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Food·Drug·Cosmetic Law JOURNAL

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

Product Liability—1975

. . . . . WILLIAM J. CONDON

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

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

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Food·Drug·Cosmetic Law
Journal

NAS-NRC GRAS List Survey (Phase III)— Incentives for Further Industry Cooperation and Participation

By ROBERT W. HARKINS, Ph.D.

Dr. Harkins Is Vice-President of Scientific Affairs of the Grocery Manufacturers of America, Inc.

A REVIEW OF THE TOPICS included in this workshop suggests that there are a number of reasons for the interest in the food additives survey. Curiosity: What are the National Academy of Sciences (NAS) and the Food and Drug Administration (FDA) planning? Skepticism: Why is a food additives survey necessary? Inevitability: If it is going to be, how can we make the food additives survey as easy as possible?

There is an expression which has been popular for the last few years: "There is no such thing as a free lunch." When it comes to regulatory questions in our increasingly complex regulatory world, there is no free lunch nor are there easy decisions. The adequacy of information is the largest component in the regulatory decision-making process. The more sketchy the information, the more treacherous and inadequate the resulting decision may be. Regulatory decisions on the safety of food ingredients have a variety of components, including:

(1) the existing food safety data base, including published and unpublished papers on the toxicological properties of the ingredient;

(2) usage information from manufacturers' recommendations, production data, market basket surveys, etc.;

(3) opinions of expert panels, the foremost being the Food and Agriculture Organization-World Health Organization Expert Committee on Food Additives, the Flavoring Extracts Manufacturers Association Expert Committee, plus a few others; and

(4) last and most critical is the triggering device—publication in the press of sketchy, unconfirmed, inevitably "preliminary" results that a particular ingredient is carcinogenic or that it causes birth defects or, perhaps, that it has been banned in Sweden, Japan or elsewhere.

These events can precipitate a regulatory crisis overnight. They receive instant coverage, such as comments on the floor of the House and the Senate, a whole 60 seconds of coverage on national news broadcasts, and calls for Congressional oversight hearings. This chant echoes in stereophonic, indeed quadrophonic, vibrations across the land. The rallying cry is: "If it is not proven safe, ban it." In this near-panic situation, decisions must be made, and decisions will be made on the basis of the then-available information.

Why should a corporation participate in a survey on the usage of food additives? How can corporate scientists moderate the regulatory environment? My thinking suggests the following major considerations:

(1) corporate public responsibility;

(2) corporate sunshine policy;

(3) corporate coordinates; and

(4) corporate auditing activity.

Corporate Public Responsibility

A deep sense of corporate public responsibility is perhaps an elusive explanation for participation in the survey. There are many companies which need no sales pitch and which understand their shared responsibility for maintaining a safe and wholesome food supply. To those companies, this presentation is unnecessary.

Others, however, may not have a history of joint participation in data-gathering projects. Certainly, there are expenses. Certainly, there

are risks in sharing confidential corporate data. A commitment to participate in the survey will involve detailing good people to assemble the best data that can be provided. Assume a business expense, and make a significant commitment.

On the issue of confidentiality, the risks are minimal. Participating in a joint survey and sharing food ingredient usage levels which are held in close confidence requires trust.

All who followed the generally recognized as safe (GRAS) survey of four years ago know that there were no breaches in the confidentiality of the data shared with the NAS. With hundreds of companies participating, and with use information compiled on hundreds of GRAS substances, the summary tables were compiled and published with discretion. The Academy has demonstrated its ability to perform with no breach in the trust of contributors.

Corporate Sunshine Policy

As to corporate sunshine policy, the term "sunshine" arises from the State of Florida's policy of making public decisions publicly or of "letting the sunshine in." Generally, those in the industrial sector do not have the same need for openness as do government officials. But when there is a question of safety, pertinent information that may have been deemed to be private and confidential nevertheless frequently merits full public disclosure.

We are now looking for techniques to facilitate such disclosure of confidential information, *without* disclosing the source, or related economic and trade secret data. Perhaps the easiest and most practical method is to pool the data from many manufacturers.

The usage level of food ingredients is one such need. It is hard to argue that the usage levels of a food additive—which, by definition, is not GRAS—should remain solely a private decision. Food additives are no different than any other food ingredient—safe for virtually all consumers at the usual use levels, but potentially unsafe at some higher level. How safe any one food additive may be depends on its usage level.

The Grocery Manufacturers of America, the association I represent, and its membership have consistently supported individual and collective actions which would bring needed private information into the public domain and provide consumers with needed information. The following is just a partial list: nutrition labeling; ingredient labeling

for standardized foods; the GRAS review; the Academy survey of the GRAS list; and the food additives survey.

Corporate Coordinates

The term "corporate coordinates" is another way of asking, "Where are we?" Decisions are made each day in product development laboratories as to which food additive should be used in a product formulation.

Usually, the first consideration is identification of a number of additives which achieve the desired technological effect and which are stable in the product. The second consideration is economic: which is least expensive? There could and should be a third consideration. The technologist should consider safety criteria.

Let me use a hypothetical example of two antioxidants, one whose use is projected by the NAS survey at about 90 percent of the Allowable Daily Intake (ADI) and the other at 50 percent of ADI. It is prudent for corporations not to push any food ingredient usage to the limits of ADI. But today, the corporation cannot make a business decision based on ADI, because there is no meaningful public data base. If you accept ADIs as a legitimate index for product development consideration (as the regulatory agencies do), the generation of a data base deserves your attention. Since there is no way to collect these data other than through a use survey, we welcome you to the Academy survey.

The larger the number of manufacturers who choose to participate in the survey, the more complete the data base will be. As the data base is strengthened, corporate decisions are improved and adverse regulatory reactions are avoided. The FDA will make decisions based on this survey even if it is less than complete. It is imperative that these decisions be as sound as possible.

Corporate Auditing Activity

The survey also permits a corporate auditing activity. Comparison of your corporation's use of food additives with the industry profile will permit you to identify outlying values. If you are making a confectionery product using 50 parts per million (ppm) of an emulsifier, while the industry average is 20 ppm, you may want and need to explore why your use levels are so much higher. However, without access to industry data, it is difficult to determine when a food additive usage may be excessive.

The food additives survey, when successfully completed, will be more sensitive to food additive usage than the GRAS survey. This increased sensitivity arises from the subdivision of the food categories into smaller segments. Those who responded to the GRAS survey will recall that all food was divided into 28 categories. By dividing processed foods into more discrete categories—281 in this survey—the users of the survey material will be able to determine whether an antioxidant is used, for example, in a variety of baked goods or only in donuts. The greater number of subdivisions will markedly reduce the grossly exaggerated use projections of food additives which was the major weakness of the GRAS survey. The corporate auditing function will increase in sensitivity by some tenfold by this one change in the survey design.

The title of this presentation is "Incentives for Further Industry Cooperation and Participation." Frankly, the alternatives to voluntary cooperation and participation are legislatively mandated requirements. I do not doubt that regulatory agencies could persuasively argue that new information-gathering authority is required to protect the public good. I fear such new broad and sweeping legislative mandates. The alternative—voluntary cooperation to meet common objectives—is to me a persuasive incentive. We trust it is a persuasive incentive for you and your corporation. **[The End]**

The Park Case in Perspective

By GEORGE M. BURDITT

Mr. Burditt Is a Member of the Law Firm of Burditt and Calkins.

I WILL DEVOTE MY OPENING COMMENTS primarily to a review of what the Supreme Court did in *U. S. v. Park*,[1] to set the background for the panel discussion and hopefully for your questions and comments.

John Park is a direct descendant of Joseph Dotterweich[2] and, whether you consider *Park* to be an illegitimate offspring or the food and drug law version of the six million dollar man, he is here. As consumers, as government officials or as industry representatives, we must figure out where he fits into the scheme of things.

One place the *Park* case does *not* fit is under the rug or in the closet. It belongs right out in front, as the first item on the agenda of the Nineteenth Annual Food and Drug Law Institute-Food and Drug Administration (FDLI-FDA) Conference, by far the largest annual conference of its kind.

Several clear messages come through in the Supreme Court opinion in the *Park* case.

First, "consciousness of wrongdoing" or "awareness of wrongdoing" is not necessary to support a criminal conviction under the Federal Food, Drug and Cosmetic Act. As the Court said: "It was enough . . . that by virtue of the relationship he bore to the corporation, the agent had the power to have prevented the act complained of."[3]

[1] 421 U. S. 658, 44 L. Ed. 2d 480 (1975).

[2] *U. S. v. Dotterweich*, 320 U. S. 277, 88 L. Ed. 48 (1943).

[3] *U. S. v. Park*, 44 L. Ed. 2d 480, 500.

Requisite Responsibility

Second, a corporate agent with the requisite responsibility and power can become criminally liable for "neglect where the law requires care, or inaction where it imposes a duty."[4] The Court said that:

". . . those corporate agents vested with the responsibility, and power commensurate with that responsibility, to devise whatever measures are necessary to ensure compliance with the Act bear a 'responsible relationship' to, or have a 'responsible share' in, violations."[5]

So "nonfeasance" apparently joins malfeasance and misfeasance as a criminal offense. The Court said: ". . . the Act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur."[6]

So we have two basic teachings of *Park:* (1) even if you do not know that your company is violating the Act, you are a criminal if you have the power to prevent the violation; and (2) if you have the responsibility and the power, you are a criminal if you do *not* act.

But before you resign from the food and drug industry, look at the positive factors—positive at least from the point of view of an industry lawyer. I am essentially an optimist and I like to look at the brighter side of things.

The first positive factor is that the Supreme Court acknowledges that:

"the Act . . . does not require that which is objectively impossible. The theory upon which responsible corporate agents are held criminally accountable for 'causing' violations of the Act permits a claim that a defendant was 'powerless' to prevent or correct the violation. . . ."[7]

This "powerless" doctrine can be enormously important in a trial situation, particularly if the boss is willing to come in and tell the jury that "the defendant didn't have any power at all—I'm the one who had the power and responsibility."

Strong Dissenting Opinion

A second positive factor lies in the strong dissenting opinion of Justices Stewart, Marshall and Powell, particularly since Justice Douglas, one of the majority of six in *Park* and five in *Dotterweich,* has now retired. The dissent is based on the ground that the instructions erroneously failed to tell the jury that before they could find Mr. Park

[4] *Id.* at 500.
[5] *Id.* at 500-501.
[6] *Id.* at 501.
[7] *Id.* at 501.

guilty, they must find that he engaged in wrongful conduct amounting at least to common law negligence. Mr. Justice Stewart found that the jury instructions "did not conform to the standards that the Court itself sets out today" and amounted to nothing more than telling the jury, "You must find the defendant guilty if you conclude that he is guilty."[8] *Park,* in large part, turns on the adequacy of the jury instructions. Based on both the majority and dissenting opinions in *Park,* government and defense counsel, and trial courts, in future criminal cases under even slightly different sets of facts will do well to pay strict attention to the wording of the instructions.

A third positive factor is that the filing of a criminal prosecution is not necessarily the end of the road for the corporation or the individual defendants. The government has the burden of proving its case beyond reasonable doubt, and *Park* reaffirms this heavy burden. In many criminal cases under the Federal Food, Drug and Cosmetic Act, the defendants have a perfectly valid scientific, technical, substantive or procedural defense, all of which can and should be used in defending a case under an Act which imposes criminal liability without "awareness of wrongdoing."

But a criminal prosecution is a dreadfully traumatic experience. Each count potentially involves a fine of $1,000 and a year in jail for each individual defendant. And there are also personal ramifications. One defendant in a criminal case under the Act told me that, during the four years between his indictment and acquittal, he and his wife had not had a single social engagement. How many social engagements have you had in the past four years?

Government of Laws

Commissioner Schmidt has emphasized that he does not intend to recommend criminal prosecution of anyone who, in his opinion, does not deserve it. Nor did Commissioner Edwards recommend indictment of my friend who had no social engagements for four years. But someone else did. And I submit that, even in food and drug law, we should have a government of *laws* and not of men. A statute which imposes personal criminal liability without knowledge and without awareness of wrongdoing runs counter to the American tradition of justice and fair play. Now that *Park* has reaffirmed *Dotterweich,* the time has come, in my opinion, to effectuate a change in the statute.

[8] *Id.* at 505.

The October 20 Staff Working Draft of S. B. 641 partially accomplishes this goal. Section 113, on page 47 of the Draft, proposes an amendment to Section 303(a) of the Federal Food, Drug and Cosmetic Act which would increase the fine from $1,000 to $10,000 for a first offense. But it also proposes that the fine and the one year jail term shall apply to an individual food violator ". . . only if such individual *knowingly, willfully,* or *negligently* violates, or causes the violation of . . ." Section 301. (Emphasis added.) This would modify the *Park* result, but not the *Dotterweich* result. While it is clearly a step in the right direction, I see no valid reason why the provision should not also be made applicable to those of you who are in the drug, device and cosmetics industries. **[The End]**

JUDGE WON'T RULE ON FDA'S PROHIBITION AGAINST SALE OF LAETRILE

Stating that the courts have no role to play in determining whether a new drug should or should not be approved by the Food and Drug Administration (FDA), a federal court in Minnesota refused to allow a Shaklee distributing agency to import and sell laetrile, also called amygdalin or vitamin B-17. The drug is believed by some to prevent and cure cancer. The court also refused to return seized laetrile tablets and vials and to stop the enforcement of criminal sanctions against the distributing agency for smuggling the laetrile in from Mexico.

Advertising laetrile for use in the prevention, control, arrest and minimization of cancer growths obviated claims that laetrile was just a vitamin or a food, the court said. Once it is determined that laetrile is a drug, then the right to market the drug would be contingent upon a determination that the drug is generally recognized as safe (GRAS), that it has been approved as a "new drug," or that it is exempt from new drug requirements under the "grandfather" clause exemption. There was no evidence to find GRAS status for laetrile, it did not fit within the "grandfather" clause, and no new drug application has ever been on file with the FDA, the court stated.

CCH Food Drug Cosmetic Law Reporter, ¶ 38,049

The FDA's OTC Review—The Light at the End of the Tunnel

By ROBERT G. PINCO

Mr. Pinco Is Director of the Division of OTC Drug Evaluation in the Bureau of Drugs in the Food and Drug Administration.

TWO YEARS HAVE PASSED since the last presentation on over-the-counter (OTC) drugs, and now the project is well under way. In fact, we are beginning to see results from the advisory panels. Four panels have finished their work and have sent adopted reports to the Commissioner, five others are finishing reports, and

The thrust of the early part of the review was more administrative in nature, to get the project started. Now, as we begin to reap the rewards of those efforts in the form of panel reports, we are confronted by a staggering number of scientific, legal and enforcement questions which somehow must be resolved. I will now discuss a few of the more important considerations.

When the review began, the FDA had a fairly informal system for choosing panel members and operating OTC advisory panels. We even added certain innovations such as the Consumer and Industry Liaisons. Since that time, and due in part to the passage of the Federal Advisory Committee Act (FACA) in 1973, the Agency began to formalize the advisory committee structure. This eventually led to publication, in the summer of 1975, of our proposed procedural regulations. Development of these regulations has caused us to rethink many of our informal working arrangements for these panels and the panel members. We have formalized or will formalize notice and conduct of meetings, status of open and closed sessions, availability of transcripts of open and closed sessions, availability of internal working documents and the status and function of industry and consumer liaison representatives. Certainly, the *Van Smart* decision and, more recently, the *Wolff v. Weinberger* decision, as well as the Consumers Union suit, will have a bearing on this formalization process. In fact, because the FDA will not appeal the *Wolff v. Weinberger* decision of Judge Richey, the transcripts of the OTC Antacid Review Panel's closed deliberative sessions will be made public. However, because the courts did not directly reach the validity of the Agency's conduct under FACA, transcripts of other panels will not be released nor will the OTC review require solely open sessions. It is my understanding that the Justice Department agrees with these views and that some of these issues are likely to be resolved in an appeal in the Commerce Department's suit (*Aviation Consumer Action Project v. Washburn*) now before the District of Columbia Circuit Court of Appeals.

We are also identifying areas of continuing confusion in the OTC review and, where practical, trying to correct them as we proceed. The proposed regulation clarifying the status of Category III ingredients is an example.

When the review began, because of time and manpower limitations, it was narrowed to claimed, active and allopathic human drug ingredients, labeling and combinations. Final product formulations, homeopathic products and inactive ingredients were consciously omitted in order to complete the main task. But as the review pro-

gresses, we find that, in certain instances, these considerations cannot be totally ignored. For example, panels have suggested that certain product formulations be tested, as in the Antacid Panel's *in vitro* test and the Antiperspirant Panel's pending final product effectiveness test. Several panels have also reported on "inactive" ingredients that "spill over" into both the cosmetic and pharmaceutic aid areas. Where there are safety considerations, I will continue to encourage such action on "inactive" ingredients by the panels. We will also continue to promulgate rules covering such ingredients as both drugs and cosmetics, as we did for Tribromsalan and Zirconium. As for "inactive" ingredients used as pharmaceutic aids, we are considering a proposed regulation to clarify a number of issues that have been raised by virtually every panel.

Beginning in 1972, a "moratorium" was publicly declared on enforcement against OTC products, except in cases of fraud or serious health hazard. Over the next three years, that policy was declared several times by Commissioner Edwards and, as late as May of 1975, by Peter Barton Hutt before Congressman Fountain's Subcommittee on Intergovernmental Relations and Human Resources. However, as the panels complete their work, the total ramifications of this policy begin to come into focus. These ramifications, which first manifested themselves in the Sedative and Sleep-Aid Report, have presented the Agency with serious enforcement questions during the pendency of the OTC Review.

It is this issue that I would like to discuss further, since we also expect to publish a general policy statement which will serve both as a proposed rule and, more importantly, as a statement of present enforcement policy.[1]

Originally, when we constituted all of our OTC advisory panels, we charged them with reviewing active ingredients and claims in nonprescription drugs and placing those ingredients and claims in one of three categories. The advisory panels also were asked to review any prescription drug ingredients which they felt could have safe and effective OTC claims. Quite honestly, those who organized the OTC review did not really expect that there would be many recommendations for movement of prescription drugs to OTC status; rather, they expected the reverse to occur. I should emphasize, however, that this policy was conceived in the context of "old" or generally recognized "OTC" drug products modifying their ingredients during the pendency of the review. The FDA also expected that the

[1] See 40 *F. R.* 56675 (Dec. 4, 1975).

modified products would be identical, similar or related to presently marketed OTC products. On this basis, the Agency determined that no regulatory action would be taken during the pendency of the OTC review. Exceptions, of course, were situations involving fraud or serious health hazard.

This policy was and is perceived as being good public policy in terms of obtaining maximal voluntary industry compliance, in terms of maximizing the Agency's limited resources and, particularly, in terms of maximizing the benefits to the public in the shortest time possible. It was, and still is, hoped that unsafe and ineffective ingredients in OTC products will be removed through reformulation and relabeling. My personal experience has been that the industry is ready and willing to make these kinds of changes. I heartily commend it for past and future actions of this kind.

But the FDA now realizes that this policy was unclear. It was perceived as being very broad, in fact, all encompassing. Ingredients that neither had been available OTC nor available at such high dosage levels were being marketed OTC. Additionally, these ingredients were being marketed not after final monographs, not even after adopted panel reports and proposed monographs, but after informal discussions by panels evidenced by summary minutes. In one instance, a prescription antihistamine was marketed not on the basis of Category I general recognition of safety and effectiveness, but upon a Category III determination that more studies were required.

In terms of actual numbers of ingredients, the problem is quite small since we are only discussing perhaps 15 out of 1,000 ingredients being studied in the OTC review. However, while the prescription ingredients now being recommended or tentatively recommended for OTC status do not necessarily represent a large number of ingredients, they do represent very broad economic interests in this highly competitive market.

What in fact has occurred because of the competitive factors involved has been what the FDA now views as a rush to market, a rush which is viewed by some as premature. To resolve these problems, the Agency is about to promulgate a policy which will have the following goals:

(1) To clearly delineate the Agency's position as to when a prescription drug can be marketed OTC.

(2) To give a clear indication of how and when the Agency will react to Categories I, II and III recommendations for OTC marketing of prescription drugs, as well as for such recommendations for dosage levels of drugs higher than those presently

sold OTC. This should help industry to know when the Agency will or will not take regulatory action against such drugs.

(3) To place in context previous informal rulings and statements so that the industry knows exactly the level of risk it incurs in moving to market in advance of final OTC monographs or in advance of publication of panel reports and proposed monographs.

(4) To make clear the difference between how a prescription drug becomes OTC through the new drug or switch regulation mechanism[2] and when the OTC review process performs a similar function for "old" or "generally recognized" drugs.

Let us begin with new drugs since the rules will not change for them. The so-called switch regulations[3] provide a mechanism whereby the holder of a new drug application for a prescription drug can petition for OTC status. It should be noted, however, that paragraph c of Section 310.200 specifically separates the prescription-OTC consideration from the new drug-old drug issue. Therefore, processing of a new drug through the switch regulation mechanism to achieve OTC status does not yield general recognition. Such general recognition status occurs only through the operation of time, marketing to a material extent and for a material time under particular conditions of use.

But another mechanism exists by which a prescription drug can be marketed OTC. That is a *sua sponte* decision by a manufacturer to market a prescription drug OTC based on its belief that the product has become "generally recognized" or "old" and that, therefore, the switch regulations no longer apply. This is and has always been an at-risk decision on the part of a manufacturer. But the OTC review was expected to provide an indication to those manufacturers of the general recognition status of a prescription drug. This indication is correct if we view these drugs from the perspective of the end of the OTC administrative procedure. When a final monograph is published, a prescription new drug in fact becomes both generally recognized as safe and effective ("old") and OTC at the same time.

Here the confusion begins. Do these two events occur only when the Agency publishes a final monograph? Do they occur at an earlier stage in the administrative procedure; that is, upon publication of the tentative final monograph or upon publication of the panel report and proposed monograph? Do they occur the first time a panel considers an ingredient and makes public those thoughts in summary minutes? Also, do these two events occur at all when the panel does

[2] 21 CFR 310.200.

[3] Sec. 310.200 (21 CFR 310.200).

not reach a decision of general recognition, such as when it places an ingredient or condition in Category III? The answer, while not simple, represents a combination of both the legal and practical realities.

Basically, the Agency will take no regulatory action against prescription drugs considered by OTC panels and placed in Category I after publication of a final report and proposed monograph with the following caveats: First, the Commissioner has and will exercise the right to disagree with the panel in the preamble. If such disagreement appears in the preamble, the manufacturer is on notice that the Agency will take prompt regulatory action if the ingredient or claim is marketed. Second, regardless of the correctness of panels' labeling recommendations, the indications, warnings, etc. which appear in the report must appear verbatim on the product, until modified in later administrative stages.

If a panel places a prescription ingredient in less than a Category I status, Category II or Category III, such products cannot be marketed unless and until the Agency reverses that position in the tentative final or final monograph. You should also be aware that this policy will apply to higher dosages of presently marketed OTC products. For example, an ingredient has been marketed OTC for many years at two milligrams and the panel places that ingredient in Category I at 4 milligrams (historically a prescription level). Upon publication of the panel report, without negative comment by the Commissioner (in the preamble), that ingredient may be marketed OTC at the higher dosage level. If the 4-milligram level is placed in Category III or Category II, marketing of that higher dosage level would be subject to regulatory action.

I think that this policy and future OTC policies will carry out what I believe is a cardinal rule of government regulation. Let the public and the regulated industry know the rules by which the regulator plays. I know some of you disagree with this policy. But you should be aware that it will be enforced as of the date of publication. Products that have been marketed prior to this policy and which fall within its purview will be reassessed.

I appreciate this opportunity to discuss at least a few of the issues that have arisen in the OTC review. I am heartened by the belief that for the first time there is a "light at the end of the tunnel." The end of the review is still in the future but now it is in sight. I believe the public interest will have been well served when the review is completed. **[The End]**

The FTC's Proposed Rule on OTC Drug Advertising

By RICHARD B. HERZOG*

Mr. Herzog Is Assistant Director for National Advertising in the Federal Trade Commission.

RECENT HEADLINES telling of an impending Federal Trade Commission (FTC) "crackdown" on over-the-counter (OTC) drug advertising have probably imparted a certain special feeling about what I am going to say. But the choice by the headline writer of the term "crackdown" was somewhat anachronistic. It carried the flavor of the days when an increase in Commission activity necessarily meant a series of cases accusing named parties of deceptive or unfair behavior that violated our statute.

This presentation involves not cases but rule-making by the Commission and, in my judgment, is closer to the legislative than to the accusatory model. I welcome this opportunity to discuss at least one of the ways we plan to give content to our broad statutory terms—deception and unfairness—as they apply to the advertising of OTC drugs.

On November 11, 1975, the Commission published a proposed trade regulation rule on OTC drug advertising. The proposed rule would prohibit in advertising any product claim that the Food and Drug Administration (FDA) has determined, through its OTC Drug Review Program, should not be allowed in labeling.

I would like to address two questions that have arisen with regard to this proposal.

* The remarks in this article represent only the views of a member of the Federal Trade Commission staff. They are not intended to be, and should not be construed as, representative of official Commission policy.

The first question is whether the proposed rule would prohibit the use of Category III claims in advertising. It would not. The rule would allow Category III claims as long as they are allowed in labeling.

Policy Considerations

Whatever arguments that might be made under our statute as to the legal significance of a Category III classification by the FDA, the policy considerations that support allowance of Category III claims seem to us, at this time, to be overriding. Category III, as you know, was expressly designed by the FDA to enable and to induce manufacturers to conduct studies about ingredients and claims for which there may be, but presently is not, sufficient evidence to justify approval. We do not wish to compromise, or perhaps even frustrate, this policy by multiplying the adverse marketing effects of a determination that a claim belongs in Category III, rather than Category I.

A second major question presented by the proposed rule is whether the rule would prohibit advertisers from making claims other than the claims enumerated in Categories I and III. When a monograph enumerates certain words or claims, does it thereby prohibit other words and claims by omission? Does an FDA rule prohibit only claims expressly placed in Category II, or does it also prohibit other claims not among those listed in Categories I or III?

One type or category of claim about which these questions may be asked is "indications for use." By "indications for use," I am referring to claims which state what the intended use of the product is, what the condition or disease is for which the product provides therapeutic benefits.

With regard to indications for use in labeling, the FDA's position is clear. Diseases or conditions that are not among those enumerated in the final rule may not appear in labeling. The FDA's general regulations pertaining to OTC drugs state that any product failing to conform to "each of the conditions . . . in an applicable monograph is liable to regulatory action."[1] Labeling which contains an indication for use that is not among those listed in an applicable monograph would not conform to the conditions in that monograph.

But there is a further question which deals with whether the indications that are enumerated in Category I may be described in words

[1] 21 CFR Sec. 330.1

other than those enumerated by the FDA in the final rule. Here, too, the FDA's position is clear.

In the Tentative Final Order for Antacids, the Commissioner of the FDA discussed this question and concluded that "[a]llowing each manufacturer to select the words to be used would result in continued consumer confusion and deception." In March of 1975, the FDA expressly amended the antacid and antiflatulent rules to state that, with respect to indications, the labeling of a product shall "identify" the product with only the specified terms. Our understanding is that this will be the approach in all future monographs.

The FTC's rule, as proposed, would have the same effects. With respect to antacids, it would prohibit advertisers from stating indications for use other than those enumerated by the FDA, and from using language other than the language set forth in Category I or III.

The limitation-to-use wording approved by the FDA affirms the need for special care on the part of advertisers. An ad communicates not only through its express claims, but through implied representations as well. Implied representations can arise not only from what is said, but from the visual aspects of the ad, including the setting or situation portrayed, what the actors are doing or appear to be feeling. All of these aspects are capable, in our judgment, of affecting audience perception of conditions for use. This point is hardly a new one under our statute, but the completion of the FDA's first monograph, and the proposal of our rule, make this an appropriate time to remind all of us of the importance of implied representations.

Wisdom of Prohibitions

I have said that our rule prohibits what the FDA's monographs prohibit. What might be said in the FTC's rule-making proceeding about the wisdom of those prohibitions in an advertising rule?

I do not believe that anyone can seriously argue that the product should be advertised for a use which is not among the uses enumerated by the FDA. To allow such claims would deny the OTC Drug Review Program its central purposes, and would result in the shipment of products for which there are no adequate directions for use, and which are not generally recognized as safe and effective for the advertised use.

Advertisers might wish to argue, however, that they should at least be allowed to describe in advertising the listed conditions in

words other than those permitted in labeling. Advertisers taking this position might argue that, even recognizing that different meanings should not be conveyed concerning the condition for which a product is offered, why not provide more flexibility in advertising than in labeling? Why not allow the advertiser to use different words to communicate the permitted meaning?

I believe that our rule-making records are enhanced as a sound basis for Commission decision-making if everyone understands what is on everyone else's mind. Accordingly, I would like to state very briefly what the Commission staff might be thinking if someone were to urge that advertisers be allowed to use terms other than the ones enumerated by the FDA to describe the condition for which the product is offered.

Either the advertiser does get some extra mileage, some special meaning, from the unenumerated term that he wants to use, or he does not. If he does not, is there really a burden in denying him the term? And if he does get some extra mileage, some distinguishing meaning, then isn't that impression in the consumer precisely what the FDA has indicated should be avoided?

Copy Testing

Moreover, the argument that different words should be allowed assumes that the state of copy testing—consumer research as to the meaning of ads—is such that we can determine with confidence when the meaning really is the same. The FTC has a great deal of difficulty with that assumption, and so, I suspect, would industry.

In the first place, the protocol for such testing probably would have to involve testing the ad with the unenumerated term against the same ad with the enumerated term. Only in that way could you establish a baseline of people who are going to receive the wrong impression even when the right term is used. It probably would be necessary to test individually in this manner virtually every ad that plans to use an unlisted term.

Certainly, it would not take a very large percentage of people who receive the wrong impression to conclude that the ad is deceptive and unfair.[2]

[2] See *Firestone Tire & Rubber Co. v. FTC*, 481 F. 2d 246, 249 (CA-6 1973), cert. denied, 414 U. S. 1112 (1973); *Benrus Watch Co.*, 64 FTC 1018, 1045 (1964), affirmed, 352 F. 2d 313 (CA-8 1965), cert. denied, 384 U. S. 939 (1966); *Feil v. FTC*, 285 F. 2d 879, 892, n. 19 (CA-9 1960).

But most importantly, we simply do not believe that the state of the art of copy testing enables us to conclude, with sufficient confidence, that a proliferation of terms is not leading to confusion, or to a deceptive kind of differentiation. To be sure, copy tests using open-ended questions do give us the actual verbatim responses of consumers. But even if verbatims are a window into the consumer's understanding of an ad, the window can sometimes be an opaque one. The vision can grow especially dim when it comes to testing for fine distinctions, as could be involved in testing for the comparative understanding of similar terms. Consumer verbatims often play back, for example, the very terms used in the ad, thereby advancing our understanding not at all as to what those terms really mean. And, of course, techniques of aided recall and close-ended questions carry with them their own problems of interpretation.

In the area of health, the Commission has emphasized that scrupulous accuracy is required.[3] Because we are attempting to fashion rules governing health claims, and because the questions would be particularly difficult ones to test, the limitations of copy testing take on particular force.

Use of Unenumerated Terms

It should be evident from what I have said that anyone wanting to make a presentation in our rule-making proceeding on the question of the use of unenumerated terms must do a great deal more than simply offer the conclusive assertion that somehow advertising is different than labeling.

So far, I have discussed the question of unenumerated claims—of prohibition by omission—with respect to indications for use.

As we look toward the future, the question of the use of unenumerated terms is going to arise with respect to types of claims other than indications for use. In those cases, many of the considerations that I have mentioned will be important. Indeed, the issue already appears in the antacid panel. As you know, the Commissioner enumerated as Category III claims a number of terms used to describe certain properties of antacids. He enumerated the terms floating, coating, defoaming, demulcent and carminative.

[3] See *Rodale Press*, 71 FTC 1184, 1241 (1967), vacated on other grounds, 407 F. 2d 1252 (CA DofC 1968).

In June of 1976, the FDA will decide whether certain of those claims should be placed in Category I. Suppose the antacid rule is amended to list some of those claims. The question will arise whether such listing is exhaustive as to a certain type or category of claim, just as the enumeration of certain indications for use exhausts the category of indication-for-use claims.

If such listing is intended to be an exclusive listing as to a certain type of claim, what is that type? Claims that the product is blue, or low cost, or sparkling, clearly are not the type of claim exemplified in the floating-coating list. Is the type perhaps properly described as claims concerning the *in vivo* mechanism by which the product provides its therapeutic benefit? In other words, if the indication-for-use claim concerns *what* the product does, then does this further enumeration deal with *how* the product does what it does? Or is the general type of claim something else?

Future Monographs

These kinds of questions will arise in other monographs, not only with respect to the claims I have mentioned but also concerning other aspects of *in vivo* performance such as strength, speed, concentration and gentleness. Future monographs might enumerate certain claims regarding strength or concentration. When such an enumeration is made, what is thereby prohibited by omission?

These are important questions for industry and for the Commission. They suggest that, during future FDA monograph proceedings, a participant should seek answers to two questions. First, was a given enumeration intended to be exhaustive as to a certain category of claims? If so, what precisely is that category?

These categories might not be described uniformly from monograph to monograph. The same term might even fall within different categories in different monographs. This does not matter. The essential thing is to elicit in a given rule a statement as to what category of claim is being dealt with, and whether the rule is dealing exhaustively with that category, prohibiting by omission what is not enumerated.

That kind of effort is in industry's interest. It enables rules, including our rule, to fulfill one of their major functions: to give guidance to those who want to obey, thereby minimizing or eliminating legal risks. In that way, we can move toward making accusatory proceedings in industry a thing of the past. **[The End]**

An Overview of Recent Regulatory Developments—Veterinary Medicine

By GARY L. YINGLING

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WHAT BUREAU OF VETERINARY MEDICINE ISSUES has the General Counsel been involved in over the last year that are of interest? What issues will be of importance in the future? In preparing this presentation, I consulted with the other two Bureau of Veterinary Medicine members of the Office of the General Counsel, Edward Allera and Jess Stribling. After the three of us finished our discussion, it was apparent what this year has meant and what we have under consideration for 1976. I thought it might be interesting to go through the Food and Drug Administration's (FDA's) list of concerns.

(1) The "sensitivity of the method" document is a familiar FDA concept. The Agency's approach is to publish a proposal which would establish the minimal criteria for carcinogenic testing. In drafting, the Agency is proposing to use a modified Mantel-Bryant procedure to determine when any residue found in tissue is so small that it represents no risk of cancer to man or animal. Any residue below that level will not constitute a residue. The Bureau of Foods and the Bureau of Veterinary Medicine have both drafted and reviewed the "sensitivity of the method" draft proposal. In fact, it may not be accurate to say that there is a proposal since there are numerous drafts. These drafts are still under review.

(2) The use of animal waste as a component of animal feed has been, in the eyes of many people, a practice as old as time. Therefore,

to some, the idea of processing animal waste for use as a component of animal feed is a reasonable proposal. Conversely, there are those who believe that the waste of any animal is a bacteria, virus and drug-bearing matter that has no place in the food chain of man or animal. The Agency is attempting to develop a *Federal Register* proposal which would provide for the interstate shipment of animal waste for use as an animal food component. The proposed regulation would allow animal waste to constitute up to a level of 25 percent of the finished animal feed. The problem is how to guarantee the safety of the animal waste that is being used as animal feed, considering the bacteria, viruses and drugs used in animal feed today. It is estimated that more than 80 percent of the animals raised today for food use are drug treated sometime during their lifetime. The FDA, in attempting to publish an animal waste document, is trying to prepare a proposal that addresses all of the issues. It will also set forth a reasonable standard of processing or testing to assure the safe use of animal waste. This is a very difficult task and it may be sometime before a proposal is published.

Pet Food

(3) From discussion of animal waste and animal food, it seems natural to proceed to an issue which has received considerable public review and discussion. How safe and nutritious is the use of pet food as human food? The Bureau of Veterinary Medicine believes that the use of pet food as human food occurs in a very small number of cases. The Bureau considers the widespread publicity and numbers quoted as having no factual basis at all. Whether or not the facts are correct, the situation does not relieve the Agency of studying pet food labeling to determine whether or not it is informative. Should the label be informative as to the advisability or desirability of using pet food for human consumption? What type of safety standards are necessary for human food which are not used in animal food production? The word "by-products" normally means rendered animal tissue from slaughter waste and dead animals. Is there a need to be more informative on a pet food label as to what an animal by-product is? Is there a need to list all of the animal parts used to prepare pet food? Is there a need for a more complete ingredient label? Is it necessary to say on the pet food label that the product is not intended for human consumption or is unfit for human consumption? At this time, the Agency is reviewing its present policy to determine what, if any, steps it should take relating to pet food labeling.

(4) I think that, in the last year in the Office of the General Counsel, the word used most often relating to veterinary medicine has been "mastitis." The office has spent more time considering the mastitis issue than any other. The present status is that the Court of Appeals has not set an argument date for the suit by Masti-Kure claiming that the FDA's denial of a hearing was inappropriate. The second suit by Masti-Kure, which was to prevent the FDA from allowing other companies to enter into a mastitis certification agreement with the Agency, has resulted in the granting of a motion for summary judgment against Masti-Kure. For all the companies involved, the Agency has published a final order in every instance but two. The FDA is continuing to review the data and information supplied by Schering and Norwich to determine whether or not these two firms have submitted substantial enough evidence of safety and effectiveness to entitle them to a hearing. In the coming year, we should see most of the mastitis combination issues resolved.

Antibiotics in Animal Feed

(5) The subject of antibiotics in animal feed is one of the most time-consuming issues in the Bureau of Veterinary Medicine. The Bureau is reviewing the data that have been submitted pursuant to the *Federal Register* notice. It may request that an advisory committee review those questions which present the most difficult scientific issues. Antibiotics in animal feed is an issue which will still be high on the list at the end of 1976.

(6) Another area that received a great deal of attention during the past year is the process by which new animal drug applications (NADAs) are approved administratively by the FDA. The question was raised concerning the lengthy administrative delays in approving NADAs. The Agency ordered a review of the paper work process to determine whether or not the review procedure was efficient. The question did not concern the quality of the scientific and legal review, but the actual time sequence of the review. A number of paper flow movements caused significant delays. It was apparent that a change could be made in the paper flow of the review which would not change the scientific and legal quality but would decrease the time necessary to complete the review process. Therefore, the paper flow of documents was changed so that the documents are reviewed in a more orderly fashion which will result in a more expeditious determination of whether or not a new animal drug is safe and effective.

Freedom of Information Statements

(7) A number of questions have been raised concerning the method of the scientific and legal review of new animal drugs. In this regard, there is a need to review the Freedom of Information (FOI) statements that are prepared for release when an NADA is approved. A notice was published in the *Federal Register* that the Bureau of Veterinary Medicine had drawn up a proposed form for preparing FOI statements for NADAs. The FOI statements which result from using that form do not always make it apparent to the FOI reader why the FDA is approving the NADA. It is also possible that the FOI statement is inconsistent with the actual reason why the Agency is approving the NADA. This possible inconsistency arises from the fact that the Bureau has determined scientifically that some parameters of the adequate and well-controlled study regulations[1] are not necessary in certain NADAs. The criteria of paragraph (a)(5) of Section 514.111 for the approval of the animal drug can be waived in whole or in part if they are not reasonably applicable to the investigation. Other studies and published data may indicate that one or more of the parameters of Section 514.111 can and should be waived. The problem arises from the fact that the FOI statement has not always indicated that the waiver of some of the parameters of Section 514.111 has occurred. In the near future, the FOI statements will indicate when a waiver is requested by a manufacturer for part of the adequate and well-controlled study regulations and when it is granted. One of the reasons that the Agency is adopting this procedure is so that everyone will understand the basis on which an application is being approved. Clearly, it will be necessary to expand the FOI statements to include more information about the types of studies that were conducted so that the reasons why the Agency made the decision to approve the NADA are apparent to the reader of the FOI statement.

Section 512(m) Waivers

(8) Another issue in connection with Agency practice and the present lack of informed public knowledge is the FDA's procedure relating to Section 512(m) waivers. According to Section 512(m), a person who intends to mix an animal drug with an animal feed must file an application for permission to mix the drug. The regulation form is called an 1800. The Agency has been waiving the requirements of

[1] 21 U. S. C. Sec. 514.111.

Section 512(m) when it can be shown by a manufacturer that: (1) feeding two times the normal feeding level will not result in a residue in the animal tissue above the tolerance; (2) the drug has been used for three years; and (3) certain other appropriate conditions are met. This procedure for waiving Section 512(m) has not been published as a proposal in the *Federal Register* and there may be a lack of knowledge concerning the waiver procedure. The General Counsel realizes that the lack of knowledge is doubtful since the Bureau of Veterinary Medicine has spent time informing the regulated industry and others of the Section 512(m) waiver procedure. The waiver provision is listed as an exemption in many of the medicated animal feed regulations. The listing in the *Code of Federal Regulations* clearly requires the FDA to publish a proposal setting forth the criteria for the Section 512(m) waiver and to receive comments on it. This publication should occur in the near future. In the interim, the Agency probably will include, in the *Federal Register* preamble to Section 512(m) waiver drugs, a statement of the criteria that has been used to waive the particular drug from the Section 512(m) provision of the Federal Food, Drug and Cosmetic Act.

Medicated Feed

(9) In a discussion of Section 512(m) waivers and medicated feed, it is difficult to ignore other issues in the area of medicated feed. The Agency published a medicated feed proposal for current good manufacturing practices (GMPs) on August 8, 1975.[2] This was an update of the current GMP regulations of 1965. However, the current proposal is only half of the proposed updating of the GMP regulations. The second half of the proposal has not been published because a number of issues are under review. One of the questions relates to the names used to identify the various medicated feed levels. The present terms are feed additive concentrate, feed additive premix, feed additive supplement and complete feeds. Obviously, confusion is possible when these terms are used. The FDA is developing a new set of terms that are clear, understandable and easy to use. Another issue in the same GMP proposal concerns cross-contamination of medicated feeds. The Agency cannot ignore the fact that cross-contamination of medicated feeds occurs. Under present industry practices with large integrated mills, there is no way that some drug residue from the first mix in the morning is not in the second mix of the day. This probably is true also of the medium and small milling operations. The

[2] 40 *F. R.* 33554 (Aug. 8, 1975).

question that the FDA is trying to resolve is how much cross-contamination is acceptable from a safety standpoint. Within that issue is the question of whether cross-contamination differs depending on the drug used. Is a larger percentage cross-contamination with monensin less serious than a small cross-contamination with diethylstilbestrol? These questions are under serious study, and there will be a *Federal Register* proposal dealing with them.

Approval of New Drugs

(10) I have saved until last an issue for which I have no answer but which is under review. How does Judge Green's decision in *Hoffmann-La Roche* relate to some of the *Federal Register* proposals of the Bureau of Veterinary Medicine. The *Hoffmann-La Roche* decision states that the FDA cannot approve the use of new human drugs unless it has actually approved the new drug application. The Bureau of Veterinary Medicine has stated in a *Federal Register* notice[3] that it allows the marketing of what it considers to be a new animal drug pending the submission of data and information which will allow for the approval of the NADA. Under a strict reading of *Hoffmann-La Roche,* the Agency is required to suspend the use of these new animal drugs until it approves NADAs for their use. As I stated in the beginning, whether or not this is the necessary result, it is clearly a question that is under review and for which I propose no answer.

I have set forth the list of concerns and discussed many of the issues under consideration. There will be *Federal Register* notices for review in the future. I am sure that industry is not going to worry about the FDA's proposal until it is published. I hope that today's discussion of the list will provide at least some idea of the issues that the Agency has before it. The proposals which the FDA publishes are not published without serious long-term thought as to the impact on the consumer, the industry and the Agency. In closing, I wish to emphasize that Dr. Van Houweling and the Bureau are concerned with maintaining the quality and abundant quantity of our animal food supply through the use of safe and effective animal drugs.

[The End]

[3] 38 *F. R.* 9811.

An Overview of Recent Regulatory Developments— The Case for Evidentiary Hearings

By ROBERT N. ANDERSON

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I THINK there is no more hackneyed concept in the lore of criminal law than that of the criminal returning to the scene of the crime. For this reason, perhaps more than any other, I have avoided visiting the Food and Drug Administration's (FDA's) Rockville complex since November 10th, the day upon which the Methuselah of legal proceedings, the FDA's Vitamin-Mineral Hearing, was reconvened. While I was employed as a trial attorney for the FDA, I represented that Agency during the two-year main bout on these regulations which was held between 1968 and 1970. The avowed purpose for this latest chapter in the 13-year saga of these regulations is to clear up some procedural oversights and to provide further opportunity for cross-examination of one of the many witnesses. Personally, I believe the participants merely yearn for simpler days. I think that they are trying to resurrect the protected feeling we all had as we passed two summers and two winters together locked in the windowless hearing room on Independence Avenue.

Enough time and distance now exist between me and that proceeding to make it proper for me to make these remarks, remarks which are general in nature, not at all inflammatory, and based, I hope, on at least a small degree of dispassion.

The event which has prompted these thoughts is the publication of the FDA's ponderous procedural regulations, which seek to revise and redefine the ways in which the Agency will conduct its exchanges with the public and with the industries it regulates. The regulations

have been temporarily turned aside by judicial action. However, this does not affect what I have to say, for it is the attitude inherent in these regulations toward evidentiary hearings which I would like to address, and not so much the particulars of the proposal.

My thesis is a simple one. I think there is really no effective substitute for a hard adversary proceeding if the objective is a reviewable record which will eventually sustain or condemn the Agency decision when the inevitable judicial appeal is taken. Unfortunately, the clear objective of the proposed procedural regulations is to *avoid* rather than utilize and *improve* the formal hearing.

I recommend a reading of the preamble to these regulations. It is filled with laments. In brief, the message is that things have been awful mostly because of a disinterested public, misguided consumerists and a private bar. But, the preamble promises, things will be better as soon as all of these due-process logjams are eliminated. I must say that I am always impressed by the lengthy and discursive preamble to new regulations which have been the FDA's fashion during the last five years. I endorse the practice entirely, because it truly reveals the Agency's mind set, its underlying attitudes and its intentions. Unfortunately, the preambles often are more clear than the attendant regulations. What, then, in these regulations makes me think that the FDA is unlikely ever to hold a formal evidentiary hearing again, unless ordered to do so by the courts?

Formal Evidentiary Hearing

The regulations themselves are quick to specify that there are two, and only two, situations in which the Agency will consider granting a formal evidentiary hearing. These are: (1) when there is a statutory right to such a hearing; and (2) when "the Commissioner concludes, in his discretion, that it would be in the public interest" to hold a formal hearing. I am willing to post odds as to the likelihood of number two ever occurring. I can accept only small bets, but I do so with consummate confidence in their outcome. Indeed, even under number one, when the law grants the right to hearing, there is no assurance that one will ever be held.

A member of the public, or an affected corporation, faced with a regulatory proposal or with a refusal which he or it does not like

is certainly anxious to have an opportunity to make a record of his side of the story and to require the FDA to do the same. He may even have the refreshing optimism to think that the hearing itself might change the Agency's position. I should not be cynical, for this does happen. Reading the applicable law, he might even expect that he will, if he speaks up, have that opportunity. This, of course, is not necessarily so.

Filing of Objections

Once a proposal or other Agency action is published, a party who seeks a hearing must quickly file objections to the Agency action and ask for the hearing. If he does not do this, the Agency action becomes final. More distressing is the fact that a person may lose the right to a hearing if he files objections or requests for the hearing that do not conform to the specifications of Section 2.112 of the proposed regulations. Under that section, each objection must "specify with particularity the provision of the regulation or proposed order under which the objection is made."[1] An objector must expressly request a hearing on each objection; a catchall request for a hearing is inadequate.[2] In each instance in which a hearing on an objection is requested, the objector must describe, in detail, the factual information he plans to submit in support of the objection. Failure to include this information results in a waiver of the right to a hearing.[3] Documentary material upon which the objector plans to rely must accompany each objection, and there must be a summary of testimony intended to be presented by any witness the objector intends to call.[4] The objector can adduce additional testimony if a hearing is held, but this, to me, is cold comfort.

Incidentally, the regulations appear to require that any objector must amass and present this material in support of the objections within 30 days of the Agency publication to which he objects.[5]

Summary Judgment Powers

Assuming these deadlines are met and this voluminous demonstration of the need for a hearing is made, the Commissioner then considers whether to grant a hearing. As part of his cogitation, he may consider whether to assert the so-called summary judgment pow-

[1] Sec. 2.112(a)(3).
[2] Sec. 2.112(a)(4).
[3] Sec. 2.112(a)(5).
[4] *Id.*
[5] Sec. 2.110(e).

ers of the FDA confirmed in *Weinberger v. Hynson, Westcott & Dunning Inc.*[6] and codified in the regulations in Section 2.113(b). Only if all of the following criteria are met, according to the regulations, will the Commissioner withhold his authority to summarily terminate the proceeding:

(1) there must exist "a genuine and substantial issue of fact";

(2) the factual issue must be one which is resolvable by the proffered evidence;

(3) the proffered evidence must support the factual assertions;

(4) the factual assertions must support the objection in a manner which would lead the Commissioner to adopt a course of action different from that which he proposes to take;

(5) the alternative action requested must be in compliance with the principles of the Federal Food, Drug and Cosmetic Act and attendant regulations; and

(6) all other conditions specified in the announcement of the FDA's action, including the proposal, the final regulation or the notice of opportunity for hearing, must be met.

If, under these rules, the Commissioner, not surprisingly, finds that no hearing should be held, he must publish the details of his reasons for refusing the hearing.[7] Publication of this denial constitutes final Agency action which is judicially appealable, provided, the regulations are quick to remind us, the objector acts within the statutory period for judicial appeal.

The attitude is clear. I think we have a right to ask why it exists. The answer, in part, is that the FDA has allowed itself to be convinced that hearings are bad simply because some past hearings, including the Vitamin-Mineral Hearing, have been an embarrassment. However, I would like to think that the source of that embarrassment was not the procedure whereby the hearing was conducted but, rather, the fact that the hearing disclosed flaws in the proposals and the fundamental frailty in the process whereby Agency proposals are internally generated.

Transcontinental jumbo jets are still a new enough experience for most of us to make riding in one an exciting prospect. It seems

[6] 412 U. S. 609 (1973).

[7] Sec. 2.115(a).

that many of the pilots of these huge airplanes share this feeling. It is not unusual, when riding in a 747, to hear the captain, having little else to do, rhapsodize, over the public address system, about the size, the capacity and the range of the aircraft. He describes its length, the number of passengers it will carry, the size of its cargo hold and the distance which it can travel.

Vitamin-Mineral Hearing

The FDA Vitamin-Mineral Hearing was convened in May of 1968, based on a proposal originally published in 1962. The evidentiary hearing lasted, unbroken, for two years. During that time, the testimony of about 200 witnesses was presented, either by oral or written direct examination, and over 2,000 exhibits were introduced in evidence. The transcript was more than 36,000 pages. When stacked on the floor (something I never did but which seemed customary in the FDA), it towered over most men. The government attorney was new, it was the hearing examiner's first case, and there were over two dozen of the best Washington law firms representing over 100 participants. But that hearing flew. I agree that the flight, at times, was precarious and erratic. However, this was not due to the design of the craft, but rather the burden it was asked to carry. Many people forget that the Vitamin-Mineral Hearing proposal was not limited to dietary supplements, the one-each-day type of preparation. The proposal included the entire volatile subject of proper food fortification in the United States, encompassed the composition and the labeling of diet foods offered for weight control, and ended with a catchall coverage of such diverse items as muscle-building food, foods used in hospitals for patients on special diets, and the kelp, wheat germ and other exotic substances which are consumed by food faddists. There is no doubt in my mind that this proceeding could have and should have been divided into no less than five separate hearings. Whose fault is that? Needless to say, the ultimate legal test of the propriety and the validity of any administrative proceeding is the judicial review of it. The Vitamin-Mineral Hearing has had intense scrutiny by the Second Circuit, although, as the United States District Court of the District of Columbia observed, in earlier litigation, the FDA had not been a "model of sure footed administration."

Reliable Record

On reflection and analysis, it is my deep belief that the formal hearing process itself, when allowed to function as intended, is an irreplaceable method for producing a tested, factual record which is the only basis upon which the courts—the ultimate arbiter—can determine the propriety and the accuracy of the eventual Agency action. Without a reliable record of how the Agency reached a decision, it is too tempting for most courts simply to endorse the decision on the basis that they must know what they are doing.

I certainly do not represent that there is no room for procedural improvement in the method of conducting formal evidentiary hearings. Indeed, there is much in the proposed regulations which reflects that the FDA has learned valuable lessons. There is a vastly improved prehearing discovery procedure. The FDA has acknowledged the often unendurable expense involved in participating in the hearings, and has created a *forma pauperis* method of participation. The techniques for organizing and assembling evidence and witness lists prior to the prehearing conference is laudable, as is the encouragement of cooperative documentary submissions. Perhaps best of all is the Agency's acknowledgement, learned in the Vitamin-Mineral Hearing, that written direct testimony can be an extremely effective way of saving time and sharpening the presentation of witnesses.

Peanut Butter Hearing

However, the existence of any of these problems, demonstrably curable, is certainly not the basis for discarding the entire hearing process. In reviewing the Vitamin-Mineral Hearing, and also its infamous predecessor, the Peanut Butter Hearing, I can only conclude that the real basis for the embarrassment which the FDA associates with these proceedings is the fundamental weakness of the underlying proposal, either because of its complexity, as in the Vitamin-Mineral Hearing, or its questionable regulatory objective, as in the Peanut Butter Hearing.

At this point, it is fair to ask, "What's so bad about the alternatives?" After all, the proposed regulations offer three alternatives to the formal evidentiary hearing. These are: (1) boards of inquiry; (2) hearings before the Commissioner and his staff; and (3) regulatory hearings. Indeed, the preamble to the proposal suggests that the Agency will be more willing to grant some hearing, provided the

petitioner settles for one of the three alternatives and forgoes the formal hearing. I am professionally affronted by this dangling of individual substantive rights on the condition of procedural concessions. I also object to each of these alternatives for the simple reason that, stripped to their essentials, each is nothing more than a committee. It is very difficult for me to endorse the shifting of fact-finding and preservation away from trained, quasi-judicial officers, grounded in the rules of evidence and the techniques of factual determination, and toward an informal aggregation of "experts." This is particularly true when the supposed objective of this exercise is to improve the precision and the quality of the Agency's determination. These alternatives may shorten the process but I am not convinced that they will sharpen it.

Cross-Examination

We should have a word here about that favorite whipping boy of administrative due process—cross-examination. The new regulations severely limit cross-examination. Indeed, even in the formal hearing, cross-examination is allowed only when the presiding officer determines that without cross-examination there could not be a full development of the facts.[8] I must admit, candidly, that I have never seen a witness quail in terror, confess error and throw himself on the mercy of the court as the result of any cross-examination conducted by me. Neither have I seen this occur as the result of the efforts of any of my associates. However, whether or not cross-examination is really an "anvil upon which truth is tested," I think my method of preparation and presentation of witnesses would change if I expected that it was unlikely that the witness would be cross-examined. I think the same would be true with respect to the attitude of the witness. I make no particular apology for this acknowledgement. It does not reveal a duplicity of character on my part, nor undue cynicism about witnesses in general. It is simply a fact of human nature. I am convinced that the elimination of cross-examination is likely to encourage generality, foster imprecision and have a generally negative effect on the factual integrity of any Agency action.

Another reason for eliminating formal hearings, which the FDA is anxious to offer these days, is that such proceedings have a negative impact on the "scientific community" which is supposed to be

[8] Sec. 2.154(c).

offended by having to be exposed to the "trial-like" rigors of a hearing. I can only say that of the 30 or so physicians and Ph.D.'s whose testimony I presented at the Vitamin-Mineral Hearing, only one, a notable exception, was offended by the actual process. He walked off the stand during what I considered to be a very mild cross-examination. The rest rather enjoyed themselves. However, more than one or two were offended by what they saw as substantive shortcomings in the proposed regulations, particularly as those shortcomings were illuminated and elaborated through the hearing procedure. Whose fault is that?

I could speak volumes on the obligations of the private bar and other non-Agency participants to observe and preserve the integrity of the hearing process. It is always difficult for me to listen seriously to attorneys who mourn the threatened loss of rights such as cross-examination when I know that it is the abuse of such rights, by the very same individuals, which has been the principal reason for their decline.

However, the formal hearing is acknowledged to be adversary in character, and has rules which, if properly wielded, can contain and control such mischief. I think it is *most* properly suited as the forum of choice for production of an exact, reviewable record.

I exhort the FDA not to make it a thing of historical interest only.

[The End]

ANIMAL TESTS RAISE QUESTIONS CONCERNING SAFETY OF RED NO. 40

Preliminary findings from animal tests have raised questions about the safety of the artificial coloring FD&C Red No. 40, according to a recent Food and Drug Administration (FDA) Release. The FDA reported that, after 41 weeks of a 78-week feeding study involving 400 mice, six of the mice developed premature and unexpected malignant lymphomas. The Agency has asked Allied Chemical, the company conducting the study, to determine the significance of the findings. The work will require a minimum of 30 days to complete. The FDA intends to present all available data on Red No. 40 to its Toxicology Committee.

CCH Food Drug Cosmetic Law Reporter, ¶ 41,588

Cosmetic Quality Assurance—Alias Cosmetic Good Manufacturing Practices

By MICHAEL A. PIETRANGELO

Mr. Pietrangelo Is Secretary and Legal Director of Plough, Inc.

THE TOPIC for this portion of the Cosmetic Workshop Session is Cosmetic Quality Assurance. I think it's appropriate to relate how this title was selected. When James Merritt, the President of the Cosmetic, Toiletry and Fragrance Association (CTFA), invited me to participate in this session, he said that the topic for this program was to be "Cosmetic Good Manufacturing Practices" (GMPs). I told him that we could not have such a topic because there is no such thing as cosmetic GMPs. After some discussion, it was decided that the phrase "quality assurance" would be used. I suspect that the Food and Drug Administration (FDA) does not see the difference between the terms "quality assurance" and "GMPs" as anything more than a semantic difference. According to rumors, which have been confirmed at this workshop, cosmetic GMPs are being drafted by the Agency and will be included in the *Federal Register*.

My remarks will address two very basic questions concerning cosmetic GMPs. First, is there legislative authority under the Federal Food, Drug and Cosmetic Act for substantive cosmetic GMP regulations? Second, is there a demonstrated need for such regulations, in light of current industry practices and current FDA authority?

Let's first consider what authority, if any, the FDA has to issue substantive GMPs for cosmetics. The statutory authority for drug GMPs arose from the 1962 Amendments to the Act (the so-called Kefauver-Harris Amendments) under which the FDA was authorized

to establish, by regulation, current GMPs for drugs. Drugs not manufactured according to current GMPs would be considered adulterated and would be subject to multiple seizures.[1] The legislative history of this section of the 1962 Amendments to the Act is noteworthy, as it illustrates that Congress understood the need for such provisions as regards to drugs, but only to drugs. Congress recognized that, except for drugs subject to premarket clearance (new drugs, certain antibiotics and insulin) and drugs prepared or manufactured under insanitary conditions (Section 501(a)),

"nothing can be done under the present act if these essential requirements demanded by good manufacturing practices are not met, until a particular shipment of drugs is marketed and the Food and Drug Administration can prove that the drug itself is deficient."[2]

So, in 1962, the concept of current GMPs was added to the Act, for drug products only, even though the Act already contained language making drugs adulterated if they were prepared, packed or held under insanitary conditions.[3] Although similar language regarding insanitary conditions existed under the Act for food[4] and cosmetics,[5] Congress did not deem it appropriate or necessary to consider GMPs for either cosmetics or food.

There can be little doubt that administrative agencies, such as the FDA or the Federal Trade Commission (FTC), have authority to issue substantive regulations, in accordance with their own administrative procedures and with the Administrative Procedures Act.[6] The authority to issue such substantive regulations (often referred to as legislative regulations) can arise only from a statutory delegation to the agency and as a manifestation of Congressional intent.[7] The legis-

[1] Sec. 501(a) of the Federal Food, Drug and Cosmetic Act provides that "drugs not manufactured in conformity with current good manufacturing practices . . ." are deemed adulterated.

[2] House Report No. 2464, 87th Congress, 2nd Session, pp. 2-3; Senate Report No. 1744, 87th Congress, 2nd Session, pp. 13-14.

[3] Sec. 501(a).

[4] Sec. 402(a)(3).

[5] Sec. 601(c).

[6] *National Petroleum Refiners Association v. FTC*, 482 F. 2d 672 (CA DofC 1973), cert. denied, 415 U. S. 951.

[7] The difference between substantive (legislative) and interpretative regulations may be briefly summarized as follows: when a statute delegates to an agency specific authority to publish regulations having the full force and effect of law (statutory), they are substantive. While the reasonableness of such regulations is subject to judicial review (just as statutes are), this cannot be subject to collateral attack, and the correctness as to interpretation is thus not subject to review. Interpretative regulations are (merely) interpretations of what an agency views the law to be. They do not have the force and effect of law. They are not binding upon the courts and are subject to

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lative history of the 1962 Amendments indicate that Congress never intended the FDA to have rule-making authority to promulgate substantive regulations for current GMPs for cosmetic products.

Efficient Enforcement

Presumably, any proposed cosmetic GMPs that the FDA plans to promulgate will be based upon authority contained in Section 701 (a) of the Act, and to implement Section 601(c) of the Act (insanitary conditions). Section 701(a) vests in the Secretary of the Department of Health, Education and Welfare (HEW) the authority to "promulgate regulations for the *efficient enforcement of this Act.*"[8] (Emphasis supplied.) This section of the Act does not, however, give the Secretary *carte blanche* to issue regulations, be they called substantive or interpretative.[9] We can assume that the FDA will only issue regulations which will assist it in discharging its duties and functions under the Act; in other words, to aid in the "efficient enforcement" of the Act. Consequently, unless some restraints are placed upon the authority to issue "regulations for the efficient enforcement of this Act," virtually any regulation issued pursuant to Section 701(a) would be legal. This, of course, is not the case because an agency's authority to issue regulations is limited to issuing regulations which implement the statutory provision upon which such regulations are allegedly based.[10] In every case where regulations (substantive or interpretative) have been issued by agencies and upheld by courts, the regulations have been found to interpret reasonably or to implement the specific substantive statutory provision upon which they were based.

For example, in *Toilet Goods Association v. Finch*,[11] the Court agreed that while it might aid in the "efficient enforcement of this

(Footnote 7 continued.)
collateral attack, including review as to correctness of interpretation. See Di Prima, "The OTC Review—Viewpoint of the Industry House Counsel," 27 FOOD DRUG COSMETIC LAW JOURNAL 532-540 (Sept. 1972).

[8] Sec. 701(a) of the Federal Food, Drug and Cosmetic Act provides as follows: "The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary."

[9] Historically, the FDA regarded regulations issued under authority of Sec. 701(a) as interpretative, not substantive. *Abbot v. Gardner*, 387 U. S. 136 (1967).

[10] *National Nutritional Foods Association v. Weinberger*, 512 F. 2d 688 (CA-2 1975).

[11] 419 F. 2d 21 (CA-2 1969). See also *National Petroleum Refiners Association v. FTC*, *supra*, and *National Nutritional Foods Association v. Weinberger*, *supra*. While the case upheld the FDA's au-

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Act" to have finished cosmetics certified by the FDA pursuant to the 1960 Color Additive Amendments to the Act,[12] the FDA could not use this provision of the Act (Section 706) as authority to issue "701 (a)-type" regulations requiring the certification of finished cosmetic products. The Court noted that it was clear from the legislative history and the language of the Act that Congress did not intend the FDA to have such certification authority for finished cosmetics, as opposed to "color additives." While a regulation providing for certification of cosmetic products would clearly have provided for more efficient enforcement of the Act, this alone was not enough to have the regulation survive judicial review.

Two other provisions of the Federal Food, Drug and Cosmetic Act pertinent to this discussion are Sections 601 and 704.

Conditions of Adulteration

Section 601 lists conditions under which cosmetics shall be deemed to be adulterated. Section 601 (a, b and d) provides that "a cosmetic shall be deemed adulterated if it contains any poisonous or deleterious substance which may render it injurious to users" or if it consists in whole or in part of any filthy, putrid or decomposed substance or if its container is composed of any poisonous or deleterious substance. Section 601(c) provides that a cosmetic shall be adulterated "if it has been prepared, packed or held under insanitary conditions whereby it may have been rendered injurious to health."

The statutory authority under the Act for federal inspection of establishments is contained in Section 704. Section 704 allows FDA representatives reasonable access to any factory, warehouse or establishment where foods, drugs and devices or cosmetics are manufactured, processed, packed or held to inspect the premises, finished and unfinished materials, pertinent equipment, containers and labeling.[13]

(Footnote 11 continued.)
thority to classify vitamins at certain concentrations as prescription drugs, the Court stated that the ultimate validity of such classifications (which was the very issue of the contested regulations) would depend upon whether the regulations were rational interpretations of those sections of the statute (Section 201(g) of the Act; the definition of "drug").

[12] Sec. 706 of the Act, enacted in 1960, provides, in part, that conditions for safe use of a color be provided by regulation, and required batch certification of all color additives unless exempt by the Secretary of HEW.

[13] For a detailed discussion of the legislative history surrounding the topic of factory inspections, see Hoge, "Factory Inspection Under the Food, Drug and Cosmetic Act," 21 FOOD DRUG COSMETIC LAW JOURNAL 673-679 (Dec. 1966).

The foregoing sections of the Act constitute the current statutory authority for issuing cosmetic GMPs for efficient enforcement of the Act. They also constitute the FDA's authority to take action against adulterated cosmetics.

The second point I would like to address is whether or not there is a demonstrated need for cosmetic GMPs, in light of current FDA authority and certain industry practices.

All of us occasionally lose sight of the forest because of the trees, and lawyers and regulators are no exceptions. While we debate the legal issues involved in whether or not the FDA has statutory authority to issue cosmetic GMPs and whether or not such GMPs should be substantive or interpretative, we may lose sight of one very important issue—are such regulations necessary *or* is current authority sufficient for the FDA to carry out its obligations under the Act?

Voluntary Industry Programs

I believe that under current authority and under certain voluntary industry programs, the FDA has authority to efficiently enforce the provisions of Section 601(c) of the Act concerning the manufacturing, packing or holding of cosmetics under insanitary conditions. Section 704(a) (factory inspection) provides the Agency with the authority it needs to enter premises and ensure compliance with Section 601(c). Additional substantive regulations on cosmetic manufacturing practices would not only be beyond the scope of current authority, but seemingly unnecessary.

The three voluntary programs in which a large segment of the cosmetics industry participates provide the FDA with sufficient information—perhaps more than it could obtain under any GMP regulations. Under these voluntary programs, the Agency has the names and addresses of cosmetic plants (establishment registration), formula and ingredient disclosure (product ingredient and cosmetic raw material composition) and information on cosmetic product experiences (product experience reports).[14] I might also include cosmetic ingredient labeling, which is now mandatory under 21 CFR Part 701 and which provides yet another dimension to the FDA's current knowledge of the cosmetics industry.

[14] 21 CFR 730, Product Experience Reporting; 21 CFR 720, Product Ingredient and Cosmetic Raw Material, Composition Statements; 21 CFR 710, Registration of Cosmetic Product Establishment.

An example of just how much authority the Agency has under Section 704 of the Act can be seen in the results of the *Park* case. In June of 1975, the Supreme Court announced its decision in *United States v. Park.*[15] Mr. Park, President of Acme Markets, with 874 retail outlets and 16 warehouses, was convicted of violating Section 402(a)(3) of the Act[16] by virtue of food being held under insanitary conditions. In this case, a 12-day inspection[17] of the company's Baltimore warehouse in 1971 had uncovered insanitary conditions which had not been corrected completely since the inspection of the previous year. The Court found Mr. Park criminally liable under the Act because of his "responsible relationship."

Insanitary Conditions

The basic statutory provisions concerning insanitary conditions for food and cosmetics are quite similar. Therefore, in regard to manufacturing, packing or holding food or cosmetics under insanitary conditions, it would be logical to assume similar results if Mr. Park had been president of a large cosmetics manufacturer, wholesaler or retailer, and similar conditions were found to exist. The point is obvious—ample authority and sanctions (criminal liability for a chief executive officer) presently exist for the efficient enforcement of the Act by the FDA.

Another reason the *Park* decision is relevant to this discussion is because substantive cosmetic GMPs would only increase the criminal exposure under which executives of cosmetics companies would operate. Presumably, the FDA would insist that cosmetic GMPs be substantive in nature and similar to drug GMPs. Failure to comply with such GMPs would make the cosmetics adulterated, candidates for multiple seizures, and would make the president of the company a candidate for jail (or at least criminal liability and fines). This

[15] 421 U. S. 658 (1975).

[16] Sec. 402(a)(3) of the Act provides that a food shall be deemed to be adulterated if it consists in whole or in part of any filthy, putrid or decomposed substance, or if it is otherwise unfit for food, or if it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

[17] It should be noted that a 12-day inspection, without any more precise or detailed authority than presently contained in the Act (no GMPs), must have been a rather thorough and detailed inspection. One can only speculate how long such an inspection would have taken with more detailed regulations.

could occur from a failure to comply with a GMP provision which has nothing to do with sanitation.

Cocoa Products

I say this because of a similar situation which presently exists with food, specifically, cocoa products and confectionery. Under recently issued GMPs for cocoa products and confectionery, there are provisions requiring code marking and record keeping to identify "initial distribution of the finished product."[18] Clearly such requirements as lot coding and record keeping have little, if anything at all, to do with sanitation. The FDA asserts that these specific provisions were included in the GMP regulations to aid in recalls. This conjures up another question which is wholly separate and apart from this discussion, that is, mandatory and binding regulations to implement an act (recall) which is voluntary and not provided for in the statute.[19] Since the FDA has already shown its propensity to include provisions unrelated to sanitation in food GMPs, are we wrong to assume the same will be included in any proposed cosmetic GMPs?

Before concluding my comments, I would like to read a portion of a paper presented at the 16th Annual Educational Conference of the Food and Drug Law Institute. The speaker, in discussing the Federal Food, Drug and Cosmetic Act, made the following observation:

"In this respect, the Act must be regarded as a constitution. It establishes a set of fundamental objectives—safe, effective, wholesome, and truthfully-labeled products—without attempting to specify every detail of regulation. The mission of the Food and Drug Administration is to implement these objectives through the most effective and efficient controls that can be devised.

"This does not mean that the Act provides unfettered discretion for the Agency to do whatever it wishes in pursuing these objectives. We may not and do not ignore the statute. In some areas, Congress did lay down very specific rules which, until changed, must control. If we wish to obtain authority to inspect records during factory inspections for other than prescription and new drugs, for example, we must seek a change in the law. We cannot overrule Congress by administrative fiat."[20]

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[18] 21 CFR 128(c) published by FDA in the *Federal Register* of June 4, 1975 (40 *F. R.* 24162-24172) effective August 4, 1975. See also *National Confectioners Association 1225-19 v. David Mathews et al.*, Civil Action 75-1272 (DC DofC 1975).

[19] On this general subject, see *United States v. C. E. B. Products, Inc.*, 380 F. Supp. 64 (DC Ill. 1974).

[20] The speaker was Peter Barton Hutt, then Assistant General Counsel of the FDA. Hutt, "The Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act," 28 FOOD DRUG COSMETIC LAW JOURNAL 178-179 (March 1973).

In view of the foregoing, substantive cosmetic GMPs are unnecessary and inappropriate. They are unnecessary and inappropriate for the following reasons:

(1) The FDA presently possesses sufficient authority to inspect establishments and convict cosmetics manufacturers for manufacturing, packaging or holding cosmetics under insanitary conditions.

(2) The Act does not authorize the promulgation of substantive GMPs for cosmetics.

(3) Current cosmetics industry practices make such GMPs unnecessary as the industry, through its voluntary programs and quality assurance programs, makes detailed GMPs unnecessary.

This final point—industry practice—which I have not discussed will be discussed by other panelists, Edward Milardo[21] and John Wenninger.[22] The fact is that the CTFA, through input of its member firms—the cosmetics industry—has developed detailed Technical Guidelines for Quality Assurance of Cosmetic Products. Such work will continue, with or without cosmetic GMPs, because the cosmetics industry, as well as the FDA, is interested in providing only safe and wholesome cosmetic products. **[The End]**

[21] See Milardo, "Quality Assurance Guidelines—The Industry's Viewpoint," 31 FOOD DRUG COSMETIC LAW JOURNAL 105-108 (Feb. 1976).

[22] See Wenninger, "Quality Assurance Procedures for the Cosmetics Industry," 31 FOOD DRUG COSMETIC LAW JOURNAL 101-104 (Feb. 1976).

Product Liability—1975

By WILLIAM J. CONDON

Mr. Condon, an Attorney-at-Law, Teaches at New York University Law School.

ONE OF THE INTRIGUING ASPECTS of product liability law is the apparent ease with which our courts change long-standing rules of law. For example, it has long been the law in New York that a manufacturer or seller of food will not be liable for injuries caused by natural substances in the product. Examples of this are bones in meat dishes, cherry pits in cherry pies, and the like. Now, however, the Appellate Division, First Department, without reference to prior New York cases, has announced the adoption of the rule of "reasonable expectation." This doctrine applies alike to breach of warranty and negligence causes of action, and essentially means that liability may be imposed if it is found that the natural substance was not reasonably to be anticipated in the food as served. *(Stark v. Chock Full O'Nuts.)* In this particular case, plaintiff had injured her tooth when she encountered a bit of shell in a nutted cheese sandwich. The trial judge had directed a verdict for the plaintiff on the issue of liability. The Appellate Division noted that the question of reasonable expectation is normally one for the jury. However, in light of the fact that plaintiff's testimony concerning the occurrence was uncontroverted and that the amount of the recovery was small, the Court held the error not prejudicial to the defendant and thus allowed the judgment to stand. The dissenting justice found this to be a serious departure. In the course of his opinion, he said:

"Zeal to more firmly establish, in this jurisdiction, the correct rule of the so-called 'reasonable expectation test' and the smallness of the verdict, should not, in effect, be permitted, on appeal, to convert this $10,000 jury cause (with counsel on both sides) to the reduced status of a trivial small claims case. Yet that is the result accomplished here, to the great prejudice of defendant (which had no burden of proof), because it permits plaintiff to succeed on vague, amorphous, considerations of substantial justice, despite acknowledged error in the trial court's radical departure from basic principles of jury-trial practice and procedure."

Rule of Strict Liability

The problem of the correct rule to be applied in this type of case was also faced by the United States District Court for the Southern District of Texas. In this case, plaintiff had located a pearl in defendant's oyster stew. It appears that this question had never been decided by the courts of Texas and, therefore, was the responsibility of the Federal Court to determine how the Texas courts would rule. The judge concluded that Texas would also adopt the reasonable expectation test because he felt that this was more consistent with the rule of strict liability, which is the law of Texas. He criticized the foreign-natural test because of its artificial application. In his view, that test focuses on a single ingredient rather than on the final consumer product. He concluded that by shifting the focus to the consumable item, the foreign-natural distinction, as measured by the consumer's reasonable expectation, becomes a valid and relevant standard. Under this test, the question will always be one of fact rather than one of law. *(Matthews v. Campbell Soup Company.)*

The duty to warn continues to be a fertile area, one whose boundaries seem to defy definition. A case in point is *McEwen v. Ortho Pharmaceutical Corp. et al.* The case, decided by the Supreme Court of Oregon, arose by virtue of a claim that plaintiff's blindness resulted from the successive use of contraceptive pills manufactured by the two defendant pharmaceutical companies. Plaintiff had used the pill of one defendant for one year. She then switched to the pill of the second defendant upon the advice of an examining physician. She used the second pill for another year. There were several issues of interest in this case.

First of all, the Oregon Court made it plain that defendants had a duty to warn concerning dangers which they knew or ought to have known were attendant upon the use of their products. While the duty in connection with prescription drugs requires only that the warnings be transmitted to physicians, the Court emphasized that it is at least as important that these warnings be brought to the attention of treating physicians as it is that they be communicated to prescribing physicians. The Court quite properly noted that the symptoms which would be described in any appropriate warning would more likely be observed by treating physicians than by prescribing physicians.

Inadequate Warnings

The Court next concluded that there was evidence in this case sufficient to support a jury's finding that the warnings given by these

defendants were inadequate. The Court seemed to indicate that a warning or contraindication containing the language that a cause and effect relationship between the use of the product and certain conditions has been neither established nor disproved could be found to be inadequate.

The next, and perhaps most important, issue was that of causation. Defendants argued that there was no evidence that the pills would not have been prescribed if adequate warnings had been given. In light of present day knowledge and the continued extensive use of oral contraceptives, it would seem that this argument might have considerable merit. However, the Court held that it was not necessary to consider this particular point because there was adequate evidence to indicate that the treating physicians would have discontinued the use of the drugs in time to avoid permanent injury, if they had been properly warned. Finally, the Court said that there was sufficient evidence of the cumulative nature of the injury to hold both defendants.

In this area of the duty to warn, we have another chapter this year in the saga of Nancy Moran. You may recall that Ms. Moran was severely burned when a young friend of hers poured the contents of a bottle of cologne on a burning candle. The purpose was to create a scented candle. The trial court had entered a judgment n.o.v. for the defendant and the intermediate appellate court affirmed on the theory that these two young girls had put the cologne to an unforeseeable use. The Maryland Court of Appeals reversed. *(Moran v. Faberge, Inc.)*

Foreseeability

Liability was imposed upon Faberge because of its failure to warn of the flammability of its product. The issue in this case was foreseeability. The Court decried the quagmire into which this issue had descended in connection with product liability cases, and proceeded to suggest that the problem was simple and the solution clear if standard principles of negligence law were applied. After reviewing these principles, which are well known to all, the Court concluded that defendant's liability was clearly appropriate in the present circumstances. The holding of the Court is summed up in the following two quotations:

"It is not necessary that the manufacturer foresee the exact manner in which accidents occur. Thus, in the context of this case, it was not necessary for a cologne manufacturer to foresee that someone would be hurt when a friend poured its product near the flame of a lit candle; it was only necessary that it be foreseeable to the producer that its product, while in its normal environment,

may be brought near a catalyst, likely to be found in that environment, which can untie the chattel's inherent danger.

"It was only necessary that the evidence be sufficient to support the conclusion that Faberge knowing or deemed to know that its Tigress cologne was a potentially dangerous flammable product, could reasonably foresee that in the environment of its use, such as the home of the Grigsbys, this cologne might come close enough to a flame to cause an explosion of sufficient intensity to burn property or injure bystanders, such as Nancy."

Under this concept of foreseeability, it would appear that the only escape for a defendant would lie in some application of the concept of contributory negligence. Unforeseeable use as an intervening cause, or as a limitation on the duty to warn, loses all meaning. Clearly, this Court is suggesting that foreseeability should be determined by taking a clear view through the other end of the telescope. Twenty-twenty hindsight is the order of the day.

Duty to Warn

While we are on the subject of the duty to warn, what would you expect to find on the label of a bottle of champagne? George Shuput complained that he had not been warned that it would be unhealthy for him to get hit in the eye with a cork. Although the District Court directed a verdict for the bottler, the United States Court of Appeals for the Tenth Circuit agreed with Mr. Shuput. Noting that cold champagne may eject a stopper with 63 percent of the momentum of a 22-caliber pistol firing a short cartridge, the Court held that plaintiff's evidence was sufficient to allow a jury to find that defendant's champagne created an unreasonable danger of hazard to plaintiff and that defendant had failed to correct this defect with a warning. *(Shuput v. Heublein, Inc.)*

In spite of what we have seen in the *Moran* case, the concept of misuse of the product still retains some viability. Thus, plaintiff failed to make a case in strict liability against the manufacturer of a surgical pin where the evidence showed that plaintiff had walked on the fractured leg containing the pin, after the cast was removed and contrary to his doctor's instructions. The pin was intended to align and to stabilize the fracture, but was never intended to bear bodily weight. *(Stewart v. The Von Solbrig Hospital, Inc.)*

With the extension of liability under modern product liability concepts, it is not surprising that we might see cases involving "products" which only a short time ago would not have been thought of in this context. Take, for example, the case of *Whitmer v. Schneble.*[1]

[1]CCH PRODUCTS LIABILITY REPORTER ¶7489 (Ill. App. Ct.).

The named plaintiff was an infant who was bitten by a Doberman Pinscher dog when she came to admire the dog's puppies. We are concerned with the third party action of the dog's owners against the kennel which sold the dog to them. The owner claimed, first of all, a breach of warranty because, upon the purchase, they had been assured by the seller that this was a "docile dobe." They also claimed that the seller was liable to them in strict liability because the dog was unreasonably dangerous and the seller had failed to warn them of the dog's dangerous propensities. The Court disposed of the warranty contention on the basis that there was no indication of a breach, and certainly no indication that the dog was other than a "docile dobe" at the time of the sale. With respect to strict liability, the Court simply felt that there was no obligation to warn the owner of the propensities of the animal under these circumstances. The Court concluded its discussion of this issue by saying:

"In short, all mankind, and this court as well, is aware that dogs bite and that bitches which have just whelped and are watching their pups will fulfill their natural maternal instinct and bite a stranger who approaches. It is unfortunate of course that in this case the dog's bite was worse than her bark."

Elements of Proof

Considering the tendency among appellate courts to alter and liberalize long-established theories of liability, it is not entirely surprising that a trial court now and then may, on its own motion, seek to eliminate one or more of the elements of proof. For example, in *Brewington v. Coca-Cola Wometco Bottling Company,* plaintiff's proof showed only that she purchased a bottle of Tab from a local retailer, drank it and became ill. The trial court solved plaintiff's problem of proof with respect to the bottler with the following statement: "I think the Court could take some knowledge of the fact that there's been one principal bottler of Coca-Cola products in this area I think for the last 75 years and that the odds are at least in favor of the fact that Wometco did bottle this particular bottle of Tab." This was reversed on appeal. The Appellate Court contended itself with the observation that plaintiff must show that the retailer purchased or acquired the bottle in some fashion from the defendant. Absent such proof, there is no basis upon which a recovery can be sustained.

Last year, we discussed very briefly the case of *Vincent v. Thompson,* wherein the trial court in Nassau County approved the application of the doctrine of collateral estoppel against a drug manufacturer, based upon a finding of a defective product which had been made in a prior case in federal court involving a different plaintiff. This action

has now been reversed by the Appellate Division. While it agreed that mutuality is not necessary, the Court held that collateral estoppel was erroneously applied in this case. In order to prevent unfairness to the party involved in the prior litigation, it is essential that plaintiff establish that the issue to which estoppel is sought to be applied is identical in the two cases and that it is decisive in both. In the instant situation, it appears that the defect in the product found in the prior case could not have been the cause of the injury to the plaintiff in the subsequent case. Therefore, the identity of issue did not exist. The Court also held that it was error to exclude evidence, newly discovered by defendant, which tended to prove that the finding of defect in the prior case was unsound.

Collateral Estoppel

While the Court did not negate the possibility that collateral estoppel might be available in product liability cases, it did severely limit the scope of that application. The only example which came readily to the Court's mind was a situation where several persons eat the same food and all become ill thereafter.

There remains to mention two cases which should provide some food for thought. The first of these is *Anderson v. Somberg*, decided in the Supreme Court of New Jersey. This involved a situation where a surgical instrument broke in the course of a very delicate operation and a piece of that instrument became lodged in plaintiff's spinal cord. This required further surgery and resulted in serious and permanent injury. Plaintiff sued the surgeon for malpractice, the hospital for negligently furnishing a defective instrument, the medical supply distributor for breach of warranty, and the manufacturer for strict liability in tort. When all the evidence was in, the case was given to the jury on special interrogatories. The jury, unable to fix liability on any of the defendants, returned a verdict of no cause of action against each of them. The Supreme Court of New Jersey was understandably distressed that the plaintiff, who suffered severe injury while he was both innocent and unconscious, should go uncompensated. In order to prevent such an untoward result, the Court developed what appears to be an entirely new theory. It said that, where all parties who could have been responsible for this injury are before the Court, and the injury must have occurred as the result of the fault of one of them, the jury should be instructed that plaintiff must recover. It will be the responsibility of the jury to determine against whom such recovery should be had. As the vehicle for this recovery, the Court altered the impact of the

doctrine of *res ipsa loquitur*. Under circumstances such as these, the rule that the application of *res ipsa* shifts to the defendant the burden of going forward with the evidence is inadequate. Therefore, the Court adopted the rule that the burden of proof is shifted to the defendants. It is not entirely clear, and further cases will be required to spell out the types of situations involving multidefendants where this new rule will be applicable.

Violent Dissent

As one might expect, there was a rather violent dissent. The dissenting justices raised some rather interesting philosophical questions. They wondered how the proposed instruction to the jury would be squared with the jurors' oath to render a verdict only according to the evidence. They wondered further, if this posed a problem to a juror and he sought the aid of the trial court, what additional instructions might be given. The dissenters feared that, under this rule, there would be many instances where liability would be visited upon wholly innocent persons. As indicated, these philosophical arguments were inadequate to deter the majority of the Court from adopting the course which had been established.

The second case is *Hauter v. Zogarts*.[2] This case involved a training device called the "Golfing Gismo." This device consists of two metal pegs which were inserted in the ground, an elastic cord stretched over the two pegs, a cotton cord attached to the middle of the elastic, with a regulation golf ball attached to the end of the cotton cord. The idea is to stretch out the cotton cord to its full length and then hit the ball. From the position of the ball after its return to the player, one can presumably determine whether his stroke produced a slice or a hook. If the player tops the ball, it won't fly back and he must retrieve it himself. The device came with instructions to hit the ball with full power, and the shipping carton and the instructions bore the legend in large letters "COMPLETELY SAFE BALL WILL NOT HIT PLAYER."

Plaintiff, a 13 year old boy, who had recently become interested in golf, set up the device and proceeded to practice. Apparently, he hit

[2] CCH Products Liability Reporter ¶ 7461 (Cal. S. Ct.).

under the ball and on his follow-through, the club head became entangled with the cotton cord, creating something of a bolo effect and the ball struck plaintiff in the head. He sued the manufacturer on theories of misrepresentation, express and implied warranties, and strict tort liability. At the conclusion of the trial, the jury brought in a unanimous verdict for the defendant on all counts. The trial judge granted plaintiff's motion for judgment n.o.v.

Breach of Express Warranty

On appeal, the Supreme Court of California affirmed the judgment for the plaintiff. The Court held that defendant was liable as a matter of law on each cause of action. One justice concurred in the result because he felt that the record established a breach of express warranty as a matter of law. He found the majority's discussion of the other causes of action unnecessary and unpersuasive. The jury had heard all of the evidence, and in view of the trial court's action in upsetting the verdict, we may properly assume that the instructions given to the jury were certainly not unfavorable to plaintiff. Yet, that Los Angeles jury, not as a class generally ranked as conservative, unanimously found for the defendant.

What is significant in both of the foregoing cases is that the New Jersey and California courts have mandated recoveries for plaintiffs after the respective juries concluded otherwise. This raises serious questions as to whether these two courts, at least, have doubts concerning the efficacy of the jury system. One may very well agree that recoveries by the particular plaintiffs involved in these two cases is a highly desirable result. However, in neither case did the court so confine its language as to be applicable solely to the peculiar facts involved. Both cases present a clear invitation to trial courts to remove issues of liability from the consideration of juries.

The question which comes to mind is whether the development of strict product liability, which in theory is not bad, might not be threatening to imbue our courts with an aura of absolutism. Juries have a way of mellowing harsh doctrines, whether they be contributory negligence or strict liability. In the case of contributory negligence, the courts treated the actions of juries with a sort of benign indulgence. In the case of strict liability, they may not.

PRODUCT LIABILITY CASES FOR 1975

The list of cases for 1975, grouped according to classification, is as follows: (All paragraph numbers refer to CCH PRODUCTS LIABILITY REPORTER)

Foreign Substance and Contaminated Food Cases

Stark v. Chock Full O'Nuts, ¶ 7336 (N. Y. S. Ct., App. Div. 1st Dept.)
Matthews v. Campbell Soup Company, ¶ 7339 (DC Tex., S. D.)
Dawson v. Canteen Corp., ¶ 7406 (W. Va. S. Ct.)
Stelly v. Gerber Products Company, ¶ 7431 (La. Ct. App.)
Huckleby v. Nor-Am Agricultural Products, Inc., ¶ 7524 (N. M. Ct. App.)

Foreign Substance Beverage Cases

Gigliotti v. Coca-Cola Bottling Company, ¶ 7347 (Wis. S. Ct.)
Brewington v. Coca-Cola Wometco Bottling Company, ¶ 7537 (Tenn. Ct. App.)

Bursting Bottle Cases

Giant Food Inc. and Sheeskin v. Washington Coca-Cola Bottling Company, Inc., ¶ 7389 (Md. Ct. App.)
Royal Crown Bottling Company v. Ward, ¶ 7414 (Tex. Ct. Civ. App.)
Embs v. Pepsi-Cola Bottling Company of Lexington, Kentucky Inc., ¶ 7454 (Ky. Ct. App.)
Vega v. Royal Crown Bottling Company, ¶ 7513 (Tex. Ct. Civ. App.)
Marko v. Stop & Shop, Inc., ¶ 7533 (Conn. S. Ct.)

Drug Cases

Gilbert v. Jones and Ortho Pharmaceutical Corp., ¶ 7350 (Tenn. Ct. App.)
McEwen v. Ortho Pharmaceutical Corp., ¶ 7358 (Ore. S. Ct.)
Goodman v. Mead Johnson & Company, ¶ 7360 (DC N. J.)
Whitley v. Cubberly and Parke, Davis & Company, ¶ 7380 (N. C. Ct. App.)
Allen v. Ortho Pharmaceutical Corp., ¶ 7415 (DC Tex., S. D.)
Thrift v. Tenneco Chemicals, Inc., ¶ 7432 (DC Tex., N. D.)
Oresman v. G. D. Searle & Company, ¶ 7473 (DC R. I.)
G. D. Searle & Company v. Seaton, ¶ 7498 (Cal. Ct. App.)
Vaughn v. G. D. Searle & Company, ¶ 7512 (Ore. S. Ct.)
Roman v. A. B. Robins Company, Inc., ¶ 7519 (CA-5)
Salmon v. Parke, Davis & Company, ¶ 7539 (CA-4)
Vincent v. Thompson, N. Y. L. J. 1/9/76 (N. Y. S. Ct., App. Div.)

Cosmetic Cases

Conlon v. G. Fox and Company, ¶ 7351 (Conn. S. Ct.)

Moran v. Faberge, Inc., ¶ 7393 (Md. Ct. App.)

Device Cases

Stewart v. The Von Solbrig Hospital, Inc., ¶ 7375 (Ill. App. Ct.)

Ethicon, Inc. v. Parten, ¶ 7411 (Tex. Ct. Civ. App.)

Anderson v. Somberg, ¶ 7439 (N. J. Super. Ct., App. Div.); ¶ 7508 (N. J. S. Ct.)

Defective Container Cases

Shuput v. Heublein, Inc., ¶ 7403 (CA-10)

Green v. Safeway Stores, Inc., ¶ 7429 (Okla. S. Ct.)

Waller v. Coca-Cola Bottlers Association, ¶ 7447 (Tex. Ct. Civ. App.)

Economic Poisons Cases

Bigelow v. Agway, Inc., ¶ 7327 (CA-2)

Simchick v. I. M. Young & Co., ¶ 7383 (N. Y. S. Ct., App. Div.)

Kleven v. Geigy Agricultural Chemicals, ¶ 7420 (Minn. S. Ct.)

Elanco Products Company v. Akin-Tunnell, ¶ 7430 (Tex. Ct. Civ. App.)

William Cooper & Nephews, Inc. v. Pevey, ¶ 7504 (Miss. S. Ct.)

Swenson v. Chevron Chemical Company, ¶ 7525 (S. D. S. Ct.)

Blood Transfusion Cases

Fruge v. Blood Services, ¶ 7369 (CA-5)

Williamson v. Memorial Hospital, ¶ 7384 (Fla. DC App.)

Brody v. Overlook Hospital, ¶ 7390 (N. J. S. Ct.)

Jennings v. Roosevelt Hospital, ¶ 7395 (N. Y. S. Ct., Spec. Term)

St. Luke's Hospital v. Schmaltz, ¶ 7441 (Colo. S. Ct.)

Sawyer v. Methodist Hospital of Memphis, ¶ 7491 (CA-6)

[The End]

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