintiff's product. It concluded that anyone could make this identical product but that the public should be aware of the duplication. It then proceeded to require the defendant to make a warning that in a sense was something of a disclaimer statement. It had been shown that defendant's salesmen had suggested to pharmacists that they might be able to substitute their product for Lilly's. Thus, the Supreme Court required the defendant to place warning labels on the bulk size bottles sold to pharmacists.

[1] *William R. Warner & Co. v. Eli Lilly & Co.*, 265 U. S. 526 (1924).

The warning stated that the defendant's preparation was not to be sold or dispensed as Lilly's nor should it be used in filling prescriptions for Lilly's drug. I think this kind of warning is somewhat ineffective and tends to draw the pharmacist's attention to the fact that here is a product at a lower cost that is similar to the Lilly product. Nevertheless, as we will see from some other cases, this type of warning was adopted by several other courts.

Can a party use identically colored cream and brown capsules containing the chemically equivalent drug and promote it as being similar to the original drug? In 1936, the New York Court of Appeals found in favor of the plaintiff, Martin H. Smith Company, which had shown that the defendant's selling agent had been writing a "similar to" statement referring to plaintiff's products on the look-alike drug's labels.[2] This inducement by defendant's salesmen was the influencing factor and the Court of Appeals granted an injunction against the marketing of this look-alike capsule. It is interesting to note that there was no reference made to the *Lilly/Warner* Supreme Court decision of twelve years earlier.

What remedy will the court use when defendant has copied plaintiff's round white tablets with similar beveled edges and scorings and orally suggested through its salesmen that substitution was possible? Smith, Kline and French Laboratories, in suing Clark and Clark in the District Court of New Jersey, received a remedy that had some similarity to the *Lilly/Warner* case.[3] The court noted that defendant's salesmen had suggested to pharmacies that its product could be substituted for the plaintiff's product. The Court of Appeals recognized this as being an unfair practice. It took into consideration the ruling of the *Lilly/Warner* case and decided that the placing of the defendant's initials, "C and C" on the tablets would be sufficient to disassociate them from plaintiff's products. It expressly refused to grant a permanent injunction that would go beyond the expiration of the patent covering plaintiff's product. Perhaps the Court viewed warning statements as potential inducements to substitute. The ruling suggests that the Court felt it would be better to advise the patient on the source of the drug. As to whether or not the stamping of the letters "C and C" on the tablets could accomplish this job I leave for your own conjecture.

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[2] *Martin H. Smith Co. v. American Pharmaceutical Co.*, 270 N. Y. 2d 184, 200 N. E. 779 (1936).

[3] *Smith, Kline & French Laboratories v. Clark & Clark*, 157 F. 2d 725 (CA-3 1946).

What remedy might you expect to receive for stopping the promotion of look-alike drugs with comparison cards? In 1957, comparison advertising was not in the state of art that it is today. The Upjohn Company objected to the practices of one David Schwartz doing business as Bryant Pharmaceutical Company and filed for trademark infringement and unfair competition in a district court of New York.[4] Eight drug preparations were involved and in each instance the defendant had copied the same size of capsule or tablet and the same color. The lower court ruled in favor of defendant on the basis that there had been no proof of instances of actual palming-off of defendant's drugs in place of plaintiff's drugs. However, the Court of Appeals observed that the defendant had distributed cards which had a listing of its products with a blank line along each listed product on which one of defendant's salesmen had written the name of plaintiff's corresponding products. This was interpreted as being an aid to the druggist in making substitutions. The court then ruled that the lower court had erred in requiring proof that the druggists substituted since the defendants had at least made it possible for them to substitute. The *Lilly/Warner* case was taken into account and the defendants were enjoined from selling the look-alike products unless a statement was attached to the bottles that the contents therein were not to be sold or dispensed as the products of plaintiff. In connection with the non-prescription look-alike drugs, the court said that such a warning was not needed since the customers would be able to make their own observation and selection of the drugs.

Secondary Meaning

In each of the foregoing cases the courts first ruled that the plaintiff's drugs had not acquired a secondary meaning on the basis of their product's color and shape. A clear understanding of secondary meaning is difficult to grasp. However, one of my favorite examples is to ask a person what he visualizes when he hears the national park, Yellowstone National Park mentioned. A large majority of people responding to this question will immediately state "Old Faithful Geyser" and ignore the clear meaning of the title of the park. Yellowstone Park has a large quantity of yellow stone in its canyons. Consequently, I contend that Yellowstone Park as a title has clearly achieved a secondary meaning that goes far beyond its descriptive connotation. Thus, a non-functional word or device that initially con-

[4] *The Upjohn Co. v. Schwartz,* 246 F. 2d 254 (CA-2 1957).

veys a descriptive meaning, and which through extensive use and promotion, acquires a new significance as an indication of origin, is a trademark based on this secondary meaning.

If the look-alike drug is an over-the-counter drug, will it be enjoined if the color for the liquid contents is non-functional, unlike the situation where functional chocolate was added to the quinine produced by Lilly? In 1959, Norwich Pharmacal Company filed an unfair competition action against Sterling Drug on the basis of its well known PEPTO-BISMOL product that is marketed in a bottle which clearly shows its pink color.[5] The lower court had found that a public opinion survey showed that the pink color of PEPTO-BISMOL had acquired a secondary meaning. However, the appellate court concluded that this survey merely showed the popularity of plaintiff's product and refused to enjoin the imitation pink product. It concluded that an imitation without a finding of a secondary meaning or a predatory practice is permissible. A distinction to keep in mind on this case is that it involved non-prescription drugs packaged in their finished form. Thus, the purchasers or patients were in a position to fully examine the origin of each drug. Since the packaging of the defendant's look-alike drug differed in all respects the court concluded there was not any real likelihood of confusion from the use of an identical color.

Predatory Practices

Does a comparison catalog listing the plaintiff's drug alongside the defendant's look-alike brown and clear capsule drug with a statement of "for your reference and reminder" amount to a predatory practice? Marion Labs in its 1972 suit against Michigan Pharmacal Corporation was told "No."[6] This suit was based on alleged acts of unfair competition in that the defendant was marketing a chemically equivalent drug in capsules that were identical to the brown and clear capsules used by plaintiff for a number of years. The court found defendant's catalog to be acceptable despite its comparison reference to plaintiff's drug. It was noted that the catalog did not make any reference to similarity in colors. Nor was there any evidence produced showing that actual substitution or inducement by defendant to substitute had been made. The capsule was held to not have acquired a secondary meaning prior to the introduction of the defendant's capsules and since no predatory practice was proven an injunction was refused.

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[5] *The Norwich Pharmacal Co. v. Sterling Drug Inc.*, 271 F. 2d 569 (CA-2 1959).

[6] *Marion Laboratories, Inc. v. Michigan Pharmacal Corp.*, 338 F. Supp. 762 (DC Mich. 1972).

If, in the foregoing case substitution by pharmacists had been proven could the plaintiff have obtained an injunction? Perhaps so, or at least a preliminary injunction. In March of this year, Merrell-National Laboratories obtained a preliminary injunction against Zenith Laboratories and Paramount Surgical Supply Corp.[7] The look-alike products were chemically similar to the diet tablets marketed by plaintiff and were being promoted as comparable to or similar to plaintiff's products. One dosage size of the tablets is circular with beveled edges and blue. The larger dosage size is an elongated tablet with beveled edges and white. Both tablets bear plaintiff's trademark MERRELL and an identification number. The look-alike tablets did not bear any mark or number. However, unlike the *Marion Labs* case, plaintiff showed nine instances of passing off by pharmacists who were included as defendants in the action.

Unfair Competition Laws

Now, it should be pointed out that in 1964 the U. S. Supreme Court came out with its famous *Sears v. Stiffel*[8] and *Compco v. Day-Brite*[9] decisions. These cases held that states under unfair competition laws cannot give protection of a kind that clashes with the objectives of the federal patent laws. However, the courts since 1964 have consistently held that two areas remain for the operation of state unfair competition laws. In the *Marion Labs* case the courts said that unfair competition can still be based on palming-off and the protection of non-functional features if the state has a policy requiring the copier to take precautions to prevent confusion as to his product's source. Plaintiff in the *Merrell-National* case was not pre-empted by federal statutes and upon showing evidence of palming-off was entitled to a preliminary injunction.

Your attention should also be directed to Section 43(a) of the 1946 Trademark Act. In the last 15 years this section has become recognized as the federal law on unfair competition. Its references to the use of a false designation of origin or any false description or representation including words or other symbols tending falsely to describe or represent the same have been given fairly broad treatment in the courts within the last several years. If a plaintiff can show that the appearance of the look-alike drug is tantamount to being a

[7] *Merrell-National Laboratories, Inc. v. Zenith Laboratories, Inc.*, No. 76-2440 (DC NJ March 8, 1977) (order granting preliminary injunction).

[8] *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U. S. 225 (1964).

[9] *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964).

false designation of origin he certainly stands an excellent chance of prevailing under Section 43(a). I would equate this to the requisite of showing a secondary meaning when no predatory practice has been proven.

Conclusion

To sum up the various factors considered by the courts in the previously mentioned cases, it is apparent that the courts are going to first ask as to whether or not the particular tablet or capsule that is being imitated has any non-functional distinctive feature that has acquired a secondary meaning. If the finding is in the affirmative an injunction is likely to be granted. The distinctive feature is a trademark and is infringed even though not registered as a trademark. The courts will also ask about the existence of predatory practices. It appears that this may vary in degree and that in some instances evidence showing that druggists have substituted will be sufficient by itself. However, I think you can expect that in many jurisdictions the courts will require evidence showing that the defendants themselves have either committed or induced substitutions. Such inducement might be sufficiently proven in the form of comparison catalogs. The remedy granted may be an injunction but if the courts look back about 10 years they will observe that in some instances the remedy has been limited to a warning statement or merely the placing of a legend on the defendant's tablet. In my opinion, these are remedies that are somewhat superficial and I do not expect them to become popular in those jurisdictions where substitution is not popular.

Although none of the cases I have discussed were involved with state laws permitting substitutions, I'd like to speculate on what the courts might hold in such states. Predatory practices will become less significant except if there is an actual mis-marking or other fully deceitful practice performed by the distributor of the drug or the retailer. This means then that the courts will be primarily considering whether the tablet or capsule has a secondary meaning. Secondary meanings are not easily proven and it behooves the manufacturers to consider the possibility of making their tablets or capsules with more ornate, distinctive features if they wish to prevent look-alikes. In short, I feel that the future for stopping look-alikes may be a bit gloomy as more states repeal their anti-substitution laws but not necessarily hopeless.

I do not intend to plead the case for the imitator but I will point out one of his major reasons given for producing a look-alike product. Some patients are on a daily regimen of a particular drug for a number

of years. The arthritic patient becomes quite familiar with the tablet that he takes day after day. Thus, imitators point out that if a patient is suddenly receiving a drug that looks different from one that he has become familiar with he will feel that he has not received the same chemical. In my opinion, this position suggests that the pharmacist is intending to do something other than what the repeal of anti-substitution laws has meant to accomplish. Those advocating free substitution of chemically equivalent drugs do so on the premise that the patient can save large amounts of money. Now, if this is true, the pharmacist who is passing on a savings to the patient is very likely to advise the patient that he is receiving a substitute. Surely the pharmacist would want to point this out in order to let the patient know that so many cents or dollars have been saved by the substitution. I feel that once the patient is advised that a substitution has occurred and that he has nevertheless received the same chemical composition, he will not be concerned about finding his tablet is of a different color or of a different shape. Most persons realize that the colors of capsules and tablets are not necessarily the colors of the drugs. Certainly if the pharmacist is pointing out to the patient that substitution has occurred it would be quite easy for him to reassure the nervous patient that the color is different but of no significance.

On the other hand, if the pharmacist is not pointing out to the patient that substitution has occurred, one might ask, "Why?" Is it possible that the savings alleged to be available by advocates of anti-substitution repeal are not actually occurring? If the courts are presently finding predatory practices in the form of illegal substitutions, I suggest that they will also be inquiring about the passing on of cost savings to the patient in those states permitting substitution. Proof of a pharmacist failing to pass on a savings would seem to be relevant in determining the existence of unfair competition. Therefore, even in those states where substitution is permitted, the look-alike drug can still serve as an instrumentality of fraud and will run the risk of an injunction. **[The End]**

Participating in a TRR

By PAUL M. HYMAN

Mr. Hyman Is a Member of the Law Firm of Rogers, Hoge & Hills.

TO THOSE FAMILIAR with some of the Food and Drug Administration's (FDA's) marathon rulemaking proceedings, the Federal Trade Commission's (FTC's) Trade Regulation Rules (TRRs) may not seem so formidable. Certainly none of the current proposed TRRs seems likely to last 17 years and still not be finally resolved, as are the FDA's special dietary foods regulations.[1]

But in their unnecessary breadth, vagueness of procedures and opportunities for court challenge, the TRRs, especially those dealing with food and over-the-counter (OTC) drug advertising, appear to be direct descendants of the FDA regulations—sort of a "son of dietary foods hearings" or, more modestly, a "grandson of peanut butter hearings." In fact, the three-phase food advertising TRR conceivably could begin to rival the FDA hearings for time and complexity before it is finally promulgated or otherwise laid to rest.[2]

These new rulemaking proceedings have created new challenges for those who wish to—or must—participate in them. Since the TRR is still in its early stages of procedural development, much of the activity must be regarded as experimental by both government and private participants. With each new proposed TRR and each new hearing, the FTC staff and others affected by such rules hopefully are learning to improve and refine the procedures in order to try to fashion the appropriate fact-finding mechanisms intended by Congress.

That there is still a long way to go probably will not be denied by anyone familiar with TRR procedures and practices today. At

[1] 21 CFR Parts 80.1 and 125. See, *e.g.*, Hamilton, R., "Rulemaking on a Record by the Food and Drug Administration," 50 *Tex. L. Rev.* 1132 (1972).

[2] Food Advertising, Proposed Trade Regulation Rule and Staff Statement, 39 *F. R.* 39842 (Nov. 11, 1974); Republished proposal, 40 *F. R.* 23086 (May 28, 1975); Final Notice, 41 *F. R.* 8980 (March 2, 1976).

least two important sources of input into the procedures still have yet to be heard from—the Commission and the courts. Since passage of the Magnuson-Moss—Federal Trade Commission Improvements Act,[3] which explicitly authorized the FTC to promulgate TRRs, no final rule has been issued by the Commission or appealed to the courts.

Thus, we are dealing today with a great number of unresolved legal, procedural and factual issues. My discussion of participation in a TRR must be seen in that context—as a description of actions at a particular point in time, hopefully subject to change for the better as experience is gained with the procedures.

Practice and Procedure

It is necessary first to review briefly the statute and the FTC's rules of practice and procedure. These provide the general guidelines for participating in a TRR. They are, as well, the sources of inherent conflict in the TRR proceeding between the desire for informality and the need to protect the rights of the regulated.

The Magnuson-Moss—FTC Improvement Act expressly authorizes the FTC to "prescribe . . . rules which define with specificity acts or practices which are unfair or deceptive" within the meaning of Section 5(a)(1) of the FTC Act.[4] This authority clarified the legal situation surrounding several pending or final TRR's that the FTC had proposed and justified under existing law.[5]

At the same time, Congress expressly prescribed rulemaking procedures intended to replace the "inadequate" notice-and-comment informal rulemaking used by the FTC in the earlier TRRs.[6] While avoiding a formal, trial-type rulemaking, Congress fashioned a hybrid procedure which would blend what it deemed to be the most desirable features of formal and informal rulemaking requirements.

Specifically, the FTC must follow the informal rulemaking provisions of the Administrative Procedure Act, providing notice and an opportunity for interested persons to file written comments on a proposed TRR.[7]

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[3] P. L. No. 93-637, Jan. 4, 1975.

[4] Sec. 18(a)(1)(B) of the Federal Trade Commission Act, 15 U. S. C. 57a(a)(1)(B), as amended (hereinafter FTC Act Sec. —).

[5] H. R. Rep. No. 93-1107, 93rd Cong., 2d Sess. 32-3 (1974) (hereinafter House Report). And see *National Petroleum Refiners Ass'n v. FTC*, 482 F. 2d 672 (CA D of C 1973), *cert. denied* 415 U. S. 951 (1974).

[6] House Report at 33.

[7] FTC Act Sec. 18(b); Administrative Procedure Act, 5 U. S. C. Sec. 553.

But the agency must also provide an opportunity for an "informal hearing" and must permit interested persons to conduct (or have conducted) cross-examination and to submit rebuttal on any "disputed issues of material fact . . . necessary to resolve."[8] Failure to permit cross-examination or rebuttal which "has precluded disclosure of material facts" is an explicit ground for reversal by a reviewing court.[9] The rule must also be based upon "substantial evidence in the rulemaking record . . . taken as a whole," a requirement usually associated with formal rulemaking.[10]

Having established these relatively formal procedural rights, however, Congress then permitted the FTC to limit the free exercise of those rights in order "to avoid unnecessary costs or delay."[11] Thus, the FTC may place time limits on oral testimony, may require cross-examination to be conducted by the Commission or its representatives, and may force persons with the "same or similar" interests into groups with a single representative chosen to conduct cross-examination. These provisions have become sources of great friction as well as confusion in the proceedings.

The result of these statutory requirements is a proceeding that seems to resemble a legislative hearing rather than rulemaking or a trial. This is undoubtedly not accidental, for despite the opportunities for participation by other parties, the FTC is sitting as a legislature in promulgating the broad, industry-wide rule that it proposes. Whether participants will have a real opportunity to influence that "legislation" remains to be seen, as does the ultimate reception of the TRR by the courts.

The FTC's procedural rules add some refinements to the statutory procedures.[12] Perhaps most important is the role given to the Presiding Officer to conduct the proceeding. The Presiding Officer, who is a member of the Bureau of Consumer Protection staff and is not an objective administrative law judge, is responsible for such things as designating the disputed issues of material fact; placing participants in groups, and, if necessary, choosing a group representative; conducting the hearing; making virtually all legal and procedural rulings and controlling the right to appeal to the Commission by the need to obtain his certification (only review of the designated issues may be sought without such certification); and providing the Commission with a summary of the record and findings and conclusions as to dis-

[8] FTC Act Sec. 18(b) and (c)(1).
[9] FTC Act Sec. 18(e)(3)(B).
[10] FTC Act Sec. 18(e)(3)(A).
[11] FTC Act Sec. 18(c)(2).
[12] 16 CFR Subpart B.

puted issues.[13] The Presiding Officer is also authorized to subpoena witnesses and documents,[14] but, to my knowledge, this authority has yet to be exercised by any such Presiding Officer.

The procedural rules also provide the Presiding Officer with further criteria for restricting cross-examination beyond the general strictures of the statute.[15] To their credit, the Presiding Officers have invoked those criteria on only rare occasions.

Promulgating a TRR

Let me now turn to the procedures involved in promulgating a TRR. While I shall briefly sketch the chronology, I shall try to focus primarily on those aspects that are unique to a TRR proceeding.

Following investigation and drafting by the staff, approval by the Bureau of Consumer Protection Director and the Commission, the proceeding commences with publication of an initial notice of rulemaking.[16] This normally includes a proposed rule (although the antacid TRR contains none), the legal authority for the rule, a statement of reasons, an invitation for interested persons to propose disputed issues of material fact within 60 days, and an invitation to submit written comments. The notice may also include questions concerning the proposal that the Commission deems pertinent. The Presiding Officer is also named at this time.

Any person may participate at this stage, which may be regarded as the informal rulemaking stage, by submitting disputed issues of fact and/or written comments. In practice, such participation is usually handled by the interested party internally. However, in most of the industry-wide proceedings, major industry trade associations as well as companies have already begun their preparation for the hearing.

The concept of "disputed issues of material fact . . . necessary to resolve" is a statutory innovation of the Magnuson-Moss Act for administrative procedures. "Genuine issues of material fact" are, of course, not new to civil litigation, where the existence of such issues determines whether or not summary judgment is appropriate.[17] Indeed, the legislative history shows that Congress "considers the rules of summary judgment applied by the courts analogous" to the phrase "disputed issues of material fact."[18]

[13] 16 CFR Sec. 1.13(c).
[14] 16 CFR Sec. 1.13(c)(1)(vi).
[15] 16 CFR Sec. 1.13(d)(5).
[16] 16 CFR Sec. 1.11.
[17] Rule 56, F. R. Civ. P., 28 U. S. C.
[18] House Report at 46.

Nor are such issues foreign to administrative law, where such agencies as the FDA have been able to avoid holding hearings where they could convince a court that no such material issue of fact exists.[19]

However, in the TRR proceedings such disputed issues are not used to avoid a hearing but are intended to be criteria for exercising the right to cross-examine and to present rebuttal.[20] They are also used to group participants by interest.

Because of the apparent importance of these issues—and because the FTC has proposed such broad rules—interested persons have recommended literally hundred of disputed issues in pending proceedings. However, the Presiding Officers have invariably chosen only a few broadly worded issues, usually fewer than 30.[21] In the OTC advertising rule, only three issues of a very broad and almost "synonymous" nature were designated.[22]

Despite their statutory importance, however, in practice the designated issues may not significantly affect the conduct of the hearing or the ultimate resolution of the rule. They have only infrequently been used to restrict cross-examination and their generality would seem to offer little help to the FTC in directing support for a rule. Undoubtedly, their role will one day be clarified by the courts.

After reviewing the proposed issues, the Presiding Officer publishes a final notice which includes: (1) the designated issues of fact; (2) hearing schedules; (3) instructions to potential witnesses; and (4) notice to "interested persons" to notify the Presiding Officer of their interest in particular issues and of his intent to group persons with the "same or similar" interests.[23]

Participating in a Hearing

At this point, a decision must be made as to whether or not to participate in the hearing stage of the proceeding, since only those who file a notice of interest may be active participants thereafter.

Of course, failure to note interest does not preclude companies from being represented by or assisting participating trade associations of which they are members. Conversely, notification of interest does not

[19] *E.g., Weinberger v. Hynson, Westcott and Dunning*, 412 U. S. 609 (1973).

[20] FTC Act Sec. 18(e)(1)(B); 16 CFR Sec. 1.13(d)(5) and (6); House Report at 46.

[21] See, *e.g.*, Final Notice in Food Advertising TRR, 41 *F. R.* 8980 (Mar. 2, 1976) (27 issues).

[22] Final Notice, 41 *F. R.* 39768 (Sept. 16, 1976).

[23] 16 CFR Sec. 1.12.

necessarily commit or entitle a firm to any particular course of action. The requirement of grouping often can act to relieve a firm from the need for constant active participation, if it so desires, or to prevent the firm from fully exercising its right to cross-examine.

The decision on whether to participate at hearing depends upon the weighing of such factors as the importance of the rule to the person, the likelihood that the person's interest will be adequately represented by others, the resources available, and the person's willingness to accept the risk of publicity for opposing a TRR.

After he receives the notifications of interest, the Presiding Officer advises interested persons of their groups and invites each group to select a representative. If the group fails to select a representative on its own, the Presiding Officer is authorized to select one.[24] A single representative is not always required, and alternates may be named. The representative may be the party, counsel for one party, or even counsel specially retained by the entire group. The most important requirement, as far as Presiding Officers are concerned, is that the group representatives be available and completely informed on the proceedings.

The grouping of parties with the "same or similar" interests is another unique aspect of the TRR procedures.[25] Thus, while agencies such as the FDA encourage participants with similar interests to present testimony through a coordinated group representative,[26] to my knowledge, none has restricted cross-examination to such representative. It will be interesting to see whether the statutory concept in the Magnuson-Moss Act survives a challenge on the basis of denial of due process.

Group Representation

The grouping concept can create some significant problems for participants who wish to take an active role in the hearing. The first problem the participant faces is to state his interest in a particular issue so as to avoid being placed in a group that actually does not share his interest. The group may, for example, have such broad interests that they may conflict with a participant's single or narrow interest. There may also be competing participants for the role of group representative.

[24] FTC Act Sec. 18(c)(3)(B); 16 CFR Sec. 1.13(d)(5)(ii).

[25] FTC Act Sec. 18(c)(3).

[26] Public Hearing Before the Commissioner, 21 CFR Sec. 15.21(b).

To date, few significant problems apparently have arisen which have interfered with the conduct of a hearing. The broad scope and impact of most rules have required trade associations to participate actively and they tend to be the natural representatives for many groups. In addition, Presiding Officers have been relatively liberal in permitting alternates to cross-examine and, where time has permitted or the facts required, in permitting individual firms to conduct cross-examination on their own interests. However, problems have arisen in the course of some proceedings which may well lead to court review of the grouping issue.

In the advertising proceedings, groups have generally been formed of the manufacturing interests, the advertising and media interests, the FTC staff and a so-called "consumer" group. In the food advertising case, there was another group representing the health food industry and three further subgroups who basically litigated a single issue involving the advertising of fat and cholesterol content in food.

The problems with group representation are not unique to industry, and may be worse for the so-called consumer groups. The question must arise of whether there can be a single consumer interest in any TRR proceeding. Consumers surely must have divergent interests, with some more concerned about economic effects of a rule; others about environmental factors, etc. Yet, the Presiding Officer must determine who represents the consumer.

As usual, in practice this has not been too great a problem since only a few consumer organizations are actively involved in most proceedings. With aid from government grants, these organizations have been willing and able to participate as fully as industry parties.

That raises another unique aspect of the TRR, the Magnuson-Moss Act authority to compensate participants in a proceeding who will represent material interests that will not otherwise be adequately represented.[27] This provision places the FTC in the forefront of the current movement to compensate consumer groups and others who purport to represent the public interest in administrative proceedings.[28] Interestingly, the Act permits the FTC to grant up to 25 percent of the funds to members of the potentially regulated industry, who otherwise meet the criteria of interest and need.[29]

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[27] FTC Act Sec 18(h).

[28] See, *e.g.*, FDA proposal to provide funding for public interest and consumer groups in regulatory proceedings, 41 *F. R.* 35855 (Aug. 25, 1976).

[29] FTC Act Sec. 18(h)(2).

In practice, the FTC has used this authority to insure legal representation of consumers in TRR proceedings and to help certain consumer groups to prepare testimony and evidence for presentation in hearings. In the food advertising TRR, the FTC authorized funds for expert groups to suggest revisions of the proposal. It has also granted a substantial sum to a group to present testimony on the impact of the rule on children's advertising, even though children's advertising was neither a specific part of the rule nor a disputed issue in the hearings.

The FTC's procedures to award compensation require, among other things, that the applicant demonstrate that he represents an interest not otherwise adequately represented, but which is necessary for a fair determination of the proceeding.[30] The applicant must also demonstrate that he cannot participate effectively without financial assistance. This may well eliminate most industry applicants. There is no express provision for objection by other interested persons.

The actual decision is made by the Presiding Officer and the Director of the Bureau of Consumer Protection. This raises the interesting possibility that the FTC staff can help to support its position by appropriate awards of compensation.

In any event, Congress has been reviewing the FTC's compensation procedures to be certain that the money has been appropriately granted and to determine whether similar provisions should apply to other administrative agencies.[31]

Prehearing Conference

The next step generally is an informal pre-hearing conference where final procedures are worked out for the hearings. Procedures for distributing witness statements in advance of hearing, scheduling and other problems are generally discussed. The Presiding Officer also uses the pre-hearing conference to advise participants of the groundrules for the hearing, stressing heavily its informality and the inapplicability of the rules of evidence.

Written comments may be filed by any interested person, whether or not a participant in the hearing, up to 45 days before the first day of the hearings. Officially, the record is then closed to outsiders, but in practice a great number of other documents somehow manage to get into the record by one means or another.

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[30] 16 CFR Sec. 1.17.

[31] Senate Bill S. 270, 95th Cong., 1st Sess.

The hearing itself is usually a lengthy, often a dull and repetitious proceeding. Prior hearings were often divided into several regional hearings. For example, Phase 1 of the food advertising TRR had 48 days of hearings in four locations.[32] In the recent OTC advertising TRR only a single, five-week hearing was held in Washington and this reportedly will be the general rule in the future proceedings.

At the hearings, witnesses, who have filed their statements or "detailed outlines" in advance, appear and present their testimony either in a narrative form or in question and answer examination by counsel whose interests they represent. They are not under oath nor has their attendance normally been compelled by subpoena.

Although Presiding Officers frequently disclaim that the proceedings are adversary in nature, they do recognize competing interests by having the party who presents the witness or a group representative whose interests the witness most nearly represents conduct "direct" examination briefly to clarify any points made in the statement. Then opposing group representatives may cross-examine the witness. While cross-examination is supposed to be limited only to those disputed issues designated in the final notice, Presiding Officers usually are liberal in permitting a broader range of cross-examination if time allows. Attacks on a witness' credibility or even qualifications, however, are usually not permitted.

Cross-examination by individual participants sometimes must be preceded by a request and a showing to the Presiding Officer that they have an interest that is not otherwise being adequately represented. Where time permits, Presiding Officers are usually more liberal in this regard than where there is a tight schedule.

The unique importance of cross-examination must be recognized. There are very difficult competing statutory interests which must be judged in the context of each individual hearing. While the Presiding Officers have tried to be extremely liberal in permitting cross-examination, they have not fully satisfied participants in many of the proceedings. Thus, it is inevitable that the issue of adequate cross-examination in TRR proceedings will be presented to a court in the near future. Exactly how a court will balance the statutory contradictions cannot be predicted at this time. However, some indication of at least one court's view of that right may be seen in the Second Circuit Court of Appeals' remand a few years ago of the FDA special dietary foods

[32] San Francisco, July 12-23, 1976; Chicago, Sept. 13-17, 1976; Dallas, Oct. 12-15, 1976; Washington, D. C., Nov. 15, 1976 through Jan. 12, 1977.

regulations for failure of the hearing examiner to grant adequate cross-examination to one party, even in the absence of a statutory requirement.[33]

Despite the fact that the rules of evidence do not apply, objections are often entertained, if not usually granted. Where the Presiding Officer agrees, he may dispute the right to object but still grant the relief sought. Otherwise, there seems to be an overwhelming tendency to let any information in and to leave to the Commission the task of determining the weight to be given such evidence.

There is also a statutory right to present rebuttal, although the exact time and procedure for such rebuttal varies with the proceeding. In some instances, oral rebuttal may be permitted at the hearing, provided that some notice is given as to the substance of the testimony. Written rebuttal is always permitted at any time during the hearing and for a period of time after the close of the hearing. Sur-rebuttal may also be permitted, but is a matter within the discretion of the Presiding Officer.

Under the rules and the statute, rebuttal should only be presented by interested persons who participated in the hearings.[34] In practice, rebuttal has been presented by witnesses and even by individuals who at least purport not to have any connection with any of the participants.

Conclusions of the Commission

After the hearing record is closed, the Presiding Officer prepares a summary of the record and his findings and conclusions with respect to the disputed issues and to any other issues he sees fit.[35] The FTC staff then prepares its report and recommendations to the Commission, based on the record and the Presiding Officer's findings.[36] After the staff report is available, the record is opened for 60 days for public comment on the Presiding Officer's findings and the staff report, based on information in the record.[37] Presumably, the comments may include a request for oral argument before the Commission if desired. At this point, the procedural rules appear to open up the proceeding again to the public at large and comments may be filed by persons who have not otherwise participated in the hearings.

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[33] *National Nutritional Foods Ass'n v. FDA*, 504 F. 2d 761 (CA-2 1974), *cert. denied* 420 U. S. 946 (1975).

[34] FTC Act Sec. 18(c)(1)(B); 16 CFR Sec. 1.13(d)(5).

[35] 16 CFR Sec. 1.13(f).

[36] 16 CFR Sec. 1.13(g).

[37] 16 CFR Sec. 1.13(h).

The Commission then reviews the record, which includes not only all of the materials presented at the hearing and afterwards, but all written comments and any other materials placed in the rulemaking record.[38] In fact, the statute provides that the Commission may also include "any other information which the Commission considers relevant to such rule."[39] The Commission may then issue, withdraw, or modify the rule. Within 60 days, any interested person, expressly including a consumer or consumer organization, may petition for review in a court of appeals.[40]

The entire proceeding is likely to take two years or more before the matter even reaches the courts. None has progressed beyond the post-hearing comments stage to date.

As this overview of participation in a TRR demonstrates, the TRR is still a new and developing form of administrative rulemaking. Those who are participating in such proceedings now will help to determine the procedures for future TRRs, as well as the outcome of their own rules. Given the obvious interest of the FTC in this rulemaking mechanism, we may expect many more opportunities to help in this maturation process. **[The End]**

COURT RESTRAINS INTERSTATE TRAFFIC OF LAETRILE

A federal district court has granted a preliminary injunction prohibiting a manufacturer of laetrile from shipping articles containing laetrile in interstate commerce or holding laetrile-containing articles that have been, or whose raw materials have been, in interstate commerce. Laetrile, or amygdalin, was a drug, a new drug, and a misbranded and adulterated drug, the court found, and the substance was an adulterated food because it contained cyanide. The testimony of lay witnesses as to the safety and efficacy of the alleged cancer treatment, based on personal experience, could not be admitted.

CCH Food Drug Cosmetic Law Reporter, ¶ 38,120

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[38] FTC Act Sec. 18(e)(1)(B); 16 CFR Sec. 1.18(a).

[39] *Id.*

[40] FTC Act Sec. 18(e)(1).

MORE TIME ALLOWED FOR FILING EXCEPTIONS TO REDUCED-CALORIE FOOD RULE

The August 18, 1977 deadline for filing exceptions to the Food and Drug Administration's (FDA's) tentative order concerning special dietary foods for use in reducing or maintaining body weight or caloric intake and for use by diabetics has been extended to October 18, 1977. The 60-day extension was granted by the FDA in response to a request from Markel, Hill & Byerley, the Grocery Manufacturers of America, Inc., and others who believe that the filing of meaningful exceptions would require more than the 30-day period originally offered.

Those requesting the extension stated that they do not intend to file merely cursory protests and that the extension is needed in view of the size of the record and the length of time since the closing of the hearing 15 years ago. In granting the extension, the Agency stated that exceptions must be specific in pointing out alleged errors in the findings of fact and tentative order and must refer to particular pages of the transcript of testimony and to particular exhibits on which the exceptions are based.

CCH Food Drug Cosmetic Law Reporter, ¶ 41,981

FDA TO WITHDRAW PROPOSED GMPs FOR BAKERY PRODUCTS

In testimony given before the House Subcommittee on Special Small Business Problems on August 3, 1977, Food and Drug Administration (FDA) Associate Commissioner for Compliance, Joseph Hile, announced his Agency's intention to withdraw its proposed good manufacturing practices (GMPs) regulations for bakery products. Other draft GMPs for specific products will be cancelled as well, and, in their place, the FDA will expand the basic "umbrella" GMP rule which applies to all food processing, Hile stated.

The FDA has issued advisory opinions confirming the applicability of alternative ingredient labeling declarations to certain bakery products. The opinions state that cake filling and icing, dough conditioners, leavening, and yeast ingredients may be declared as such in ingredient statements, followed in parentheses by a list of the specific ingredients in each category. According to Hile, this will avoid the necessity for the exact disclosure of the quantity of proprietary components, and will not impede the development of improved components.

CCH Food Drug Cosmetic Law Reporter, ¶ 42,016

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